Approaches to the Management of Difficult Airways in Adults

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Difficult Airways in Adults

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Declaration

Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

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Abbreviations

The presented work involves a number of devices that are protected by trademark labels. For better readability, trademark symbols (®, ™) are not used in this text. The company names of the studied devices are indicated in the original publications, which can be found at the end of this thesis.

ADEPT	Airway Device Evaluation Project Team
ASA	American Society of Anesthesiologists
CICO	Cannot Intubate, Cannot Oxygenate
DAS	Difficult Airway Society
DESA	Diplomate of the European Society of Anaesthesiology
e-FONA	Emergency Front Of Neck Access
FERC	Fellow of the European Resuscitation Council
LMA	Laryngeal Mask Airway
MD	Doctor of Medicine; Medicinae Doctor
MME	Master of Medical Education
NAP4	Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society
PhD	Doctor of Philosophy; Philosophiae Doctor
SAD	Supraglottic Airway Device
SGA	Supraglottic Airway Device
THRIVE	Transnasal Humidified Rapid-Insufflation Ventilatory Exchange
UK	United Kingdom
USA	United States of America

Preface

Airway management is a field of anaesthesia, critical care and emergency medicine that is highly relevant for patients and clinicians. This thesis incorporates 10 years of clinical research on difficult airway management. It includes 8 peer-reviewed original articles and 3 case reports and editorials on airway management that I have authored or co-authored over this period of time.

My research studies comprise three areas: tools for tracheal intubation such as rigid scopes and videolaryngoscopes, the use of supraglottic airway devices, and the use of ultrasound for front of neck access. These areas represent distinct techniques, which all play an important role at different stages in the management of a difficult airway.

The commentary provides a summary of this research in the context of the current guidelines for the management of a difficult airway, the current clinical environment, international research efforts and the available literature. The original articles in their full text format are included at the end of this thesis.

Abstract

Airway management is a core competency in anaesthesia, critical care and emergency medicine and a crucial task for these medical specialties. Problems with airway management and subsequent inadequate ventilation of the lungs can rapidly lead to hypoxia, hypoxic brain injury or death. It is known that problems with airway management contribute significantly to morbidity and mortality in anaesthesia.

The presented work comprises a series of trials that investigated a variety of different approaches to the management of difficult airways in adults. The trials were mostly randomized controlled clinical trials. Areas of research included the use of tools for tracheal intubation such as rigid scopes and videolaryngoscopes, the use of supraglottic airway devices, and the use of ultrasound for front of neck access.

Rigid scopes were shown to be highly successful for tracheal intubation in patients with a simulated difficult airway. They also proved useful for intubation of spontaneously breathing patients under conscious sedation. We identified clinically important differences with regard to the performance of different videolaryngoscopes and showed that in the hands of experienced anaesthetists an added channel for tube guidance does not seem to improve the success of videolaryngoscopes. The publications on supraglottic airway devices assessed performance, risk factors for device failure, and describe a rare complication of supraglottic airway devices. The use of ultrasound was assessed as an aid to identify the tracheal midline for front of neck access.

The results of the trials provide a foundation for an evidence-based choice of airway devices and management strategies. Future research will focus on the implementation of research data and new techniques into clinical practice, improvement of institutional airway management strategies, and new techniques such as clinical applications of high flow humidified oxygen.

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1. Commentary: Approaches to the management of difficult airways in adults

1.1. Introduction to airway management and to the difficult airway

Airway management is a core competency in anaesthesia, critical care and emergency medicine and a crucial task for these specialties. Essentially, airway management relates to the control of a patient's airway when the patient has lost the control over his or her airway due to anaesthesia, or due to illness or trauma. Different techniques share the common goal of providing adequate ventilation to assure oxygenation and carbon dioxide elimination. Failure to do this can rapidly lead to hypoxia, hypoxic brain injury and death. Airways can be managed by different means such as by a facemask (with or without adjuncts such as oropharyngeal or nasopharyngeal airways), by supraglottic airway devices (SGA), by tracheal tubes or by emergency front of neck access (e-FONA: cricothyroidotomy or tracheostomy).

Trained anaesthetists can ultimately manage most airways, but minor or major airway related incidents occur in approximately 15% of anaesthesia cases.[1] Following the "Swiss cheese model" of accident causation introduced by Reason,[2] a cluster of minor airway incidents at different levels of the process can lead to fatal airway failures. In 2011, the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4) revealed a reported incidence of major complications of airway management in the UK of one per 22 000 anaesthetics, with an estimated true incidence of up to one per 5 500 anaesthetics.[3] These major incidents were defined as death, brain damage, emergency surgical airway, or unanticipated intensive care unit admission.[3]

Major incidents of airway management are a main reason for fatal and severe complications in anaesthesia. They often occur in previously fit and healthy patients undergoing elective surgery and are a catastrophe for involved patients, relatives and healthcare professionals. Given the clinical relevance of this field, I have chosen difficult airway management as my core research topic. The underlying theme of all my studies and publications on airway management is the question on how to improve airway management with the goal to ultimately improve patient safety in anaesthesia.

In their latest Practice Guidelines, the Task Force on Management of the Difficult Airway of the American Society of Anesthesiologists (ASA) defines a difficult airway as follows: "For these Practice Guidelines, a difficult airway is defined 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 guidelines also state: "The difficult airway represents a complex interaction between patient factors, the clinical setting, and the skills of the practitioner."[4]

Difficulties can be encountered with facemask ventilation, with the use of supraglottic airway devices or with tracheal intubation. The worst-case scenario is the cannot intubate, cannot oxygenate situation (CICO) in which the patient is not breathing spontaneously and cannot be oxygenated following failure of both facemask ventilation and tracheal intubation. This situation is acutely life-threatening. The incidence of difficult facemask ventilation has been reported as 0.8-7.8%, and the incidence of difficult laryngoscopy as 0.8-7.0%, with 0.9-1.9% of patients requiring three or more intubation attempts.[5]

In patients with certain anatomical characteristics such as a small mouth opening, a short neck or retrognathia, or with certain pathological characteristics such as oropharyngeal cancer or other masses involving the airway, in airway bleeding, airway trauma or after previous airway surgery or irradiation of the airway, difficulties with airway management can be expected (anticipated difficult airway). Airway management in these situations has to be planned accordingly. For the management of an anticipated difficult airway, flexible fibreoptic intubation of the spontaneously breathing patient under conscious sedation has traditionally been the gold standard. With recent technological developments, this gold standard has been challenged. It has been proposed that other techniques such as videolaryngoscopy of the spontaneously breathing patient under conscious sedation could be valid alternatives.[6-8] The key principle for all techniques is to maintain spontaneous breathing while securing the airway.

Importantly, a difficult airway can in many instances be unexpected. In Denmark, for example, unanticipated difficult intubations have been reported to occur in around 1.9% of anaesthesia cases.[9] Unanticipated difficult airways must be managed very promptly since the patient is usually apnoeic, deeply anaesthetised and usually paralysed. Various anaesthesia societies have developed difficult airway algorithms to guide clinicians in managing these unexpected emergency situations.[4, 5, 10-12] Separate algorithms also exist for children.[13] Overall, these algorithms emphasize that a technique that is not working should be abandoned if nothing can be changed that would increase the likelihood of success. Repeated intubation attempts are associated with worse outcomes.[14-16] They are time consuming and can cause trauma and airway swelling, which can convert an airway with possible facemask ventilation into a cannot intubate, cannot oxygenate situation. This is what happened in the case of Elaine Bromiley, a 37-year-old healthy woman who died in 2005 from a failed airway during anaesthesia for an elective sinus operation.[a] Deterioration of a cannot intubate, CAN

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[a]Text and video information available on http://simpact.net.au/bromiley.html, last accessed May16[th], 2018

oxygenate situation into a cannot intubate, CANNOT oxygenate situation by multiple intubation attempts has also more recently been reported by the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4).[3, b]

The algorithm of the UK-based Difficult Airway Society for management of unanticipated difficult tracheal intubation is shown in Figure 1.[10] It leads the clinician from Plan A (facemask ventilation and intubation) with a maximum of three intubation attempts plus an additional attempt by a more experienced colleague to Plan B (maintaining oxygenation with a supraglottic airway device) with a maximum of three attempts. In case of failure of Plan A and Plan B, the guidelines proceed to Plan C (a final attempt of facemask ventilation) and then to Plan D (emergency front of neck access by scalpel cricothyroidotomy). Besides the focus on an early "call for help" and the importance of non-technical skills in airway management, the latest guidelines from 2015, in contrast to the older guidelines from 2004,[17] include the use of videolaryngoscopes as an alternative to the classic Macintosh laryngoscope within Plan A. They also specifically state: "All anaesthetists should be trained to use, and have immediate access to, a videolaryngoscope."[10] This reflects the important technical advances that have been made in the field of applied video technology for laryngoscopy over the last decade. Also, flexible fibrescopes and rigid scopes like the Bonfils are specifically mentioned in the guidelines as options for Plan A.[10] Apart from the technical skills and specialised airway equipment, it has become clear that non-technical skills and human factors play a major role in airway emergencies. In the case of Elaine Bromiley, for example, task fixation was identified as a major problem in management. It seems that task fixation, communication errors, the hierarchical structure of the current health care system, and an overall reduced performance of health care professionals in situations with high levels of stress all contribute to poor outcomes of airway emergencies. In the NAP4 analysis, other common themes were poor airway assessment, poor planning of airway management and repeated airway management attempts. Elements of care were judged as poor in three quarters of the NAP4 cases.[3]

My research focuses on the technical aspects of airway management and targets the mentioned management strategies at different levels. My studies on tools for intubation comprise studies on rigid scopes and videolaryngoscopes, and aim to improve the success of Plan A. My publications on supraglottic airway devices apply to Plan B of the difficult airway algorithm as well as to the elective use of supraglottic airway devices. Finally, my study on ultrasound in front of neck access targets the final rescue plan, Plan D, aiming to improve the accuracy and success of front of neck access.

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[b]Full PDF of NAP4 available on the website of the Royal College of Anaesthetists at https://www.rcoa.ac.uk/system/files/CSQ-NAP4-Full.pdf, relevant cases described in chapter 24, last accessed May 16th, 2018

Figure 1: Algorithm of the Difficult Airway Society (DAS) for the management of unanticipated difficult tracheal intubation in adults.[10]

SAD: supraglottic airway device. Reproduced from: Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. C. Frerk, V. S. Mitchell, A. F. McNarry, C. Mendonca, R. Bhagrath, A. Patel, E. P. O'Sullivan, N. M. Woodall and I. Ahmad, Difficult Airway Society intubation guidelines working group. British Journal of Anaesthesia, 115 (6): 827–848 (2015) doi:10.1093/bja/aev371

Management of unanticipated difficult tracheal intubation in adults

2015

Plan A: Facemask ventilation and tracheal intubation

Optimise head and neck position
Preoxygenate
Adequate neuromuscular blockade
Direct / Video Laryngoscopy (maximum 3+1 attempts)
External laryngeal manipulation
Bougie
Remove cricoid pressure
Maintain oxygenation and anaesthesia

If in difficulty → call for help

Succeed → Confirm tracheal intubation with capnography

↓ Declare failed intubation

Plan B: Maintaining oxygenation: SAD insertion

2nd generation device recommended
Change device or size (maximum 3 attempts)
Oxygenate and ventilate

Succeed →

STOP AND THINK
Options (consider risks and benefits):
1. Wake the patient up
2. Intubate trachea via the SAD
3. Proceed without intubating the trachea
4. Tracheostomy or cricothyroidotomy

↓ Declare failed SAD ventilation

Plan C: Facemask ventilation

If facemask ventilation impossible, paralyse
Final attempt at facemask ventilation
Use 2 person technique and adjuncts

Succeed → Wake the patient up

↓ Declare CICO

Plan D: Emergency front of neck access

Scalpel cricothyroidotomy

Post-operative care and follow up
- Formulate immediate airway management plan
- Monitor for complications
- Complete airway alert form
- Explain to the patient in person and in writing
- Send written report to GP and local database

This flowchart forms part of the DAS Guidelines for unanticipated difficult intubation in adults 2015 and should be used in conjunction with the text.

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1.2. Approach to research on difficult airway management

During conventional laryngoscopy, the oral, pharyngeal and tracheal axes must be aligned to gain visibility of the vocal cords.[18] The so-called sniffing position has been established to favour this alignment and is therefore part of standard intubation procedures. It involves manipulation of the head and the cervical spine with near-full extension of the occipito-atlanto-axial articulations and flexion of the lower cervical spine.[19] During laryngoscopy, elevation of the laryngoscope blade also causes extension in all cervical motion segments, particularly in the high segments.[20] As this motion has to be avoided in patients who have sustained trauma to their spine to prevent secondary spinal cord trauma, stiff cervical collars have been used for more than 30 years to stabilize the cervical spine following trauma and form part of international trauma guidelines.[21] These collars are used to inhibit cervical spine movement, in particular the extension of the atlanto-occipito and atlanto-axial joints and the flexion of the lower cervical spine. It is known that they also reduce mouth opening,[22] can cause compression of soft tissues of the neck and the airway, and can cause respiratory restriction.[21]

As outlined above, anticipated difficult airways should be managed while patients are breathing spontaneously. Unanticipated difficult airways are rare and acutely life-threatening. Clinical research in the form of randomized controlled trials in real difficult airways is therefore not feasible and would be ethically questionable. Therefore, many airway-related studies are performed in manikins, but it is known that findings from these studies cannot be extrapolated to patients.[23] As a more clinically relevant alternative to manikin studies, many clinical studies on difficult airway management are carried out in a setting which is called the "simulated difficult airway".[24-29] In this approach, a difficult airway is artificially and reversibly created in patients with an anticipated normal airway by manual inline stabilization[28] or by tightly adjusting a stiff cervical collar.[24-27, 29] Manual inline stabilization inhibits neck movement which makes airway management significantly more difficult. Stiff cervical collars, as outlined above, inhibit head extension and flexion of the lower cervical spine, and limit mouth opening.[22] Inhibited neck movement and a small mouth opening are frequent and important factors leading to a difficult airway.[30, 31] With the help of a tightly-fitting stiff cervical collar a difficult airway can therefore be simulated in a very reproducible and standardized way, which is ideal for clinical studies. Of note, difficult airways in clinical anaesthesia can present with varying degrees of difficulty caused by a variety of factors. While the described simulated difficult airway does not simulate factors such as secretions and upper airway masses, it enables randomization of different airway management techniques to relatively uniform, standardized difficult airways. Also, the simulated difficult airway in this research setting can immediately

be reversed by removing manual inline stabilization or the stiff cervical collar whenever a studied technique fails or in case of unexpected medical problems. The reversibility of the created difficulty, detailed patient information and clear and unambiguous study protocols including criteria that lead to restoration of the airway to its normal condition are paramount to assure the ethical conduct of these clinical studies.[23] Also, since difficult airways can be caused by a variety of factors, results of clinical studies using a simulated difficult airway cannot directly be translated to all difficult airway settings and, strictly-speaking, are only valid for the described airway situation. However, the simulated difficult airway focuses on technical aspects and is the only approach that allows for randomized controlled trials on management of unexpected difficult airways. Outside this approach only clinical studies on airway management of normal airways, manikin or cadaver studies, or case series on the management of real difficult airways are feasible.

Most of the studies presented for this PhD by Publication were carried out in a simulated difficult airway setting. Other studies assessed airway management techniques in patients with a predicted normal airway. The studies were carried out while I was working at the Bern University Hospital and University of Bern in Switzerland, where I worked as a research fellow in 2008 and as a registrar in anaesthesia from 2009 to 2016. My mentor and supervisor for all presented studies was Professor Robert Greif, MD, MME, FERC, Professor at the Department of Anesthesiology and Pain Therapy at the Bern University Hospital and University of Bern in Switzerland. Other members of the research group were Lorenz Theiler, MD (consultant anaesthetist), Natalie Urwyler, MD (consultant anaesthetist), Christine Riggenbach (study nurse), and several research fellows and medical students.

With my studies, I have explored several options for the management of difficult airways:

- ***Tracheal intubation with rigid scopes or videolaryngoscopes***
  Rigid scopes are metal stylets which enable a view from the tip of the stylet. These scopes can be guided to the glottis or into the trachea to railroad a tracheal tube over the scope into the trachea. Rigid scopes have long been used in respiratory medicine and otorhinolaryngology,[32] and are very fast to set up. In a randomized controlled trial in a simulated difficult airway scenario, I compared the performance of two scopes that had been developed for airway management.[33]
  Similar to rigid scopes, videolaryngoscopes provide a view from the tip of the device to enable a view of the glottis during insertion of the tracheal tube. Videolaryngoscopes essentially combine the features of a standard laryngoscope with the optical features of a fibrescope. Blades of different shapes have been

developed for optimal performance in different situations, including blades resembling the classic Macintosh blade and difficult airway blades which are more angulated. A wide variety of videolaryngoscopes has been marketed. I compared the performance of several videolaryngoscopes in a simulated difficult airway setting,[34-36] explored the usefulness of an added channel for tube guidance,[37] and the performance of videolaryngoscopes under extreme outdoor conditions.[38]

- ***Placement of supraglottic airway devices to ventilate the patient's lungs***
  Supraglottic airway devices are a good option in many non-emergency cases, but also in cannot intubate, cannot oxygenate (CICO) situations. As such, the use of supraglottic airway devices constitutes Plan B of the DAS difficult airway algorithm.[10] In an observational multicentre trial I assessed the performance of the supraglottic airway device i-gel in adults and studied risk factors for device failure.[39]

- ***Emergency front of neck access***
  Front of neck access is the last resort of airway management when all other options have failed. As such, it constitutes Plan D of the DAS difficult airway guidelines.[10] Identification of the trachea can often be challenging, particularly in patients with an altered anatomy that leads to a difficult airway. I have therefore explored the use of ultrasound to identify the midline of the trachea to facilitate front of neck access.[40]

In summary, all my studies explore different approaches to the management of difficult airways in adults. Since airway complications are a leading cause of anaesthesia-related morbidity and mortality, advances in airway management carry a large potential to improve patient safety in anaesthesia.

1.3. Tools for intubation: Rigid scopes and videolaryngoscopes

As alternatives to the standard Macintosh laryngoscope, other tools can be used to attempt direct tracheal intubation. The main groups of tools are flexible or rigid fibrescopes and videolaryngoscopes.

Flexible fibrescopes have been the established gold standard for management of predicted difficult airways. It is, however, well-known that flexible fibreoptic intubation is a complex technique and it has recently been proposed to use alternative techniques such as awake videolaryngoscopy for the management of predicted difficult airways.[6-8] Rigid scopes might be valuable alternatives since existing data suggest high intubation success rates in difficult airway scenarios[26] and faster intubation with rigid scopes compared to flexible fibreoptic scopes.[41, 42] Since data were overall very scarce, I compared the two rigid scopes Bonfils and SensaScope in a randomized controlled trial for intubation of 200 patients with a simulated difficult airway.[33] The scopes substantially differ in design: The Bonfils features a straight rigid shaft with a curved rigid tip, while the SensaScope has an S-formed shaft with a short flexible tip. In my study, both devices achieved overall success rates approaching 90%.[33] This is similar to videolaryngoscopes[25, 35, 36] in this airway situation and much better than the performance of the standard Macintosh laryngoscope.[26, 36] In a case series we also showed that the rigid scope SensaScope can be used for intubation of spontaneously breathing patients with a predicted difficult airway,[43] confirming that rigid scopes could in fact be valuable alternative tools for the management of both predicted and unpredicted difficult airways.

Similar to rigid scopes, videolaryngoscopes provide a view from the tip of the device to facilitate visualisation of the oropharynx and the glottis. In contrast to rigid scopes which are essentially made of a long and rigid shaft, videolaryngoscopes are laryngoscopes which have been equipped with a video function and which have been adjusted in their blade design to facilitate a view of the glottis. After videolaryngoscopes became commercially available in 2001, they very rapidly became popular among clinicians and a variety of devices was marketed. Data also became rapidly available, but these data were mainly data from rather small clinical trials and from manikin trials. Nevertheless, they all supported the notion that videolaryngoscopes improved visualisation of the vocal cords and intubation success.[25, 28, 44, 45] It was, however, immensely difficult to compare data of different studies on videolaryngoscopes, since study protocols and study settings differed substantially. In a multicentre, randomized controlled trial we compared six different videolaryngoscopes in 720 patients with a simulated difficult airway. The study protocol was published in the journal Trials[34] and the main study article was published in the British Journal of Anaesthesia.[35]

Three of the six studied videolaryngoscopes featured an extra channel to guide the tube into the trachea (channelled videolaryngoscopes) and three of them did not (unchannelled videolaryngoscopes). Interestingly, we found very profound differences in performance between the devices: Two of the unchannelled devices (McGrath and C-MAC) showed success rates above 90% and low complication rates, while one of the channelled devices (A.P. Advance) showed a success rate of only 37%. This might have been due to the fact that mouth opening was limited in our setting, favouring slim devices over devices featuring an extra guiding channel. Given these results, we followed up with another randomized controlled trial that studied the unchannelled versions of the channelled videolaryngoscopes which had been assessed in the described study. We assessed the performance of these 3 unchannelled videolaryngoscopes (unchannelled KingVision, Airtraq and A.P. Advance) and the standard Macintosh laryngoscope, again in a simulated difficult airway setting and using the same methods that were used for the first study on videolaryngoscopes.[36] Success rates again differed significantly with Macintosh laryngoscope and A.P. Advance performing substantially inferior to the KingVision and the Airtraq. Interestingly, success rates with the unchannelled KingVision and the unchannelled Airtraq were very similar to the success rates of their channelled versions. This was confirmed in a separate data analysis which directly compared the channelled with the unchannelled versions of the KingVision, the Airtraq and the A.P. Advance.[37] It indicates that in the hands of experienced anaesthetists the performance of videolaryngoscopes largely depends on the design of the devices and their blades, and not on the presence or absence of a guiding channel for the tracheal tube.

Despite the fact that in difficult airways many videolaryngoscopes perform much better than the standard Macintosh laryngoscope, there are some potential drawbacks. For example, many videolaryngoscopes rely on visibility of anatomical structures on a screen. We performed a manikin study assessing the ease of intubation with different devices in outdoor conditions in bright sunlight on a glacier. We showed that the sunlight was hindering the intubation success with videolaryngoscopes due to decreased visibility on the screen. Wearing sunglasses did improve success rates with some devices and covering the doctor and the patient with a blanket overcame the detrimental effects of sunlight during intubation completely.[38] Usefulness and limitations of videolaryngoscopes were also addressed in an editorial.[46] These limitations include the fact that even with a good view of the glottis, advancement of the tube into the trachea is sometimes impossible with videolaryngoscopes. This is by now a well-recognized problem of videolaryngoscopes which is often referred to as "you see that you fail".

Overall, my studies on rigid scopes and videolaryngoscopes showed high success rates with the rigid scopes Bonfils and SensaScope and with several videolaryngoscopes,

indicating that these devices can be valuable tools for the management of difficult airways. In adverse environmental conditions in a prehospital setting, additional equipment such as a blanket might be required to maintain the high level of performance. Tube-guiding channels of videolaryngoscopes do not seem to provide advantages in the hands of experienced anaesthetists. This might differ when videolaryngoscopes are used for awake intubations where minimal stimulation of the airway is desirable. Results might also differ when the same devices are used in other settings such as in normal airways, other types of difficult airways, or when used by other healthcare providers such as anaesthetic trainees or paramedics. Direct transference of the results to such settings is difficult and the optimal tool for intubation will depend on the specific characteristics of the patient's airway and the healthcare provider performing airway management. However, my studies provide solid evidence of a generally high level of performance of videolaryngoscopes and rigid scopes in challenging airways with a severely limited mouth opening and no neck movement.

1.4. Supraglottic airway devices

In contrast to tracheal tubes, supraglottic airway devices are positioned in the hypopharynx and sit above the level of the vocal cords (Figure 2). Supraglottic airway devices are undoubtedly the biggest invention in anaesthesia over the last decades. They were invented by Dr Archie Brain and were developed and first assessed in the early 1980s.[47] Since then, they have revolutionized airway management as an alternative to tracheal intubation and facemask ventilation. Nowadays, supraglottic airway devices are widely used as the primary airway tool in elective anaesthesia. In 2000, it was reported that at least 30% of patients in the UK and 20% of patients in the USA were anaesthetised using supraglottic airway devices.[48] More recently, in 2013, it was reported that in the UK supraglottic airway devices are used for over 50% of anaesthesia cases.[49] They also are the main rescue tool for difficult airways.[10] Since supraglottic airway devices are so widely used, new devices are often marketed without prior proper clinical investigation. In this context, the Difficult Airway Society developed the "Airway Device Evaluation Project Team" (ADEPT) guidance to facilitate the assessment and choice of devices.[50] Overall, too little is known about the performance and complications of specific supraglottic airway devices and about risk factors for supraglottic airway device failures.

Figure 2: Position of the supraglottic airway device i-gel in the hypopharynx, above the level of the vocal cords. Image courtesy of Intersurgical Ltd.
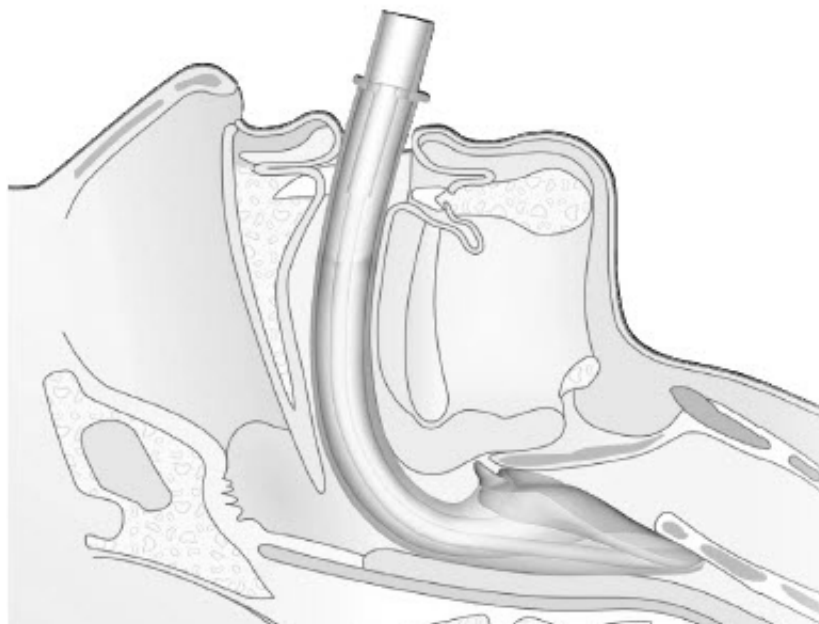
In most supraglottic airway devices, an inflatable cuff assures a tight airway seal to allow for positive pressure ventilation. The supraglottic airway device i-gel was designed without an inflatable cuff, which was a true novelty at the time. It still is the only supraglottic airway device without an inflatable cuff.

In a small, randomized controlled trial with 60 patients I compared the i-gel to the supraglottic airway device LMA Supreme. It is not included in this body of work as it was my MD thesis at the University of Bern, Switzerland. Surprisingly, even without an inflatable cuff, the i-gel had success rates (i-gel 93%, LMA Supreme 95%, p = 1.0) and leak pressures (i-gel 27 ± 9 cm H_2O, LMA Supreme 26 ± 8 cm H_2O, p = 0.44) similar to the LMA Supreme, which has an inflatable cuff to provide a seal of the airway.[51] The trial indicated a high performance of the i-gel. However, assessing the safety of airway devices is much more difficult since rare complications can be missed in randomized controlled trials with small patient numbers. We therefore chose to follow-up on the initial trial by assessing the i-gel in a prospective, observational multicentre study with over 2000 patients.[39] This allowed more accurate assessment of indicators of performance such as success rates and leak pressures, but also enabled assessment of adverse events and risk factors for failure. The study confirmed the previously established high success rates of the i-gel: The first attempt success rate was 93% and the overall success rate was 96%. Also, similar to the previous study, the mean airway leak pressure of the i-gel in this large observational multicentre study was 26 ± 8 cm H_2O, which allows for positive pressure ventilation of most patients. Risk factors for i-gel failure were male sex, impaired mandibular subluxation, poor dentition, and older age. Some similar risk factors had previously also been identified as risk factors for failure of facemask ventilation (Langeron et al.: age older than 55 years, lack of teeth; Kheterpal et al.: male sex),[52, 53] and for failure of the Laryngeal Mask Airway Unique (male sex, poor dentition).[54] This indicates that supraglottic airway devices like the i-gel might be at risk of failing when other techniques like facemask ventilation have already failed. This could compromise their usefulness as a rescue tool. In accordance with this, Ramachandran et al. reported a three-fold increase in difficult mask ventilation in patients with supraglottic airway device failure.[54]

One important feature of the i-gel is the option to insert a gastric catheter, aiming to prevent aspiration of gastric contents by enabling evacuation of gastric contents through the catheter. No aspiration was observed in our study. Adverse events were overall rare and included laryngeal spasms (1.2%), blood stained airway devices (3.9%), transient nerve damage (0.1%), one case of transient vasovagal asystole, and one glottic haematoma. Comparison of the incidence of these complications to other supraglottic airway devices is

impossible due to a lack of data for other devices and the rare occurrence of these complications.

A complication that we experienced with a different supraglottic airway device was that the LMA Supreme caused airway obstruction by epiglottic downfolding and by obstruction of the laryngeal inlet by the cuff of the LMA. This was published as a case report.[55]

The mentioned publications have added evidence to clinical practice and the i-gel has become widely used in adult anaesthesia. Besides the scientific evidence, other factors such as familiarity with the devices, availability and cost play an important role in clinical choices. Second generation supraglottic airway devices are currently recommended for use. However, a survey among UK anaesthetists shows that despite this recommendation, 88% of paediatric anaesthetists preferentially use first generation supraglottic airway devices.[49] This highlights that apart from further clinical trials, effort is also needed to translate the gathered evidence into clinical practice.

1.5. Ultrasound in front of neck access

If the less invasive approaches of managing a difficult airway fail, the last resort of airway management is the emergency front of neck access. One crucial factor with all front of neck access techniques is the correct identification of anatomical structures to allow for a quick and safe access to the trachea. However, identification of landmarks is often difficult and correct identification of the ligamentum conicum has been reported to be as low as 30%.[56]

In a cadaver study that was controlled by computer-tomography I assessed the use of ultrasound for identification of anatomical landmarks for front of neck access.[40] The study assessed the success of ultrasound-guided placement of a guidewire in the midline of the trachea, as it is done for dilatational tracheostomies. Insertion was successful at the first attempt in 89% of cases and in 100% on the second attempt. The wire was placed in the midline of the trachea in 89% of cases, showing that an anatomically optimal position was achieved in the majority of cases when using ultrasound. Of note, the study assessed tracheal puncture as it would be done for tracheostomies and not for emergency cricothyroidotomies. The study did, however, demonstrate successful ultrasound-guided identification of tracheal rings, of the ligamentum conicum and of the tracheal midline, which would be required equally for tracheostomies and for cricothyroidotomies. In accordance with this publication, Curtis et al. described a successful technique for ultrasound-guided, open cricothyroidotomy,[57] and Kristensen described further applications of ultrasound in airway management.[58] Also it was recently suggested that the cricothyroid membrane should be identified by ultrasound in all patients prior to induction of anaesthesia.[59] However, while airway ultrasound is becoming increasingly popular in the literature and in airway management courses, the technique of airway ultrasound has not yet been translated into broadly applied clinical practice.

1.6. Impact of work

Measuring the impact of research on scientific and clinical communities is very challenging. One method is to indicate how often publications are cited by other authors. This is done below in chapter 4 on metrics, contributions and original versions of the presented body of work. Not surprisingly, older publications generally have more citations as more time has passed for them to be cited by other authors. For example, my first full research paper (Crossover comparison of the laryngeal mask supreme and the i-gel in a simulated difficult airway scenario in anesthetised patients. Anesthesiology 2009)[51] has 144 citations, and my second full research paper (Performance of the pediatric-sized i-gel compared with the Ambu AuraOnce Laryngeal Mask in anesthetised and ventilated children. Anesthesiology 2011)[60] has 78 citations according to Google Scholar.

My work is cited from researchers around the world including researchers from Europe,[10] New Zealand,[61] Singapore,[62] India,[12] and the United States.[63] Importantly, it is being cited by several airway guidelines,[10, 12] which are likely to be the most widely read publications in anaesthesia and airway management. As such, airway guidelines likely have the most important impact on clinical practice as they are not only read by researchers and airway enthusiasts, but by a wider range of anaesthetists who are mostly working clinically. Amongst other publications, the British guidelines of the Difficult Airway Society cite my work. They conclude that a maximum of three attempts at insertion of a supraglottic airway device is recommended, and that a different type of supraglottic airway device should be trialled after two failed attempts.[10] In agreement with my study on the use of ultrasound for front of neck access, the guidelines state that ultrasound might be helpful in identifying airway landmarks.[10] The Indian guidelines come to very similar conclusions.[12]

1.7. Future work

Airway management is a field in anaesthesia, intensive care and emergency medicine that is constantly changing as new technologies evolve. This is well illustrated by the impact that the introduction of supraglottic airway devices in the 1980s and the introduction of videolaryngoscopes in the 2000s had on anaesthesia practice, to name a few. Some of the new developments have been excellent and anaesthesia has become safer over time. Nevertheless, important challenges remain and I plan to pursue the following topics with my ongoing and future work:

- New airway devices are often marketed without prior appropriate clinical research, since companies, unlike pharmaceutical companies, do not need to provide evidence regarding clinical performance and safety of airway devices prior to marketing. I will continue to evaluate airway devices regarding their performance and safety.

- Evolving technologies will require thorough investigation. Such new technologies and techniques include apnoeic ventilation and ventilation through small calibre cannulas. In adults, it has been proposed that transnasal high-flow humidified oxygen can achieve apnoeic oxygenation combined with a degree of continuous positive pressure and carbon dioxide elimination (transnasal humidified rapid-insufflation ventilatory exchange - THRIVE).[64] This is extremely promising as it could facilitate a degree of ventilation of apnoeic patients in situations such as induction of anaesthesia, in difficult airway situations and for specific surgical procedures such as laryngeal surgery. In children, data on the effects of THRIVE are scarce and knowledge on the effectiveness and usefulness of this new technique in children is warranted. I am working on studies aiming to clarify the effect and possible applications of high-flow humidified oxygen in children.

- Evidence from clinical trials is often not translated into clinical practice. For example, first generation supraglottic airway devices are still widely used in the UK,[49] despite the fact that second generation devices are recommended by the DAS guidelines on the grounds of available data.[10] Also, complications in airway management are often not caused by poor equipment, but by organisational and human factors. I am working on a study which is aiming to improve airway management at an institutional level.

2. References to the commentary

Publications by Maren Kleine-Brueggeney which contribute to the body of work submitted for the award of PhD by Publication are listed in **bold** letters.

1.   **Kleine-Brueggeney M, Greif R, Pedersen T, Buttenberg M, Hornshaw T, Theiler L. Prospective Assessment Project on Airway Management in Anaesthesia – Improving airway management and patient safety through optimisation of airway management strategies.** *Abstract Presentation at Euroanaesthesia 2016, Annual Conference of the European Society of Anaesthesiology, London, UK* 2016

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3. Academic contributions by Maren Kleine-Brueggeney

Articles are listed in chronological order. Contributions that are part of this submission are listed in **bold** letters.

3.1. Original Articles

1. Riva T, Pedersen T, Seiler S, Kasper N, Theiler L, Greif R, <u>Kleine-Brueggeney M</u>: Oxygenation of children during apnoea with Transnasal Humidified Rapid Insufflation Ventilatory Exchange (THRIVE): A prospective randomised controlled trial.
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Impact factor 6.238

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Impact factor: 3.55

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CiteScore 0.46

4. <u>Kleine-Brueggeney M</u>, Kotarlic M, Theiler L, Greif R: Limitations of pediatric supraglottic airway devices as conduits for intubation.
Canadian Journal of Anesthesia 2018;65(1):14-22
Impact factor 2.312

5. <u>Kleine-Brueggeney M</u>, Gottfried A, Nabecker S, Greif R, Book M, Theiler L: Pediatric supraglottic airway devices in clinical practice: A prospective observational study. BMC Anesthesiology 2017;17(1):119
Impact factor 1.525

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Impact factor 3.570

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Impact factor 6.238

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Anesthesiology 2009; 111(1):55-62
Impact factor 5.66

3.2. Editorials, Reviews, Case Reports and Correspondence

1. Kleine-Brueggeney M: Abstract presentations at the Third European Airway Congress.
   Trends in Anaesthesia and Critical Care 2017; 12: 19; Editorial
   CiteScore 0.46

2. Noppens R, Kleine-Brueggeney M: Original research articles on airway management in TACC - What we can expect.
   Trends in Anaesthesia and Critical Care 2016; 10: 1; Editorial
   CiteScore 0.46

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   Trends in Anaesthesia and Critical Care 2016; 10: 20-21; Editorial
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   Forensic Science International 2010, 15; 203(1-3):63-70; Review
   Impact factor 1.989

8. **Greif R, <u>Kleine-Brueggeney M</u>, Theiler L: Awake tracheal intubation using the Sensascope in 13 patients with an anticipated difficult airway.**
    Anaesthesia 2010; 65(5):525-8; Case report
    Impact factor 4.741

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    Anesthesiology 2009; 111(2):452-453; Correspondence
    Impact factor 5.66

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    Anesthesiology 2009; 110(1):189-90; Case report
    Impact factor 5.66

3.3. Invited Talks and Faculty at Scientific Meetings

1. Instructor: Pre-Congress Course on current concepts in airway management. Euroanaesthesia, Annual Meeting of the European Society of Anaesthesiologists, UK 2016 and Switzerland 2017

2. Invited talk: The role of preoxygenation in airway management. Eighth Annual Spring Symposium in Anesthesiology and Intensive Care, Serbia 2017

3. Instructor: Airway Management Course. German Anaesthetists' Annual Conference DAC, Germany 2017

4. Instructor: Basic and Advanced Airway Management Course, University Hospital Bern, Switzerland, 2015 – 2018

5. Instructor: Airway Management Course, European Airway Management Society EAMS Annual Meeting, Spain 2016

6. Invited talk: Training the Airway Trainers - How to improve and maintain airway management competencies? World Airway Management Meeting WAMM, Ireland 2015

7. Instructor: Airway Workshop at the World Airway Management Meeting WAMM, Ireland 2015

8. Invited talk: Use of laryngeal masks and laryngeal tube in emergency medicine. Euroanaesthesia, Annual Meeting of the European Society of Anaesthesiologists, Spain 2013

9. Invited talk: Genomics: Why do "similar" patients have different outcomes? Review Course Lecture, International Anesthesia Research Society Annual Meeting, Canada 2011, Co-talk with DA Schwinn

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4. Metrics, contributions and original versions of the presented body of work

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Overall metrics

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Original Article

The performance of rigid scopes for tracheal intubation: a randomised, controlled trial in patients with a simulated difficult airway*

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Summary

We compared the Bonfils™ and SensaScope™ rigid fibreoptic scopes in 200 patients with a simulated difficult airway randomised to one of the two devices. A cervical collar inhibited neck movement and reduced mouth opening to a mean (SD) of 23 (3) mm. The primary outcome parameter was overall success of tracheal intubation; secondary outcomes included first-attempt success, intubation times, difficulty of intubation, fibreoptic view and side-effects. The mean (95% CI) overall success rate was 88 (80–94)% for the Bonfils and 89 (81–94)% for the SensaScope (p = 0.83). First-attempt intubation success rates were 63 (53–72)% for the Bonfils and 72 (62–81)% for the SensaScope (p = 0.17). Median (IQR [range]) intubation time was significantly shorter with the SensaScope (34 (20–84 [5–240]) s vs. 45 (25–134 [12–230]) s), and fibreoptic view was significantly better with the SensaScope (full view of the glottis in 79% with the SensaScope vs. 61% with the Bonfils). This might be explained by its steerable tip and the S-formed shape, contributing to better manoeuvrability. There were no differences in the difficulty of intubation or side-effects.

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Introduction

Numerous techniques have been developed to manage difficult airways and to avoid problems with airway management [1, 2]. Flexible fibreoptic scopes have been regarded by some as the gold standard for managing predicted difficult airways [3]. Depending on the specific airway situation, they reach success rates of 79–100% [4, 5], but, even for (notwithstanding

a description of 'rapid sequence fibreoptic intubation' [6], they need time for set-up, and the technique has been described to require extensive training [7]. Intubation with videolaryngoscopes might be easier to learn than the flexible technique [7], but success rates vary considerably and there is a high proportion of patients in whom the glottic opening can be seen, but the tube cannot be directed into the trachea [8].

In otorhinolaryngology and respiratory medicine, rigid scopes have, for a long time, been used with great success for various types of airway procedures [9]. In anaesthesia, rigid fibreoptic scopes such as the Sensa-Scope™ and the Bonfils™ may be used as alternatives to flexible fibreoptic and videolaryngoscopic techniques, for both predicted and unpredicted difficult intubation [10, 11]. They are fast to set up, portable and more durable than flexible scopes [12]. Their use may be associated with a higher success rate than Macintosh laryngoscopes in difficult airway scenarios [10], and, compared with flexible scopes, rigid scopes may reduce intubation time [13, 14]. Also, complication rates are similar to flexible scopes [13, 14] and the Macintosh laryngoscope [10].

The SensaScope (Acutronic Medical Systems AG, Hirzel, Switzerland, Fig. 1) is a semirigid scope with a steerable flexible tip and an S-formed shaft [15]. Oxygen can be supplied over the attached tracheal tube and an adapter. Reports claim 100% success rates in a difficult airway manikin study [16], and in sedated, spontaneously breathing patients [11]. Larger clinical trials, especially involving patients with a difficult airway, and comparative studies are sparse.

More trials have been conducted with the Bonfils (Karl Storz GmbH, Tuttlingen, Germany, Fig. 1) [12]. Byhahn et al. showed an overall success rate of 82% for the Bonfils in 38 patients with a simulated difficult airway compared with only 40% success with the Macintosh laryngoscope [10]. Others compared the Bonfils with flexible fibreoptic scopes and found the Bonfils reduced intubation time [13, 14].

The mentioned studies evaluated the Bonfils in a limited number of patients and comparative studies with the SensaScope are lacking. While the available studies compare different groups of airway devices such as flexible and rigid scopes, there is no evidence which of the rigid scopes performs best. We therefore performed a randomised controlled trial to compare the two types of rigid scopes.

Methods

This prospective, patient-blinded, randomised, controlled trial was designed to compare tracheal intubation with the Bonfils and the SensaScope in patients with a difficult airway created by a cervical collar [10, 17]. With local ethics committee approval and written informed consent, we included patients aged
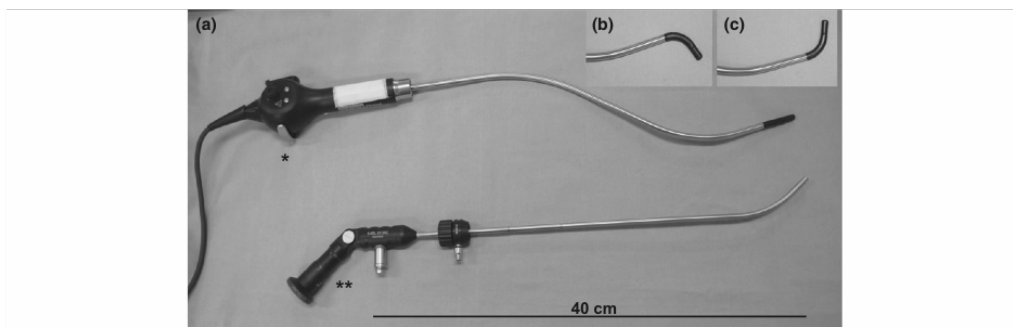
Figure 1 Visual comparison of the SensaScope and the Bonfils. Main panel (a): the SensaScope (upper device) is overall slightly longer than the Bonfils (lower device) and has an S-formed shaft, while the Bonfils has a straight shaft with a curved tip. Inset panel (b): the tip of the SensaScope is steerable both dorsally (b) and ventrally (c) with a control (marked at * in main panel) at the handhold. The Bonfils has a movable ocular fitting, to which a camera can be attached if desired (marked at **, main panel).

18–85 years, ASA physical status 1–3, scheduled at the Bern University Hospital for elective surgery requiring general anaesthesia with tracheal intubation. Exclusion criteria were: risk of aspiration of stomach contents; known difficult mask ventilation; mouth opening < 30 mm; or patients not speaking German or French, or refusing to participate.

Anaesthesia was induced and maintained with propofol and fentanyl with or without remifentanil, and deep anaesthesia was confirmed clinically by loss of eyelash reflexes, loss of reaction to jaw thrust and stable vital parameters. While providing bag-mask ventilation, a cervical collar (Stifneck™; Laerdal, Copenhagen, Denmark) was fitted tightly around the neck, reducing mouth opening and inhibiting cervical movement. Rocuronium 0.6 mg.kg^{-1} or atracurium 0.5 mg.kg^{-1} was given and neuromuscular blockade confirmed by loss of 1 Hz muscle twitching (TOF Watch, Organon, Dublin, Ireland) [18].

Patients were randomly allocated to the Bonfils or SensaScope using computer-generated randomisation numbers in sealed opaque envelopes. Both devices were readily available at the start of anaesthesia and the seal of the envelope was broken after induction of anaesthesia, when bag-mask ventilation was successfully provided.

The Macintosh laryngoscope was used to create a minimal retropharyngeal space for both the SensaScope and the Bonfils as described in the manufacturers' user manuals. The SensaScope was advanced midline just beyond the vocal cords [15]. The tracheal tube was then advanced under direct view [10]. For the Bonfils, the retromolar approach [12, 19] was used. Whilst directly viewing the vocal cords, the tube was advanced into the trachea without advancing the Bonfils beyond the level of the vocal cords. The video images were displayed on a screen. The SensaScope features a built-in camera ('chip in the tip'), while an additional camera was attached to the proximal end of the Bonfils. Throughout intubation, 4 l.min^{-1} of oxygen flow was applied via an adaptor. Tracheal tube sizes were 7.0 mm for women and 8.0 mm for men. After insertion of the tracheal tube and removal of the scope, the tube was connected to the anaesthesia circuit for assessment of ventilation and the study ended at this point [20].

Device failure was declared if the tube could not be placed in the trachea within two attempts: patients were ventilated by face-mask between attempts. Failure was also declared with the following criteria: oxygen saturation < 93% [21], soft tissue trauma with bleeding, laryngospasm, bronchospasm, oesophageal intubation and failed face-mask ventilation. Device failure led to stopping the study for this patient, removal of the extrication collar and airway management according to the attending anaesthetist.

The participating consultant anaesthetists were skilled and experienced in conventional laryngoscopy and flexible fibreoptic intubation [22, 23]. None of the devices was a standard intubation tool at the study site before the start of the study. All anaesthetists underwent airway manikin training and performed intubations on patients with the study devices until they, as airway management experts, felt competent, resulting in an equal level of experience with both devices for all participating anaesthetists.

Sex, age, height, weight, body mass index, ASA class, Mallampati score, thyromental distance, artificial dentition and mouth opening with and without the adjusted cervical collar were recorded.

The primary outcome parameter was overall intubation success rate; that is, successful intubation at the first or second attempt. A successful attempt was defined as tube placement in the trachea within 120 s [10]. First-attempt intubation success rate and intubation time were secondary outcome parameters. Intubation time was measured from the moment the face-mask was taken away from the face until the tube was placed and cuff inflated in the trachea. Time for positioning the device was the time from removing the face-mask until achievement of the correct device position to railroad the tube into the trachea. The intubation attempt was stopped after 120 s. If, however, after 120 s the tracheal tube was already being advanced, the attempt was not abandoned as long as oxygen saturations remained stable. If this happened during the first intubation attempt, the device counted as a failure in the first attempt, but as overall success. If the second attempt took > 120 s, the device counted as overall failure. If two attempts were necessary, 120 s of the first attempt was added to the time needed for the second attempt to calculate an 'overall intubation time'.

Insertion of the device into the oropharynx and correct positioning for intubation were subjectively classified as excellent, good, fair or poor by the intubating anaesthetist [24]. The difficulty of railroading the tube over the scope was graded. Fibreoptic view was graded as full view of the glottis, partial view of the glottis, only epiglottic structures visible or no glottic/epiglottic structures visible [20, 25]. Decreased visibility from mucus or fogging was noted.

Suspicion of aspiration or regurgitation, hypoxia (S_pO_2 < 93%), bronchospasm, airway obstruction, coughing, and dental, tongue or lip trauma were recorded. Twenty-four hours after surgery, a blinded investigator performed a structured interview with the patient to obtain data about side-effects [26]. The investigator was blinded to group allocation and device performance. They asked about sore throat, hoarseness, dysphagia, numbness of the tongue, and postoperative nausea and vomiting.

We expected that the SensaScope's steerable tip would improve manoeuvrability and that it would therefore perform better than the Bonfils. A different study in broadly the same setting reported a success rate for the Bonfils of 82% [10]. Our primary hypothesis was that the SensaScope has an overall intubation success rate that would be 15% higher compared with the Bonfils (alternative hypothesis), and we calculated the necessary sample size based on the expected failure rate of 18% for the Bonfils [10] and 3% for the SensaScope, Chi-square power analysis with a two-sided alpha level of 0.05 and a beta level of 0.1 calculated that 172 patients were necessary to confirm a difference. To compensate for dropouts, we planned to enrol 200 patients.

Binary data were compared with the Chi-squared test, or with Fisher's exact test if > 20% of expected values were below 5. Normal distribution was assessed using Q-Q plots and the Shapiro–Wilk test. Non-parametric data were analysed with a Mann–Whitney U-test, and continuous data with independent samples Student's t-test. Effect sizes and 95% confidence intervals [27] are reported as odds ratio for binary data. A probability of $p \leq 0.05$ was considered statistically significant. All statistical analyses were performed with Stata V.13.1 (StataCorp, College Station, TX, USA).

Results

A total of 236 patients agreed to participate. Because of lack of study personnel, 36 of these could not be included, leaving a total of 200 patients who were included and randomly allocated to a group. Twelve consultant anaesthetists participated. Intubations with the Bonfils and the SensaScope were equally distributed between them (p = 0.96).

Despite randomisation, weight and BMI were higher in the SensaScope group (both p = 0.01, unpaired Student's t-test) and showed a non-parametric distribution: 29 patients with a BMI > 30 kg.m^{-2}, 11 were in the Bonfils and 18 in the SensaScope group. All other patient characteristics and predictors of difficult airways were equally distributed between groups (Table 1, all p > 0.05). The cervical collar inhibited neck movement and reduced mouth opening significantly to a mean (SD) of 23 (3) mm, creating a difficult airway (Table 1).

There was no statistically significant difference in the overall intubation success rate (95% CI) between the devices: Bonfils 88 (80–94)%; SensaScope 89 (81–94)%; p = 0.82. The difference in success rate was 1.0 (−8 to 10)%, so that the null hypothesis was not rejected. Effect sizes are given in Table 2.

The first-attempt intubation success rate was 63 (53–72)% with the Bonfils and 72 (62–81)% with the SensaScope (p = 0.17, Table 2). The difference in first-attempt success rates was 9 (−4 to 22)%.

Table 1 Patient characteristics and predictors of a difficult airway. Values are number or mean (SD).

	Bonfils n = 100	SensaScope n = 100
Sex; females	49	37
Age; years	51 (17)	51 (17)
Height; cm	170 (9)	172 (9)
Weight; kg	73 (15)	79 (14)
BMI; kg.m^{-2}	25 (4)	27 (4)
ASA physical status 1/2/3	28/39/33	21/53/26
Mallampati score 1/2/3	63/33/4	56/42/2
Thyromental distance < 6 cm	0	2
Artificial dentition	26	20
Mouth opening without cervical collar; mm	45 (6)	45 (6)
Mouth opening with cervical collar; mm	23 (3)	23 (3)

Table 2 Tracheal intubation success rates with the two rigid scopes. Values are number (proportion), including 95% CI.

	Bonfils n = 100	SensaScope n = 100	Odds ratio 95% CI	p value
First-attempt success; 95% CI	63 (63%); 53–72%	72 (72%); 62–81%	1.50 (0.80–2.87)	0.17
Overall success; 95% CI	88 (88%); 80–94%	89 (89%); 81–94%	1.10 (0.42–2.92)	0.82

The time needed to correctly position the device and the time needed to place the tube in the trachea in the successful attempt did not differ between devices (Table 3). However, overall median intubation time was slightly but significantly longer with the Bonfils compared with the SensaScope (Table 3).

The difficulty of inserting and positioning the scope was graded similarly for both devices (Table 3). The fibreoptic view was significantly better with the SensaScope compared with the Bonfils (p = 0.01) and a full view of the vocal cords was achieved in 79% with the SensaScope and in 61% with the Bonfils.

Sometimes, secretions were suctioned (Bonfils 37 times; SensaScope 29 times, p = 0.23). These were mostly mucus or saliva and in few cases small amounts of blood. Intubation failed in eight Bonfils and in six SensaScope cases in which secretions were suctioned. In patients with successful intubation, only

a few were rated as showing reduced visibility from fogging or fluids after suctioning (Table 3).

In the Bonfils group, intubation was unsuccessful in 12 patients. Eleven of these were due to poor view of laryngeal structures and were declared as failures after two intubation attempts > 120 s. One attempt was declared as having failed when, despite a primary correct position of the scope, tube advancement was not possible and mucosal bleeding occurred. In the SensaScope group, intubation was unsuccessful in 11 patients. Ten of these were declared as failures after two intubation attempts > 120 s each. Nine failures were attributed to poor view of laryngeal structures and two were attributed to impossible tube advancement. In another patient, view of the vocal cords was not possible and the tube was blindly advanced into the oesophagus in the second intubation attempt. In 14 patients in whom intubation failed (eight Bonfils,

Table 3 Successful intubation attempts: Intubation times, ease of intubation and quality of view of anatomical structures. Values are median (IQR [range]) or number (proportion).

	Successful Bonfils n = 88	Successful SensaScope n = 89	p value
Times			
Time for positioning of the device; s	21 (12–40 [5-129])	15 (9–38 [2-125])	0.06
Intubation time of the successful attempt; s	34 (22–55 [12-145])	29 (18–49 [5-190])	0.14
Overall intubation time; s	45 (25–134 [12-230])	34 (20–84 [5-240])	0.04
Device positioning			
Insertion into the oropharynx easy/good/fair/poor	44/28/15/1 (50/32/17/1%)	52/25/12/0 (58/28/13/0%)	0.23
Correct positioning for intubation easy/good/fair/poor	42/37/8/1 (48/42/9/1%)	57/23/9/0 (64/26/10/0%)	0.06
View			
Best fibreoptic view 1/2/3/4†	54/32/1/1 (61/36/1/1%)	70/19/0/0 (79/21/0/0%)	0.01
Visibility good/reduced by fogging/by mucus or blood	84/1/3 (95/1/3%)	86/1/2 (97/1/2%)	0.69
Tube advancement			
Advancement of tracheal tube easy/with manipulations	83/5 (94/6%)	86/3 (97/3%)	0.46

†Fibreoptic view graded as 1: full view of the glottis, 2: partial view of the glottis, 3: only epiglottic structures visible, 4: no glottic/epiglottic structures visible [20, 25].

six SensaScope), mucus or blood was suctioned to improve visibility, but this did not lead to intubation success.

All cases of failed intubation were managed uneventfully after removal of the cervical collar by direct laryngoscopy or by intubation with the rigid scope (Bonfils five times direct laryngoscopy, seven times rigid scope; SensaScope: seven times direct laryngoscopy, four times rigid scope).

In one patient in the SensaScope group, a cuff leak was discovered after intubation and the tube was exchanged via an exchange catheter (Cook™ Airway Exchange Catheter; Cook Medical, Bloomington, IN, USA). Despite the cuff leak, this intubation was rated as successful. In another case, which was rated as a failure due to oesophageal intubation, oxygen saturation briefly dropped below 93%. This patient was promptly ventilated by face-mask and the clinical course was uneventful.

There was no aspiration of stomach contents, regurgitation, bronchospasm, airway obstruction, coughing, dental or tongue trauma in either group. Lip or mucosal trauma occurred in 10% of Bonfils and in 5% of SensaScope patients (p = 0.18, Table 4). Postoperative side-effects are reported in Table 4 and were similar between groups.

Discussion

The success rate with the Bonfils in our study was somewhat higher than previously reported [10], and our data showed no difference in overall success rate between the two scopes. We previously defined a success rate of at least 90% to be the target for devices designed to manage difficult airways [28, 29]. Both

Table 4 Side-effects and adverse events. Values are number.

	Bonfils n = 100	SensaScope n = 100	p value
Lip or mucosal trauma	10	5	0.18
Sore throat†	8	9	0.83
Hoarseness†	22	28	0.37
Dysphagia†	22	18	0.44
Numbness of the tongue†	1	1	1.00
Nausea†	31	33	0.84
Vomiting†	22	20	0.67

†Data missing for 2 Bonfils patients.

devices narrowly missed this target, but nevertheless their success rates were in the range reported for videolaryngoscopes that showed overall success rates ranging from 88 to 100% and first-attempt success rates ranging from 57 to 98% in simulated difficult airways [8, 30, 31]. For flexible fibreoptic scopes, some studies reached higher overall success rates ranging from 95 to 100% and first-attempt success rates ranging from 79 to 100% [4, 5], but other studies that directly compared flexible fibreoptic scopes with rigid scopes showed that success rates with flexible and rigid scopes are comparable [12–14]. These studies also showed that intubation times were shorter with rigid scopes.

We decided to compare two devices from one class instead of devices from different classes such as flexible fibreoptic scopes or videolaryngoscopes. In particular, we did not include the Macintosh laryngoscope, since it had already been shown that the Macintosh laryngoscope is clearly inferior to rigid scopes in the same simulated difficult airway scenario, with first-attempt success rates around 40% [10].

In our study, first-attempt intubation success rates were substantially lower than overall success rates. The difference in first-attempt success rate with the Bonfils between our study (63%) and the study by Byhahn et al. (71%) [10] might be related to the smaller mouth opening in our study [23 (3) mm] compared with Byhahn's study [26 (8) mm].

Reduced visibility from mucus and blood is a known problem with fibreoptic devices and in the 14 described cases where intubation failed and mucus or blood was suctioned, suctioning did not lead to intubation success. Reduced visibility may not have been the only cause for failure to intubate but neither continuous flow of oxygen or suctioning prevented the problem of reduced visibility.

Overall intubation time was significantly shorter and fibreoptic view was significantly better with the SensaScope than with the Bonfils. We attributed this difference to better manoeuvrability of the SensaScope, which is as a result of its flexible tip.

With soft tissue trauma rates of 5–10%, both devices performed in a range similar to other intubation devices in patients with simulated difficult airways or patients with only predictors for difficult airways [31–33].

Our study included patients with a simulated and not a real difficult airway. The cervical collar reduced mouth opening significantly and inhibited neck movement, thus creating a difficult-to-intubate situation, as has been performed in many previous airway management studies [10, 17, 34]. The setting of a difficult airway caused by inhibited neck movement and limited mouth opening represents a relevant reason for a difficult airway, but it remains speculative how the scopes would perform in other difficult airway situations or with different intubation techniques that do not use a Macintosh laryngoscope to create retropharyngeal space described for the Bonfils. Also, we did not measure cervical spine tension or movement during intubation, as this was not in the scope of the study. Studying patients with a real difficult airway in a randomised, controlled trial is ethically challenging which is why our chosen study approach has been widely used by different researchers [10, 17, 34].

By chance and despite random allocation, patients in the SensaScope group were heavier and had a higher BMI than patients in the Bonfils group. Logistic regression with 'device' and 'BMI' as factors did not indicate an influence of the difference in BMI on overall (p = 0.83) or first-attempt intubation success (p = 0.48).

We acknowledge that the relevance of our results may be limited for hospitals where rigid scopes are not available. Even at our own institution, neither device was standard, but, as described, we were careful to ensure prior training before the study, and we found good and equal performance of both rigid scopes in the described difficult airways, with success rates that were similar to those of flexible fibreoptic scopes and videolaryngoscopes.

Acknowledgements

Competing interests

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TRIALS

SWIVIT - Swiss video-intubation trial evaluating video-laryngoscopes in a simulated difficult airway scenario: study protocol for a multicenter prospective randomized controlled trial in Switzerland

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Abstract

Background: Video-laryngoscopes are marketed for intubation in difficult airway management. They provide a better view of the larynx and may facilitate tracheal intubation, but there is no adequately powered study comparing different types of video-laryngoscopes in a difficult airway scenario or in a simulated difficult airway situation.

Methods/Design: The objective of this trial is to evaluate and to compare the clinical performance of three video-laryngoscopes with a guiding channel for intubation (Airtraq™, A. P. Advance™, King Vision™) and three video-laryngoscopes without an integrated tracheal tube guidance (C-MAC™, GlideScope™, McGrath™) in a simulated difficult airway situation in surgical patients. The working hypothesis is that each video-laryngoscope provides at least a 90% first intubation success rate (lower limit of the 95% confidence interval >0.9). It is a prospective, patient-blinded, multicenter, randomized controlled trial in 720 patients who are scheduled for elective surgery under general anesthesia, requiring tracheal intubation at one of the three participating hospitals. A difficult airway will be created using an extrication collar and taping the patients' head on the operating table to substantially reduce mouth opening and to minimize neck movement. Tracheal intubation will be performed with the help of one of the six devices according to randomization. Insertion success, time necessary for intubation, Cormack-Lehane grade and percentage of glottic opening (POGO) score at laryngoscopy, optimization maneuvers required to aid tracheal intubation, adverse events and technical problems will be recorded. Primary outcome is intubation success at first attempt.

Discussion: We will simulate the difficult airway and evaluate different video-laryngoscopes in this highly realistic and clinically challenging scenario, independently from manufacturers of the devices. Because of the sufficiently powered multicenter design this study will deliver important and cutting-edge results that will help clinicians decide which device to use for intubation of the expected and unexpected difficult airway.

Trial registration: NCT01692535

Keywords: Video-laryngoscope, Difficult airway, Airtraq, A. P. Advance, C-MAC, Glidescope, King vision, Mcgrath

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Background

Difficult airway management remains a cornerstone of clinical anesthesiology. Difficulty in tracheal intubation is the most common factor related to serious airway complications during general anesthesia [1]. Recently, the combination of the fiberoptic bronchoscope and the laryngoscope led to the development of video-laryngoscopes, providing a video-based view of the glottic opening, with or without additional guidance of the tube towards the tracheal opening. Six devices are under prominent focus in recent publications.

1) The Airtraq (Prodol Meditec SA, Vizcaya, Spain) was the first video intubation device that featured a channel guiding the tube towards the tracheal opening. The blade of the Airtraq is disposable. One study published in 2007 in *Anesthesiology* showed a 100% success rate at first attempt when using manual inline stabilization [2].

2) The A. P. Advance Video-laryngoscope (Venner Medical SA, Singapore) is based on a standard Macintosh laryngoscope that can be used as a stand-alone direct laryngoscope, or as a video-laryngoscope with a monitor attached to the handle and includes a "difficult airway" blade. A manikin study showed short intubation times for certified paramedics with the A.P. Advance [3], but large adequately powered, randomized controlled trials in difficult airway scenarios are lacking.

3) The C-MAC (Karl Storz, Tuttlingen, Germany) features size 2, 3 or 4 Macintosh blades or a "D"-blade (Difficult Airway Blade). The D-blade failed at first attempt in 30% of patients who showed a Cormack-Lehane grade 3 or 4 in a study by the inventor of the design [4]. One study shows a 93% success rate with the C-MAC using size 3 and 4 blades, compared to 84% for direct laryngoscopy when using manual inline stabilization, but intubation took longer [5].

4) The GlideScope (Verathon Inc., Bothell, WA, USA) is a widely used non-guided video-laryngoscope consisting of a curved video blade (single-use or reusable) and a special stylet to be used with the tracheal tube. An observational study in 50 patients showed a 100% success rate of the GlideScope in a difficult airway model using stiff extrication collars [6]. It also reduced intubation times compared with the conventional Macintosh laryngoscope in patients under manual inline stabilization [7].

5) The King Vision (Kingsystems, Noblesville, IN, USA) features either a channeled or a regular, disposable blade size 3. To date, there are no randomized controlled trials available for this device.

6) The McGrath MAC (Aircraft Medical Lt., Edinburgh, UK) is a non-guided video-laryngoscope that features disposable blades. It has been developed from the McGrath Series 5. In a randomized controlled trial with patients with a Mallampati grade of ≥3, the McGrath Series 5 provided a better laryngeal view compared to the C-MAC, but intubation took longer and more intubation attempts where needed [8]. To date, there are no randomized controlled trials available for the McGrath MAC video-laryngoscope.

These optical intubation devices or video-laryngoscopes (VLS) have dramatically improved the quality of glottic visualization. Multiple studies have proven enhanced visibility but not necessarily faster intubation times. Interestingly, in a study on manikins simulating difficult airway with stiff collars, VLS was not superior to direct laryngoscopy, but the sample size was low [9]. Furthermore, while VLS improve visualization of the airway, it is important to realize that a good view of the laryngeal opening does not automatically lead to intubation success. For example, in a recent study, the C-MAC VLS showed a good view of the larynx in 95% of cases, but the actual success rate of the intubation was only 88% [10]. These different success rates cannot directly be compared since these studies were performed in different patient populations by different operators, in different settings regarding difficult airways, and with different outcome parameters. Most importantly, the majority of patients enrolled presented with a normal airway, or only manual inline stabilization was used to simulate a difficult airway. No study compared all these devices in the same setting, and no sufficiently powered study used extrication collars to adequately simulate a clinically important difficult airway situation.

Specific aims of the study are:

1) To investigate which VLS devices reach a clinically acceptable minimal first attempt success rate of 90% in a simulated difficult airway scenario (primary outcome). We assume this lower limit of "90% first attempt success rate" is the lowest tolerable success rate in a difficult airway scenario.

2) To compare primary and overall success rates, view on the tracheal opening and time until intubation with the help of the guided vs. unguided VLS devices.

3) To evaluate possible adverse events, complications and side effects.

According to these specific aims, we propose the following hypotheses:

1) For our primary outcome, we assume that the lower limit of the 95% confidence interval (95% CI) of the

first attempt success rate is not lower than 90%. The null hypothesis states that the 95% CI of first attempt success rate is below 0.9.

2) Successful tracheal intubation takes more time using unguided VLS compared with the other VLS devices that guide the tube towards the tracheal opening. The secondary null hypothesis states that there is no statistically significant difference in time until intubation success between a guided and an unguided VLS (two-sided). Other secondary outcome-hypotheses include that the overall attempt success rates are higher in guided VLS compared with unguided VLS.

3) Minor airway injury rates are within a maximum of 10% comparing guided vs. unguided VLS. The null hypothesis states that the differences of minor airway injury rates are higher than 10%.

Methods/design

Study design

The SWIVIT trial is a prospective, patient-blinded, multicenter, randomized controlled trial at the anesthesia departments of the University Hospital of Bern, the University Hospital of Lausanne and the University Hospital of Geneva, all in Switzerland.

Patient population

With ethics committee approval (KEK Bern ref. nr. 106/12 on 11 September 2012; Chairperson: Prof. Dr. N. Tueller) and written informed consent, we will include adult patients of both genders, ASA (American Society of Anesthesiologists) physical status I to III, and scheduled at one of the participating hospitals for elective surgery under general anesthesia requiring tracheal intubation.

Patients are not eligible if they are at risk for aspiration (non-fasted, severe gastro-esophageal reflux disease, hiatal hernia), with known or presumed difficult airways (body mass index >35 kg/m^2, Mallampati >III, thyromental distance <6 cm, interincisor distance <3.5 cm [11], known difficult mask ventilation or difficult laryngoscopy, or scheduled for awake tracheal intubation), or if they refuse to participate or are unable to give informed consent.

Sample size calculation

Most previous studies have based sample size calculations on differences of the intubation difficulty score (IDS), developed by Adnet in 1997 for direct laryngoscopy [12]. However, a retrospective study by McElwain has raised concerns about the validity of the IDS with VLS [13]. The most important outcome parameter for VLS or any guided intubation devices is the success rate. Most available data are from patients with normal airway anatomy and, therefore, not comparable with our setting. Only one study immobilized the patients' necks

with collars to investigate the C-MAC in 43 patients. That study found an overall success rate of 88% [10]. This is an unacceptable low success rate for the management of a difficult airway, but the study was underpowered: we calculated the 95% CI in that study to be 0.75 to 0.95 for overall success rate.

In order to rate an intubation device as "successful", we define that the lower limit of the 95% CI should not be smaller than 0.9. We based our sample size on these values, congruent with our findings in a small pilot sample. We calculated the necessary sample size to obtain a distance of 0.05 to the expected success rate of 0.95, provided a probability of 0.95 and a power of 80% (SAS v.9.1, SAS Institute Inc., Cary, NC, USA). A total of 107 patients per device are necessary for this lower limit of 0.9. A total of 642 (6 × 107) patients will be necessary based on these assumptions, which leads us to include 720 patients to compensate for dropouts or missing data.

Secondary endpoints include parametric data, such as time necessary until success. Time until success has varied widely among different devices in published studies. Furthermore, that parameter seems to be influenced by the anesthesia provider. Therefore, we based our sample size calculation on first attempt success rate.

Because available data about our primary outcome, the first attempt success rate in a simulated difficult airway scenario, are scarce, we will recalculate sample size after the first 120 patients, based upon the values obtained from the first 20 patients for each device. In order to reduce bias, all participating investigators will remain unaware of results obtained from these 120 patients.

We will compare time to intubate in unguided vs. guided VLS as the secondary outcome. There are not sufficient data available to calculate sample size for this secondary outcome parameter. Therefore, we base our sample size calculation on effect size: based on an estimated medium effect size (Cohen's d of 0.5; assuming normal distribution), 64 samples per group are necessary, given a 0.05 level (P = 0.05) and 80% power. Because our primary outcome requires 107 patients per group, we are well within the necessary sample size even for this secondary outcome parameter.

Experience with the device is expected to be a major confounding factor. Only a limited number of experienced anesthesiologists at each study center will perform the intubation. To avoid a learning curve bias and to minimize variation in the performance, only anesthesiologists who have intubated patients without any airway pathology several times with each device until they feel competent with the devices will participate. We did not set *a priori* a fixed figure of intubations for each device because the individual experience with different devices is very divergent between the study centers and the participating anesthesiologists. Ideally, experience with the

device should be equal, and prior experience will be recorded. We limit participants per center to a maximum of four physicians.

Statistical analysis

For the primary outcome, it will be analyzed for each laryngoscope whether the 95% confidence interval of its primary success is below 0.9. For the secondary outcome parameters, the data distribution will determine which statistical test will be used. For frequencies (for example, number of required manipulations, overall attempt success, complications) chi-square test or Fisher's exact test will be used. Parametric data will be analyzed using ANOVA; for non-parametric continuous data Kruskal-Wallis test will be used. For comparison between two devices, we will use Student's *t*-test

and Mann-Whitney's *u*-test, as appropriate. We will do *a priori* comparisons of the time necessary until success between the unguided VLS and any of the guided VLS.

Data will be presented as mean with standard deviation, median and interquartile range, or number and percent. Effect sizes (with 95% CI) will be reported as Cohen's d for interval data and as odds ratio for proportions. A probability of 0.05 is considered as statistically significant.

The patient flow diagram according CONSORT guidelines is provided in Figure 1.

Detailed study plan
Consent procedure

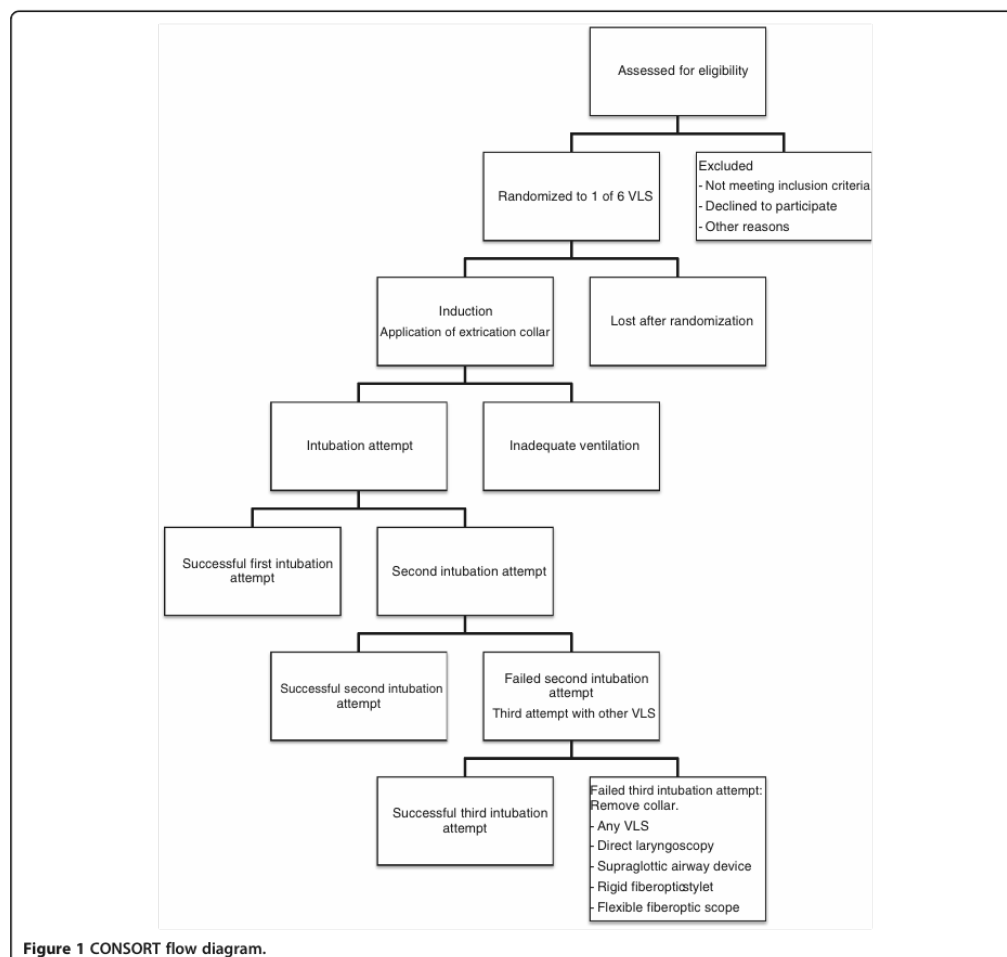Patients will be recruited from the operating room schedule of the corresponding hospitals. Written, informed consent

Figure 1 CONSORT flow diagram.

will be obtained from each patient on the day before surgery. All participants will be given a copy of the *Patient Information Sheet* and be specifically informed that they may decline to participate in or withdraw from the study at any time.

Allocation of patients

Patients with written informed consent are randomly allocated to one of the six devices. The allocation sequence will be generated using online randomization software (http://randomization.com) in blocks of 30 intubations for the devices and stratified for each participating center and for each physician. The allocation will be concealed in sealed, opaque, sequentially numbered envelopes and will not be opened until the patient is anesthetized.

Clinical study procedure

Premedication will be according to the standard operating procedures of the participating centers. Standard non-invasive monitoring includes ECG, non-invasive arterial blood pressure, oxygen saturation (SpO_2), end-tidal CO_2 and volatile anesthetic level if applicable. A bispectral index (BIS, Aspect Medical Systems, Norwood, MA, USA) or a different processed EEG monitoring will be used whenever available. Anesthesia will be induced with propofol 1.5 to 3 mg/kg body weight and fentanyl 1 to 2 mcg/kg body weight. After facemask ventilation is established, neuromuscular blocking agents (rocuronium 0.6 mg/kg body weight) will be given and appropriate action monitored by neuro-stimulation. The inter-incisor distance at maximum mouth opening will be measured while the patient is asleep. Then, the extrication collar (Stifneck™, Laerdal, Copenhagen, Denmark) will be properly adjusted, and a self-adhesive tape will be used to fix the head on the operating table, as done in an earlier study by our group [6]. The inter-incisor distance will be measured at maximal mouth opening aiming at a mouth opening between 20 to 25 mm.

If mask ventilation remains adequate and a sufficient level of anesthesia is confirmed (BIS <55, stable hemodynamic parameters, unresponsiveness to jaw thrust), the tracheal intubation will be performed with the help of one of the six VLS, according to randomization.

Selection of tracheal tube size (Mallinckrodt Hi-Contour Oral/Nasal Tracheal Tube Cuffed, Covidien, Hazelwood, MO, USA)

Women: 6.5 mm ID (internal diameter)
  Men: 7.5 mm ID

Selection of blade size

1) Airtraq: Size #2 in women (6.5 mm tracheal tube does not fit in size #3 device), size #3 in men

2) A. P. Advance: Difficult airway blade for guided intubation
3) C-MAC: D-blade. Additionally, a pre-shaped stylet (shaped according to the decision of the consultant anesthesiologist) will be used for tracheal insertion.
4) GlideScope: GVL single use blade #3 with reusable GlideScope stylet for tracheal tube
5) King Vision: Blade #3 (channeled)
6) McGrath MAC: Disposable McGrath MAC blade. Additionally, a pre-shaped stylet (shaped according to the decision of the consultant anesthesiologist) will be used for tracheal insertion.

The primary endpoint is successful tracheal intubation confirmed by capnography (CO_2 monitoring). Further management of anesthesia is according to the consultant anesthesiologist.

Device failure

A device failure is defined as two unsuccessful intubation attempts with a maximum of 180 seconds for each attempt while oxygen saturation remains >90%. The intubation attempt is allowed to continue if the laryngeal opening is identified after 180 seconds and the patient does not desaturate (SpO_2 >90%). However, this will not count as success at the first attempt, but as an overall attempt success. After the second unsuccessful attempt, a third and last attempt will be performed with another device, chosen according to the decision of the attending anesthesiologist with the rigid collar in place. In case of failure of the second device, further airway management will be according to the decision of the attending anesthesiologist, and without the rigid collar.

Break-up criteria (leading to removal of the rigid collar)

– Primary and secondary VLS device failure
– Bronchospasm, injury
– Technical failure of the intubation devices during insertion attempt (for example, light bulb failure or monitor failure)

If a break-up criterion is reached, the extrication collar will be removed, the patient ventilated if necessary and the trachea will be intubated via either the randomized device (one attempt) or any other further airway management device, according to the attending anesthesiologist. The attending anesthesiologist may choose another airway management strategy once a break-up criterion is reached.

Measurements

– Insertion success (first and second attempt success rate).

Definition of success

Lung ventilation through the cuffed tracheal tube, confirmed by end-tidal CO_2.

– Time necessary for completion of the first attempt intubation, second attempt (if applicable) and overall intubation (calculated as the sum of the first and, if applicable, second attempt).

Definition of time

Time necessary until success is measured from the time the facemask is taken away from the face until the end-tidal CO_2 curve appears on the monitor of the respirator. Time for each attempt is measured separately.

– Cormack-Lehane (CL) grade [14] at laryngoscopy (not developed for indirect laryngoscopy, but necessary for the calculation of the IDS).
– Inter-incisor distance before induction of anesthesia and after placement of the collar to measure maximum mouth opening and the reduction of mouth opening by the collar (collar adjusted to permit a minimal opening of 18 mm, according to the minimal requirements for Airtraq and King Vision)
– Number of optimization maneuvers required (cricoid pressure or BURP, backward, upward, rightward pressure), second assistant, adjustment of head positioning) to aid tracheal intubation [15].
– View on the glottic opening in percent (%) as judged by the operator: Percentage of Glottic Opening (POGO) Score [16].
– Adverse events: cardiovascular extremes: any hypo-/hypertension and tachycardia/ bradycardia exceeding 20% from baseline. Blood on device, and injury during intubation attempt, suspicion of aspiration/regurgitation (gastric fluid in the ventilation tube or in the hypopharynx), hypoxia (SpO_2 <90%), bronchospasm, airway obstruction or any other form of stridor, coughing, dental, tongue or lip trauma.
– Technical problems with the device, such as fogging, impeded vision and monitor/light source failure.
– The Intubation Difficulty Scale (IDS) score will be calculated as previously published [12], using the following parameters: number of attempts and operators, alternative techniques, Cormack-Lehane grade, lifting force, laryngeal pressure and vocal cord mobility.
– Demographic and perioperative data: sex, age, weight and body mass index, dentition, surgical procedure/ duration, duration of anesthesia, date/ time of hospital discharge.

Postoperative evaluation by blinded personnel

After anesthesia, the recovery room nurse (blinded about randomization) will use a checklist to assess for any airway trauma. The checklist, which includes questions about active oral bleeding, coughing blood, blood-stained saliva, sore throat, pain when swallowing, coughing, postoperative nausea and hoarseness, follows a 3-graded assessment by the patient (mild, moderate, severe). Timing of this assessment will be standardized to one hour after post-anesthesia care unit admission. If patients are extubated in the intensive care unit (ICU), the ICU nurse will make the assessments. On postoperative day one, a member of the study personnel will make a further assessment, using the same checklist. In case of ambulatory surgery, assessment will be done by telephone. The investigator will be unaware of the randomization, any problems encountered during intubation or surgery, and will be blinded about the performance of the airway device.

Data collection techniques

All clinical data will be collected by a research assistant at bedside, using digital data recording devices (tablets). In case of device failure, a back-up paper form will be available. All data will be sent to a secure, central data storage immediately after the closure of the local case report form.

Ethical approval

The SWIVIT randomized controlled trial has been approved by the ethic committee of the canton of Bern (KEK Bern ref. nr. 106/12 on 11 September 2012).

A summarizing study flow chart is provided in Figure 2.

Discussion

According to the latest national audit in anesthesia in the UK, major adverse events are estimated to be as high as 1 in 5,500 anesthesia cases, leading to brain damage and even death [1]. Airway management was deemed to be good in only 19% of these cases. This is an unacceptable high failure rate for our patients' safety. Therefore, new and supposedly better devices to manage the difficult airway are necessary and continue to enter the market, often without thorough evaluation of their efficacy. In case of use of such devices in a difficult airway situation, it is vital to know which device will perform best. While VLS are marketed to facilitate the tracheal intubation in difficult airway management, there are no adequately powered data available comparing VLS in real difficult airway situations or, at least, adequately simulated difficult airway models. We intend to deliver this evidence. This will be for the benefit and safety of patients presenting with an expected or unexpected difficult airway needing general anesthesia for surgery or interventions.
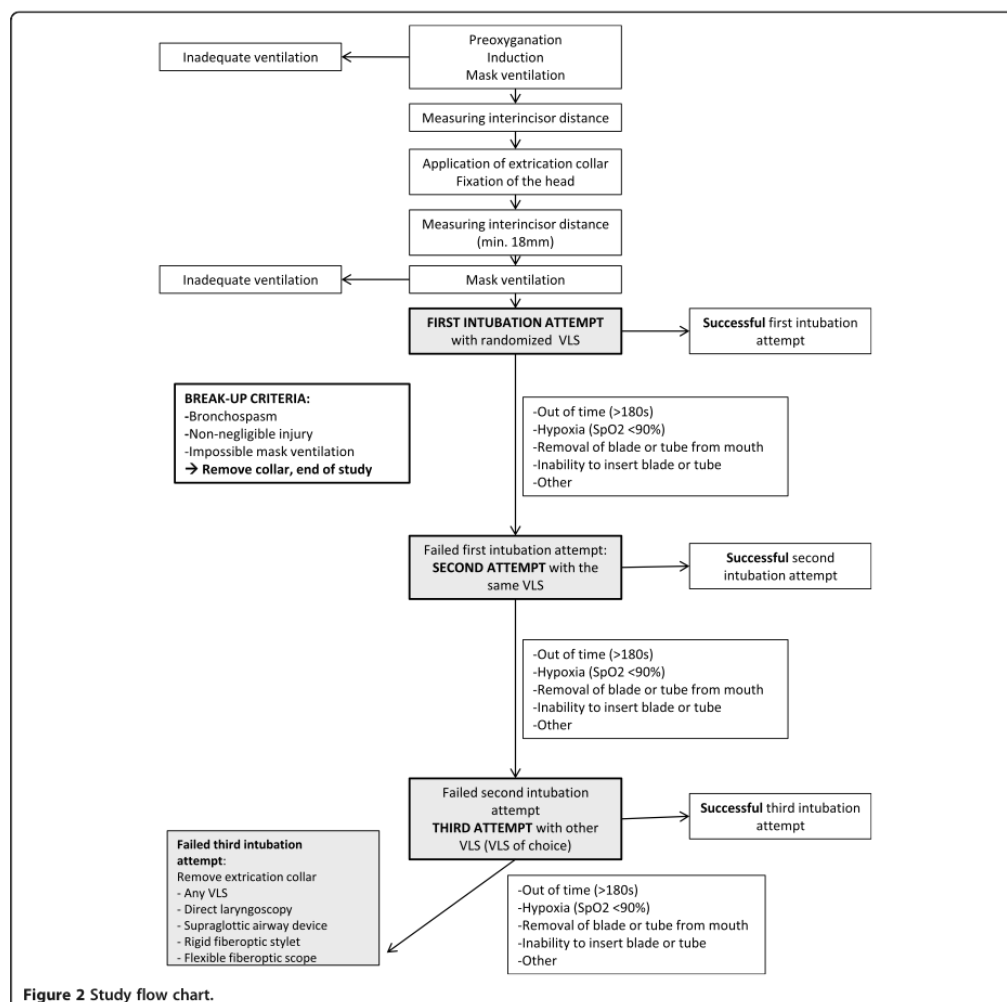
Figure 2 Study flow chart.

Potential problems and limitations

Because sample size has been calculated based on relatively vague figures, some adjustments in the total, necessary sample size may have to be incorporated when we re-calculate our sample size after the first 120 patients as per protocol. However, the statistical calculation is sound, and our assumptions are based on highly probable clinical expectations. Furthermore, the results of our study will be of clinical relevance regardless of whether our primary hypothesis will be confirmed or not and the much-feared "negative results" should be of no concerns in this study.

Generalizability

In this clinical trial, we will use a statistical model that may be incorporated in future trials as well. Most clinical airway studies seek to prove a difference between devices, or postulate agreement within pre-defined values, some are designed as so called "non-inferiority" trails. In this study, we pre-define an important clinical value as a benchmark on which all devices studied are compared with the 90% minimal first attempt success rate. We believe an airway device should strive for this success rate, although that would still mean a failure in 1 out of 10. However, standard procedures in the difficult airway model used for this study

have been shown to perform even less well: direct laryngoscopy succeeds only in 39.5% of cases [17] and rigid fiberoptics fail in 9 to 14% (own data, not published yet). Flexible fiberoptic intubation would be the method of choice, however, it is highly operator dependent and time consuming [18], and showed recently a not that impressive first attempt success rate of only 79% [19].

Trial status

At the time of submission, the study was actively enrolling patients. Fewer than 10 patients had been enrolled in total in all three centers.

Abbreviations

ASA: American Society of Anesthesiologists; BIS: Bispectral index; BURP: Backward, upward, rightward pressure; CI: Confidence interval; CL: Cormack-Lehane; ECG: Electrocardiography or electrocardiogram; EEG: Electroencephalography or electroencephalogram; ID: Internal diameter; IDS: Intubation Difficulty Scale; POGO Score: Percentage of glottic opening score; SpO$_2$: Oxygen saturation; SWIVIT: Swiss video-intubation trial; VLS: Video-laryngoscopes.

Competing interests

We received the Airtraq™ from Prodol Meditec SA represented by MK-MED AG in Switzerland, the A. P. Advance™ from Venner Medical SA, the C-MAC™ from Karl Storz represented by Anklin in Switzerland, the Glidescope™ from Verathon Medical Inc. represented by Anandic Medical Systems in Switzerland, the King Vision™ from Kingsystems represented by Anel GmbH in Switzerland, and the McGrath™ from Aircraft Medical Lt. represented by Covidien in Switzerland, all without costs. The authors declare that they have no competing interests.

Authors' contributions

RG and LT are the principle investigators of this study, both developed the study design and drafted and revised the protocol. KH contributed to the preparation of the study, the clinical report form, and the final protocol, designed the first draft of the manuscript, and is responsible for the organization of data acquisition as well as the coordination among the three centers (study coordinator). NU and MKB assisted in the development of the protocol, and in the final writing and reviewing of the manuscript. PS is the local principle investigator at the University Hospital of Lausanne, contributed to the final protocol and oversees the study project at that site. GS is the local principle investigator at the University Hospital of Geneva, contributed to the final protocol and oversees the study project at that site. KA helped in establishing the protocol and contributed the statistical calculations. All authors read and approved the final manuscript.

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Original article

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      Concept & planning

      Data collection

      Data analysis

      Manuscript writing & editing

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Evaluation of six videolaryngoscopes in 720 patients with a simulated difficult airway: a multicentre randomized controlled trial

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Abstract

Background: Videolaryngoscopes are aggressively marketed, but independent evaluation in difficult airways is scarce. This multicentre, prospective randomized controlled trial evaluates six videolaryngoscopes in patients with a simulated difficult airway.

Methods: With ethics committee approval and written informed consent, 12 senior anaesthetists intubated the trachea of 720 patients. A cervical collar limited mouth opening and neck movement, making intubation difficult. We evaluated three unchannelled (C-MAC™ D-blade, GlideScope™, and McGrath™) and three channelled videolaryngoscopes (Airtraq™, A.P. Advance™ difficult airway blade, and KingVision™). The primary outcome was first-attempt intubation success rate. Secondary outcomes included overall success rate, laryngeal view, intubation times, and side-effects. The primary hypothesis for every videolaryngoscope was that the 95% confidence interval of first-attempt success rate is ≥90%.

Results: Mouth opening was decreased from 46 (SD 7) to 23 (3) mm with the cervical collar. First-attempt success rates were 98% (McGrath™), 95% (C-MAC™ D-blade), 87% (KingVision™), 85% (GlideScope™ and Airtraq™), and 37% (A.P. Advance™, P<0.01). The 95% confidence interval of first-attempt success rate was >90% only for the McGrath™. Overall success, laryngeal view, and intubation times differed significantly between videolaryngoscopes (all P<0.01). Side-effects were minor.

Conclusions: This trial revealed differences in the performance of six videolaryngoscopes in 720 patients with restricted neck movement and limited mouth opening. In this setting, first-attempt success rates were 85–98%, except for the A.P. Advance™ difficult airway blade. Highest success and lowest tissue trauma rates were achieved by the McGrath™ and C-MAC™ D-blade, highlighting the importance of the videolaryngoscope blade design.

Clinical trial registration: ClinicalTrials.gov: identifier NCT01692535.

Key words: anaesthetic techniques, laryngoscopy; equipment, airway; intubation, tracheal tube

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Editor's key points

- Videolaryngoscopes may be useful in patients with difficult airways, but there may be differences in their efficacy.
- Six videolaryngoscopes were compared in patients with simulated difficult airway (application of a cervical collar to limit mouth opening and neck movement) in the ease of tracheal intubation.
- There were marked differences between six videolaryngoscopes in the efficacy of tracheal intubation.

In the Fourth National Audit Project on major complications of airway management in the UK, the reported incidence of major adverse airway events was 1 in 22 000 anaesthesia patients, but the real incidence was estimated as 1 in 5500 anaesthesia patients.[1] Videolaryngoscopes have been developed by combining features of classic laryngoscopes and fibre-optic bronchoscopes in an effort to increase intubation success rates and to decrease anaesthesia-related morbidity and mortality. A steadily increasing number of videolaryngoscopes are marketed, but a sound evaluation before marketing is often missing.[2–4] Videolaryngoscopes vary with regard to the shape of their blades, camera location, video screen, integration of a channel for tracheal tube guidance, and single-use vs multiple-use design.

Many studies on videolaryngoscopes were carried out in manikins,[5–8] in cadavers,[7] or in patients with normal airways. In the setting of predicted, simulated, or genuine difficult airways, studies demonstrated superiority of videolaryngoscopes compared with the classic Macintosh laryngoscope, with better laryngeal views[7 9–15] and higher intubation success rates[10 12–18] with the videolaryngoscopes.

In patients with positive predictors for difficult intubation, such as a Mallampati score of III or IV, the C-MAC™ (93%)[12] and the Berci–Kaplan™ videolaryngoscope (99%)[10] showed higher first-attempt success rates than the Macintosh laryngoscope (84 and 92%, respectively, in the two studies). Other studies confirmed overall success rates of more than 90% in this setting with the C-MAC™,[14 19 20] the GlideScope™,[14 19] and the McGrath™.[20] However, the inclusion criterion for these studies was the presence of one predictor for difficult intubation, and it is known that predictors such as the Mallampati score have high inter-rater variabilities[21 22] and that the sensitivity of single predictors for difficult intubation is low (Mallampati: pooled sensitivity of 49%).[23] The high success rates with the Macintosh laryngoscope of more than 80% show that, indeed, most of the included patients probably did not have a true difficult airway.[10 12]

Other studies evaluated videolaryngoscopes in patients with manual in-line stabilization, reducing neck movement as much as possible. In this setting, Liu and colleagues[24] compared the Airway Scope™ and the GlideScope™ and found high success rates with the use of both devices (100 and 89%, respectively).[24] McElwain and Laffey[15] showed that the Airtraq™ performed better than the C-MAC™ with its Macintosh-style blade,[15] and Enomoto and colleagues[13] found that the Pentax-AWS™ had higher success rates than the Macintosh laryngoscope (100 vs 89%, respectively).[13] A study in patients in whom conventional laryngoscopy had failed confirmed success rates of more than 90% with the Pentax-AWS™.[11]

Given that videolaryngoscopes are promoted as tools for the difficult airway, their performance in difficult airways needs to be known. As true difficult airways are rare and possibly life threatening, the performance of intubation devices for difficult

airways is frequently evaluated by reversibly creating 'difficult-to-intubate' situations with cervical collars.[9 25–27] These collars restrict neck movement and, importantly, also limit mouth opening (which could not be achieved by manual in-line stabilization). The cervical collar creates airways that are far more difficult to intubate (success rates with the Macintosh laryngoscope around 40%)[25] than airways under manual in-line stabilization only (success rates >80%).[13] With a cervical collar, Byhahn and colleagues[9] evaluated the Macintosh laryngoscope compared with the C-MAC™ and found better glottic views with the C-MAC™.[9] However, larger randomized trials comparing different videolaryngoscopes in patients with genuine difficult airways or in patients with difficult airways simulated with a cervical collar are missing, and it remains unclear which videolaryngoscopes perform best in these situations.

To provide the missing evidence, we compared six videolaryngoscopes in a prospective randomized controlled multicentre trial in patients with a difficult airway simulated with a cervical collar. For every single videolaryngoscope, the primary hypothesis was that the 95% confidence interval (CI) of the first-attempt success rate is ≥90%.

Methods

This prospective randomized controlled patient-blinded multicentre trial evaluates the performance of six videolaryngoscopes in patients with a simulated difficult airway. It was performed at the University Hospitals of Bern, Lausanne, and Geneva in Switzerland from December 3, 2012 to January 20, 2015. It was approved by each local ethics committee (Kantonale Ethikkommission Bern, approval 106/12; Commission Cantonale d'éthique, Lausanne, approval 444/12; Comité d'Ethique, Geneve, approval 12-251). Patients were included with written informed consent, and the study was registered at www.clinicaltrials.gov (identifier NCT01692535). The detailed study protocol was published as a methods paper before the start of this clinical study.[28]

Participants and inclusion and exclusion criteria

We prospectively included 720 adult patients with ASA status I–III who were to undergo elective surgery requiring tracheal intubation at one of the participating hospitals. Exclusion criteria were risk of aspiration and known or predicted difficult airway (BMI >35 kg m^{-2}, Mallampati >III, thyromental distance <6 cm, interincisor distance <3.5 cm, known difficult mask ventilation/laryngoscopy, and planned or previous history of awake tracheal intubation).

Study devices

The six videolaryngoscopes (Fig. 1) included three videolaryngoscopes without a guiding channel and three videolaryngoscopes with a guiding channel for intubation. Unchannelled videolaryngoscopes were the C-MAC™ (Karl Storz, Tuttlingen, Germany) with its D-blade and a stylet, the GlideScope™ (Verathon Inc., Bothell, WA, USA) blade 3 with GlideScope™ stylet, and the McGrath™ (Aircraft Medical Ltd, Edinburgh, UK) with MAC blade #3 and a stylet. Channelled videolaryngoscopes were the Airtraq™ (Prodol Meditec SA, Vizcaya, Spain) #2 in women and #3 in men, the A.P. Advance™ (Venner Medical SA, Singapore) difficult airway blade, and the KingVision™ (Kingsystems, Noblesville, IN, USA) blade #3. The C-MAC™ D-blade is reusable; all other blades are single use. Tracheal tubes were cuffed

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Fig 1 The six videolaryngoscopes evaluated in the present study. Top row from left to right: the unchannelled videolaryngoscopes C-MAC™ D-blade, GlideScope™, and McGrath™. Bottom row from left to right: the channelled videolaryngoscopes Airtraq™, A.P. Advance™, and KingVision™. Note the differences in design, angulation, and length of the blades.

Mallinckrodt Hi-Contour Tracheal Tubes™ (Covidien, Hazel-wood, MO, USA; 6.5 mm for women and 7.5 mm for men).

Study personnel

All participating consultant anaesthetists were airway management experts and trained with all videolaryngoscopes on both manikins and patients until they, as airway specialists, felt competent with each device. We did not set a fixed number of pretrial intubations because previous clinical experience with the different videolaryngoscopes was not uniform and manual skills are acquired at an individual rate. None of the videolaryngoscopes had been a standard intubation device at any of the centres before the start of the study.

Randomization and blinding

Patients were randomly assigned to one of the six videolaryngoscopes by computer-generated randomization using sealed opaque envelopes. To ensure that each anaesthetist intubated 10 times with each videolaryngoscope, we block randomized separately for each anaesthetist participating in this study. A member of the study team was responsible for correct enrolment and assignment of patients. Patients were blinded to randomization. The postoperative interview with the patient was carried out by a blinded member of the research team.

Anaesthesia and intubation

Premedication with midazolam 7.5 mg or lorazepam 1 mg was administered at least 30 min before the start of anaesthesia.

Standard monitoring included ECG, non-invasive blood pressure measurements, oxygen saturation, capnography, and volatile anaesthetic concentration. Anaesthesia was induced with propofol 1.5–3 mg (kg body weight)$^{-1}$ and with fentanyl 1–2 µg (kg body weight)$^{-1}$. Neuromuscular block was then achieved with rocuronium 0.6 mg (kg body weight)$^{-1}$ and was controlled by loss of 1 Hz muscle twitching (TOF Watch™; Organon, Dublin, Ireland). The inter-incisor distance at maximal mouth opening was measured before and after adjustment of a size-adjustable cervical collar for adults (Stifneck™; Laerdal, Copenhagen, Denmark), and the size of the collar was adjusted according to the manufacturer's recommendations depending on the anatomy of the patient. The collar was adjusted to permit a minimal mouth opening of 18 mm, and the head was taped to the trolley to inhibit neck movement.

Two intubation attempts with the randomized videolaryngoscope were allowed. The study was terminated once tracheal intubation was achieved, after two unsuccessful attempts, or when airway injury, bronchospasm, technical failure of the videolaryngoscope, or a reduction of oxygen saturation below 90% occurred.

Measurements

Patient and airway characteristics, such as age, BMI, Mallampati score, and thyromental distance <6 cm, were recorded. Success of the first intubation attempt was the primary outcome parameter. Success was defined as placement of the tube in the trachea within 180 s, confirmed by end-tidal carbon dioxide.[28] Overall success rate (i.e. success in the first or second attempt) was a secondary outcome parameter. Other secondary outcome parameters included the Cormack–Lehane class, percentage of glottic opening (POGO) score,[29] Intubation Difficulty Scale (IDS),[30] intubation times, reasons for intubation failure, adverse events, and side-effects. An interim time was recorded at the moment when the vocal cords were seen. Additionally, as an amendment to the published protocol, anaesthetists graded the ease of device insertion, quality of the view, and ease of tube advancement on a subjective scale (excellent/good/fair/poor).

Hypothesis and calculation of sample size

We defined a success rate of 0.9 as the clinically acceptable lower limit for a device that is designed for management of difficult airways.[28 31] Thus, our primary hypothesis for every single videolaryngoscope was that the lower limit of the 95% CI of first-attempt success rate is at least 0.9. With these values, we calculated the necessary sample size as 107 per device, given an α level of 0.05 and a power of 0.8. We decided to include 120 patients per device (total of 720 patients) to compensate for dropouts and missing data.

Statistical analysis

Intention-to-treat analysis according to randomization was performed. Binary data were analysed using the χ^2 test, or by Fisher's exact test if more than 20% of expected values were below 5. Ordinal data were evaluated using the Kruskal–Wallis test. Continuous data were checked for normality by Q-Q plots, histograms, and Shapiro–Wilk W-test. Normal data were analysed by Student's unpaired *t*-test (two groups) or one-way ANOVA (more than two groups). Non-normal data were analysed by independent samples Kruskal–Wallis test.

Pairwise *post hoc* comparisons by logistic regression were corrected for multiplicity with the Bonferroni–Holm method.

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Binary data are presented as numbers (%), whereas continuous data are presented as the mean (SD) if normally distributed and otherwise as the median (25th and 75th percentile). The range is reported where indicated. A probability of P<0.05 was considered statistically significant. Data were analysed using Stata V.13.1 (StataCorp, College Station, TX, USA).

Results

Seven hundred and twenty patients were included without dropouts after randomization (Fig. 2). Each of 12 participating anaesthetists performed 10 intubations with each videolaryngoscope in random order. Patient and airway characteristics are given in Table 1. Using a cervical collar, neck movement was inhibited and mouth opening was significantly reduced from 46 (7) to 23 (3) mm (P<0.01), creating a difficult airway (Table 1). The 95% CI of the mean of the difference of mouth opening without and with the cervical collar was 22–23 mm. There was no difference in mouth opening with the cervical collar between the devices (P=0.30).

Primary outcome parameter: first-attempt success rate

The 95% CI of first-attempt success rate was >0.9 only for the McGrath™, leading to rejection of the primary hypothesis for all videolaryngoscopes except the McGrath™ (Table 2). First-attempt success rates differed significantly between videolaryngoscopes (P<0.01) and ranged from 37% with the A.P. Advance™ difficult airway blade to 98% with the McGrath™ (Table 2). Oesophageal intubation occurred in one C-MAC™, two GlideScope™, three Airtraq™, and six A.P. Advance™ patients (P=0.02).

Failures because of problems with tube advancement were relatively more frequent with unchannelled devices (tube advancement problems in 76% and viewing problems in 24%) than with channelled devices (tube advancement problems in 45% and viewing problems in 55%; P<0.01). The technical problems encountered included loose contacts and problems with the screen.

Post hoc pairwise comparisons revealed that the A.P. Advance™ had a significantly lower first-attempt intubation success rate than all other videolaryngoscopes (all P<0.01). Additionally, the McGrath™ had a significantly higher first-attempt intubation success rate than the GlideScope™, the Airtraq™, and the KingVision™ (all P<0.03), and a similar success rate to the C-MAC™ D-blade. Even when excluding the A.P. Advance™ from the analysis, the first-attempt success rate still differed significantly between the remaining five videolaryngoscopes (P<0.01).

Laryngeal view

Cormack–Lehane classes and POGO scores differed significantly between devices (Table 2). *Post hoc* pairwise comparison revealed
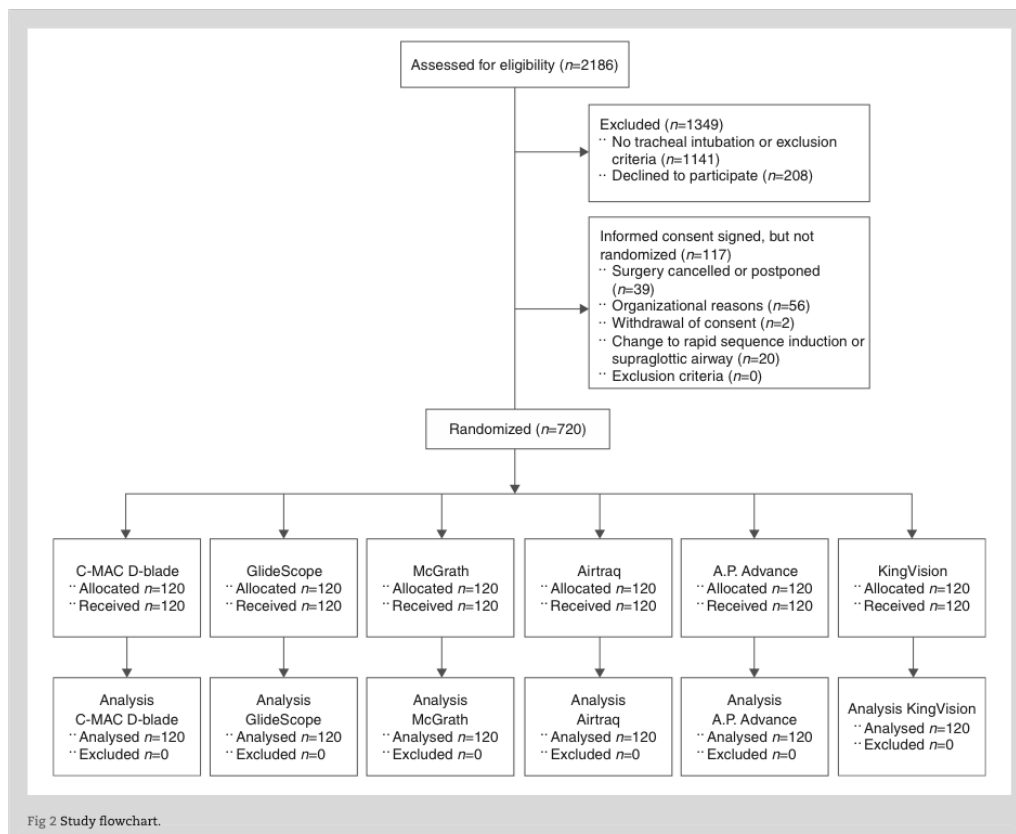

Fig 2 Study flowchart.

Table 1 Baseline patient and airway characteristics, presented as numbers or mean (SD). Missing data for Mallampati: two McGrath™, three Airtraq™, one A.P. Advance™, and two KingVision™

Characteristic	Devices without a guiding channel			Devices with a guiding channel		
	C-MAC™ D-blade (n=120)	GlideScope™ (n=120)	McGrath™ (n=120)	Airtraq™ (n=120)	A.P. Advance™ (n=120)	KingVision™ (n=120)
Sex male/female (n)	71/49	63/57	67/53	67/53	77/43	69/51
Age (yr; mean [range])	49 [19–100]	52 [21–83]	50 [18–86]	49 [18–87]	49 [18–89]	47 [18–86]
ASA I/II/III (n)	31/67/22	28/74/18	25/78/17	32/63/25	28/76/16	38/68/14
BMI (kg m⁻²)	25 (4)	25 (4)	25 (4)	25 (4)	25 (4)	26 (5)
Mallampati I/II/III/IV (n)	72/44/4/0	62/50/7/1	56/53/7/2	63/49/5/0	65/47/7/0	64/49/5/0
Thyromental distance <6 cm (n)	5	5	5	6	8	8
Mouth opening without collar [mm; mean (SD)]	46 (7)	45 (6)	45 (7)	46 (7)	47 (7)	45 (6)
Mouth opening with collar [mm; mean (SD)]	23 (3)	22 (3)	23 (3)	23 (3)	23 (3)	23 (3)
Difference in mouth opening caused by cervical collar [mm; mean (SD)]	23 (6)	23 (6)	22 (6)	23 (6)	23 (7)	22 (6)

Table 2 First intubation attempt, presented as number, as percentage, or as median (25th; 75th percentile). No reason for failure was reported for one C-MAC™ D-blade, one GlideScope™, three Airtraq™, 13 A.P. Advance™, and three KingVision™ patients. No Cormack–Lehane grade was reported for one C-MAC™ D-blade, three GlideScope™, one McGrath™, nine Airtraq™, 24 A.P. Advance™, and four KingVision™ patients. *χ^2 test. *Post hoc* logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ *vs* all other videolaryngoscopes, and P<0.05 for McGrath™ *vs* GlideScope™, Airtraq™, and King Vision™. †Kruskal–Wallis test. *Post hoc* ordered logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ *vs* all other videolaryngoscopes. ‡Fisher's exact test

	Devices without a guiding channel			Devices with a guiding channel			P-value
	C-MAC™ D-blade (n=120)	GlideScope™ (n=120)	McGrath™ (n=120)	Airtraq™ (n=120)	A.P. Advance™ (n=120)	KingVision™ (n=120)	
First-attempt success {n (%); [95% CI]}	114 (95); [89–98]	102 (85); [77–90]	117 (98); [92–99]	102 (85); [77–90]	44 (37); [28–46]	104 (87); [79–92]	<0.01*
Cormack–Lehane grade I/IIa/IIb/III/IV (n)	76/36/7/0/0	80/29/3/2/3	64/45/9/1/0	74/30/4/0/3	19/28/22/8/19	63/41/7/1/4	<0.01†
Percentage of glottic opening [median (percentiles)]	90 (80; 100)	100 (83; 100)	90 (80; 100)	90 (80; 100)	60 (10; 80)	90 (80; 100)	<0.01†
Failure because of technical problems/poor view/intubation difficulty (n)	0/0/5	0/5/12	0/1/2	3/7/5	2/34/27	0/6/7	0.05‡

significantly worse views with the A.P. Advance™ compared with all other videolaryngoscopes (all P<0.01). No statistically significant difference was found for Cormack–Lehane class or POGO score if data from the A.P. Advance™ were excluded from the analysis.

Overall success rate

Overall success rates differed significantly between the videolaryngoscopes and ranged from 40% with the A.P. Advance™ to 98% with the C-MAC™ D-blade and the McGrath™ (Table 3). When excluding data from the A.P. Advance™, overall success rate still differed significantly between the remaining five videolaryngoscopes (P=0.04).

Subjective grading of handling

Results of the subjective grading of handling differed between the videolaryngoscopes (P<0.01; Table 3). Overall, taking all six videolaryngoscopes into account, the view was rated as excellent in 59%, and tube advancement in 37% (P<0.01).

Intubation times

Time to view the vocal cords, time to advance the tracheal tube into the trachea, and overall intubation times showed a broad range and differed significantly between devices (P<0.01; Table 3). Times also differed when data from the A.P. Advance™ were excluded from the analysis (P<0.01).

Table 3 Overall performance, presented as number, percentage, or median (25th; 75th percentile) [range]. Missing data for insertion of the device into the oropharynx and quality of view: one C-MAC™ D-blade, three GlideScope™, one Airtraq™, eight A.P. Advance™, nine A.P. Advance™, and three KingVision™ patients. Missing data for ease of tube insertion: three C-MAC™ D-blade, three GlideScope™, one Airtraq™, nine A.P. Advance™, and four KingVision™ patients. CI, confidence interval. *χ^2 test. Post hoc logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ vs all other videolaryngoscopes. †χ^2 test. Post hoc logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.04 for C-MAC™ D-blade and for McGrath™ vs all channelled videolaryngoscopes. ‡Kruskal–Wallis test. Post hoc logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ vs all other videolaryngoscopes. ¶Kruskal–Wallis test. Post hoc logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ vs C-McGrath™ and Airtraq™, and P=0.03 for Airtraq™ vs GlideScope™. §χ^2 test. Post hoc logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ vs C-MAC™ D-blade, McGrath™, and KingVision™, and P<0.03 for GlideScope™ vs C-MAC™ D-blade and McGrath™. ‖Kruskal–Wallis test. Post hoc ordered logistic regression and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ vs all other videolaryngoscopes. #Kruskal–Wallis test. Post hoc ordered logistic regression of log-transformed data and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for A.P. Advance™ vs all other videolaryngoscopes, and P<0.03 for KingVision™ vs all other videolaryngoscopes. **Kruskal–Wallis test. Post hoc logistic regression of log-transformed data and pairwise comparison with Bonferroni–Holm corrections: P<0.05 for Airtraq™ vs all other videolaryngoscopes, P<0.01 for KingVision™ vs A.P. Advance™ and GlideScope™, and P<0.04 for McGrath™ vs GlideScope™ and A.P. Advance™. ††Kruskal–Wallis test. Post hoc logistic regression of log-transformed data and pairwise comparison with Bonferroni–Holm corrections: P<0.01 for Airtraq™ vs C-MAC™ D-blade, Glidescope™, and KingVision™, and P<0.01 for McGrath™ vs GlideScope™

	Devices without a guiding channel			Devices with a guiding channel			P-value
	C-MAC™ D-blade (n=120)	GlideScope™ (n=120)	McGrath™ (n=120)	Airtraq™ (n=120)	A.P. Advance™ (n=120)	KingVision™ (n=120)	
Overall success [n (%); [95% CI]]	117 (98%; [92–99])	110 (92%; [85–95])	118 (98%; [93–100])	112 (93%; [87–97])	48 (40%; [32–49])	110 (92%; [85–95])	<0.01*
Insertion of the device into the oropharynx, excellent/good/fair/poor (n)	69/40/9/1	47/48/19/3	71/42/7/0	41/47/27/4	26/43/29/14	26/54/26/11	<0.01†
Quality of view, excellent/good/fair/poor (n)	79/31/7/2	78/33/4/2	74/38/7/1	78/33/7/1	38/50/14/10	68/41/6/2	<0.01‡
Ease of tube insertion, excellent/good/fair/poor (n)	41/42/26/8	36/41/26/14	52/41/22/5	61/37/16/5	25/37/26/23	41/47/24/5	<0.01¶
Soft tissue lesion or bleeding (n)	9	27	6	19	43	14	<0.01§
Intubation Difficulty Scale	0 (0; 1) n=117	0 (0; 1) n=110	1 (0; 1) n=118	0 (0; 1) n=112	∞ (1; ∞) n=48	1 (0; 1) n=110	<0.01‖
Time to view the vocal cords [s; median (25th; 75th percentile) [range]]	17 (12; 23) [6–46]	19 (14; 29) [3–100]	18 (13; 24) [6–53]	20 (12; 28) [5–110]	30 (21; 55) [9–142]	26 (16; 32) [7–117]	<0.01#
Time to advance tube [s; median (25th; 75th percentile) [range]]	36 (28; 61) [8–154]	40 (29; 71) [10–157]	33 (26; 51) [6–147]	27 (19; 36) [6–148]	50 (27; 88) [14–138]	31 (24; 46) [4–140]	<0.01**
Intubation time of successful attempt [s; median (25th; 75th percentile) [range]]	56 (45; 85) [20–177]	60 (48; 98) [17–180]	53 (42; 77) [20–179]	47 (36; 60) [18–175]	93 (54; 144) [33–180]	59 (46; 78) [31–180]	<0.01††

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Intubation difficulty scale

The median IDS score was 0 or 1 for all devices, with no differences between the devices except for the A.P. Advance™. Given that more than 50% of the intubation attempts with the A.P. Advance™ were failures, the median IDS for the A.P. Advance™ was, by definition, infinite (Table 3).

Adverse events

The most frequent adverse event was soft tissue lesion or bleeding (Table 3), ranging from six patients (McGrath™, 5%) to 43 patients (A.P. Advance™, 36%; P<0.01). This included even minor tissue trauma. Two cuff leaks occurred after intubation, both related to a videolaryngoscope with a guiding channel (one Airtraq™ and one KingVision™). There was no dental trauma, aspiration, or bronchospasm during anaesthesia.

Side-effects

There were no statistically significant differences between the videolaryngoscopes for side-effects such as hoarseness (11–18%), sore throat (10–19%), dysphagia (2–8%), or postoperative nausea and vomiting (9–14%; all P>0.05). There was a statistically significant difference for pain during swallowing (9% with C-MAC™ D-blade and McGrath™ to 22% with the A.P. Advance™; P=0.02), but *post hoc* pairwise comparisons missed statistical significance. Even though blinded to the device, fewer patients in the A.P. Advance™ group (81%) than in all other groups (94–98%) would choose to participate again in the study (P<0.01).

Comparison between the study centres

We evaluated a possible influence of the study centre on the primary outcome parameter. Logistic regression with study centre and device as factors revealed a statistically significant difference in first-attempt success rate in favour of Geneva compared with Bern (odds ratio = 3.71, 95% CI 1.78–7.76; P<0.01), but not compared with Lausanne. However, the model revealed no significant interactions between study centre and device (all P>0.21), and in all study centres the order of performance of the six videolaryngoscopes was the same.

Discussion

The present study evaluated the performance of six videolaryngoscopes in 720 patients with a simulated difficult airway that was created by a stiff cervical collar that restricted neck movement and reduced mouth opening to 23 (3) mm. First-attempt success rates differed significantly and were 98% (McGrath™), 95% (C-MAC™ D-blade), 87% (KingVision™), 85% (GlideScope™ and Airtraq™), and 37% (A.P. Advance™). We predefined a benchmark for first-attempt success rate as a 95% CI of at least 90%. This was achieved only by the McGrath™ (95% CI 92–99%) and was very narrowly missed by the C-MAC™ with its D-blade (95% CI 89–98%). Overall success, laryngeal view, and intubation times differed significantly between videolaryngoscopes, and regarding most outcome parameters, the C-MAC™ D-blade and the McGrath™ performed best and the A.P. Advance™ worst.

First-attempt success rates were highest with devices that featured a blade that was easy to introduce into the mouth and small enough to allow for adjustments within the oral cavity. Unchannelled blades are usually less bulky and allow for independent manoeuvring of the tracheal tube. In contrast, bulkier videolaryngoscopes and channelled videolaryngoscopes rely on

perfect positioning of the videolaryngoscope in front of the glottic opening. The design of the blade (shape, curvature, and position of the video camera) influences the performance of the device. For example, a large portion of the video screen of the A.P. Advance™ shows the plastic part of the laryngoscope tip and not the relevant airway anatomy, which could contribute to its poor performance.

Interestingly, manikin studies with the A.P. Advance™ difficult airway blade presented success rates of 97–100%,[5] [32] [33] whereas first-attempt intubation success decreased from 100 to 60% when a difficult airway was created.[5] Providing the first clinical data of the A.P. Advance™ in humans, we cannot confirm these success rates of preclinical studies, which also questions airway studies performed with manikins only.[5]

In contrast, single-comparison studies in humans reported first-attempt success rates of 88–93% for the C-MAC™,[9] [12] [20] up to 100% for the GlideScope™[19] [27] [34] and the Airtraq™,[35] and 69% for the McGrath™ MAC blade.[20] Studies in patients with positive predictors for difficult intubation showed overall success rates of more than 90% with the C-MAC™,[14] [19] [20] the GlideScope™,[14] [19] and the McGrath™.[20] Another study showed a success rate of 94% in patients after failed intubation with the GlideScope™.[34] Direct comparisons of these studies are difficult because of heterogeneity of clinical settings, airway situations (predicted *vs* simulated *vs* genuine difficult airway), and different levels of experience. Therefore, we included the six videolaryngoscopes in a single study. A recent meta-analysis showed a superiority of the Airtraq™ over the Macintosh laryngoscope to reduce the risk of intubation failure, whereas the C-MAC™, the GlideScope™, and the McGrath™ missed statistical significance.[36] This meta-analysis included studies with cervical spine immobilization, whereas our study included patients who had severely reduced mouth opening in addition to cervical spine immobilization. This demonstrates that the performance of videolaryngoscopes depends on the exact circumstances of the difficult airway and that the optimal videolaryngoscope might differ for various types of difficult airway situations.

Several studies compared different videolaryngoscopes with the classic Macintosh laryngoscope and agree on a higher success rate of the videolaryngoscopes compared with the Macintosh laryngoscope.[12] [37] Likewise, the meta-analysis of Suppan and colleagues[36] showed that the risk of intubation failure in patients with immobilization of the cervical spine was lower with videolaryngoscopes compared with the Macintosh laryngoscope. Laryngeal view consistently improved with videolaryngoscopes compared with the Macintosh laryngoscope,[7] [9] [13–15] [38] but this does not necessarily lead to improved intubation success. The well-known phenomenon 'you see that you fail' describes the fact that the ability to see the glottis does not automatically facilitate tracheal intubation.

Likewise, in our study, intubation failures were often because of problems with tube advancement. In general, the view was rated as 'excellent' in 59%, but tracheal intubation in only 37%, demonstrating that tube advancement is often a crucial problem with videolaryngoscopes. In direct laryngoscopy, the oropharyngeal curve and the pharyngoglottotracheal curve need to be aligned to permit a direct glottic view.[39] In indirect laryngoscopy with videolaryngoscopes, these curves are not necessarily aligned. Stylets to mimic the curve of the blade are mandatory for intubation with angulated blades without a guiding channel, but even with optimally shaped stylets tracheal intubation can be cumbersome.

Intubation times differed between devices, but these statistically significant differences were clinically irrelevant and similar

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to those reported by others.[5 12 20 27] Interestingly, the time needed to obtain an optimal view of the glottis was longer with the channelled videolaryngoscopes. However, once the blade position was optimized, tracheal intubation was fastest with the channelled Airtraq™, which is in agreement with a previous study.[40] All videolaryngoscopes showed a broad range of intubation times. We therefore performed a *post hoc* analysis and recalculated first-attempt success rates by applying a more restrictive definition of success with a cut-off time of 60 s. With this definition, first-attempt success rates were as follows: C-MAC™ D-blade 55%, GlideScope™ 43%, McGrath™ 64%, Airtraq™ 65%, A.P. Advance™ 9%, and KingVision™ 48% (P<0.01). Thus, first-attempt success rates decreased significantly and all devices had a first-attempt intubation success rate below 70%, which we consider unacceptable. We conclude that tracheal intubation in difficult airways often takes time, and therefore, optimal pre-oxygenation is paramount. Although obese and pregnant patients might not tolerate an apnoea phase of 180 s even with optimal preoxygenation, none of the 720 patients included in our study desaturated below 90%.

Limitations

Given that this trial studied simulated difficult airways, conclusions regarding genuine difficult airways must be drawn with caution. Studying difficult airway management by reversibly creating a difficult airway with cervical collars is common research practice.[9 26 27 41 42] Cervical collars uniformly inhibit neck movement and reduce mouth opening, providing standardized and reproducible airway research conditions that represent important causes of difficult airways, such as, for example, in trauma. In contrast, we did not study difficult airways caused by other factors, such as obesity. It is possible that the performance of videolaryngoscopes varies depending on the type of difficult airway so that there might not be a single perfect videolaryngoscope, but instead videolaryngoscopes that are ideal for specific airway situations.

Although previous clinical experience with the videolaryngoscopes was not uniform among participating anaesthetists, none of the videolaryngoscopes was a standard intubation device at any of the study centres before and during the study. Given that no validated tool for objective assessment of competency exists and because suggested training repetitions are very vague,[43] we relied on the self-assessment of the participating airway experts who trained with all videolaryngoscopes until they felt competent. The absolute performance of the study centres varied, but there were no statistically significant interactions between the study centre and the device. Thus, although the absolute success rates differed, the same pattern, with McGrath™ and C-MAC™ D-blade performing best, closely followed by GlideScope™, Airtraq™, and KingVision™, and lastly followed by the A.P. Advance™, was seen in all centres.

All study-related measurements during induction of anaesthesia and intubation were carried out by a member of the research team who was not involved in the clinical procedure. To assure a smooth conduct of the study with adherence to the protocol and with valid measurements of parameters such as intubation time, this researcher was not blinded.

We did not include a standard Macintosh laryngoscope with direct laryngoscopy because it is known that in patients with difficult airways videolaryngoscopes are superior regarding intubation success rates, glottic view, and rates of difficult intubation.[9 12 16–18 37]

Conclusions

This study showed marked differences between six videolaryngoscopes in patients with inhibited neck movement and limited mouth opening. The McGrath™ and C-MAC™ D-blade showed highest success rates and lowest rates of tissue trauma. KingVision™, GlideScope™, and Airtraq™ followed in performance. The A.P. Advance™ difficult airway blade performed weakest and cannot be recommended in the described setting. Half of the failures were because of problems with tube advancement despite a good view of the glottic opening. Future studies should clarify the impact of guiding channels on the performance of videolaryngoscopes and whether performance depends on the presence or absence of guiding channels or on the design of the blades.

Authors' contributions

Study design: M.K.-B., R.G., P.S., G.L.S., S.N., L.G.T.
Conduct of the study: M.K.-B., R.G., P.S., G.L.S., L.G.T.
Data control: S.N.
Data analysis: M.K.-B., L.G.T.
Work on preliminary version of manuscript: P.S., G.L.S., S.N.
Writing of the final manuscript: M.K.-B., R.G., L.G.T.

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Declaration of interest

None declared.

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Original Article

Evaluation of three unchannelled videolaryngoscopes and the Macintosh laryngoscope in patients with a simulated difficult airway: a randomised, controlled trial[*]

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Summary

This prospective randomised, controlled trial compares the performance of three unchannelled videolaryngoscopes (KingVision™, Airtraq™, A.P. Advance™ MAC) and the standard Macintosh laryngoscope. With ethics committee approval and written informed consent, 480 patients were included. A difficult airway was created with a cervical collar, limiting mouth opening and neck movement. Primary outcome was first-attempt orotracheal intubation success. Overall success, laryngeal view, intubation difficulty scale, handling, intubation times and side-effects were secondary outcomes. First-attempt success rates were: KingVision 90% (95% CI 83–94%), Airtraq 82% (74–88%), A.P. Advance MAC 49% (40–58%), Macintosh 44% (35–53%; p < 0.001). The 95% confidence interval of first-attempt success rate was thus below 90% for all devices, but the KingVision and the Airtraq performed better than the A.P. Advance MAC and the Macintosh laryngoscope. Also, performance was better with the KingVision and the Airtraq in terms of overall success, laryngeal view, intubation difficulty scale and quality of view. Problems with tube advancement were a frequent cause of intubation failure. In summary, the KingVision and the Airtraq performed better than the A.P. Advance MAC and the Macintosh laryngoscope. Success rates of the unchannelled KingVision and Airtraq were similar to those of their channelled versions reported previously, indicating that performance largely depends on blade design rather than the presence of a channel for tube advancement.

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Introduction

Videolaryngoscopes have recently become very popular as primary or rescue intubation tools in anaesthesia [1, 2], intensive care [3] and emergency medicine [4, 5]. Their use for tracheal intubation is more successful compared with the standard Macintosh laryngoscope in patients with simulated or real difficult airways [6–10] and they have also been successfully used in patients with a predicted difficult airway [11, 12].

Videolaryngoscopes combine blades of different shapes with video techniques and screens that facilitate the view of anatomical structures from the tip of the blade. It is thus no longer necessary to achieve a direct view on the glottic opening, but often a very specific curve of the tube is necessary to manoeuvre the tube into the trachea. Even with stylets that optimise the curve of the tracheal tube, intubation is sometimes impossible despite a good laryngeal view [2]. A channel was added to some videolaryngoscopes to facilitate tube guidance into the trachea, but channelled devices are often bulky and can be difficult to use in patients with limited mouth opening. We recently performed a randomised, controlled trial in patients with a simulated difficult airway that compared the performance of three videolaryngoscopes with and three videolaryngoscopes without an integrated channel [2, 13]. This study could not demonstrate an advantage of the channel in the hands of experienced anaesthetists. Instead, the unchannelled videolaryngoscopes C-MAC™ and McGrath™ had higher success and lower tissue trauma rates than the channelled videolaryngoscopes Airtraq™, A.P. Advance™ and KingVision™ [2].

The above mentioned channelled videolaryngoscopes are also available without the guiding channel, although data about their performance are very limited. The unchannelled Airtraq showed success rates of 88–94% for nasotracheal intubation [14, 15] compared with a 85% success rate of the channelled Airtraq [2]. Manikin studies with the unchannelled A.P. Advance MAC and KingVision reported success rates of up to 100% [16, 17], much higher than the success rates reported in our previous study (37% and 87%, respectively). However, clinical data on the performance of unchannelled videolaryngoscopes for orotracheal intubation of patients with difficult airways are lacking. We performed this randomised, controlled trial to fill this data gap.

Methods

In this prospective randomised, controlled, patient-blinded trial, we compared the performance of the three unchannelled videolaryngoscopes Airtraq, A.P. Advance MAC and KingVision and the standard Macintosh to facilitate orotracheal intubation in patients with a simulated difficult airway. Our hypothesis was that for every single device, the lower limit of the 95% confidence interval (CI) of the first-attempt success rate for orotracheal intubation is at least 90% [2, 13].

The study was carried out at the University Hospital of Bern, Switzerland, and was approved by the local ethics committee. Anaesthesia and procedures were the same as described in a methods paper [13] for a previously published study [2]. After obtaining written informed consent, we prospectively included patients of both sexes. ASA status 1–3 and scheduled for elective surgery requiring tracheal intubation. We did not study patients at risk of aspiration and patients with known or predicted difficult airways (body mass index > 35 kg.m^{-2}, Mallampati > 3, thyromental distance < 6 cm, interincisor distance < 3.5 cm, known difficult mask ventilation/laryngoscopy, planned or previous history of awake tracheal intubation). Patients were electively anaesthetised and a difficult airway was created by tightly adjusting a cervical collar to patients' necks [2, 13, 18].

Study devices are displayed in Fig. 1. All videolaryngoscope blades were unchannelled and single-use. We used the Airtraq blade size 2 in women and 3 in men (Prodol Meditec SA, Vizcaya, Spain), the A.P. Advance MAC blade size 3 (Venner Medical SA, Singapore), and the KingVision blade size 3 (Kingsystems, Noblesville, IN, USA). The standard Macintosh laryngoscope blade was used as a control (size 3 for women; 4 for men). Cuffed Mallinckrodt Hi-Contour Tracheal Tubes™ with a stylet were used for all intubations (Covidien, Hazelwood, MO, USA, 6.5-mm internal diameter for women, 7.5 mm for men). The unchannelled A.P. Advance used in the present study features a Macintosh-style blade in contrast to the

more angulated difficult airway blade of the channelled A.P Advance.

All participating consultant anaesthetists were airway management experts and trained with all videolaryngoscopes on manikins and patients until they felt competent with each device. The level of experience was the same with all videolaryngoscopes and none of the devices had been a standard intubation tool before the study start except for the standard Macintosh laryngoscope.

We used computer-generated randomisation with sealed opaque envelopes to randomly assign an intubation tool to a patient. Block randomisation was done separately for each anaesthetist to assure equal numbers of intubations with all devices (block of 80 intubations per anaesthetist with 20 intubations per device). Patients were blinded to randomisation and the postoperative interview was performed by a blinded member of the research team.

Premedication with midazolam 7.5 mg or lorazepam 1 mg was administered. Balanced anaesthesia was induced with propofol 1.5–3 mg.kg^{-1} and fentanyl 1–2 μg.kg^{-1}. Neuromuscular blockade with rocuronium, initially 0.6 mg.kg^{-1} was controlled by loss of 1 Hz muscle twitching (TOF Watch™; Organon, Dublin, Ireland). The inter-incisor distance at maximum mouth opening was measured before and after adjustment of a size-adjustable, adult-sized cervical collar (Stifneck™; Laerdal, Copenhagen, Denmark) [13, 18]. The collar was adjusted as described in the manufacturer's manual, allowing for a mouth opening of at least 18 mm. The head was taped to the trolley. Then, a maximum of two attempts of orotracheal intubation with the randomly selected device were performed. In case of two failed attempts, airway injury, bronchospasm, technical device failure or desaturation below 90% the study was abandoned and the airway secured according to the anaesthetist's preference, after removing the cervical collar.

Baseline patient and airway characteristics were recorded. The primary outcome measure was first-attempt orotracheal intubation success, defined as placement of the tube in the trachea within 180 s [2]. Secondary outcome measures included: reasons for intubation failure; laryngeal view as assessed by Cormack–Lehane grade; glottic opening (POGO) score [19]; and number of oesophageal intubations. Furthermore, overall success rate, Intubation Difficulty Scale (IDS) [20] and intubation times were assessed. Time was measured from taking the face-mask away from the face until appearance of end-tidal CO_2. An interim time was recorded as soon as the vocal cords were seen. Subjective secondary outcome parameters, graded by the anaesthetist, were the ease of device insertion into the oropharynx, quality of view and ease of tube advancement, all graded as excellent, good, fair or poor. Impaired vision from blood, mucus or fogging, as well as adverse events and side-effects were recorded. A study nurse who was not involved in the clinical procedure recorded all measurements.
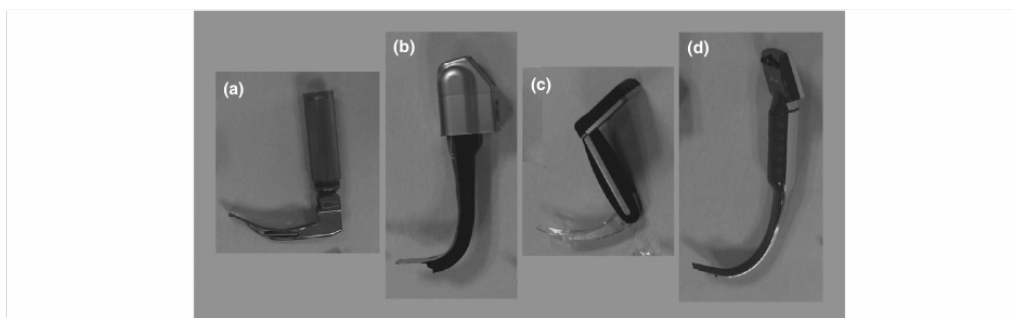
Figure 1 Visual comparison of the four study devices. (a) The standard Macintosh laryngoscope, (b) the unchannelled videolaryngoscope Airtraq, (c) the unchannelled videolaryngoscope A.P. Advance, and (d) the unchannelled videolaryngoscope KingVision. Differences in design, angulation and length of the blades are visible.

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For difficult airway management, we previously defined a minimal success rate of 90% as clinically acceptable [2, 13, 21]. Our primary hypothesis applied for every single device and stated that the lower limit of the 95% confidence interval of the first-attempt success rate of orotracheal intubation is at least 0.9. With an alpha level of 0.05 and a power of 0.8 the necessary sample size was calculated as 107 per device. We decided to include 120 patients per device to compensate for dropouts and missing data [2, 13].

We performed intention-to-treat analysis according to randomisation. Binary data were analysed using Chi-square or by Fisher's exact test if more than 20% of expected values were below 5. The Kruskal–Wallis test was used for ordinal data. For continuous data, we tested normal distribution using Q–Q plots, histograms and the Shapiro–Wilk test. An independent samples Kruskal–Wallis test was used for comparison of more than two groups of non-continuous data. An unpaired student's t-test was used for the comparison of two groups of continuous data. Logistic regression with pairwise comparisons and Bonferroni–Holm corrections were used for post-hoc comparisons of statistically significant results. A probability of $p < 0.05$ was considered statistically significant. Data were analysed using Stata V.13.1 (StataCorp, College Station, TX, USA).

Results

In total, 480 patients were included without dropouts after randomisation. Each of the six participating anaesthetists performed 20 intubations with each device. Baseline patient and airway characteristics are given in Table 1. The cervical collar created a difficult airway by inhibiting neck movement and reducing mean (SD) mouth opening from 46 (6) mm to 24 (3) mm ($p < 0.0001$).

Regarding the primary outcome measure first-attempt intubation success rate, none of the devices achieved a lower 95% confidence interval > 90% (Table 2). First-attempt intubation success rate ranged from 44% (95% CI 35–54%) with the Macintosh laryngoscope to 90% (95% CI 83–94%) with the KingVision ($p < 0.001$, Table 2). Post-hoc pairwise comparisons revealed that first-attempt success rates with the Macintosh laryngoscope and the A.P. Advance were significantly lower than with the Airtraq or KingVision ($p < 0.001$ for the respective comparisons). Few failures were due to technical problems like a flickering light source or a black videoscreen (3% of failures). The other failures were due to problems with tube advancement in 33% and to problems with view in 64%. There was no interruption of an intubation attempt for reasons such as hypoxia or bronchospasm.

Cormack–Lehane grades differed significantly between devices ($p < 0.001$, Table 2). Post-hoc pairwise comparisons revealed significantly worse views with the Macintosh laryngoscope and the A.P. Advance compared with the Airtraq and the KingVision ($p < 0.001$ for the respective comparisons). The POGO score also differed significantly between devices (Table 2).

Overall success rates ranged from 57% (95% CI 48–65%) with the Macintosh laryngoscope to 94% (95% CI 88–97%) with the KingVision ($p < 0.001$, Table 3). None of the devices reached a 95% confidence interval >90% (Table 2). Post-hoc pairwise

Table 1 Baseline characteristics. Values are number (proportion) or mean (SD).

	Macintosh n = 120	Airtraq n = 120	A.P. Advance n = 120	KingVision n = 120
Women	46 (38%)	54 (45%)	60 (50%)	57 (48%)
Age; years	51 (19)	53 (18)	51 (18)	54 (17)
ASA class I/2/3	28/65/27 (23/54/23)	18/73/29 (15/61/24)	29/63/28 (24/53/23)	29/63/28 (24/53/23)
BMI; kg.m^{-2}	25 (4)	25 (4)	26 (4)	25 (4)
Mallampati 1/2/3/4	66/50/2/0 (56/42/2/0)	57/56/7/0 (48/47/6/0)	62/49/6/0 (53/42/5/0)	71/44/4/1 (59/37/3/1)
Mouth opening without collar; mm	46 (6)	45 (6)	46 (6)	45 (6)
Mouth opening with collar; mm	24 (3)	24 (3)	24 (3)	23 (3)

Missing data for Mallampati score: 2 Macintosh, 3 A.P. Advance. BMI, Body Mass Index.

Table 2 First intubation attempt. Values are number (proportion) with 95% confidence intervals [CI], or median (IQR [range]).

	Macintosh n = 120	Airtraq n = 120	A.P. Advance n = 120	KingVision n = 120	p value
First-attempt success [(proportion)] [95% CI]	53 (44%) [35–53%]	98 (82%) [74–88%]	59 (49%) [40–58%]	108 (90%) [83–94%]	< 0.01
Cormack–Lehane 1/2a/2b/3/4	4/9/21/38/44 (3/8/18/33/38%)	67/34/9/1/3 (59/30/8/1/3%)	14/17/26/38/20 (12/15/23/33/17%)	77/36/4/0/0 (66/31/3/0/0%)	< 0.01
Percentage of glottic opening	0 (0–10 [0–100])	90 (75–100 [0–100])	0 (0–60 [0–100])	95 (80–100 [10–100])	< 0.01
Failure due to poor view/ problems with tube advancement/technical device failure	44/21/2 (67/31/3%)	10/11/1 (45/50/5%)	47/12/2 (77/20/3%)	2/10/0 (17/83/0%)	0.01
Oesophageal intubation	2 (2%)	2 (2%)	3 (3%)	0 (0%)	0.53

Missing data for Cormack–Lehane grade: 4 Macintosh, 6 Airtraq, 5 A.P. Advance, 3 KingVision.

Table 3 Overall performance. Values are number (proportion) with 95% confidence intervals [CI], or median (IQR [range]). Data for IDS includes successful intubations only.

	Macintosh n = 120	Airtraq n = 120	A.P. Advance n = 120	KingVision n = 120	p value
Overall success (proportion) [95% CI]	68 (57%) [48–65%]	104 (87%) [79–92%]	79 (66%) [57–74%]	113 (94%) [88–97%]	< 0.01
Insertion of the device into the oropharynx; excellent/ good/fair/poor	47/52/13/1 (42/46/12/1%)	54/35/23/3 (47/30/20/3%)	34/64/12/0 (31/58/11/0%)	80/28/7/1 (69/24/6/1%)	< 0.01
Quality of view; excellent/ good/fair/poor	44/48/14/7 (39/42/12/6%)	65/39/10/1 (57/34/9/1%)	39/41/22/8 (35/37/20/7%)	86/27/3/0 (74/23/3/0%)	< 0.01
Ease of tube advancement; excellent/good/fair/poor	31/56/26/0 (27/50/23/0%)	44/45/21/5 (38/39/18/4%)	38/42/27/3 (35/38/25/3%)	50/32/27/7 (43/28/23/6%)	0.71
Impaired vision due to mucus/blood/condensation	3/1/1 (3/1/1%)	3/1/0 (3/1/0%)	3/1/9 (3/1/8%)	4/0/2 (3/0/2%)	0.09
Intubation Difficulty Scale (IDS)	3 (2–4 [0–5])	1 (0–1 [0–5])	2 (1–3 [0–5])	1 (0–1 [0–3])	< 0.01
	Macintosh n = 68	Airtraq n = 104	A.P. Advance n = 79	KingVision n = 113	
Time to visualise vocal cords; seconds	18 (14–24 [7–45])	18 (13–28 [6–58])	25 (17–30 [9–52])	17 (14–24 [4–67])	< 0.01
Intubation time of successful attempt; seconds	50 (41–62 [29–133])	52 (44–67 [21–164])	57 (48–81 [31–151])	56 (42–80 [27–178])	0.01

Missing data for insertion of the device into oropharynx, quality of view and ease of tube advancement: 7 Macintosh, 5 Airtraq, 10 A.P. Advance, 4 KingVision.

comparisons showed significantly worse overall success rates of the Macintosh laryngoscope and A.P. Advance compared with the Airtraq and the KingVision (p < 0.001 for the respective comparisons).

The subjective grading of device insertion into the oropharynx (p < 0.001) and of the quality of view (p < 0.001) differed significantly between devices, while the ease of tube advancement did not differ (p = 0.71, Table 3). Overall, view was rated as excellent in 52%, and tube advancement was rated as excellent in 36%. In only a few cases, vision was impaired by mucus, blood or condensation.

Median IDS score of the successful attempts ranged from 1 with the KingVision and Airtraq to 3 with the Macintosh laryngoscope (p = 0.0001, Table 3). IDS score was higher with Macintosh laryngoscope and A.P. Advance than with Airtraq and KingVision (Table 3).

Table 4 Adverse events and side-effects. Values are number (proportion).

	Macintosh n = 120	Airtraq n = 120	A.P. Advance n = 120	KingVision n = 120	p value
Bleeding or mucosal injury	20 (17%)	11 (9%)	19 (16%)	8 (7%)	0.04
Hoarseness; none/mild/ moderate/severe	89//24/5/1 (75/20/4/1%)	86/24/5/2 (74/21/4/2%)	95/17/5/2 (80/14/4/2%)	97/17/3/0 (83/15/3/0%)	0.26
Sore throat; none/mild/ moderate/severe	91/17/7/4 (76/14/6/3%)	96/17/4/0 (82/15/3/0%)	100/13/6/0 (84/11/5/0%)	91/23/3/0 (78/20/3/0%)	0.39
Pain swallowing; none/ mild/moderate/severe	96/14/5/4 (81/12/4/3%)	96/15/4/2 (82/13/3/2%)	98/14/7/0 (82/12/6/0%)	96/14/7/0 (82/12/6/0%)	0.98
PONV; none/mild/ moderate/severe	101/9/6/3 (85/8/5/3%)	96/8/8/5 (82/7/7/4%)	93/10/13/3 (78/8/11/3%)	98/8/6/5 (84/7//5/4%)	0.55

PONV, postoperative nausea and vomiting. Missing data for hoarseness, sore throat, pain swallowing, PONV: 1 Macintosh, 3 Airtraq, 1 A.P. Advance, 3 KingVision.

Time to visualise the glottis differed significantly between devices (p = 0.0003, Table 3) and was significantly longer with the A.P. Advance compared with all other devices (p < 0.001 for the respective comparisons). Intubation time of the successful attempt (time to visualise the glottis plus tube advancement) also differed significantly between devices (p = 0.0129, Table 3) and was significantly shorter with the Macintosh laryngoscope than with the A.P. Advance or the KingVision (p < 0.001 for the respective comparisons).

Minor mucosal injuries or bleeding were the most frequent adverse events, occurring in 7–17% (p = 0.04, Table 4). Post-hoc analysis did not reveal statistically significant differences in the pairwise comparisons. One patient who underwent cervical stabilisation developed postoperative dysphagia. Neurological and ENT examinations showed dysfunction of the glossopharyngeal nerve, which arguably could be related to either anaesthesia or surgery. The patient fully recovered within 6 months. No other adverse events such as dental injury, bronchospasm or aspiration were noted. Side-effects are described in Table 4 (all p > 0.05). If at all present, symptoms were mild in most cases. Patients stated that they would choose to participate again in the study in 95% of Macintosh, 97% of Airtraq, 96% of A.P. Advance and in 96% of KingVision cases (p = 0.90).

Discussion

Our main result is that none of the devices achieved a first-attempt success rate with a 95% confidence interval > 90% in this simulated difficult airway setting, with both the Macintosh laryngoscope and A.P. Advance showing success rates that were considered insufficient for difficult airway management.

Apart from the presented data, little evidence about the performance of the studied unchannelled videolaryngoscopes appears to exist. In patients with a predicted difficult airway, the unchannelled Airtraq showed 88–94% first-attempt success for nasotracheal intubation [14, 15] and similar results were found in normal airways [22]. Manikin studies showed 100% success rates of the unchannelled KingVision and A.P. Advance [16, 17], but to our knowledge no controlled study has yet evaluated the performance of the unchannelled KingVision or A.P. Advance in patients.

In contrast, several clinical trials have evaluated other videolaryngoscopes in difficult airways simulated with a cervical collar and found first-attempt success rates of 88% with the C-MAC [6] and 93–96% with the GlideScope™ [18, 23]. Studies in patients with predictors for difficult intubation showed success rates over 90% with the GlideScope [24, 25], the C-MAC [24–26], and the McGrath [26]. In accordance with our data, a recent meta-analysis showed that the Airtraq reduces the risk of intubation failures in patients with cervical spine immobilisation [1], but the KingVision and the A.P. Advance were not included in this meta-analysis. After assimilation of all the available data, it seems that our pre-defined target first-attempt success rate with a 95% confidence interval above 90% would be desirable, but is very ambitious in patients

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with inhibited neck movement and reduced mouth opening. Also, the unchannelled KingVision and Airtraq performed in the range of other videolaryngoscopes that were evaluated in similar settings. The present study confirms published evidence that success rates with the Macintosh laryngoscope are lower than with videolaryngoscopes [7–10, 24, 27, 28], with the possible exception of the A.P. Advance, which is rather bulky and might therefore be of limited value in patients with reduced mouth opening [2].

With the Macintosh laryngoscope and the A.P. Advance, the paramount reason for intubation failure was impossible glottic view. As previously shown with the unchannelled Airtraq [14], the Airtraq and King-Vision demonstrated better laryngeal views than the Macintosh laryngoscope. However, intubation failures with the KingVision and the Airtraq were often due to problems with tube advancement, demonstrating that 'you see that you fail' situations occur even in experienced hands and with optimal use of stylets.

In accordance with previous studies showing that intubation with videolaryngoscopes is slower than with the Macintosh laryngoscope [7, 24] intubation in our study was fastest with the Macintosh laryngoscope. Of the videolaryngoscopes, the Airtraq seems to allow for relatively fast intubation, similar to the Macintosh laryngoscope. A different study showed that intubation with the unchannelled Airtraq was even faster than with the Macintosh laryngoscope [14]. However, the time difference between the devices seems clinically irrelevant and intubation times only represent successful attempts. Since intubation under difficult conditions can require considerable time, optimal pre-oxygenation is absolutely necessary, particularly in patients with limited oxygen reserve such as obese or pregnant patients. Although these patients were intentionally not included in the present study, none of our patients desaturated during intubation attempts of up to 180s.

Bleeding or mucosal injuries occurred in 7–17% of patients, similar to our previous study with tissue trauma in 16% [2], and other studies with tissue trauma in 16–18% [7, 29].

Our recent study with the same study setting suggested advantages of unchannelled over channelled videolaryngoscopes [2]. In this separate randomised,

controlled trial we now evaluated the unchannelled versions of the channelled videolaryngoscopes studied before. The first-attempt success rate with the unchannelled A.P. Advance (49% in the current study) was higher than that of its channelled version (37% in the recently published study) [2], but still lower than success rates with the Airtraq and KingVision. The unchannelled A.P. Advance features a Macintosh blade, while the channelled version features a more angulated blade, making comparison of the results difficult. In contrast, the shape of the unchannelled and channelled KingVision and Airtraq differ only in the presence or absence of the tracheal tube guiding channel. First-attempt success rates of the unchannelled and channelled blades of both devices were very similar [KingVision unchannelled 90% (current study) vs. channelled 87% (recently published study [2]); Airtraq unchannelled 82% (current study) vs. channelled 85% (recently published study [2]). This comparison is limited by the fact that the numbers originate from two separate studies, however, they were both performed by the same study group and with the exact same methods. The similar success rates of the channelled and unchannelled blades indicate that performance in experienced hands largely depends on blade design, rather than on the presence of a channel for tube advancement. This is in contrast to another study, which concluded that the guiding channel of the KingVision facilitated intubation, but this was only true for novice doctors intubating manikins [16].

Our data describe the performance of intubation tools in difficult airways simulated with a cervical collar. Although this is an accepted standard of simulating difficult airways for research purposes [2, 6, 18, 23, 29, 30], data must be interpreted with caution since they do not represent genuine difficult airways. However, we consider it ethically questionable to study new devices in genuine difficult airways, since these can be life-threatening [31, 32]. Our data represent the specific difficult airway scenario of inhibited neck movement and reduced mouth opening. Although this is a frequent and important cause of difficult airways (e.g. in trauma), device performance in other difficult airway situations such as obese patients might differ. None of the videolaryngoscopes had been a standard

intubation device at the study site, but all participating consultant anaesthetists were airway management experts and extensively trained with all videolaryngoscopes before the start of the study. Since no validated tool for objective assessment of competency exists and since suggested training repetitions are vague [33], we relied on the self-assessment of the participating airway experts. Experience was the same with all videolaryngoscopes.

We reported our data using 95% confidence intervals as has been recommended for airway research [34]. Our study clearly exceeded our planned power, since for a prevailing 'failure rate' of ~10%, the minimum sample size is ~50 [34]. For each of our devices we studied 120 patients.

Intubation success rates with the Airtraq and the KingVision were largely the same between their unchannelled versions assessed in this study and their channelled versions assessed with the same study methods in a previous study [2]. In contrast, success rates differed substantially between brands, suggesting that intubation performance of videolaryngoscopes largely may depend on blade design, rather than on the presence of a channel for tube advancement. Problems with tube advancement despite a good view of the larynx were frequent causes of failure.

Acknowledgements

Competing interests

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Effect of the tube-guiding channel on intubation success with videolaryngoscopes

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ABSTRACT

Background: Videolaryngoscopes are widely used to secure normal and difficult airways. A wide variety of devices has been marketed and videolaryngoscopes with and without a channel to guide the tube into the trachea are available. It is however unclear whether or not a tube-guiding channel does indeed facilitate intubation with videolaryngoscopes.
Aim: The aim of this analysis is to study the effect of the tube-guiding channel on the first attempt intubation success rate of different videolaryngoscopes and on other intubation parameters (such as time to successful intubation and visualisation parameters) in humans with a simulated difficult airway.
Methods: We analysed data of two previously published randomised controlled trials, both performed under the lead of our study group at the Department of Anaesthesiology and Pain Therapy at the Bern University Hospital and University of Bern, Bern, Switzerland. One study, published in cooperation with the University Hospitals of Lausanne and Geneva, evaluated the channelled versions of the video-laryngoscopes Airtraq™, A.P. Advance™ and KingVision™. The other study assessed the unchannelled versions of the same videolaryngoscopes. In the current analysis, the combined data of both studies was compared, the channelled version against its unchannelled counterpart. All patients had a simulated difficult airway with no neck movement and limited mouth opening.
Results: We found no difference in first attempt intubation success rates for all 3 devices in their channelled and unchannelled versions. Overall success rate was significantly better with the unchannelled A.P. Advance™ compared to the channelled A.P. Advance™ ($p < 0.01$). It did not differ between the channelled and unchannelled versions of the Airtraq™ and the KingVision™. Interestingly, the Cormack-Lehane grade and the Percentage of Glottic Opening (POGO) score were significantly worse for the unchannelled A.P. Advance™ compared to its channelled version (both p-values < 0.01).
Conclusion: General blade design seems to be more important for the performance of video-laryngoscopes than the presence of a tube-guiding channel.

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1. Introduction

Airway management remains one of the most important skills of anaesthetists [1,2]. Airway management related deaths have decreased over the last decades [3]. Nevertheless, unanticipated difficult airways are still a main cause of anaesthesiology-related morbidity and mortality [4–8] and remain challenging for

anaesthesiologists [9,10].

The NAP4 audit project in Great Britain showed an incidence of serious complications in 1 of 22.000 and an incidence of serious adverse events in 1 of 180.000 airway management cases [11]. According to a number of studies the rate of difficult mask ventilation varies between 0.83 and 1% [12]; the rate of difficult direct laryngoscopy varies between 1.5 and 8% [13]; the rate of difficult intubation varies between 1.8 and 5.8% [12,14,15]; and the failed intubation rate varies between 0.1 and 0.3% [12,16].

The current gold standard to manage a patient with an anticipated difficult airway is the awake fibre-optic intubation. However, videolaryngoscopy is increasingly used to manage predicted and

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unpredicted difficult airways [17,18].

For routine airway management the 'sniffing position' is the preferred position [19]. However, in patients with suspected head and/or neck trauma this position is avoided [20] and instead, manual in-line stabilisation is applied to reduce c-spine movement during airway management [21]. Similarly, an extrication collar inhibits cervical spine movement and reduces mouth opening, which as a consequence worsens visualisation of the glottis during standard laryngoscopy [20,22–25]. Videolaryngoscopes usually provide a better laryngeal view compared to the standard Macintosh laryngoscope [1,2,4–7,13,17,18,23,25–52]. Using standard Macintosh laryngoscopes requires the alignment of the oral, pharyngeal and laryngeal axes for intubation to obtain a good glottic view. Videolaryngoscopes do not need to align these 3 axes to visualise the glottis opening; however, it is necessary to angulate the tracheal tube similar to the angulation of the blade in order to direct the tube into the trachea [8,25,48,49,53].

Studies showed a lower incidence of primary oesophageal intubations when using videolaryngoscopes compared to using standard Macintosh laryngoscopes [30]. However, the use of videolaryngoscopy prolongs the time to establish a patent airway [37].

Nowadays, videolaryngoscopes are often used as rescue devices for the management of the unanticipated difficult airway [13,37,40,54,55]. Additionally, there is a tendency to use videolaryngoscopes also as first line airway management devices for routine and difficult airway management [35,50,56,57]. Despite the fact that many videolaryngoscopes showed a high first attempt success rate of about 88–100% [45], conventional direct laryngoscopy is still used primarily in 83% of emergency airway management cases [58]. However, videolaryngoscopes are recommended to be used widely [34,45,48,50] to reduce intubation attempts during routine and difficult airway management [57].

Pieters and colleagues tested a wide variety of videolaryngoscopes with all key operators (consultants, residents, nurse anaesthetists), but could not identify a single best videolaryngoscope [55]. It also remains unclear, which kind of videolaryngoscope would be superior - with or without a tube guiding channel. To answer this question, we analysed two data sets obtained by studies of our own group: The randomised controlled study published by Kleine-Brueggeney et al. from our study group (in cooperation with the University Hospitals of Lausanne and Geneva), including 3 channelled and 3 unchannelled videolaryngoscopes, suggested that the blade design indeed might determine the performance of the device rather than the presence of a tube-guiding channel [33]. A second randomised controlled trial by our study group, which used the same study design and methods, then assessed the unchannelled versions of the channelled videolaryngoscopes tested in the first study and found mixed results [36].

To our knowledge there are no randomised controlled trials directly comparing channelled and unchannelled videolaryngoscopes to investigate the effect of a tube-guiding channel. To close this knowledge gap, we performed this additional analysis of our previously published data [33,36]. We therefore compared the performance of the channelled and the unchannelled versions of 3 videolaryngoscopes.

2. Methods

This analysis of previously published data [33,36] was performed under the lead of the Department of Anaesthesiology and Pain Therapy, Bern University Hospital and University of Bern, Bern, Switzerland from April to June 2017. As this is an analysis of already recorded data no new IRB approval was needed. Both original studies obtained ethics committee approval by the local cantonal

ethics committee and all study participants provided written informed consent as described in the respective publications [33,36].

Data of the following three channelled videolaryngoscopes and their three unchannelled counterparts were used: the Airtraq™ (Prodol, Meditec SA, Vizcaya, Spain), the A.P. Advance™ (Venner Medical SA, Singapore) and the KingVision™ (Kingsystem, Noblesville, IN, USA). The data of the three channelled videolaryngoscopes originate from a randomised controlled trial from our study group [33], while the data of the three unchannelled versions of the videolaryngoscopes originate from another randomised controlled trial from our study group which used the same study design [36].

Both prospective randomised controlled trials included patients with a simulated difficult airway created by using an extrication collar (Stifneck™; Laerdal, Copenhagen, Denmark) to reduce mouth opening and inhibit neck movement. The primary hypothesis of both studies was that the 95% confidence interval of the first attempt intubation success rate would be above 90% for each device.

The methods and measurements as well as the in- and exclusion criteria were the same for both studies and were published in 2013 [29]. There were slight methodological differences between both studies: The first study was performed at three centres: the University Hospitals of Bern, Lausanne and Geneva, all in Switzerland. It included 120 patients for each videolaryngoscope. Twelve experienced anaesthesiologists performed 10 intubations with each device [33]. The second study was a single-centre study at the University Hospital of Bern, Switzerland and also included 120 patients for each videolaryngoscope. In this study only 6 experienced anaesthesiologists participated and each of them performed 20 intubations with each device [36]. Before the start of the studies none of the videolaryngoscopes was a standard intubation device at the departments. All participating experienced anaesthesiologists practiced with all devices on manikins, and on patients with predicted normal airways, until they gained competency with the devices.

For the current analysis we extracted the data from these original studies [33,36]. We performed a comparison of the channelled versus the unchannelled versions of the respective devices. The comparisons included 120 patients for each device:

(1) Airtraq™ (Prodol Meditec SA, Vizcaya, Spain), channelled blade, size 2 in women; size 3 in men [33] versus Airtraq™ (Prodol Meditec SA, Vizcaya, Spain), unchannelled blade, size 2 in women; size 3 in men [36].
(2) A.P. Advance™ MAC (Venner Medical SA, Singapore), channelled difficult airway blade [33] versus A.P. Advance™ MAC (Venner Medical SA, Singapore), unchannelled Macintosh-style blade size 3 [36].
(3) KingVision™ (Kingsystems, Noblesville, IN, USA), channelled blade size 3 [33] versus KingVision™ (Kingsystems, Noblesville, IN, USA), unchannelled blade size 3 [36].

To control whether both cohorts are comparable we assessed baseline characteristics such as sex, age, ASA status, BMI, Mallampati score, and mouth opening before and after adjustment of an extrication collar.

Primary outcome parameter was the first attempt intubation success rate. Secondary outcome parameters included the Cormack-Lehane (CL) grade [59] and percentage of glottic opening (POGO) score [60], the overall success rate, device insertion into the oropharynx, quality of view, ease of tube advancement, time to visualise the glottis, the intubation time as well as any adverse events. Time was measured from the moment the facemask was

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Table 1
Baseline patient characteristics. BMI = Body Mass Index; SD = standard deviation.

	Airtraq™			A.P. Advance™			KingVision™		
	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value
Female sex, n (%)	53 (44)	54 (45)	0.90	43 (36)	60 (50)	0.03	51 (43)	57 (48)	0.44
Age in years, mean (SD)	49 (19)	53 (18)	0.11	49 (17)	51 (18)	0.59	47 (17)	54 (17)	<0.01
ASA class 1/2/3, n (%)	32/63/25 (27/52/21)	18/73/29 (15/61/24)	0.08	28/76/16 (23/64/13)	29/63/28 (24/53/23)	0.29	38/68/14 (32/57/11)	29/63/28 (24/53/23)	0.03
BMI (kg m^{-2}), mean (SD)	25 (4)	25 (4)	0.69	25 (4)	26 (4)	0.72	26 (5)	25 (4)	0.76
Mallampati score 1/2/3/4, n (%)	63/49/5/0 (54/42/4/0)[3]	57/56/7/0 (48/47/6/0)	0.31	65/47/7/0 (55/39/6/0)[1]	62/49/6/0 (53/42/5/0)[3]	0.86	64/49/5/0 (54/42/4/0)[2]	71/44/4/1 (59//37/3/1)	0.47
Mouth opening without collar in mm, mean (SD)	46 (7)	45 (6)	0.53	47 (7)	46 (6)	0.23	45 (6)	45 (6)	0.55
Mouth opening with collar in mm, mean (SD)	23 (3)	24 (3)	0.02	23 (3)	24 (3)	0.09	23 (3)	23 (3)	0.75

Missing data: [1]1 missing value, [2]2missing values, [3]3 missing values.

taken away from the patient's face until the end-tidal carbon dioxide curve appeared on the monitor.

Additionally, we evaluated data of adverse events from the original studies that have not been published so far.

Statistical analysis was performed using STATA version 14.0 (StataCorp LT, Texas, USA). Nominal data was analysed using Fisher's exact test or Chi square test as applicable. Ordinal data was analysed using Mann-Whitney-U-test. Interval data was analysed using Student's t-test or Mann-Whitney-U-test as appropriate.

Data are presented as mean (standard deviation), median (25th percentile; 75th percentile) or number (percent). A p-value < 0.05 was considered statistically significant.

3. Results

Patient characteristics are given in Table 1. There were no differences except for sex in the A.P. Advance™ group (p = 0.03); age (p < 0.01) and ASA class (p = 0.03) in the KingVision™ group, and mouth opening with collar (p = 0.02) in the Airtraq™ group.

There was no difference in our primary outcome, first attempt intubation success rate between the channelled and unchannelled versions of all 3 devices (Table 2).

CL grade and POGO score were better for the channelled version of the A.P. Advance™ (both p < 0.01); CL grade was better for the unchannelled version of the KingVision™ (p = 0.04) (Table 3).

Results of other secondary outcome parameters are given in Table 4. The intubation time for the channelled Airtraq™ (47 vs. 54 s. for the unchannelled) was statistically significant different (p = 0.01). The A.P. Advance™ showed significant differences for all parameters (p < 0.05) except for quality of view (p = 0.81) and the time to view the vocal cords (p = 0.06). Thus, the unchannelled version of the A.P. Advance™ performed better than the channelled version of the A.P. Advance™. For the KingVision™ overall success rates and intubation time was comparable, although the insertion and quality of view were rated significantly better for the unchannelled version (p < 0.01).

The overall incidence of adverse events and other effects was very low (Table 5). Interestingly, more hoarseness was found for the unchannelled version of the Airtraq™ compared to its channelled version, and more blood stained saliva within the first hour was found for the channelled version of the A.P. Advance™ compared to its unchannelled version (p = 0.01). The willingness to participate again in such a study was very high (94—98%), except for participants with the channelled A.P. Advance™: For the A.P. Advance™ only 81% of the channelled group wanted to participate again compared to 96% with the unchannelled version (p < 0.01).

4. Discussion

This comparison of the performance of channelled and unchannelled versions of three videolaryngoscope suggests that tube-guiding channels do not facilitate intubation with videolaryngoscopes in the hands of experienced anaesthesiologists in the investigated setting. In contrast, the results suggest that the general design of the blade seems to be the most influential factor to facilitate intubation.

As no statistically significant differences between the first attempt intubation success rates of the channelled and unchannelled versions of each tested device were found, we conclude that the tube-guiding channel does not offer an advantage to facilitate first attempt intubation in the hand of experienced anaesthesiologists. This was also true for the A.P. Advance™ even though the unchannelled version of the A.P. Advance™ showed better performance for several parameters, such as higher overall success rate, ease of insertion of the laryngoscope, ease of tube insertion, and time to intubation. The low first attempt intubation success rate (below 50%) and the low overall success rate (below 70%) for the A.P. Advance™, compared to the other devices might be explained by the design of both blades. The disadvantages of the channelled blade were described earlier [33] and the unchannelled version is designed like the classic Macintosh blade [36].

The differences according to sex, age and ASA class are most likely due to chance, with little to no influence on the results of the airway management analysis. While the difference in mouth opening for the Airtraq™ might has a small influence; the mouth opening was 23 (3) mm in the channelled group vs. 24 (3) mm in the unchannelled group. Therefore, this statistical significant difference has no clinical importance.

To our knowledge, only one manikin study compared the channelled and unchannelled versions of the A.P. Advance™. Unfortunately intubation success was not compared, but the channelled version of the A.P. Advance™ performed about 15 s faster than its unchannelled version [43]. This is in contrast to our study, which showed that the channelled A.P. Advance™ was 8 s faster than its unchannelled version. Certainly this 8-s difference will not be clinically relevant. It seems much more relevant that the unchannelled A.P. Advance™ has a higher overall success rate than its channelled version. Anaesthesiologists rated the CL grade and the POGO score significantly better for the channelled A.P. Advance™ compared with the unchannelled version, however, this did not translate into better intubation success. This confirms that improved visualisation of the glottic opening does not guarantee the successful tracheal intubation as described in many studies

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Table 2
Primary outcome: First attempt intubation success rate.

	Airtraq™			A.P. Advance™			KingVision™		
	channelled n = 120	unchannelled n = 120	p-value	channelled n = 120	unchannelled n = 120	p-value	channelled n = 120	unchannelled n = 120	p-value
First attempt success, n (%)	102 (85)	98 (82)	0.49	44 (37)	59 (49)	0.05	104 (87)	108 (90)	0.42

Table 3
Visualisation parameters. POGO = Percentage of glottic opening.

	Airtraq™			A.P. Advance™			KingVision™		
	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value
Cormack-Lehane I/IIa/IIb/III/IV, n (%)	74/30/4/0/3 (66/27/4/0/3)[5]	67/34/9/1/3 (59/30/8/1/3)[4]	0.17	19/28/22/8/19 (20/29/23/8/20)[6]	14/17/26/38/20 (12/15/23/33/17)[3]	<0.01	63/41/7/1/4 (55/35/6/1/3)[2]	77/36/4/0/0 (66/31/3/0/0)[1]	0.04
POGO score median (25th; 75th percentile)	90 (80; 100)	90 (75; 100)	0.46	60 (10; 80)	0 (0; 60)	<0.01	90 (80; 100)	95 (80; 100)	0.19

Missing data: [1]3 missing values, [2]4 missing values, [3]5 missing values, [4]6 missing values, [5]9 missing values, [6]24 missing values.

Table 4
Further parameters of the device performance.

	Airtraq™			A.P. Advance™			KingVision™		
	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value
Overall success, n (%)	112 (93)	104 (87)	0.19	48 (40)	79 (66)	<0.01	110 (92)	113 (94)	0.41
Insertion of the device excellent/good/fair/poor, n (%)	41/47/27/4 (34/40/23/3)[1]	54/35/23/3 (47/30/20/3)[4]	0.10	26/43/29/14 (23/38/26/13)[5]	34/64/12/0 (31/58/11/0)[6]	<0.01	26/54/26/11 (22/46/22/10)[2]	80/28/7/1 (69/24/6/1)[3]	<0.01
Quality of view excellent/good/fair/poor, n (%)	78/33/7/1 (65/28/6/1)[1]	65/39/10/1 (57/34/9/1)[4]	0.15	38/50/14/10 (34/45/12/9)[5]	39/41/22/8 (35/37/20/7)[6]	0.81	68/41/6/2 (58/35/5/2)[2]	86/27/3/0 (74/23/3/0)[3]	<0.01
Ease of tube insertion excellent/good/fair/poor, n (%)	61/37/16/5 (xy/yz/ab)[1]	44/45/21/5 (38/39/18/4)[4]	0.07	25/37/26/23 (xy/yz/ab)[5]	38/42/27/3 (35/38/25/3)[6]	<0.01	41/47/24/5 (xy/yz/ab)[2]	50/32/27/7 (43/28/23/6)[3]	0.69
Time to view vocal cords in seconds, median (25th; 75th percentile)	20 (12; 27)	19 (13; 28)	0.67	24 (18; 40)	23 (16; 30)	0.06	26 (16; 32)	17 (13; 24)	<0.01
Intubation time of successful attempt in seconds, median (25th; 75th percentile)	47 (37; 62)	54 (45; 71)	0.01	65 (51; 115)	57 (46; 81)	0.02	59 (47; 81)	57 (24; 80)	0.13

Missing data: [1]1 missing value, [2]3 missing values, [3]4 missing values, [4]5 missing values, [5]8 missing values, [6]10 missing values.

about videolaryngoscopes [1,2,4–7,13,17,18,23,25–52]. However, success rates, of the A.P. Advance™, both of the channelled and the unchannelled version, were unacceptably low in the studied setting.

This study has its limitations. First, the current results derive from an analysis of data from two previously published randomised controlled trials. However, we believe that it is valid and valuable to compare the data since both studies had the same study design [29] and were performed by the same study group. Baseline patient characteristics showed few differences, which likely occurred by chance. It appears that these differences are of no clinical importance for airway management and do not influence the given result of our analysis between the channelled and unchannelled versions of the devices. It can also be argued that anaesthesiologists in the second study had more experience with the devices compared with the first study, but devices differed in the presence or absence of the tube-guiding channel and handling was therefore different and not directly transferrable. A potential limitation of the original studies was the use of an extrication collar to create a simulated difficult airway with limited mouth opening and impossible movement of the neck to facilitate laryngoscopy and intubation. This model represents one of many causes of difficult airway management, albeit an important one. The performance of the different blades and the different devices in patients with a real difficult airway might be different.

The current comparative data analysis reports never published results. Additionally, the view on the side effects is new. Although the same results could have been obtained by re-doing a randomised controlled trial, the benefit of our analysis is that no further patients had to undergo such a study with its inherent risks of testing devices again. While appreciating the inherent limitations of this analysis of already existing data, we were able to show new insights.

5. Conclusion

This data analysis on performance of videolaryngoscopes in patients with a simulated difficult airway suggests that the general blade design of the A.P. Advance™, the Airtraq™, and the KingVision™ is more important to facilitate intubation than the presence of a tube-guiding channel. The tube-guiding channels do not seem to facilitate intubation in this setting in the hands of experienced anaesthetists.

Table 5
Adverse events and side effects.

	Airtraq™			A.P. Advance™			KingVision™		
	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value	Channelled n = 120	Unchannelled n = 120	p-value
Active oral bleeding within 1h none/mild/moderate/severe, n (%)	119/0/0/0 (100/0/0/0)[1]	119/0/0/0 (100/0/0/0)[1]	–	118/0/0/0 (100/0/0/0)[2]	119/0/0/0 (100/0/0/0)[1]	–	120/0/0/0 (100/0/0/0)	117/1/0/0 (99/1/0/0)[2]	0.50
Active oral bleeding within 1d none/mild/moderate/severe, n (%)	115/0/0/0 (100/0/0/0)[4]	116/0/0/0 (100/0/0/0)[3]	–	118/0/0/0 (100/0/0/0)[2]	119/0/0/0 (100/0/0/0)[1]	–	120/0/0/0 (100/0/0/0)	117/1/0/0 (99/1/0/0)[2]	0.49
Coughing blood within 1h none/mild/moderate/severe, n (%)	119/0/0/0 (100/0/0/0)[1]	119/0/0/0 (100/0/0/0)[1]	–	118/0/0/0 (100/0/0/0)[2]	119/0/0/0 (100/0/0/0)[1]	–	120/0/0/0 (100/0/0/0)	117/1/0/0/ (99/1/0/0)[2]	0.50
Coughing blood within 1d none/mild/moderate/severe, n (%)	115/0/0/0 (100/0/0/0)[4]	115/1/0/0 (99/1/0/0)[3]	1.00	118/0/0/0 (100/0/0/0)[2]	119/0/0/0 (99/1/0/0)[1]	–	120/0/0/0 (100/0/0/0)	117/1/0/0 (99/1/0/0)[2]	0.50
Blood stained saliva within 1h none/mild/moderate/severe, n (%)	117/2/0/0 (98/2/0/0)[1]	117/2/0/0 (98/2/0/0)[1]	1.00	112/6/0/0 (95/5/0/0)[2]	119/0/0/0 (100/0/0/0)[1]	0.01	119/1/0/0 (99/1/0/0)	117/1/0/0 (99/1/0/0)[2]	1.00
Blood stained saliva within 1d none/mild/moderate/severe, n (%)	114/1/0/0 (99/1/0/0)[4]	116/0/0/0 (100/0/0/0)[3]	0.50	118/0/0/0 (100/0/0/0)[2]	119/0/0/0 (100/0/0/0)[1]	–	120/0/0/0 (100/0/0/0)	118/0/0/0 (100/0/0/0)[2]	–
Hoarseness within 1h none/mild/moderate/severe, n (%)	98/18/3/0 (82/15/3/0)[1]	80/29/8/2 (67/24/7/2)[1]	0.03	91/22/4/1 (77/19/3/1)[2]	76/30/12/1 (64/25/10/1)[1]	0.06	99/18/2/1 (82/15/2/1)	83/26/7/2 (70/22/6/2)[2]	0.10
Hoarseness within 1d none/mild/moderate/severe, n (%)	101/11/3/0 (88/9/3/0)[4]	88/23/5/0 (76/20/4/0)[3]	0.05	97/15/6/0 (82/13/5/0)[2]	96/15/4/4 (81/13/3/3)[1]	0.26	103/14/3/0 (86/12/2/0)	94/20/4/0 (80/17/3/0)[2]	0.44
Sore throat within 1h none/mild/moderate/severe, n (%)	102/11/5/1 (86/9/4/1)[1]	92/22/5/0 (78/18/4/0)[1]	0.12	93/19/6/0 (79/16/5/0)[2]	88/24/7/0 (74/20/6/0)[1]	0.70	100/16/3/1 (82/14/3/1)	90/20/7/1 (76/16/7/1)[2]	0.44
Sore throat within 1d none/mild/moderate/severe, n (%)	95/16/4/0 (83/14/3/0)[4]	99/15/2/0 (85/13/2/0)[3]	0.72	95/18/4/1 (81/15/3/1)[2]	98/17/4/0 (83/14/3/0)[1]	0.94	106/10/4/0 (88/8/4/0)	90/21/7/0 (76/18/6/0)[2]	0.04
Pain swallowing within 1h none/mild/moderate/severe, n (%)	102/11/3/3 (86/10/2/2)[1]	97/18/3/1 (82/15/2/1)[1]	0.43	95/14/8/1 (80/12/7/1)[2]	87/23/7/2 (73/19/6/2)[1]	0.42	102/14/2/2 (84/12/2/2)	95/14/7/2 (80/12/6/2)[2]	0.40
Pain swallowing within 1d none/mild/moderate/severe, n (%)	103/4/6/2 (90/3/5/2)[4]	100/13/3/0 (86/11/3/0)[3]	0.04	92/18/7/1 (78/15/6/1)[2]	95/16/7/1 (80/13/6/1)[1]	0.97	103/13/4/0 (86/11/3/0)	95/14/8/1 (80/12/7/1)[2]	0.43
PONV within 1h none/mild/moderate/severe, n (%)	107/2/10/0 (90/2/8/0)[1]	106/7/6/0 (89/6/5/0)[1]	0.15	105/5/7/1 (89/4/6/1)[2]	105/9/4/1 (88/8/3/1)[1]	0.56	106/5/8/1 (88/4/7/1)	99/12/5/2 (84/10/4/2)[2]	0.24
PONV within 1d none/mild/moderate/severe, n (%)	104/4/5/2 (90/4/4/2)[4]	96/10/7/3 (83/9/6/2)[3]	0.31	107/4/4/3 (91/3/3/3)[2]	100/7/7/5 (84/6/6/4)[1]	0.53	105/9/4/2 (88/7/3/2)	91/9/13/5 (77/8/11/4)[2]	0.07
Dysphagia within 1h none/mild/moderate/severe, n (%)	112/5/1/1 (94/4/1/1)[1]	110/6/2/1 (92/5/2/1)[1]	0.91	108/8/2/0 (92/7/1/0)[2]	109/7/3/0 (92/6/2/0)[1]	1.00	115/5/0/0 (96/4/0/0)	107/5/6/0 (91/4/5/0)[2]	0.04
Dysphagia within 1d none/mild/moderate/severe, n (%)	109/4/1/1 (95/3/1/1)[4]	110/4/1/1 (95/3/1/1)[3]	1.00	109/6/2/1 (92/5/2/1)[2]	114/5/0/0 (96/4/0/0)[1]	0.40	111/8/1/0 (92/7/1/0)	104/7/7/0 (88/6/6/0)[2]	0.10
Would participate again, n (%)	111 (98)[6]	106 (98)[7]	1.00	96 (81)[2]	111 (96)[3]	<0.01	113 (94)	109 (96)[5]	0.77

Missing data: [1]1 missing value, [2]2 missing values, [3]4 missing values, [4]5 missing values, [5]6 missing values, [6]6 missing values, [7]12 missing values.

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ORIGINAL ARTICLE

Outdoor performance of different videolaryngoscopes on a glacier: a manikin study

Sabine Nabecker, Robert Greif, Manuel Kotarlic, Maren Kleine-Brueggeney, Christine Riggenbach, Lorenz Theiler

Background and objective. Little information about the performance of videolaryngoscopes outdoors is available. We aimed to test the hypothesis that a Mackintosh direct laryngoscope would perform less well than videolaryngoscopes under difficult environmental conditions (high-altitude glacier, sun-reflecting snow).

Methods. After local research ethics committee approval, this randomized controlled trial enrolled 20 physicians who intubated manikins with limited cervical extension mouth opening under 5 conditions: 1) in hospitals (indoors), 2) indoors at a high altitude, 3) outdoors on a glacier in sunlight without sunglasses, 4) outdoors on a glacier with sunglasses, and 5) outdoors on a glacier with the physician and manikin covered with a blanket. The following devices were compared to the Macintosh laryngoscope, McGrath, Airtraq-SP, GlideScope, KingVision, C-MAC-D-Blade, AP Advance Difficult Airway Blade and Bonfils. The main outcome was first-attempt intubation success; secondary outcomes were intubation time, visibility on the screen, and view of the glottis.

Results. The best intubation success rates were observed indoors asnd on the glacier under a blanket. The Macintosh performed better than the videolaryngoscopes under bright sunlight. We observed significant differences in the performance of devices with built-in screens under varying conditions. Wearing sunglasses improved performance with some but not all devices. Intubation times differed significantly between devices, regardless of the environmental condition ($P<0.01$). Screen visibility differed significantly between conditions and devices.

Conclusions. Successful intubation with videolaryngoscopes is less likely under bright sunlight conditions. The Macintosh laryngoscope performs better than videolaryngoscopes. Covering the heads of both the physician and the patient with a dark blanket sufficiently overcomes the detrimental effects of sunlight during intubation.

Keywords: Intubation. High altitude. Outdoors. Videolaryngoscope. Manikin.

Rendimiento de diferentes tipos de videolaringoscopios en un glaciar al aire libre: estudio con maniquíes

Introducción y objetivo. Existe muy poca información sobre la realización de videolaringoscopias al aire libre. Investigamos el rendimiento de una variedad de dispositivos de intubación en comparación con la laringoscopia directa y bajo condiciones ambientales difíciles (glaciar de gran altitud, nieve con efecto reflectante).

Métodos. Tras la aprobación por el comité local de ética, este estudio aleatorizó a 20 médicos que intubaron maniquíes con limitación en la apertura bucal y en la extensión cervical, bajo cinco circunstancias: 1) en el interior de hospitales, 2) en interiores a la altitud del glaciar, 3) en un glaciar a plena luz solar, 4) en un glaciar con gafas de sol, y 5) en un glaciar, con el médico y el maniquí cubiertos por una manta. Los dispositivos evaluados fueron: laringoscopio *Macintosh* y los videolaringoscopios *McGrath, Airtraq-SP, GlideScope, KingVision, C-MAC-D-blade, APAdvance-difficult-airway-blade* y *Bonfils*. El resultado principal a analizar fue el éxito de intubación al primer intento; y los resultados secundarios el tiempo de intubación, la visibilidad de de la glotis en la pantalla.

Resultados. Se observó un mayor índice de éxito de intubación en el interior, así como al aire libre en el glaciar cuando se cubría con una manta. El rendimiento a plena luz del día del Macintosh fue superior a la de los videolaringoscopios. En los dispositivos con pantallas incorporadas se percibieron diferencias significativas en condiciones ambientales cambiantes. El uso de gafas de sol mejoró el rendimiento de algunos dispositivos, pero no de todos. El tiempo de intubación difirió sustancialmente entre los dispositivos, independientemente de las condiciones ambientales (p < 0,01). La calidad de visibilidad de la pantalla varió significativamente según las condiciones y los dispositivos.

Conclusiones. El laringoscopio Macintosh se comporta mejor que los videolaringoscopios. Las posibilidades de éxito en la intubación con videolaringoscopios es menor en condiciones de luz solar brillante. Cubrir la cabeza con una manta oscura bloquea suficientemente los efectos perjudiciales de la luz solar durante la intubación a pleno sol.

Palabras clave: Intubación. Altitude. Exterior. Videolaringoscopio. Maniquí.

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Introduction

Prehospital airway management is difficult and complications such as failed intubations are frequent[1-3]. On the other hand, recent evidence supports the notion that proper airway management provided by experienced practitioners improves patient outcome[4,5]. Factors that increase difficulties in prehospital airway management are the specific environmental conditions outdoors. Videolaryngoscopes (VLS) have become increasingly popular as intubation aids and they may perform better than direct laryngoscopy[6,7]. In the last years, a variety of VLS have been marketed with substantial improvements, promising a better view of the glottis, even in difficult intubation situations[8-10]. A common intubation impediment for emergency physicians on rescue helicopters is bright sunlight. While VLS on board of rescue helicopters might help physicians facilitate intubation prior to transporting a patient to the hospital[11-14], very few studies have evaluated the use of VLS outdoors[15-17]. No data are available about the performance of these devices in sun-reflecting conditions outdoors.

This prospective randomised controlled manikin study evaluates whether VLS offer benefits for successful intubation in comparison to direct laryngoscopy. While the superiority of VLS compared to the standard Macintosh blade in the emergency department is well known[18], this fact might be challenged under difficult outdoor conditions. We hypothesised that direct laryngoscopy with a Macintosh blade would perform consistently inferior to the VLS under specific environmental conditions on the glacier. The primary and secondary objectives are to determine the performance of a variety of intubation aids compared to direct laryngoscopy under difficult environmental conditions (high altitude glacier, sun-reflecting snow).

Method

This study was carried out by members of the Difficult Airway Research Collaboration (DARC) at the University Hospital of Berne, Inselspital, Switzerland, with local Institutional Review Board approval (approval number 13-053). The study site was on the Aletsch glacier at the Jungfraujoch in the Swiss Alps, at an altitude of 3450 meters above sea level. Anaesthesiologists with at least two years of clinical experience participated after providing written informed consent. The participants were recruited from the University Hospitals of Berne, Lausanne and Geneva, where anaesthesiologists also work as emergency physicians on the Swiss Helicopter Rescue Service (REGA). Each participant received a standardized introductory training in the use of the study devices. This consisted of a short lecture and at least 10 supervised intubation attempts on a manikin, followed by deliberate practice in the use of each device prior to the study.

Intubation was performed using an intubation ma-nikin (HAL® Gaumard, Miami, FL, USA). A cervical collar (Stifneck™, Laerdal, Copenhagen, Denmark) was fitted around the neck of the manikin to immobilize the neck and to reduce mouth opening. One intubation attempt was allowed. A tracheal tube I.D. size 7.5 mm was used (Mallinckrodt® Hi-Contour, Covidien, Hazelwood, MO, USA). In case of blades without a tube-guiding channel, the tracheal tube was equipped with a malleable stylet (Flexislip®, Teleflex, Westmeath, Ireland), which did not extend beyond its distal opening. For the GlideScope®, the GlideScope stylet was used.

The following devices[11,19] were evaluated: 1) Macintosh laryngoscope (Heine®, Herrsching, Germany) blade size 4; 2) McGrath™ (Aircraft Medical Ltd., Edinburgh, UK)20, with a MAC single-use blade size 3; 3) Airtraq SP™ (Prodol Meditec SA, Vizcaya, Spanien), with a single-use blade size "large" that features a tracheal tube guiding channel; 4) GlideScope™ (Verathon Inc., Bothell, WA, USA), with a single-use blade size 3; 5) KingVision™ (Kingsystems, Noblesville, IN, USA), with a single-use blade size 3 that features a tracheal tube guiding channel; 6) C-MAC™ (Karl Storz, Tuttlingen, Germany)[21] with a reusable difficult-airway blade; 7) A.P. Advance™ (Venner Medical SA, Singapur), with a single-use "difficult airway" blade that features a tracheal tube guiding channel; 8) Bonfils™ (Karl Storz, Tuttlingen, Germany)[22], a rigid optical stylet with a 40° curved tip.

The study devices were tested in five different environmental conditions: 1) Indoors at the University Hospitals where the study participants worked at an altitude of about 500 meters above sea level; 2) Indoors at 3450 meters above sea level at the High Altitude Research Station on the Jungfraujoch (HFSJG), Switzerland; 3) Outdoors at the High Altitude Research Station on the Jungfraujoch, in bright sunlight, on snow, without eye protection; 4) Outdoors at the High Altitude Research Station on the Jungfraujoch, in bright sunlight, on snow, with sunglasses; 5) Outdoors at the High Altitude Research Station on the Jungfraujoch, in bright sunlight, on snow, the head of the manikin and study participant covered with a dark blanket (Figure 1).

We randomised the order of the three outdoor environmental conditions and the order of use of the devices by computer randomisation and kept numbers in sealed opaque envelopes. To quantify the radiation brightness (luminance) at the study site on the glacier, we used the global horizontal irradiation measurements (W/m²) of the Federal Office of Meteorology and Climatology, Payerne, Switzerland[23]. Data were transformed to lux. Indoor brightness was measured with a digital lux meter (TES 1330, TES® Electrical Electronic Corporation, Taipei, Taiwan)

Each participant performed one intubation attempt with each device in each condition, resulting in 40 intubation attempts per participant. Throughout the study, only one intubation attempt was allowed and time per intubation attempt was limited to a maximum of 120 seconds[17]. Intubation success was defined as visualization of the vocal cords followed by tracheal tube

Figure 1.

insertion resulting in symmetrical chest wall movements during bag ventilation.

The primary outcome was successful intubation within 120 seconds[17] under direct visualization of the vocal cords. Secondary outcome parameters included time for successful intubation and the POGO (percent of glottis opening) Score[24]. Unrelated to the POGO Score, the view on the anatomical structures of the manikin (either on the screen of the VLS or directly observed, e.g. Macintosh) was rated subjectively on a scale from 1 (structures clearly visible) to 5 (black screen or no structures visible). After completing the 40 intubation attempts, participants were asked to rate the devices according to their personal preference for future use in similar conditions.

Baseline demographics of participants included: age, sex, years of experience in anesthesiology, and current clinical position (resident, attending anesthesiologist). Heart rate and peripheral oxygen saturation (SaO$_2$) of the participants were recorded at base level and at the level of the research station.

The primary hypothesis was that the success rate of intubation with VLS and the Bonfils is higher than the success rate of intubation with the standard Macintosh blade for direct laryngoscopy in this simulated difficult airway scenario. We calculated the sample size using the success rate of direct laryngoscopy (39.5%) vs. the success rate of the Bonfils fiberoptic stylet (81.6%) that was previously published by Byhahn et al. in a difficult airway scenario[25]. A one-sided alpha error of 0.05, a beta error of 0.2 and a correlation of 0.2 resulted in 15 participants (Stata V.13.1, StataCorp, College Station, TX, USA). We invited 22 participants to take part in order to compensate for unstable weather conditions and possible dropouts. Stata was used for statistical calculations and comparisons (Stata V.13.1, StataCorp, College Station, TX, USA). For the calculation of frequencies such as differences in success rates between devices and between conditions we used Cochran's Q test. McNemar's test was used to compare success rates of two groups. Interval data were checked for nor-

mal distribution using Shapiro-Wilk test and visually using Q-Q plots. For the analysis of interval data not following normal distribution we used a generalized Friedman's test (Skillings-Mack test). Vital parameters such as heart rate were compared with paired t-test or Wilcoxon matched-pairs signed-ranks test, depending on data distribution. A p-value < 0.05 was considered statistically significant.

Results

Twenty-two anesthesiologists participated in the study at the research center on the Jungfraujoch. Two participants had to be excluded due to changing weather conditions with incoming clouds. Twenty participants (16 (80%) male, age 39 (SD 8)) performed the intubation attempts under a cloudless sky with corresponding lux luminance >20,000 lux. Indoor brightness ranged from 350 lux (windowless anesthesia induction area) to 3000 lux (indoors near windows in the research center). Median experience in anesthesiology was 11 (IQR 4-14) years. 13 (65%) of participants were attending anesthesiologists and 7 (35%) were anesthesiology residents with at least two years of experience in anesthesia.

Mean resting heart rate was 74 (SD 13) beats per minute (bpm) at the University hospitals at approximately 500 meters above sea level and 80 (SD 12) bpm at the altitude of the study site (p=0.23). Median participants' SaO$_2$ dropped significantly from 99 (IQR 98-100) % to 90 (IQR 88-93) % at the altitude of the study site (p<0.001). Outdoor temperature at the Alpine study site was 3°C (IQR 1-5).

The videolaryngoscopes did not perform better than direct laryngoscopy for our primary outcome, the intubation success rate (Table 1). Therefore, we were unable to reject the null hypothesis. There was no statistically significant difference between the devices indoors (hospital and at high altitude) and outdoors when covered with a blanket at high altitude. Performance differed significantly between indoors and outdoors covered with a blanket compared with the outdoor conditions in bright sunlight, with and without sunglasses (For details refer to the rows of Table 1).

Interestingly, only the devices with a built-in screen (p≤0.01 for McGrath, KingVision, C-MAC, A.P. Advance) performed statistically significantly worse in sunlight. Wearing sunglasses improved performance of some devices as compared to intubation in sunlight without sunglasses (p=0.049), but this statistical significance was lost in the pairwise comparison of the devices. (Table 1) The Macintosh blade was significantly better in the sun without sunglasses compared to the McGrath (p=0.03) and the A.P. Advance (p=0.004). However, it was not significantly better in the sun than the Airtraq (p=0.25), the GlideScope (p=1.0), the KingVision (p=0.13), the C-MAC (p=0.5), or the Bonfils (p=1.0).

The time until successful intubation differed significantly between the devices, under every environmental

Table 1. First attempt intubation success rates

	Macintosh®	McGrath®*	Airtraq®	Glidescope®	KingVision®*	C-MAC®*	A.P. Advance®*	Bonfils®	p-value
Indoors hospital (n = 20)	20 (100)	20 (100)	20 (100)	20 (100)	20 (100)	20 (100)	19 (95)	20 (100)	n.a.
Indoors Jungfrau r (n = 20)	20 (100)	20 (100)	20 (100)	20 (100)	20 (100)	20 (100)	20 (100)	20 (100)	n.a.
Sun (n = 20)	20 (100)	14 (70)**	17 (85)	19 (95)	16 (80)	18 (90)	11 (55)**	19 (95)	< 0.01
Sunglasses l (n = 20)	18 (90)	15 (75)	19 (95)	19 (95)	19 (95)	13 (65)	18 (90)	17 (85)	0.049
Cover (n = 20)	19 (95)	20 (100)	19 (95)	20 (100)	20 (100)	20 (100)	19 (95)	18 (90)	0.50
p-value	0.23	< 0.01	0.13	0.63	0.01	< 0.01	< 0.01	0.17	

Data are given as numbers (%). Test statistics: Cochran's Q. *Devices featuring a built-in monitor **Statistically different to Macintosh direct laryngoscopy (p=0.03 for McGrath, p=0.004 for AP Advance. Test statistics: McNemar. No correction factor applied).

condition (p<0.01, rows of Table 2). Despite the significant difference in participants' oxygen saturation between low and high altitude, there was no difference in intubation times under comparable conditions indoors between low and high altitude (row 1 and row 2, Table 2). All p-values for difference in times were higher than p=0.05, the lowest value was for the Airtraq, p=0.08.

The quality of visualization of the anatomical structures, either on the screen of the VLS or directly (Macintosh, Bonfils) was significantly different amongst all devices, under all environmental conditions (p<0.01, rows of Table 3). For every single VLS, the quality of the view also differed significantly among the different environmental conditions (columns, Table 3). However, there was no difference between the Bonfils and the Macintosh with respect to the subjectively rated quality of view among the different environmental conditions.

The POGO Score was significantly different between the devices under all tested conditions (rows, Table 4). Only for the A.P. Advance was a significant difference observed with respect to the POGO Score under the various conditions (p=0.01, columns of Table 4). In general, the Macintosh laryngoscope displayed the lowest POGO Scores, but this did not influence the success rate.

The participating physicians ranked the devices for outdoor use as follows: 1. Macintosh, 2. C-MAC, 3. McGrath, 4. KingVision, 5. Airtraq, 6. GlideScope, 7. Bonfils, 8. A.P. Advance.

Discussion

This study in manikins with a simulated difficult airway evaluated if videolaryngoscopes were superior to the Macintosh laryngoscope for intubation under difficult environmental conditions. Contrary to our hypothesis, the intubation success rate under these conditions was better with the standard Macintosh blade than with the VLS. Additionally, devices with a built-in screen (C-MAC, McGrath, KingVision and A.P. Advance) appeared to perform inferiorly outdoors, in the sun or with the physician wearing sunglasses. This was reflected in the success rate. Devices with external monitors (GlideScope, Airtraq) or devices not relying on a video screen (Macintosh, Bonfils) seemed to be less affected by the sunlight. The latter four devices did not show statistically significant differences in the success rate under various environmental conditions. Difficulties with tracheal intubation were reflected by the prolonged duration until successful intubation, yet these statistically significant differences have no clinical relevance.

Bright sunlight seriously impeded the correct identification of anatomical structures on the video screen (poor image quality or only a black screen visible). This did not change significantly when wearing sunglasses. Interestingly, sunglasses seemed to especially worsen visibility on the C-MAC's pocket screen. In general, wearing sunglasses did not improve the impaired image quality on the screens. Also, changing the screen's angle in relation to the sun, if possible (e.g. Airtraq), had practically no effect on the image quality. Likewise, creating a man-made shadow to avoid the glare's effects did not improve the image quality. The best solution to intubate patients in bright sunlight was to simply block the sunlight's glare with a dark blanket (Figure 1). We could show that this easy intervention resulted in nearly the same intubation success rates and times as indoors.

Our results suggest that external monitors might perform better in the prehospital environment compared with VLS that feature built-in screens. However, their increased size and weight make them more cumbersome to carry to the scene, which must be considered in the prehospital setting.

To our knowledge, only Ueshima et al[17] compared

Table 2. Time to intubation in seconds

	Macintosh®	McGrath®	Airtraq®	Glidescope®	KingVision®	C-MAC®*	A.P. Advance®	Bonfils®	p-value
Indoors hospital (n = 20)	15 (10-23)	13 (11-18)	15 (13-19)	20 (14-22)	18 (13-27)	16 (13-18)	21 (18-24)	20 (17-35)	< 0.01
Indoors Jungfrau (n = 20)	12 (10-17)	13 (11-16)	14 (11-16)	14 (13-20)	17 (13-19)	14 (12-19)	22 (16-28)	24 (17-35)	< 0.01
Sun (n = 20)	14 (10-19)	18 (13-28)	15 (12-26)	18 (16-28)	18 (14-39)	15 (13-20)	32 (21-41)	30 (20-37)	< 0.01
Sunglasses (n = 20)	15 (11-21)	17 (13-19)	18 (11-27)	19 (16-27)	16 (13-23)	15 (14-20)	27 (21-35)	23 (20-26)	< 0.01
Cover (n = 20)	13 (12-18)	15 (11-17)	14 (10-20)	19 (13-21)	14 (11-20)	13 (12-16)	21 (18-35)	20 (15-33)	< 0.01
p-value	0.07	< 0.01	0.20	< 0.01	0.74	0.29	0.38	0.47	

Data are given as median (interquartile range). Test statistics: generalized Friedman (Skillings-Mack test).

Table 3. View on the anatomical structures

	Macintosh®	McGrath®	Airtraq®	Glidescope®	KingVision®	C-MAC®	A.P. Advance®	Bonfils®	p-value
Indoors hospital (n = 20)	85/15/0/0/0	55/45/0/0/0	20/40/30/10/0	90/10/0/0/0	75/25/0/0/0	70/25/5/0/0	10/55/20/10/5	55/30/15/0/0	< 0.01
Indoors Jungfrau (n = 20)	100/0/0/0/0	75/15/5/5/0	10/16/58/16/0	80/15/5/0/0	85/15/0/0/0	80/20/0/0/0	15/40/35/10/0	35/35/25/5/0	< 0.01
Sun (n = 20)	50/25/10/15/0	0/5/32/42/21	11/26/21/42/0	5/35/35/25/0	5/30/25/30/10	10/15/50/25/0	0/15/30/30/25	30/40/25/5/0	< 0.01
Sunglasse (n = 20)	55/15/15/10/5	5/15/25/40/15	5/35/25/35/0	5/32/26/37/0	5/50/20/20/5	10/20/20/20/30	0/20/30/45/5	40/30/20/10/0	< 0.01
Cover (n = 20)	75/20/0/5/0	70/20/10/0/0	42/32/26/0/0	70/30/0/0/0	85/10/5/0/0	60/35/5/0/0	15/50/15/20/0	45/35/10/0/10	< 0.01
p-value	0.09	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.58	

Data are given as %. Test statistic: generalized Friedman (Skillings-Mack test) 1 / 2/ 3/ 4/ 5: 1=excellent, 2=good, 3= fair, 4=poor, 5= black screen

two VLS, the Pentax Airway Scope and the Airtraq, with direct laryngoscopy using a Macintosh blade in daylight and in the dark (operating room without lights). In contrast to our study, they did not use the external Airtraq monitor. Their primary outcome was the time necessary until intubation. Similarly to our findings, it took longer to intubate outdoors with the device that relied on a video screen (Pentax Airway Scope).

In our study, we also looked at differences in performance depending on altitude. In general, participants were slower in bright sunlight with or without sunglasses. However, although median peripheral SaO₂ dropped from 99% to 90% at high altitude, there was no difference in time or success whether the participants intubated indoors at the altitude of the hospitals or indoors at high altitude. We could not find a decrease in intubation success rate or time requirements as a surrogate outcome parameter for professional performance at high altitude without acclimatization. Merz et al. have shown that performance does not change at higher altitude[26]. These findings support the clinical observation that the helicopter emergency medical staff is able to do their job even after fast ascent to high altitude.

As previously described, the cervical collar reduced the percentage of visible glottic opening with the use of the Macintosh blade compared to the VLS (all p<0.01)[21,25,27]. Despite of this, the Macintosh blade outperformed other devices in intubation success rate. A possible reason for this could be that the participating physicians were experienced anesthesiologists and, therefore, able to intubate the trachea even when the view of the vocal cords was not optimal. Apparently, it is more important to have a high-quality view, albeit with a low POGO Score, than a potentially high percentage of a POGO Score on a nearly black screen. This was mirrored in the subjective ranking of the devi-

ces for outdoor use, where the Macintosh blade with direct laryngoscopy was ranked first.

Our study has some limitations. Obviously, this is a manikin study and we can only extrapolate the results to the performance in patients. By using manikins, we were able to standardize the intubation conditions for all study participants. Since in most European countries helicopter services are staffed with emergency physicians or anesthesiologists, we invited only anesthesiologists, but no paramedics. We believe that our data is applicable to real-life, out-of-hospital emergency medicine, despite the fact that we used manikins. We challenged the intubation conditions by reducing mouth opening and minimizing neck movement, thereby mimicking the real intubation conditions of trauma patients. However, we do not know how the devices would have facilitated intubation in genuinely difficult airway situations under similar outdoor conditions. Additionally, our sample size calculation had to rely on assumptions. In fact, the difference in success rate between direct laryngoscopy with the standard Macintosh blade and the video-based devices proved to be far smaller than anticipated. With the now established data, the recalculated sample size would need to include 100-200 participants in order to detect additional statistically significant differences between the devices, which is nearly impossible to realize under these outdoor conditions.

In conclusion, this manikin study revealed some serious limitations of videolaryngoscopes under bright sunlight for outdoor prehospital emergency medicine. In bright sunlight and even when using sunglasses, successful intubation was impossible because the anatomical structures could not be seen on the screen of the six different VLS. Therefore, direct laryngoscopy with the standard Macintosh blade was superior in the sunlight. Covering the physicians' heads with a dark blanket during intubation sufficiently blocked the detri-

Table 4. POGO Score

	Macintosh®	McGrath®	Airtraq®	Glidescope®	KingVision®	C-MAC®	A.P. Advance®	Bonfils®	p-value
Indoors hospital (n = 20)	60 (20-78)	95 (80-100)	85 (75-100)	90 (80-100)	100 (80-100)	95 (81-100)	80 (70-95)	93 (80-100)	< 0.01
Indoors Jungfrau (n = 20)	60 (31-80)	80 (80-100)	85 (80-90)	85 (80-100)	83 (73-90)	88 (80-100)	70 (60-80)	100 (70-100)	< 0.01
Sun (n = 20)	60 (35-93)	80 (80-100)	100 (80-100)	80 (80-100)	85 (80-90)	80 (70-90)	60 (35-93)	90 (80-100)	0.04
Sunglasses (n = 20)	50 (25-80)	80 (78-95)	80 (55-100)	90 (63-98)	80 (80-90)	90 (84-93)	65 (45-73)	80 (70-100)	< 0.01
Cover (n = 20)	60 (40-90)	90 (81-100)	80 (80-100)	93 (80-100)	90 (80-100)	100 (80-100)	85 (70-90)	83 (78-100)	< 0.01
p-value	0.28	0.21	0.41	0.27	0.07	0.14	0.01	0.37	

POGO= percentage of glottic opening visible[19].
Data are given as median (interquartile range). Test statistic: generalized Friedman (Skillings-Mack test)

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mental effects of the sunlight. Fast ascent to high altitude did not decrease intubation success despite substantial decrease in oxygen saturation in the study participants.

Acknowledgments

Conflict of interest

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Original article

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i-gel™ supraglottic airway in clinical practice: a prospective observational multicentre study

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Editor's key points

- In this paper, data on 2049 uses of i-gel have been presented.
- The overall success rate was 96% and average leak pressure 26 mm Hg.
- The risk factors for failure were male gender, impaired mandibular subluxation, poor dentition, and old age.
- Importantly, the study provides a large retrospective data on i-gel usage in the everyday clinical setting.

Background. The i-gel™ supraglottic airway device has been studied in randomized controlled studies, but it has not been evaluated in a large prospective patient cohort. Therefore, we performed this prospective multicentre observational study to evaluate success rates, airway leak pressure, risk factors for i-gel failure, and adverse events.

Methods. With Ethics Committee approval and waiver of patients' consent, data about anaesthesia providers, patient characteristics, and the performance of the i-gel were recorded in five independent hospitals in Switzerland over a period of 24 months. We analysed success rates, leak pressures, adverse events, and risk factors for failure.

Results. Data from 2049 i-gel uses were analysed. Patients' mean age was 47 (range 6–91) yr. The primary i-gel success rate without changing size was 93%; the overall success rate was 96%. Insertion was deemed very easy or easy in 92%. The mean airway leak pressure was 26 (8) cm H_2O. The mean anaesthesia time was 67 (42) min. Risk factors associated with i-gel failure were males ($P<0.001$), impaired mandibular subluxation ($P=0.01$), poor dentition ($P=0.02$), and older age ($P<0.01$). Adverse events recorded were laryngeal spasms ($n=25$, 1.2%), blood stained airway devices ($n=79$, 3.9%), transient nerve damage ($n=2$, 0.1%), one case of transient vasovagal asystole, and one glottic haematoma.

Conclusions. The i-gel is a reliable supraglottic airway device failing in <5% and providing high airway leak pressures. Males, impaired mandibular subluxation, poor dentition, and older age are risk factors associated with primary device failure. Serious adverse events are rare.

Keywords: airway management; i-gel; laryngeal masks

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The i-gel™ (Intersurgical Ltd, Wokingham, Berkshire, UK) is a supraglottic airway device that features a non-inflatable cuff and the possibility to introduce a gastric catheter. Its successful use has been described in randomized controlled studies,[1][2] including studies showing the possibility to intubate through the i-gel.[3][4] However, large prospective data about the application in daily clinical practice, side-effects, and possible predictors of i-gel failure are lacking. In order to describe rare adverse events and to find risk factors for failure, observational trials may be preferable to randomized clinical trials.[5] Only relatively small observational evaluations have been published: the largest one is a short communication about an audit of 300 cases.[6] We performed a prospective multicentre observational study in a variety of patients and surgical indications in order to obtain data about the i-gel's clinical performance, risk factors for failure, and adverse events in an everyday clinical setting.

Methods

This observational study was approved by the relevant Swiss Institutional Review Boards for each region (*Cantonal Ethics Committee Bern*, Bern, and *Commission Cantonale Valaisanne d'Éthique Médicale*, Sion). Because of the observational nature of the study, the Ethics Committees provided a waiver of patients' consent. We prospectively evaluated all i-gel insertions in five independent hospitals from the French- and the German-speaking part of Switzerland over a period of 24 months. The study did not influence the anaesthesia provider regarding the indication for the device or the mode of its use. The type of anaesthesia induction, maintenance, emergence, and ventilation mode were left to the discretion of the anaesthesia consultant. After anaesthesia, the anaesthesia provider filled out a two-page evaluation form that was attached to the i-gel device. The first

page of this questionnaire was regarding the information about the patient, the surgical procedure, and the performance of the supraglottic airway device, as further described below. The second page was filled out in the case of failure of the device. All patients in whom an i-gel was used as the initial airway device were included in the study.

Data obtained included patient characteristics (age, sex, height, and weight), airway assessment, surgical specialty, positioning of the patient, and data about the anaesthesia provider (experience with device). Initial i-gel size chosen was based on the manufacturer's recommendation based on body weight. The i-gel was evaluated in regard to the following points: ease of insertion graded from 1 (very easy) to 5 (very difficult), the use of minor airway manoeuvres (changing insertion depth or head/neck position) to correct improper seal, the ease of insertion of a catheter through the oesophageal port and whether gastric contents could be suctioned, the mode of ventilation (spontaneous, controlled, or pressure support), and the duration of anaesthesia. Airway leak pressure was measured as previously recommended,[7] with a maximum allowed pressure of 40 cm H_2O. Success was defined as insertion of the device and the ability to deliver adequate tidal volumes. In the case of i-gel failure, the anaesthesia provider described the cause of the failure in detail. The categories of failure were failed passage of the device into the hypopharynx (either because of the tongue/teeth or because of failed passage through the pharyngeal curvature), malpositioning with an airway leak pressure of <5 cm H_2O, and inadequate tidal volume/inadequate ventilation. The further airway management was recorded (change to smaller or larger i-gel size, other supraglottic airway device, or tracheal intubation), but this decision was left to the consultant anaesthesiologist and not predefined by a protocol. Finally, we prospectively evaluated perioperative complications and the causes of i-gel failures. Patients in whom any perioperative or postoperative airway-related complication occurred or who complained of discomfort were followed up until recovery. Completed forms were collected daily and checked for completion by designated study personnel. Two members of the study group checked the final digital database for accuracy.

For all statistical analysis, we used SPSS v.19.0.0 (SPSS Inc., Chicago, IL, USA). For comparisons between anaesthesia providers, the Student' t-test, Mann–Whitney's U-test, or Kruskal–Wallis' test for continuous data were used as appropriate; the χ^2 test and Fisher's exact test were used for frequencies. Correlations were analysed by Spearman's rank correlation. To identify parameters influencing i-gel performance, a manual logistic multivariable regression with a stepwise backward elimination analysis was applied and odds ratios were calculated. The following patient factors and covariates were used for the regression model: sex, age, height, weight, BMI, ASA status, Mallampati class, mouth opening <3.5 cm, impaired subluxation of the mandible, dentures (upper, lower, both), presence of loose teeth or rotten teeth, and presence of a beard. Results are presented as mean (SD) or number and percentage. A P-value of <0.05 was considered statistically significant.

Results

Over a period of 24 months, we prospectively collected and analysed data from 2049 i-gel uses. Another five data sheets could not be analysed because of insufficient data. Patient characteristics, type of surgery, and patients' positions during surgery are listed in Table 1.

A size 3 i-gel was used in 197 cases (10%), size 4 in 1531 cases (75%), and size 5 in 249 cases (12%). Seventy-two (4%) data sets did not indicate i-gel size.

Data regarding i-gel performance and alternative airway management in the case of failure of the primarily chosen i-gel are summarized in Table 2. A total of 1914 (93.4%) i-gel devices were successful without changing the size of the device (primary success rate); 135 devices failed initially. In 52 of these failures (2.5%), changing the size of the i-gel was sufficient to achieve a patent airway. Successful ventilation was therefore established by an i-gel device of some size in 1966 (95.9%) cases (overall success rate). The mean airway leak pressure was 26 (8) cm H_2O. The allowed maximum of 40 cm H_2O was reached in 213 cases (10%).

In 65 of 1966 cases (3.3%), the i-gel was removed before the end of surgery. In 48 cases (2.4%), this was planned and the i-gel served as a guide for fibreoptic intubation. In 17 (1%) cases, this was not planned and the i-gel was removed for either surgical or patient-related reasons such as uncontrollable hiccup.

In total, 47 cases (2.3%) of sore throat were reported. Throughout the period of observation, a total of 25 cases of laryngo-/bronchospasms were reported (1.2%). One case of vagal reflex bradycardia followed by asystole during i-gel insertion was reported. Cardiopulmonary resuscitation was initiated and atropine administered, with return of spontaneous circulation after ~1 min. Despite chest compressions, ventilation was successfully maintained with the i-gel in place throughout the episode. The patient was young and healthy and showed no signs of neurological or cardiac sequelae after emergence from anaesthesia. One case of bilateral paraesthesia at the tip of the tongue persisted after operation for 2 months and one case of transient glossopharyngeal nerve impairment was reported. Lastly, one case of glottic haematoma was encountered after an uneventful insertion of an i-gel. The patient showed marked sore throat and pain upon swallowing. ENT consultation revealed a glottic haematoma that was treated symptomatically and resolved after 2 days without long-term sequelae.

Table 3 lists data about the anaesthesia providers who inserted the i-gel. All providers were under surveillance of a consultant anaesthesiologist. Airway leak pressure was not influenced by experience with the i-gel (P=0.18). There was no correlation between experience with the i-gel and percentage of airway manoeuvres necessary (P=0.12), or difficulty of insertion (P=0.51). There was a negative correlation between experience with the i-gel and success rate

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Table 1 Patient characteristics (*n*=2049). *For termination of pregnancy in the first trimester

	Mean (SD) or number (%)
Sex	883 (43%) males
Age (yr)	47 (21) (range 6–91)
Weight (kg)	71 (16) (range 20–148)
Height (cm)	168 (10) (range 115–200)
BMI (kg m^{-2})	25 (5) (range 13–45)
ASA class I–IV/missing	874 (43%)/808 (39%)/302 (15%) /12 (1%)/53 (3%)
Mallampati class I–IV/missing	1194 (58%)/680 (33%)/103 (5%)/3 (<1%)/69 (3%)
Mouth opening <3.5 cm	238 (12%)
Thyromental subluxation impaired	
To level of upper front teeth	209 (10%)
Fixed retrognathia	65 (3%)
Full dentures: upper/lower/both	109 (5%)/17 (1%)/131 (6%)
Teeth: loose/rotten (poor)	31 (2%)/77 (4%)
Beard present (of males, *n*=883)	81 (9%)
Surgical specialty (missing *n*=12)	Obstetrics*/gynaecology: 648 (32%)
	Urology: 579 (28%)
	Orthopaedics: 398 (19%)
	Ophthalmology: 223 (11%)
	ENT and neurosurgery 77 (5%)
	External chest and Vascular surgery: 55 (3%)
	Paediatrics: 47 (2%)
Patients' position other than supine	Beach chair: 40 (2%)
	Prone: 11 (1%)
	Lateral: 13 (1%)
Anaesthesia time (min)	67 (42) (range 8–390)
Anaesthesia maintenance	
Total i.v. anaesthesia	1395 (68%)
N$_2$O used	76 (4%)
Patient in spontaneous ventilation	198 (10%)

(*P*=0.002), meaning more experienced providers were less likely to succeed.

The stepwise regression revealed the independent factors predicting i-gel failure reported in Table 4.

Discussion

This observational prospective multicentre study confirmed the high success rates and airway leak pressures obtained with use of the i-gel that have previously been described in a smaller number of patients. The 93% first-attempt and 96% overall success rate are similar to other second-generation supraglottic airway devices like the LMA ProSeal.[8]

The leak pressures obtained were comparable with our earlier findings.[2] [4] [9] The i-gel provided leak pressures in the upper range of comparable supraglottic airway devices, but not as high as the ProSeal Laryngeal Mask.[10]

The insertion of an i-gel is found difficult during its passage past the teeth and the tongue,[2] [11] or passage through the hypopharyngeal curvature. Therefore, a slightly off-midline approach[2] or depressing the tongue with the thumb[11] has been advocated. In addition, this study

showed the difference between successful insertion and successful ventilation: in over 90%, the anaesthesia provider graded insertion as 'very easy' or 'easy', and insertion was possible in 98% of all cases without changing i-gel size. Despite successful insertion, in 103 cases (5%), sufficient ventilation could not be established.

One of the intentions of our study was to find risk factors associated with primary i-gel failure, leading to either change of size or change of device. We found that males, older age, poor dentition, and impaired mandibular subluxation made primary i-gel success less likely. Some of these risk factors have been described for difficult facemask ventilation as well.[12] [13] Males and poor dentition have also been identified as risk factors for Laryngeal Mask Airway™ failure in a recent study.[14] This overlap of risk factors for difficult mask ventilation and risk factors for difficult ventilation with a supraglottic airway raises concerns because supraglottic airway devices are often used as back-up devices when the primary airway management attempt fails. Furthermore, these findings also suggest that the correct size of a supraglottic airway device does not only depend on weight, but perhaps also on height, age, and sex. Interestingly, neither

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Table 2 Clinical performance $n=2049$. *Primary success defined as success without changing size; overall success defined as success of i-gel device including changing size. [†]Minor airway manoeuvres defined as changing insertion depth or head/neck position. [‡]Ease of insertion of successfully inserted i-gels subjectively graded from 1 (very easy) to 5 (difficult). Missing data: 26 (1%). Ease of insertion does not reflect adequate ventilation and is therefore listed separately

	Mean (SD) or number (%)
Primary i-gel success rate*	1914 (93)
Overall i-gel success rate*	1966 (96)
Primary i-gel failures	135 (7)
Insertion impossible	31 (2)
Ventilation inadequate	103 (5)
Cause of failure unknown	1 (<1)
Alternative airway management of primary i-gel failures	
Change of i-gel size	52 (3)
Change of type of supraglottic device	34 (2)
Tracheal intubation	42 (2)
Face-mask ventilation	5 (<1)
Missing data	2 (<1)
Airway manoeuvres necessary[†]	265 (13)
Ease of insertion[‡]	
1	1466 (73)
2	390 (19)
3	96 (5)
4	33 (2)
5	7 (0.3)
Mean airway leak pressure (cm H_2O)	26 (8)
Gastric catheter insertion ($n=1171$)	
difficulty with insertion	14 (1)
gastric contents suctioned	685 (59)
Laryngospasm or bronchospasm	25 (1)
Blood on the i-gel at removal	
Stain/bloody	68 (3)/11 (1)

Table 3 Provider analyses. *Missing data, $n=27$ (1%). [†]Missing data, $n=64$ (3%)

	Numbers (%)
i-gel inserted by*	
Student Nurse Anaesthetist	376 (18)
Certified Nurse Anaesthetist	950 (46)
Resident	451 (22)
Consultant	245 (12)
Experience with i-gel[†]	
0–1 times used before	171 (9)
2–5 times used before	372 (18)
6–9 times used before	252 (13)
10–20 times used before	59 (3)
>20 times used before	1131 (57)
i-gel insertion rated 'very easy' or 'easy'	
Student Nurse Anaesthetist	342 (93)
Certified Nurse Anaesthetist	876 (94)
Resident	378 (90)
Consultant	185 (86)
i-gel overall successful	
Student Nurse Anaesthetist	372 (99)
Certified Nurse Anaesthetist	921 (97)
Resident	423 (94)
Consultant	231 (94)
Airway manoeuvres necessary	
Student Nurse Anaesthetist	58 (16)
Certified Nurse Anaesthetist	144 (16)
Resident	79 (19)
Consultant	51 (25)

Table 4 Risk factors for i-gel failure. *Effect size given as odds ratio for frequencies and as Cohen's d for interval data. CI, Confidence interval

	P-value	Effect size (95% CI)*
Males/male sex	<0.001	2.25 (1.57–3.22)
Impaired mandibular subluxation	0.012	1.76 (1.12–2.79)
Rotten (poor) teeth	0.019	2.62 (1.34–5.10)
Older age	0.001	0.38 (0.21–0.56)

weight nor BMI were identified as risk factors for i-gel failure. Therefore, the i-gel could be used as a guide for fibreoptic intubation in overweight patients.

As expected, the supine position was most often used, but we also report the successful use of the i-gel in the beach chair, lateral and prone positions. The use of supraglottic airway devices in positions other than supine is under discussion in the anaesthesia community, as experienced providers continue to expand the use of supraglottic airway devices.[15–17]

One feature of the i-gel is the possibility of gastric access via insertion of a gastric catheter. Corroborant to our earlier findings,[18] the gastric catheter suctioned gastric fluids in more than half of the patients despite the fact that all cases were elective, and all patients had fasted for >6 h. Pulmonary aspiration of gastric contents was not reported in any of the 2049 patients. However, the importance of gastric access for the prevention of aspiration remains unknown.[19]

In this study, a negative correlation between the experience of the provider and success rate was found. One likely explanation is that less experienced providers predominantly managed patients with 'easy' airways. Another explanation is that experienced providers were taking over at a certain point if the i-gel insertion was difficult, and the last provider dealing with the airway was recorded as the responsible provider. This would also explain why consultants performed more airway manoeuvres compared with Certified Registered Nurse Anesthetists (CRNAs) and Student Registered Nurse

Anesthetists (SRNAs) and why they were less likely to state that an insertion was easy. The high success rates in novices might also be a result of the apparent easy handling of the airway device. This would suggest either the absence of a learning curve or perhaps a very steep learning curve necessary to gain proficiency with this supraglottic airway device.

Among the adverse events that were noted, transient laryngospasms and bronchospasms were most common. In our view, this relates more to episodes of light anaesthesia than to the use of the supraglottic airway devices.[8] Only 47 (2.3%) sore throats were reported. We believe that sore throat was underreported because the severity of sore throat was not evaluated and therefore might not have been reported at all if mild. Of the 2049 cases analysed, two incidents of nerve damage were encountered: in one case, the tip of the tongue got caught between the i-gel and the lower teeth. This caused a bilateral numbness that recovered fully within 2 months. Although we did not specifically evaluate this problem, the relatively bulky construction of the i-gel quite frequently causes the tongue to protrude outwards and to be clenched between the teeth and the i-gel. We recommend to specifically check for this when securing the i-gel in order to avoid entrapment. Perhaps, the protrusion of the tongue occurs in other supraglottic airway devices as well, but there are no reports specifically addressing this issue. The second neurological impairment reported was damage to the glossopharyngeal nerve, which was confirmed by a neurologist. The patient recovered fully within 1 month. In this overweight patient, an i-gel size 5 was initially placed, but as explained above, we believe that the choice of the i-gel should not be made primarily according to weight, but rather according to height, sex, and age. In order to minimize pressure presumably caused by the i-gel, we would recommend using the smallest sized i-gel that provides enough airway seal pressure, especially in overweight patients and for prolonged procedures. However, according to a recent study,[20] mucosal pressures during i-gel use are generally low and not different than during the use of other supraglottic devices.

In conclusion, the i-gel proved to be a reliable supraglottic airway device with a high mean airway leak pressure of 26 (8) cm H_2O and a high overall insertion and ventilation success rate of 96%, in a broad variety of patients, patient positions, and modes of ventilation. Male sex, older age, poor dentition, and impaired mandibular subluxation were identified as risk factors for i-gel failure. Corrective minor airway manoeuvres were necessary in about one-fifth of all cases. Adverse events were rare; they included laryngeal spasms, transient nerve damage, haematoma, and vagal responses.

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Declaration of interest

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RESPIRATION AND THE AIRWAY

Ultrasound-guided percutaneous tracheal puncture: a computer-tomographic controlled study in cadavers

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Editor's key points

- A cadaver study to evaluate the potential use of ultrasound for tracheal puncture.
- First-attempt success rate of 90% for tracheal puncture and 90% of these were midline.
- Relatively high incidence of thyroid tissue damage.
- Clinical evaluation of this technique is required.

Background. Ultrasound-guided techniques are increasingly used in anaesthetic practice to identify tissues beneath the skin and to increase the accuracy of placement of needles close to targeted structures. To examine ultrasound's usefulness for dilatational tracheostomy, we performed ultrasound-guided tracheal punctures in human cadavers followed by computer-tomographic (CT) control.

Methods. The trachea of nine cadavers was punctured using an in-plane approach with a longitudinal ultrasound visualization of the trachea. As soon as a loss of resistance was felt, or air/fluid could be aspirated into the attached syringe, the syringe was disconnected and the ultrasound transducer set aside. Thereafter, a cricothyroidotomy guidewire was inserted through the needle into the trachea. The needle was then removed, leaving the wire in place and a control CT imaging of the neck and the chest was performed. Primary outcome was successful wire insertion into the trachea.

Results. Tracheal puncture and wire insertion was successful in eight of nine cadavers at the first attempt and in one at the second attempt (total of 10 puncture attempts, nine successful). In eight of nine successfully inserted wires, the wire was placed on the defined midline.

Conclusions. Ultrasound guidance can facilitate successful tracheal puncture. However, combining an in-plane approach with a longitudinal ultrasound visualization of the trachea neither guarantees an exact midline puncture nor allows detection of a misplaced guidewire.

Keywords: anatomy, airway; complications, asphyxia; equipment, airway; equipment, ultrasound machines; intubation, tracheostomy

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Airway management is a core competence of anaesthetists and critical care physicians. In a cannot ventilate, cannot intubate emergency, and in critically ill patients requiring tracheostomy in an intensive care unit, percutaneous or surgical airway access is recommended by current guidelines.[1] [2] This involves the successful localization of the trachea and the successful placement of a needle to guide a wire, or of the scalpel.

The classic approaches used are either a cricothyroidotomy or a percutaneous tracheostomy. The cricothyroidotomy's advantage is its relatively easy access due to the superficial position of the larynx, but it includes the danger of cricoid cartilage necrosis.[3–6] Compared with the larynx, the trachea lies deeper and a visual aid to guide the puncturing needle might be helpful. Because ultrasound equipment is widely used and

many clinicians feel comfortable with real-time ultrasound needle guidance for vascular access or for regional anaesthesia, an ultrasound approach to guide invasive airway procedures might be an important option.

To examine the potential use of ultrasound for airway access to the trachea, we attempted puncture of the trachea of human cadavers with ultrasound-guidance and inserted a wire. We assessed the tracheal wire position with computer-tomographic (CT) imaging.

Methods

This prospective open observational study was performed on nine cadavers in legal custody of the Department of

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Anatomy, Histology and Embryology of the Medical University, Innsbruck, Austria, with institutional approval. A special embalming fluid composed of ethanol, glycerol, and phenol (close to the method described by Thiel)[7] was used to keep the cadaveric tissue in a condition suitable for sonographic studies, as demonstrated previously.[8–12]

Two investigators each performed five ultrasound-guided tracheal punctures and wire insertions. A portable SonoSite® MicroMax (SonoSite Inc., Bothell, WA, USA) with the C11e, 8–5 MHz, 11 mm broadband curved array transducer (SonoSite Inc.) was used. This transducer is available in the operating theatres and emergency room in our hospital. With the small curved array transducer, we aimed to display a broad section of the trachea and the small skin contact surface avoided difficulties with needle insertion. At least, three tracheal rings could be visualized without impeding the needling during the puncture of the trachea.

The cadavers were placed supine with the head in a neutral position. The curved ultrasound transducer was then positioned on the midline over the lower anterior neck to visualize the skin and underlying tissues, including the laryngeal and tracheal cartilages (Fig. 1). Subsequently, the trachea was scanned in a transverse axis to define the midline (Fig. 2). Thereafter the axis of the transducer was tilted to achieve a longitudinal scan of the trachea. The aim was to perform the puncture between the 1st and 2nd, or 2nd and 3rd tracheal cartilage on the midline of the trachea with an in-plane needle approach (Fig. 1). The puncture was performed caudally with an 18 G thin wall needle. As soon as a loss of resistance was felt, or air or fluid could be aspirated into the attached syringe, the ultrasound probe was set aside and the syringe was disconnected. A 0.035 in guidewire from a pre-assembled cricothyroidotomy kit (Melker Emergency Cricothyroidotomy Catheter Set C-TCCS-400, Cook Critical Care Inc., Bjaeverskov, Denmark) was inserted through the needle into the trachea as a guidance for further tracheostomy. The needle was then removed over the wire, leaving the wire
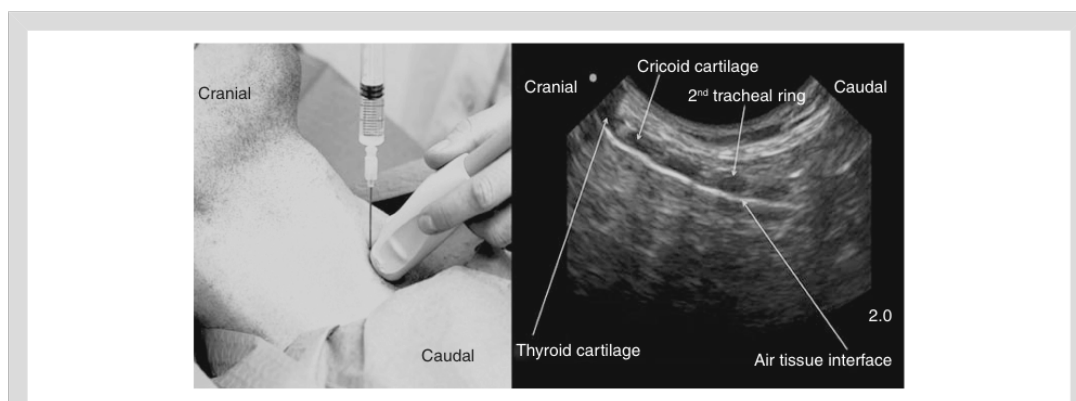

Fig 1 Photo of the position of the probe and needle (photo taken on a model instead of a cadaver, published with consent), and corresponding ultrasound scan in a longitudinal axis with the probe placed in the suprasternal notch. This figure shows how the trachea lies deeper the more distally the puncture is performed. The echogenic line is consistent with an air–tissue interface at the anterior wall of the trachea. The cartilages are echolucent; the posterior wall of the trachea is not visible.
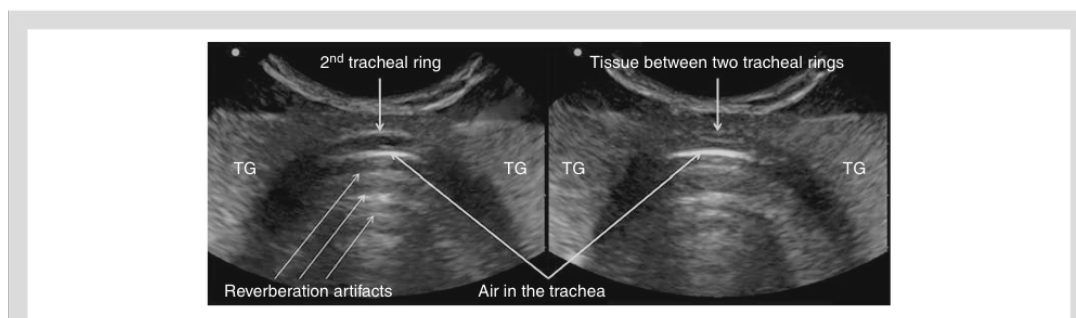

Fig 2 Ultrasound scan in a transversal axis with the probe placed in the jugular depression. TG, thyroidal gland.

Table 1 Anatomical findings and complications of the nine successful ultrasound-guided wire insertions

	Mean (sd) or *n* (%)
Shortest possible access to the trachea in the transverse plane (mm)	8.6 (2.8)
Cervical puncture level (tracheal ring 1/between tracheal ring 1–2/2–3/3–4)	1 (11)/4 (44)/2 (22)/2 (22)
Lesion of tracheal structures (yes/no)	1 (11)/8 (89)
Lesion of thyroid structures (no lesion/isthmus/lobe)	1 (11)/7 (78)/1 (11)

in place. A control CT scan of the neck and the upper part of the thorax was undertaken (Synergy; GE Medical Systems, Milwaukee, WI, USA).

Primary outcome was successful wire insertion into the trachea. Secondary outcome was correct midline wire localization using the described inline puncture technique. The exact site of tracheal puncture, evaluated by the control CT scan, was described by a clockface, with 12 o'clock being the anterior tracheal wall on the midline. Starting from this, the tracheal midline range was defined as all puncture sites between 11 and 1 o'clock.

Secondary outcome variables also included: depth of the trachea, defined as the distance from the skin to the anterior tracheal wall of the transverse plane in millimetres; the level of the puncture site defined by the cricoid cartilage, thyroid cartilage, and tracheal rings; signs of perforation of the tracheal ring, cricoid, or thyroid cartilage; and damage to thyroid tissue.

All control CT scan outcomes were evaluated by a forensic radiologist who was not otherwise involved in the study. General information about the cadavers such as age at death, height, weight, and BMI was provided by the Department of Anatomy, Histology, and Embryology, Innsbruck Medical University, Austria.

Results

A total of 10 ultrasound-guided percutaneous tracheal punctures and wire insertions in nine cadavers (seven males and two females) were performed. The cadavers' mean age (range) at death was 72 (50–91) yr, mean body weight (sd) was 69 (6) kg, mean height was 173 (6) cm, and mean BMI was 24 (6) kg m^{-2}. None had a history of traumatic head or neck injury.

Wire insertion into the trachea was successful in eight of nine cadavers (89%) at the first attempt and in one at the second attempt.

Ultrasound visualization of the tracheal rings was possible in all cases (Figs 1 and 2). The trachea was punctured at sites varying from 10 to 1 o'clock (in the transverse plane). Eight of nine (89%) successful wires were placed at the defined tracheal midline range between 11 and 1 o'clock (Table 1). Damage to the thyroid tissue was found in eight out of nine successful punctures (89%). Seven of these were located at the thyroid isthmus, which is difficult to visualize with ultrasound, but one guidewire perforated a thyroid lobe, which was in the normal anatomical position. In this

case, the trachea was not penetrated in the midline, but at 10 o'clock. One CT scan showed that the wire had perforated a tracheal ring.

A failure of tracheal puncture and wire insertion at the first attempt occurred in one cadaver with a BMI of 24 kg m^{-2}. The distance between the skin and trachea in the midline of the transverse plane was 12 mm. The wire penetrated the right lobe of the thyroid, and touched and passed, but did not penetrate the trachea. The second attempt was successful and uneventful.

Discussion

Ultrasound is a well-established technology in anaesthesia for regional nerve blocks and for vascular access. However, only one study group has reported the use of ultrasound-guided percutaneous dilatational tracheostomy.[13][14] In contrast to their 100% first-attempt success rate, we had an 89% first-attempt success rate in the cadavers studied. In one cadaver, the CT scan revealed that the wire was not placed in the trachea despite an uneventful and accurate real-time ultrasound-guided puncture of the trachea with aspiration of air as confirmation for the correct needle-tip position. Possible explanations include movement of the needle tip when the pressure of the ultrasound probe was removed before insertion of the wire or during removal of the attached syringe and insertion of the wire. Although the operators were experienced in airway management and in the use of ultrasound, the extra-tracheal puncture was not detected by ultrasound, but by the CT scan. Displacement of the needle and the wire out of the trachea has been reported recently.[15]

During the study, an effort was made to avoid a puncture of the cricothyroid ligament. The aim was to puncture the airway below the first tracheal ring as cricothyroidotomy bears the risk of necrosis of the cricoid cartilage. Current clinical practice at our university hospital is to convert a cricothyroidotomy into a tracheostomy. Tracheostomy performed at the correct site does not need further surgical intervention. An obvious disadvantage of this rather caudal puncture is the fact that the trachea lies deeper beneath the skin. Without the help of ultrasound imaging, many clinicians would therefore prefer cricothyroidotomy for emergency airway access.

Midline placement of the needle and the guidewire minimizes trauma if placed exactly between two tracheal rings. If the guidewire deviates too much from the midline, tissue

damage is much more pronounced during the subsequent dilatation. Our results show that the ultrasound-guided technique, with a good ultrasound image and experience in using ultrasound, allowed midline placement of the wire in 89%. Placement of the transducer transverse to the tracheal cartilage and use of short-axis ultrasound imaging allows continuous visualization of the tracheal midline. However, it is difficult to identify the right space between the tracheal rings and to differentiate cartilage from air. Therefore, we kept the transducer in a longitudinal plane and advanced the needle 'in plane' to the transducer. This should allow the needle to be followed as it is advanced, if it is kept inline throughout, while the laryngeal cartilage and the tracheal cartilages are visible and differentiable from the air between the cartilages.

The CT images revealed a high incidence of thyroid tissue damage. Perforation of the thyroid, especially the isthmus, is difficult to avoid during dilatational tracheostomy but rarely causes problems.[16] However, rare but fatal complications like lethal arterial bleeding from a thyroid artery[17 18] or from an avulsed subclavian artery[19] have been reported during or after tracheostomy. Even by using ultrasound visualization and guidance, we could not avoid thyroid damage, and we still recommend avoiding tracheal access below the third tracheal ring.[17] We found a tracheal ring perforation in one cadaver (11%). This, however, is lower than the 36% previously reported[13] which could be due to improved ultrasound quality since 2000.

This study is limited by the fact that it was performed on cadavers. Accidental vascular puncture could not be detected as the cadavers have a low intravascular volume, especially in the venous system. Nevertheless, it would not have been possible to perform this study in patients. A CT scan control would not have been possible to perform due to ethical considerations because of the exposure to radiation and the availability of a CT scan at the given moment of the surgical access to the trachea in a patient with a critical airway.

The frequent damage to the thyroid in our study might be a limitation of the percutaneous approach to the trachea, due to the risk of bleeding. Interestingly, the use of ultrasound did not avoid thyroid damage. The clinical importance of this needs to be followed up, although serious bleeding after percutaneous tracheostomy is rare.

We did not measure time for performance in this feasibility study and it was not an issue. We did not perform any sample size calculation because of the observational character without a control group. Performing the same procedure in more cadavers would need considerable resources and generate more costs. A larger study of ultrasound for airway access should be undertaken in patients.

In conclusion, ultrasound guidance can facilitate successful tracheal puncture and wire insertion. However, combining an in-plane approach with longitudinal ultrasound visualization of the trachea does not guarantee midline puncture, or detection of a misplaced guidewire. Ultrasound visualization does not avoid damage to thyroid tissue, especially when a more caudal approach is chosen.

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Case report

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CASE REPORT

Awake tracheal intubation using the Sensascope™ in 13 patients with an anticipated difficult airway

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Summary

We present the use of the SensaScope™, an S-shaped rigid fibreoptic scope with a flexible distal end, in a series of 13 patients at high risk of, or known to have, a difficult intubation. Patients received conscious sedation with midazolam or fentanyl combined with a remifentanil infusion and topical lidocaine to the oral mucosa and to the trachea via a trans-cricoid injection. Spontaneous ventilation was maintained until confirmation of tracheal intubation. In all cases, tracheal intubation was achieved using the SensaScope. The median (IQR [range]) insertion time (measured from the time the facemask was taken away from the face until an end-expiratory CO_2 reading was visible on the monitor) was 58 s (38–111 [28–300]s). In nine of the 13 cases, advancement of the SensaScope into the trachea was easy. Difficulties included a poor view associated with a bleeding diathesis and saliva, transient loss of spontaneous breathing, and difficulty in advancing the tracheal tube in a patient with unforeseen tracheal narrowing. A poor view in two patients was partially improved by a high continuous flow of oxygen. The SensaScope may be a valuable alternative to other rigid or flexible fibreoptic scopes for awake intubation of spontaneously breathing patients with a predicted difficult airway.

Difficult airway management is a core competence of every anaesthetist and remains a challenge. Among the many alternative devices to choose for tracheal intubation, rigid fibrescopes can convert difficult laryngoscopy into easy laryngoscopy [1], a key feature for changing a difficult intubation into a less difficult one.

The SensaScope™ (Acutronic Medical Systems AG, Hirzel, Switzerland) is a rigid S-shaped 43-cm-long fibreoptic scope with a 3-cm-long steerable flexible distal end (Fig. 1). Although it does not have a working channel, oxygen can be supplied via the adapter that holds the tracheal tube. The SensaScope's first use in 32 patients was described in 2006 by Biro et al. [1]. The design permits the introduction of the fibreoptic tool into the trachea and enables the identification of the carina. Intubation of the trachea with the SensaScope eases tracheal intubation by allowing the tracheal tube to slide over the rigid fibreoptic aid into the trachea.

We have used this intubation aid in several dozen patients and now present its use in a series of 13 consecutive patients with an expected difficult airway. We aimed to evaluate its use for safe tracheal intubation in

Figure 1 The SensaScope™ in neutral position and with its tip maximally flexed (a) and deflexed (b).

awake but sedated patients with maintained spontaneous ventilation.

Case Descriptions

Thirteen patients with a known or predicted difficult airway were informed in detail about the planned awake intubation. The local ethics committee (Kantonale Ethikkommission, Bern, Switzerland) classified this case series as a Quality Improvement Project and issued a waiver for obtaining study permission. Nevertheless, patients gave written informed consent for the procedure, for the analysis of their anonymised data, and for publication in a medical journal.

Patients scheduled for elective surgery at the University Hospital of Bern, Switzerland, and presenting with predictors for difficult intubation, were eligible for the case series. The predictors for difficult intubation were defined as reduced mouth opening (inter-incisor distance < 3.5 cm), reduced neck movement, large retropharyngeal or cervical tumour mass, prominent teeth, obesity (BMI > 30 kg.m^{-2}), Mallampati grade 3-4, or an increased tongue size.

Using standard operating procedures of our department, we applied non-invasive monitoring (blood pressure, heart rate and arterial oxygen saturation) and pre-oxygenated patients with oxygen by facemask. First, we anaesthetised the patient's oral and pharyngeal mucosa with topical lidocaine 10% spray and the tracheal mucosa with a trans-cricoid injection of 2 ml lidocaine 1%. Patients were then sedated with midazolam 1–3 mg or fentanyl 1–2 μg.kg^{-1} and in all patients a remifentanil infusion 2–5 μg.min^{-1} was started. After asking the patients to open their mouth, a warmed laryngoscope (Macintosh size 3 or 4) was gently introduced to elevate the tongue from the soft palate. The SensaScope was advanced under continuous vision of the anatomical structures and introduced into the trachea beyond the glottic opening. After the tracheal cartilages or the carina were seen, the previously attached tracheal tube (size 6.5–8 mm) was then advanced into the trachea and the SensaScope withdrawn. Patients were anaesthetised with propofol and anaesthesia maintained with either propofol or sevoflurane and remifentanil. During the intubation procedure itself, oxygen was insufflated through the tracheal tube via an adapter on the SensaScope.

In all 13 patients the trachea was intubated with the SensaScope by one anaesthetist (RG) with extensive experience in fibreoptic guided tracheal intubation during difficult airway management, and expert in the knowledge and skills for the use of the SensaScope in awake but sedated patients with maintained spontaneous ventilation.

anaesthetised patients. Table 1 provides details of each patient including anatomical characteristics, indications for tracheal intubation and an overview of difficulties encountered with the procedure. Difficult intubation was anticipated because of reduced mouth opening in seven patients, in three patients combined with reduced neck movement. Isolated reduced neck movement was encountered in two other patients. Further reasons for predicted difficult laryngoscopy or intubation were large retropharyngeal or cervical tumour masses in two patients, prominent upper front teeth in one patient, obesity in one patient, and an increased tongue size in another patient with Down's syndrome and known difficult mask ventilation. Trans-cricoid injection of lidocaine was used in all patients except one with Kassabach-Merritt syndrome and thrombocytopenia of $11 \times 10^9 l^{-1}$.

The median (IQR [range]) age was 49 years (31–69 [17–88] years) and BMI was 24.8 kg.m^{-2} (21.1–30.6 [17.6–39.1] kg.m^{-2}). The median (IQR [range]) insertion time (measured from the time the facemask was taken away from the face until an end-expiratory CO_2 reading was visible on the monitor) was 58 s (38–111 [28–300]s). In nine of the 13 patients, advancement of the SensaScope into the trachea was easy.

One patient with Kassabach-Merritt syndrome (patient 4) had an extremely reduced mouth opening (17 mm) and no neck or mandibular movement due to large neck scars after repeated major cervical surgery (excision of a huge haemangioma followed by reconstructive plastic surgery). The bleeding diatheses (thrombocyte count: $11 \times 10^9 l^{-1}$) combined with saliva made it difficult to obtain a proper view. After we changed from a size 6.5 to a size 7 mm tracheal tube the high continuous flow of oxygen allowed these fluids to be blown away. Saliva was also a problem in patient 3. One patient with spinal cord contusion and cervical disc herniation at C3/C4 and C4/C5 (patient 10) stopped breathing and quickly desaturated before intubation, despite meticulous titration with small doses of opioids. Brief ventilation by facemask was necessary before tracheal intubation could be accomplished at the second attempt. In patient 11, we encountered resistance in passing the tube due to unforeseen tracheal narrowing. We changed from a 7 mm sized tracheal tube to a 6.5 mm using a airway exchange catheter. That patient's extubation was uneventful and the patient was discharged without sequelae. The passage of the tracheal tube was uneventful in the other patients. Removal of the device was easy and no patient complained of side-effects such as sore throat and none remembered the intubation when questioned at 24-h follow-up.

Table 1 Anatomical characteristics, indications for intubation, clinical course, and difficulties encountered with intubation.

Patient	Age; years	BMI; kg.m^{-1}	Mouth opening; cm	Mallampati grade	Reason for difficult anatomy/diagnosis	Insertion time; s	Clinical course/outcome/ encountered difficulties at intubation
1	88	24.8	3.5	N/A	Limited neck extension, obesity, fracture of the mandible	28	Light coughing with injection of lidocaine, otherwise uneventful course
2	16	19.2	5.3	1	Prominent front teeth, hypertrophic nasal turbinates	104	Uneventful
3	49	17.6	4.3	2	Retropharyngeal tumour, oral carcinoma	117	Poor view because of saliva, oxygen flow through devices improved view
4	38	22.9	1.7	3	Kassabach-Meritt syndrome. Multiple haemangiomas, thrombocytopenia. Large neck scars with reduced neck movement and mouth opening	300	Poor view because of saliva and blood (bleeding diathesis), oxygen flow blew saliva and blood partially away, successful intubation at second attempt
5	58	34.0	3.5	2	Obesity, limited mouth opening, spinal stenosis (C6/7)	40	Uneventful
6	22	28.4	1.5	N/A	Limited mouth opening, fracture of zygomatic arch	38	Uneventful
7	24	20.9	2.3	N/A	Limited mouth opening, fracture of zygomatic arch	45	Uneventful
8	79	21.9	2.3	N/A	Limited mouth opening and extrication collar in place, fracture at C7	69	Uneventful
9	81	28.3	2.8	N/A	Stiff neck collar, fracture at C2	58	Uneventful
10	54	39.1	3.8	2	Extrication collar in place, spinal cord contusion, cervical disc herniations at C3/C4 & C4/C5	82	Apnoea and desaturation during intubation followed by mask ventilation and successful intubation at second attempt
11	40	31.8	5.9	1	Down's syndrome with hypertrophic tongue, lymphoma	130	Easy advancement of the SensaScope into the trachea, but difficulty in advancing the tube. Change from 7 to 6.5 mm tube over an airway exchange catheter
12	46	29.4	4.2	2	Extrication collar in place, cervical epidural haematoma	38	Uneventful
13	53	21.3	5.8	1	Retropharyngeal tumour, oral carcinoma	28	Uneventful

N/A, Mallampati assessment not performed because of limited mouth opening or difficulty in maintaining a sitting position.

Discussion

Several approaches to dealing with the anticipated difficult airway have been suggested [1–4]. All of these focus on the maintenance of spontaneous ventilation in responsive patients – the so-called 'awake intubation'. Most anaesthetists consider the flexible fibrescope and conscious sedation as standard tools in such cases [2, 3, 5]. An alternative approach to the flexible fibreoptic is a rigid fibreoptic. The Bonfils[TM] fibrescope (Karl Storz GmbH, Tuttlingen, Germany) was adopted from ENT practice and is an established airway management device in current practice. Recently, Byhahn et al. [6] found a success rate of 80% in a simulated difficult airway scenario with anaesthetised patients, and Abramson et al. [7] showed its successful performance in five conscious sedation patients with anticipated difficult airways.

There are no trials of the SensaScope in patients with real or simulated difficult airways. The 13 patients described in this report presented with a wide variety of airway pathologies. Of note, we did not experience any difficulties in introducing either the laryngoscope blade or the SensaScope despite the markedly limited mouth opening of some patients. The flexible tip of the device

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enabled the last important move to place the scope in the trachea, allowing the tracheal tube to be guided into position under direct vision.

In patient 4, a 6.5 mm tracheal tube was planned for surgical reasons, but the oxygen flow was inadequate to blow away saliva because of the tight fit around the SensaScope. We had to change to a tube size 7 mm. This was particularly cumbersome, but the patient was used to awake fibreoptic intubation procedures and remained compliant throughout the entire procedure of ∼ 5 min. Except for patient 11 (130 s), none of the procedures exceeded 2 min. In patient 11, we had to change the tracheal tube to one of a smaller size after intubation by using a tube exchange catheter because we encountered resistance in passing the tube into the trachea and there was no cuff leak even when the cuff was deflated. As with any other fibreoptic device, vision is poor if saliva or blood impedes a free view and we encountered this problem in two patients (3 and 4). As glycopyrronium is not used commonly in our department, we do not know whether this agent would have helped in these two cases.

The suggested introducing movement of the device involves a downward movement of the right hand holding the device while advancing it through the glottic opening – a similar movement as that required to operate a 'one-armed bandit'. Because of this movement, the use of a camera attached to the device (and a monitor) is mandatory, in our opinion.

As the tracheas of all 13 patients were intubated by the same experienced anaesthetist, these results must be interpreted with a degree of caution. However, Biro et al. [1] showed that the learning curve for the Sensa-Scope is quite small (< five uses) compared with the flexible fibrescope [8].

In conclusion, the SensaScope is a unique hybrid between a flexible and a rigid scope. This report shows that it may be a valuable and easy-to-use back-up device for the anticipated difficult airway situation in lightly sedated, spontaneously breathing patients. Based on these findings, further studies should compare the performance of the SensaScope with other rigid or flexible fibrescopes.

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Publication

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Videolaryngoscopy: may the force be with you!

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Since John Pacey, a surgeon, introduced the GlideScope® into clinical practice in 2001, videolaryngoscopes (VLS) have become increasingly successful. Similar to the use of ultrasound guided techniques for vascular puncture and nerve blocks, VLS have very quickly gained popularity among anesthesiologists. They are becoming more and more indispensable tools for teaching purposes, for the management of difficult airways and as documentation tools for everyday cases. Many different VLS are available and their number keeps steadily increasing. Prior to marketing, all these devices lack evidence of efficacy or safety. Hence, without academic guidance, the choice to use and to buy one particular VLS will depend on marketing strategies of the companies. The British Difficult Airway Society has addressed this problem in an article that defines "*a minimum level of evidence needed to make a pragmatic decision about the purchase or selection of an airway device*".[1] In this issue of *Minerva Anestesiologica*, Pieters *et al.* provide some of the necessary evidence about efficacy and safety of three VLS.[2] From everyday clinical practice we know that the force necessary to obtain a good view of laryngeal structures is markedly decreased with VLS. This has also been shown by Goto *et al.*[3] Pieters and the study group led by André van Zundert present more data enforcing this knowledge. They confirm their previously published finding that the force exerted on the maxillary incisors is lower with the use of VLS compared to the use of the Macintosh laryngoscope.[2, 4, 5] We cannot directly deduct that the

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incidence of dental lesions is reduced by using VLS, but it is difficult to study the incidence of dental lesions because they occur in only about 1/2000 (0.05%) of anesthesia cases.[6] The force exerted on the teeth appears to be an acceptable surrogate parameter. Importantly, those findings apply to the non-difficult airway, not the non-anticipated difficult airway: the title of the study might be misleading.

VLS can be divided into devices without a guiding channel for the tracheal tube (such as the three devices evaluated by Pieters *et al.*) and devices with a guiding channel. Additionally, VLS blades may resemble the standard Macintosh blade (*e.g.* the C-MAC® blades evaluated in the study) or may feature a more pronounced curve (*e.g.* the MacGrath® series 5 and the GlideScope®[7] evaluated by Pieters *et al.*, or the C-MAC "D-blade"). Curved blades are primarily designed for the difficult airway and direct comparisons with Macintosh blades are difficult. The more curved the blade, the more essential it is to introduce a stylet into the tracheal tube for guidance. If a stylet is not used, tracheal intubation will be more difficult, as shown by Pieters *et al.* who did not use stylets in their study.[2] Most likely, this is why the GlideScope® seemed to perform inferiorly.

Facing the emerging importance of VLS, a crucial question becomes whether we should abandon the 80-year old standard Macintosh blade in favor of VLS. While superiority has been claimed for VLS in the ICU setting [8] and evidence shows that in normal airways, laryngoscopy becomes even easier when using videolaryngoscopes, there are important advantages

of direct laryngoscopy using the Macintosh blades. The most obvious one is the fact that one drop of blood or mucus may be sufficient to completely obstruct the view obtained by videolaryngoscopes. Also, equipment failure remains a problem.[9] The Macintosh laryngoscope is a simple, reliable tool that is difficult to break. It is cheap, transportable, available in all sizes and usable in all settings, even in the pre-hospital setting in bright sunlight. Of note, VLS have so far not been incorporated into difficult airway algorithms, although this may change in the near future.[10] While VLS seem to be very valuable assets to the airway tool library, we risk losing our skills with two important techniques by more and more using VLS: intubation with the ubiquitously available Macintosh laryngoscope and fibreoptic intubation. Several studies on VLS in the simulated difficult airway situation using manual inline stabilization have been conducted, mostly demonstrating a better visibility of the vocal cords and some showing a higher intubation success rate with VLS compared to the Macintosh laryngoscope.[9, 11] Despite that, it is also known that even with a good view obtained by the VLS, there still might be problems to actually intubate the trachea ("you see that you fail").[11] Therefore, alternative techniques like the flexible fibreoptic intubation must continue to be taught and used on a regular basis. To secure the airway in the spontaneously breathing patient (awake intubation) remains the gold-standard in the management of the anticipated difficult airway, especially when difficult face-mask ventilation is suspected, and should not be abandoned. Videolaryngoscopes are additions, not replacements to our airway tool library. Their role in securing patients' airways is increasingly being supported by evidence like the study by

Pieters *et al*. More evidence will have to follow in the future, especially about the role of VLS in the setting of difficult airway management.

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Case report

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■ CASE REPORTS

Acute Airway Obstruction Caused by the New Single Use Laryngeal Mask Airway Supreme™

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THE *Laryngeal Mask Airway Supreme*™ (*LMA-S*™; Laryngeal Mask Company Limited, Henley-on-Thames, United Kingdom) is a single-use supraglottic airway device developed as an alternative to the reusable laryngeal mask airway *ProSeal*™ (Laryngeal Mask Company). Featuring an additional drain tube to suction gastric content, the *LMA-S*™ may be used as a backup device in emergency situations. Indeed, its use has been described in difficult emergency intubation[1] and in cardiopulmonary resuscitation.[2] However, even backup devices have their limitations to consider. We report an unforeseen acute airway obstruction directly caused by the *LMA-S*™.

Case Report

A 62-yr-old man with a body mass index of 30.2 kg/m² was scheduled for a resection of a malignant melanoma and sentinel lymph node of the left arm under general anesthesia at the Department of Plastic Surgery at the University Hospital Bern. After preoxigenation of more than 5 min, general anesthesia was induced IV (210 mg of propofol and 0.15 mg of fentanyl) and maintained IV with propofol and remifentanil to keep bispectral index between 40 and 60. Face mask ventilation was successful, and a *LMA-S*™ (size 5) was introduced easily. The *LMA-S*™ was cuffed, but ventilation was not possible. This was confirmed by missing end tidal CO_2, no visible thorax movement, and no end expiratory tidal volumes. Fiberoptic bronchoscopy showed that the *LMA-S*™ pushed the epiglottis down, resulting in obstruction of the glottis. Fiberoptic-controlled retraction of the *LMA-S*™ reversed this situation, and a partial view of the glottic opening was noted, corresponding to a grade of 2 according to a fiberscopic rating suggested by Cook[3] and earlier described by Kapila.[4] Nevertheless, ventilation was still insufficient.

Although Spo₂ continued to be stable between 98 and 99% for the entire time, we decided to remove the *LMA-S*™ and ventilate the patient by face mask, which was easily done. We then introduced the *LMA-S*™ a second time. After cuff inflation, only tidal volumes below 300 ml were achieved. Auscultation revealed expiratory and inspiratory stridor over the trachea, and ventilation worsened. Fiberoptic bronchoscopy showed severe narrowing of the laryngeal inlet with barely visible vocal cords, which was interpreted as a supraglottic laryngeal edema.

We removed the *LMA-S*™ again and intubated the patient (100 mg of succinylcholin) easily (Cormack Lehane grade 1). Surprisingly, no la-

ryngeal swelling was revealed by direct laryngoscopy. Ventilation was sufficient, and surgery was performed without further events. The patient was extubated uneventfully 15 minutes postoperatively and some 2 h and 20 min after induction of anesthesia, and he was discharged to the recovery room without any further respiratory sequels.

Discussion

Laryngeal masks are used broadly for elective and emergency airway management and are an essential part of the American and European difficult airway management algorithm.[5,6] Due to their wide use, noticeable complications and side effects have been reported over the last years. The most common side effects are hoarseness and dysphagia. More threatening situations like impossible ventilation with desaturation are much less common. The rare reports of airway obstruction directly triggered by the laryngeal mask are swelling of the pharyngeal soft tissues caused by the leakage of irrigation fluid,[7] herniation of the laryngeal mask airway cuff,[8–10] foreign bodies (Ascaris lumbricoides[11]), and intermittent obstruction related to a vagal nerve stimulator.[12]

Similar to our case, Chin reported a case of increased airway pressure in a *ProSeal*™ laryngeal mask airway[13] and related it to laryngeal edema. However, in a reply by Stix *et al.*, this case was associated with mechanical obstruction of the laryngeal inlet by the cuff and drain tube of the *ProSeal*™.[14]

We primarily attributed the rapidly deteriorating ventilation to soft tissue swelling and edema caused by airway manipulation and the mechanical stimulus of the *LMA-S*™ pushing down the epiglottis. This thesis was not confirmed; direct laryngoscopy after removal of the *LMA-S*™ showed normal laryngeal anatomy without edema. Laryngeal spasm was also excluded as an underlying cause because a propofol bolus did not improve ventilation.

We therefore attribute this case of airway obstruction to mechanical obstruction of the laryngeal inlet by the cuff as described by Stix.[14] The inflated *LMA-S*™ cuff displaced the cuneiform and corniculate cartilages medially, thereby narrowing the laryngeal inlet as observed during fiberoptic control, obstructing ventilation substantially.

In summary, laryngeal masks are often used as backup devices for the management of possible airway difficulties, and laryngeal masks have been life-saving in daily clinical practice over the years. Supraglottic airway de-

vices are easy to introduce, and they provide a patent airway in most cases. Nevertheless, even newly developed types of laryngeal masks (as the *LMA-S*™) may be cause for the obstruction of the laryngeal inlet when the mask displaces laryngeal cartilages medially, narrowing the laryngeal inlet. This is the first report of this phenomenon of medialization in a *LMA-S*™.

Because laryngeal masks are important backup devices in the management of difficult airways, this infrequent cause of a laryngeal mask failure must be made known. Strategies to handle laryngeal mask failures might be included in the algorithms for difficult airway management, and backup strategies for the "backup device" laryngeal mask should be considered.

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Technique of Lung Isolation for Whole Lung Lavage in a Child with Pulmonary Alveolar Proteinosis

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PULMONARY alveolar proteinosis is a rare disease in which accumulation of phospholipoproteinaceous material in the alveoli causes pulmonary impairment.[1] A deficiency in granulocyte-macrophage colony-stimulating factor activity results in defective macrophages and reduced clearance of surfactant from the lungs.[1,2] Bronchoalveolar or whole lung lavage is an important part of treatment for this disease and often results in temporary improvement of symptoms and radiographic appearance.

In adolescents and adults, double lumen bronchial tubes are often used to isolate the lungs for lavage; however, such tubes do not currently exist for use in smaller children. Several techniques have been described to isolate the lungs in smaller children to allow for lavage.[3-7] No single method has been shown to be ideal, and each has its risks and limitations. We report a case in which lung isolation and whole lung lavage was performed safely in a small child using two cuffed tracheal tubes without the need for postprocedural ventilation.

Case Report

An 11-kg, 2-yr-old male child with lysinuric protein intolerance and pulmonary alveolar proteinosis presented for left lung lavage. He had a history of recurrent respiratory tract infections and increasing oxygen requirement over a period of 3 months. His metabolic disease was diagnosed 14 months previous, and pulmonary alveolar proteinosis was confirmed by lobar aspirate analysis. Despite having started granulocyte-macrophage colony-stimulating factor therapy 3 months before the current admission, the patient's symptoms continued to deteriorate. His oxygen saturation was 85–93% on 2 l/min oxygen *via* nasal prongs. His respiratory rate was 52 to 70 per minute, and he presented with intercostal indrawing, tracheal tug, and inspiratory and expiratory crackles. A chest radiograph revealed bilateral mixed interstitial and airspace disease, air bronchograms, and subpleural peripheral opacities. He was scheduled to undergo left lung lavage and right lung lavage 2 days later, as tolerated.

The airway assembly consisted of two cuffed tracheal tubes (3.0 and 3.5 mm ID; Sheridan, Temecula, CA) and the angled and Y-connectors from a standard double lumen bronchial tube set (Bronchopart, Rusch, Germany). After anesthetic induction and muscle relaxation, the 3-5 mm ID cuffed tube was inserted in the left mainstem bronchus (bronchial tube), and the 3.0 mm ID cuffed tube was placed in the trachea

5. Research Ethics Review List

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Research Ethics Review Checklist

<u>Please include this completed form as an appendix to your thesis (see the
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UNIVERSITY OF PORTSMOUTH

Postgraduate Research Student (PGRS) Information		**Student ID:**	881170
PGRS Name:	Maren Kleine-Brueggeney		
Department:	School of Pharmacy and Biomedical Sciences, Faculty of Science	**First Supervisor:**	Professor Dr Graham Mills
Start Date: (or progression date for Prof Doc students)	02.10.2017		

Study Mode and Route:	Part-time	☒	MPhil	☐	MD	☐
	Full-time	☐	PhD	☒	Professional Doctorate	☐

Title of Thesis:	Approaches to the Management of Difficult Airways in Adults
Thesis Word Count: (excluding ancillary data)	10473

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