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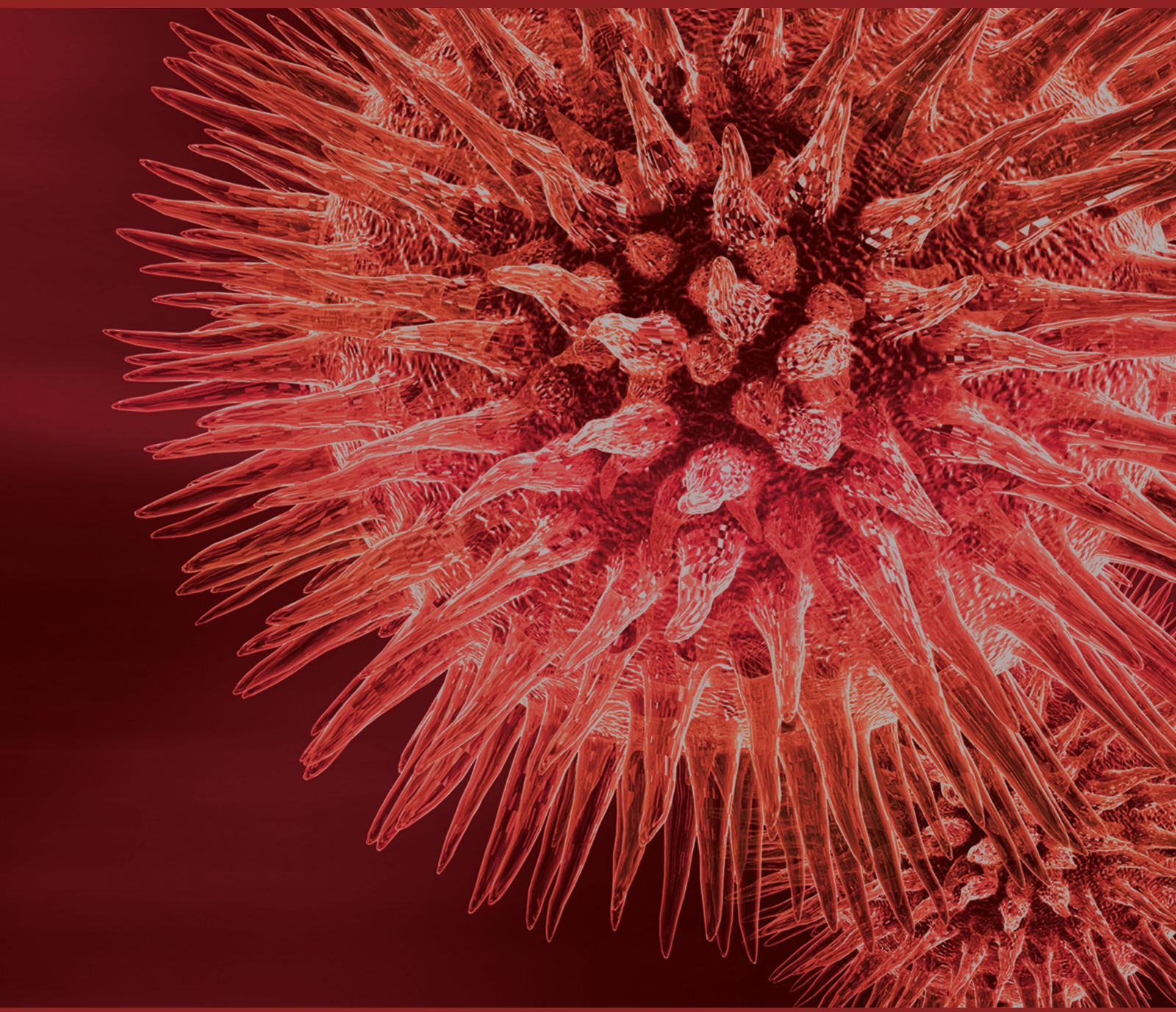
Guest Editors: Pavel Michalek, Magboul M. Magboul, Kamil Toker, William Donaldson, and Makoto Ozaki



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Contents

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Editorial

Advances and Controversies in Perioperative Airway Management

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The appropriate, case- and patient-tailored selection of an airway management technique is one of the cornerstones of safe perioperative practice. Preparation for airway management begins with assessment of the airway and with the identification of any potentially challenging anatomical variations. However, the currently available clinical tests have quite poor prognostic value in the prediction of difficult intubation [1] and use of a combination of tests is recommended in order to gain better diagnostic value [2]. At present, airway evaluation and assessment fails to completely exclude the unexpected difficult airway in daily anesthetic practice. Recently, a strong focus has been placed on imaging methods: magnetic resonance imaging (MRI), airway ultrasound, and nasal endoscopy [3].

Various new airway devices have been introduced in order to improve perioperative airway management in the last decade. These devices vary from videolaryngoscopes to innovative supraglottic airway devices, fiber-optic scopes, optical stylets, optical tracheal tubes, airway exchange catheters, and bougies. The use of most of these novel devices in difficult airway management scenarios is not supported by any robust evidence, and they remain only as devices used mostly in teaching and mannequin settings and, apart from videolaryngoscopes, they are not included in any recent guidelines [4].

Difficult or failed intubations in perioperative airway management are relatively rare and occur much more frequently in prehospital medicine, Emergency Departments, or Intensive Care Units. However, critical situations such as "cannot intubate, cannot oxygenate" are often poorly managed and may be associated with significant morbidity and mortality [5].

The invention of novel supraglottic airway devices has been driven by efforts to supersede tracheal intubation, even for traditional indications such as in obese patients, advanced laparoscopic procedures, positions other than supine, or conditions associated with an increased risk of aspiration of gastric contents [6]. These devices should exhibit high oropharyngeal seal pressures and enable smooth insertion even in the hands of novice users. Another area of development of supraglottic airway devices concentrates on their use in difficult airway management.

This special issue of the journal focuses on progress, innovations, and controversial issues in perioperative airway management. The original investigations and review articles cover different angles of this extensive anesthetic subspecialty. One clinical study investigated the changes in the intracuff pressures in two different types of tracheal tubes depending on the head and neck positioning. This paper entitled "Comparison of Pressure Changes by Head and Neck Position between High-Volume Low-Pressure and Taper-Shaped Cuffs: A Randomized Controlled Trial" found that taper cuffs were associated with a lower rise in intracuff pressures than the other

type during neck extension and flexion. This finding may be important for postoperative tracheal morbidity: increased intracuff pressures together with prolonged mechanical ventilation have been associated with an elevated incidence of tracheal ischemic lesions [7]. The clinical performance of five different supraglottic airway devices with increased aspiration protection (2nd generation) was investigated in the manuscript "Comparison of Five 2nd-Generation Supraglottic Airway Devices for Airway Management Performed by Novice Military Operators." The authors concluded that the Laryngeal Mask Airway Supreme and i-gel performed better for most insertion parameters such as insertion time, ease of insertion, and success rate than the other three devices.

Simulation studies are an important part of anesthetic research; however extrapolating their findings into clinical medicine is problematic [8]. Mannequin airway studies have been repeatedly used as a first assessment tool for new devices and airway management techniques but their oropharyngeal anatomy may differ significantly from real patients [9]. Two studies in this special issue focus on simulation in airway management. Gum-elastic bougie improved the success rate of tracheal intubation in an infant model of difficult laryngoscopy when compared with a standard procedure performed with the Miller laryngoscope, in the article entitled "Utility of a Gum-Elastic Bougie for Difficult Airway Management in Infants: A Simulation-Based Crossover Analysis." Two different types of videolaryngoscopes, McGrath and Pentax-AWS Airwayscope, and direct Macintosh laryngoscope were compared in simulated vomitus and hematemesis scenarios. This article "Comparison of Direct and Indirect Laryngoscopes in Vomitus and Hematemesis Settings: A Randomized Simulation Trial" favored Macintosh and McGrath laryngoscopes in terms of success rate and intubation time.

Bedside ultrasound has also been used within the last decade in perioperative airway management. In their review article, entitled "The Role of Airway and Endobronchial Ultrasound in Perioperative Medicine," the authors recommend the use of ultrasound for location of the cricothyroid membrane, confirmation of tracheal tube placement, or location/biopsy of pulmonary nodules but do not suggest its routine use in preoperative prediction of the difficult airway. Some rare disorders may significantly affect airway management and perioperative ventilation. The paper entitled "Respiratory Strategies and Airway Management in Patients with Pulmonary Alveolar Proteinosis: A Review" summarizes the available data on lung isolation techniques for this procedure and recommends step-by-step ventilation strategies including extracorporeal oxygenation for these patients. Pediatric airway management may be associated with controversial issues such as prediction of difficult laryngoscopy, management of the difficult airway, selection of cuffed or uncuffed tracheal tubes, timing of extubation, and indications for the use of supraglottic airway devices. The review article entitled "Controversies in Pediatric Perioperative Airways" concludes that strong evidence regarding all these controversies is missing, most data has been extrapolated from adult airway management, and more randomized controlled trials on this topic are vitally needed. Supraglottic airway devices are alternatives to tracheal intubation in elective surgical procedures without additional risk of aspiration and may be also used as an alternative airway device in difficult intubation scenarios. The paper entitled "Complications Associated with the Use of Supraglottic Airway Devices in Perioperative Medicine" highlights the incidence and significance of complications related to these devices: aspiration, nerve injuries, trauma, and postoperative sore throat.

The field of airway management is still evolving. The incidence of life-threatening events and complicated scenarios is very low and these are not completely predictable. This fact explains the lack of robust clinical trials in airway management and it is also a reason why most guidelines and recommendations are based on expert opinions, consensus, and case series rather than on high-quality evidence-based medicine. International groups of experts such as the "Difficult Airway Research Collaboration" (http://www.darc-airway.com/site/) have been established in order to create and coordinate more robust pan-European and worldwide clinical trials in airway management. Future airway research should focus on setting up large multicentre studies which are adequately powered to evaluate the incidence of even very rare complications, such as aspiration of gastric contents or significant damage to anatomical structures caused by airway interventions.

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Review Article

The Role of Airway and Endobronchial Ultrasound in Perioperative Medicine

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Recent years have witnessed an increased use of ultrasound in evaluation of the airway and the lower parts of the respiratory system. Ultrasound examination is fast and reliable and can be performed at the bedside and does not carry the risk of exposure to ionizing radiation. Apart from use in diagnostics it may also provide safe guidance for invasive and semi-invasive procedures. Ultrasound examination of the oral cavity structures, epiglottis, vocal cords, and subglottic space may help in the prediction of difficult intubation. Preoperative ultrasound may diagnose vocal cord palsy or deviation or stenosis of the trachea. Ultrasonography can also be used for confirmation of endotracheal tube, double-lumen tube, or laryngeal mask placement. This can be achieved by direct examination of the tube inside the trachea or by indirect methods evaluating lung movements. Postoperative airway ultrasound may reveal laryngeal pathology or subglottic oedema. Conventional ultrasound is a reliable real-time navigational tool for emergency cricothyrotomy or percutaneous dilational tracheostomy. Endobronchial ultrasound is a combination of bronchoscopy and ultrasonography and is used for preoperative examination of lung cancer and solitary pulmonary nodules. The method is also useful for real-time navigated biopsies of such pathological structures.

1. Introduction

Ultrasound, as a noninvasive radiological assessment, was first used in 1953 when two Swedish cardiologists performed the first successful ultrasonographic examination of the heart [1]. With the development of technology, ultrasound has been established as a rapid bedside method in preoperative assessment and perioperative practice and also in the intensive care setting.

Two modalities of respiratory system ultrasound are currently used for preoperative assessment, for postoperative examination, and for real-time guidance in some interventional airway procedures. Transcutaneous ultrasound includes translaryngeal and transtracheal ultrasound examinations which have been used for conventional scans of the oral cavity, vocal cords or trachea [2], and transcutaneous ultrasound assessment of the lungs. Endobronchial ultrasound is a novel tool combining bronchoscopic evaluation with tissue ultrasonography and has been used mainly for preoperative diagnostic purposes [3].

The following paragraphs will focus on the detailed applications of both conventional and endobronchial ultrasound in perioperative practice.

2. Methodology

The authors performed an extensive literature search using the PubMED and SCOPUS databases. The following terms were used as search parameters: "ultrasound" AND "airway", "respiratory", "vocal cords", "trachea", and "endobronchial". The selected language was English. In total, 475 articles were retrieved and, after careful selection, 83 of them were studied in detail for this review. Mainly levels I and II evidence articles and systematic reviews, if available, were included.

3. Examination with Conventional Ultrasound Techniques

Conventional external ultrasound techniques are important tools for the preoperative assessment of the airway [4] and for evaluation of endotracheal tube positioning [5]. They may also be useful for real-time guidance during interventional airway procedures, such as cricothyroidotomy or percutaneous dilatational tracheostomy [6]. In the postoperative period, ultrasound may help in the diagnosis of airway obstruction or pathological changes of the vocal cords [7].

3.1. Choice of Probe and Visualization. Choice of the appropriate ultrasound transducer and suitable mode on the ultrasound machine is basic prerequisite for successful visualization of the airway structures. A linear, high-frequency (5–14 MHz) transducer is used for visualization of the superficial anatomical structures, such as the cricoid cartilage, cricothyroid membrane, tracheal rings, or trachea itself [8].

Different transducers are used for the location of more deeply located anatomical structures, such as the base of the tongue, epiglottis, vocal cords, or arytenoid cartilages. Microconvex ultrasound probes with a working frequency of 4–10 MHz or convex (curvilinear) probes with a frequency of between 3 and 8 MHz are most frequently used in this case [9].

3.2. Airway Assessment with Ultrasound. Preoperative airway assessment has traditionally been carried out using various tests, such as Mallampati classification, Wilson grading, evaluation of neck movements, and measurement of thyromental or hyomental distance. None of these tests have been found to be sufficiently specific or sensitive, and often the combination of two or more tests is used in order to obtain more precise information [10]. Magnetic resonance imaging (MRI) of the airway may be used for obtaining sophisticated information in those patients with predicted difficulty. However, MRI is not a dynamic method; it is not available immediately and not feasible for every patient. Ultrasound may offer some advantages in preoperative airway evaluation. It is a bedside method, relatively easy, cheap, and reasonably fast and it can also provide real-time and dynamic information about the airway anatomy throughout the breathing cycle. Any organs or cavities filled with the air are not penetrated by an ultrasound beam, therefore all structures visible beyond the interface of tissue and air are considered as artifacts. Many anatomical structures of the oral cavity, oropharynx, larynx, or subglottic area may be well visualized using ultrasound. However, those structures located posterior to the tissue-air interface such as the dorsal part of pharynx, posterior commissure, or the posterior wall of the trachea cannot be evaluated with the ultrasound [4]. Ultrasonographic evaluation of the airway may be divided into several sections.

3.2.1. Examination of the Oral Cavity and Pharynx. Various structures of the oral cavity and hypopharynx may be visualized using a submental window. Curvilinear (convex) or microconvex probes are usually used. The hyoid bone lies quite superficially and can be visualized using a transversal midline position as a linear structure (inverted U-shape) or by using a parasagittal approach [4]. The epiglottis is best visualized through the thyrohyoid window either with a median transverse or with parasagittal approach using a linear probe. The median transverse approach offers better visualization of the structure [11]. Alternatively, the epiglottis is also visible with a curvilinear probe and by using a sagittal projection between the hyoid bone and the tip of the mandible. The tongue and its adjacent structures play a very important role in difficult airway management. Tongue enlargement or lingual tonsillar hyperplasia may cause significant problems with direct laryngoscopy. The tongue and surrounding structures are best viewed using submental transversal or parasagittal projections. The tongue is located deep to the mylohyoid, geniohyoid, hyoglossus, and genioglossus muscles (Figure 1) [11].

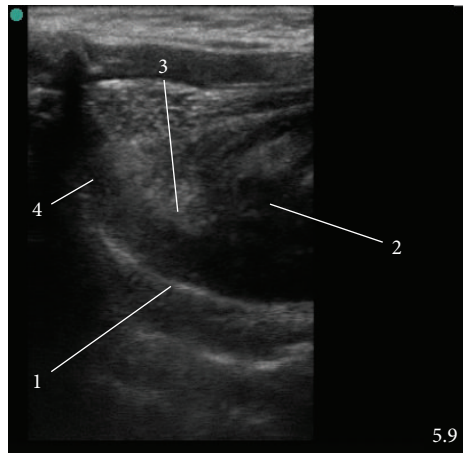


Figure 1: Ultrasound visualization of the tongue and floor of the mouth. (1) Hard palate, (2) tongue, (3) epiglottis, and (4) laryngeal inlet. The picture is "upside down" because the examination is performed via the sublingual window and therefore the hard palate is the deepest structure on the image.

3.2.2. Examination of the Vocal Cords. The vocal cords can be visualized using the linear or microconvex probe. The transducer is placed in the midline at the level of cricoid cartilage and the vocal cords are identified as inverted, "V" shaped echogenic structures (Figure 2).

The vocal cords are usually assessed in two stages—initially during shallow breathing, which allows evaluation of their shape, and, for the presence of edema, potential glottic mass, nodule, or polyp. The second stage involves evaluation of the movement during phonation [12]. Other structures adjacent to the vocal cords such as the aryepiglottic folds, anterior commissure, vocal process of arytenoid cartilages, or ventricular folds may be located using this transthyroid window. A standard B-mode is routinely used for the assessment of vocal cords while combination of the B-mode with Doppler imaging may help to evaluate function of the cords [7]. A novel mode using ultrasound, Nakagami imaging, is a functional method for visualization of the relative concentrations of collagen and elastic fibres and has

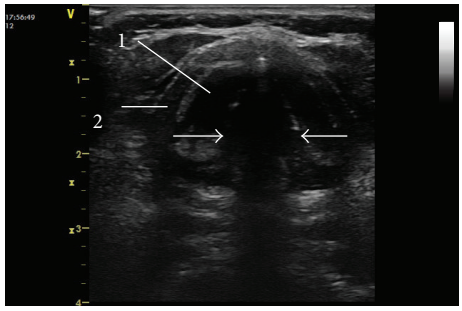


Figure 2: Ultrasound imaging of the relaxed vocal cords (white line with arrows). (1) Vocal muscle. (2) Thyroid cartilage.

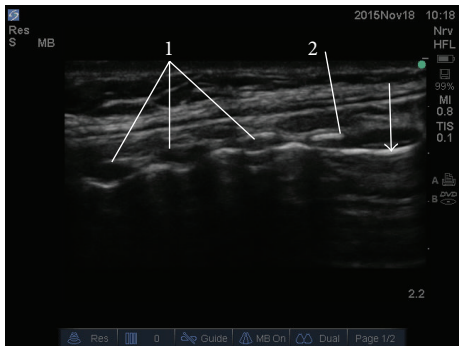


Figure 3: Cricothyroid membrane (white arrow) is best visualized using median or paramedian sagittal view. (1) Tracheal ring. (2) Cricoid cartilage.

been developed for better evaluation of the biomechanical properties of the vocal cords [13].

3.2.3. Cricothyroid Membrane and Trachea. The diameter of the subglottic space, where stenoses may often be located, can be assessed using a linear probe [14] using a midline transverse view. This measurement can serve as a guide for selection of the correct size of tracheal tube because the subglottic space is the narrowest part of trachea. The cricothyroid membrane is best located using a median or paramedian sagittal view [4]. This membrane is usually located very superficially and a high-frequency linear probe is suitable for this examination. The hyperechogenic membrane lies between two bony hypoechogenic structures—the cranially located lower border of the thyroid cartilage and caudally located cricoid cartilage (Figure 3).

The anterior parts of the tracheal rings are seen using the same views with slight movement of the probe caudally. They have the appearance of small oval structures located close to each other. Any masses located below the cricothyroid membrane or inside of the anterior part of trachea may be located using ultrasound. The transverse view at the level of the C6 vertebra provides very good information about the topographic anatomy of the trachea and surrounding structures. In addition to the trachea, performing physician can also visualize the esophagus, thyroid gland, common carotid artery, internal jugular vein, and cervical muscles (Figure 4).

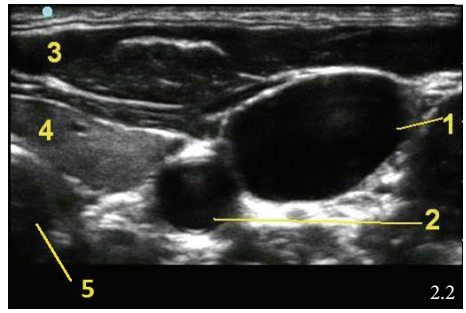


Figure 4: Transverse neck ultrasound image at the level of C6 vertebra. (1) Internal jugular vein, (2) common carotid artery, (3) subcutaneous tissue, (4) thyroid gland, and (5) trachea.

3.3. Clinical Applications of Airway Ultrasound. Ultrasound of the airway is not as frequently used as ultrasound for other perioperative indications, such as regional anesthesia, establishment of vascular access, or evaluation of cardiac performance. However, its availability and portability and the increasing experience of anesthesiologists with ultrasound in general have led to its growing utilization in this field.

3.3.1. Prediction of Difficult Laryngoscopy. A number of articles, with sometimes contradictory results, have focused on prediction of difficult laryngoscopy using ultrasound. A measurement of pretracheal tissue mass has been found to be an important factor in difficult laryngoscopy prediction in morbidly obese patients with BMI over 35 $kg \cdot m^{-2}$ [15]. Patients with difficult laryngoscopic views had a mean pretracheal thickness of 28 mm in comparison with 17.5 mm in those who presented with easy laryngoscopy. Only the pretracheal tissue mass and increased neck circumference correlated with difficult laryngoscopic views. However, another study performed in an obese population failed to confirm any correlation between the measurement of pretracheal soft tissue mass with the ultrasound and intraoperative difficult laryngoscopy [16]. Measurements of anterior neck soft tissue mass at the levels of hyoid bone, thyrohyoid ligament, and anterior commissure were found to be independent predictors of difficult laryngoscopy in 203 patients with a mean BMI within normal values [17]. Another study found a positive correlation between easy laryngoscopy (grades 1 and 2) and visibility of the hyoid bone using sublingual ultrasound [18]. Wojtczak used ultrasound for preoperative assessment of the hyomental distance and tongue volume in a pilot study and found that patients with difficult laryngoscopy had significantly shorter hyomental distance but no differences in tongue volume [19].

3.3.2. Vocal Cord Paralysis and Other Pathologies. Preoperative and postoperative assessment of mobility of the vocal cords are an important tool for airway management. Vocal cord movements may be visualized using rigid or flexible laryngoscopy or, noninvasively, by using ultrasound.

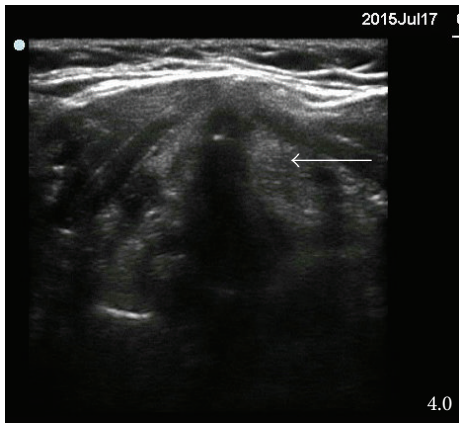


Figure 5: Unilateral vocal cord palsy (white arrow).

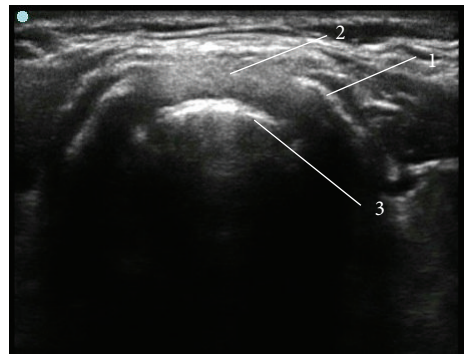


Figure 6: Ultrasound visualization of a stent inserted into the tracheal stenosis. (1) Tracheal wall, (2) intratracheal stenotic tissue, and (3) anterior part of the tracheal stent.

Miles first described the use of translaryngeal ultrasound for assessment of vocal cord movements in 1989 [20].

Translaryngeal assessment of vocal cord movements is a useful and reliable method after thyroid and parathyroid surgeries. This method may be a useful tool in diagnosing superior laryngeal nerve or recurrent laryngeal nerve injuries (Figure 5) [21].

However, success rate in visualization of true vocal cords is significantly lower than that of the false vocal cords or arytenoids [22]. Postoperative translaryngeal ultrasound has been shown to diagnose vocal cord palsy in 94% of female patients but only in 53% of males [23]. The success rate of examination is also significantly lower in patients with calcification of the thyroid cartilage [24]. Wong et al. found a high correlation between asymmetry of the vocal cords on ultrasound views and postoperative voice changes [22]. Another application of translaryngeal ultrasound in perioperative medicine is prediction of postextubation stridor [25] by measurement of the width of the laryngeal air column [26]. Cheng et al. recommend preoperative ultrasound of the vocal cords for a selection of patients with abnormal findings, such as asymmetry of the cords or their swelling before subsequent microlaryngoscopy [27]. 3D ultrasound can further help to improve efficacy in diagnosing of postoperative vocal cord paresis [28].

Rubin et al. reported that translaryngeal ultrasound showed high accuracy in patients without any pathology of the vocal cords but failed to diagnose unilateral vocal cord lesion in less than 50% of patients [29]. A significantly higher success rate in diagnosing benign lesions of the vocal cords—87%—was reported with more advanced US technologies [30]. The first paper recommending translaryngeal ultrasound for evaluation of normal anatomy of the vocal cords and various pathological findings in children and infants was published in 1991 [31]. Spadola Bisetti et al. reported a high efficacy in finding benign vocal cord lesions such as cysts, polyps, and papillomatosis in pediatric patients with translaryngeal ultrasound [32]. 2D and 3D ultrasound examinations may be used for assessment of the fetal larynx and pharynx with the aim of diagnosing upper airway pathologies [33].

3.3.3. Subglottic Space Measurement and Tracheal Tube Selection. The first animal experiments on measurement of the subglottic space with B-mode ultrasound were published in 2000 [34]. Subsequent studies have evaluated the accuracy of ultrasound measurement of this space in children [35] and adults [14]. Lakhal et al.'s study [14] also demonstrated a very good correlation between ultrasound and magnetic resonance imaging (MRI) measurements. These studies concluded that the method may reliably determine the size of endotracheal tube in adults but it underestimates the size in pediatric patients. Newer studies on children confirm the fact that ultrasound measurement of the upper subglottic diameter correlates highly with the desired outer diameter of both uncuffed and cuffed endotracheal tubes [36, 37]. US-measured minimal subglottic diameter showed very good correlation with the appropriate endotracheal tube outer diameter in children older than 12 months but a worse correlation in younger pediatric patients [38]. Bae et al. concluded that, even with the ultrasound, the success rate of a correct choice of endotracheal tube in small children does not exceed 60% [39].

Modern applications of ultrasound such as the three-dimensional (3D) reconstructions allow better assessment of airway anatomy including the anterioposterior (AP) diameter which is not possible to visualize using conventional ultrasound. All measurements seem to correlate very well with the MRI scanning [40].

Ultrasound may also be a very useful tool in evaluation of the severity and extent of tracheal stenosis (Figure 6).

This was initially documented in a case of a woman presenting at the emergency department with progressive shortness of breath [41]. A bedside ultrasound was able to locate the stenosis and estimate the narrowest diameter of the trachea. In a study on 26 patients, conventional B-mode ultrasound has shown 88.5% correlation with fibreoptic findings and a 80.7% correlation with computed tomography (CT) [42].

3.3.4. Confirmation of Endotracheal Tube Position. Ultrasound may be reliably used for direct or indirect confirmation of the correct placement of an endotracheal tube. One of the

indirect methods is based on confirmation of the incorrect position of the tube in the esophagus. The specificity of ultrasound detection of the tube inside the esophagus is extremely high [5]. Ultrasound confirmation of tracheal placement of the tube may be performed using real-time ultrasound with the probe placed over the anterior part of the neck or after intubation with the aim being to find the shadow caused by the endotracheal tube inside the trachea. In the operating room, scanning of the neck at the level of the suprasternal notch detected both tracheal intubation and esophageal tube placement with very high specificity and sensitivity [43]. Abbasi et al. found a very high specificity and sensitivity with both dynamic (real-time) and static ultrasonography in confirmation of tracheal tube position in the emergency department [44]. Transcricoid US examination was used for dynamic evaluation while a suprasternal notch view was employed for postprocedural static evaluation. Transtracheal sonography showed 98.1% correlation with confirmation of emergency endotracheal tube placement [45]. Chou et al. recommends T.R.U.E. (tracheal rapid ultrasound exam) as a reliable and fast method for confirmation of correct and incorrect tracheal intubation [46]. This method can also be used without any difficulties during cardiopulmonary resuscitation [47]. Muslu et al. reported 100% sensitivity and specificity for tracheal and esophageal intubation in the operating room [48]. Another indirect method is based on looking for the signs of ventilation at the level of the pleurae [49] or diaphragm muscle [50]. Lung sliding/lung pulse is caused by movement of the lung in relation to the chest wall. Presence of this sign on the ultrasound is an indirect sign of correct tracheal tube placement [49]. Park et al. recommend a combination of transtracheal ultrasound for confirmation of the tube location in the trachea and transthoracic sonography for evaluation of lung sliding [51]. Transthoracic ultrasound has been successfully used in confirmation of correct double-lumen tube in thoracic surgical procedures [52]. In pediatric practice, translaryngeal ultrasonography can help to confirm correct laryngeal mask airway placement or its malposition [53].

3.3.5. Location of Cricothyroid Membrane and Cricothyrotomy. Emergency cricothyrotomy is a life-saving procedure in acute upper airway obstructions or in "cannot intubate, cannot ventilate" situations [54]. However, correct location of cricothyroid membrane can prove difficult in some patients. In one paper, use of three different landmark or palpation methods showed only 46–62% success rate [55]. Preemptive ultrasound location of the cricothyroid membrane in the patients with expected difficulty to manage airway is easy and reliable technique [56, 57]. You-Ten et al. compared the palpation method with ultrasound location of the membrane in obese peripartum females and showed only 39% accuracy for palpation versus 100% accuracy with the use of ultrasonography [56]. Campbell et al. reported a more difficult location using palpation of the cricothyroid membrane in females whereas the ultrasound technique showed similarly high efficacy in both genders [57]. Another study also reported the lowest success rate of the cricothyroid ligament palpation in obese women [58].

A possibility of real-time ultrasound guidance for the puncture of cricothyroid membrane and bougie-assisted cricothyroidotomy (BACT) was first studied on cadaver models [59]. The participants were able to locate the membrane within 5 sec and the mean time for completion of the procedure was 26 sec. Suzuki et al. used real-time ultrasound for percutaneous insertion of a cannula through the cricothyroid membrane in the acute setting [60].

Ultrasound may be used for the location of cricothyroid membrane in emergency departments. The method shows high accuracy and its learning curve is very shallow [61].

3.3.6. Percutaneous Dilatational Tracheotomy. Percutaneous dilatational tracheotomy (PDTS) is one of most commonly performed procedures in intensive care units. Ultrasound imaging may be used before the procedure for identification of the trachea and its adjacent anatomical structures [62]. It has been used for preprocedural assessment since 1999 to locate the trachea, isthmus of the thyroid gland, and any vascular structures in the anterior neck area [63]. Ultrasound may also help to find the most appropriate level for tracheotomy with determination of a safe trajectory for incision and preparation [64]. A change of the puncture site determined with a landmark technique was recommended in 24% of patients when ultrasound was used prior to puncture in the ICU [65]. Protocols have already been established in some institutions for the strict application of US scanning before PDTS [66].

The feasibility of ultrasound-guided puncture of the trachea in real-time was first studied using fresh cadavers [67]. The neck was scanned with a linear probe giving a longitudinal visualization of the trachea. Dinh et al. compared US-guided approach with a landmark technique and concluded that the use of ultrasound increased the percentage of midline punctures, decreased the total number of attempts, and aided in placing the tracheotomy tube safely into the trachea [68]. These findings were confirmed by another study that also showed a lower number of complications in the US-guided group [69]. US-guided PDTS have been also compared with bronchoscopy-guided PDTS in a retrospective cohort trial with similar results apart from shorter procedure time in the ultrasound group [70]. The influence of the ultrasound use on the complication rate in the PDTS was studied by Rajajee and colleagues [71]. The authors showed a significantly lower incidence of potential complications, such as bleeding, early tube dislocation, or granuloma in the US-guided group. Despite these positive results, a recent review concluded that US-guided PDTS is a promising method but its superiority over other techniques should be confirmed in robust randomized trials [6].

4. Endobronchial Ultrasound

The last decade has seen rapid development of novel ultrasonography technologies. These methods have found roles in the preoperative assessment of cancerous and noncancerous lesions in various locations of the body. Pulmonary pathologies such as tumors and affected lymph nodes were mainly

diagnosed in the past using CT and positron emission tomography/computed tomography (PET/CT). However, CT had not been successful in evaluation of nodal staging and airway wall infiltration [72]. PET/CT combines anatomical information from CT and metabolic information obtained from PET scanning and therefore it is potentially an accurate and noninvasive method in the staging of cancer. This method also may improve the mediastinal lymph node staging. However, both specificity and sensitivity are far from being high enough to abandon biopsy confirmation of disease.

The following factors are challenging in the preoperative assessment of any respiratory tract lesion. First of them is a precise, fast, safe, and affordable tumor and nodal staging. The second factor is proving or excluding tumor infiltration of the airway wall and the third one is the diagnosis of solitary pulmonary nodules (SPNs). This is an isolated lung abnormity on the chest X-ray, smaller than 3 cm, surrounded by normal lung tissue, and not associated with any other pulmonary pathology.

These are reasons why new imaging tools for preoperative thoracic cancer staging were sought in the early 1990s. Existing bronchoscopic techniques for nodal staging—TBNA (transbronchial needle aspiration) and TBB (transbronchial biopsy)—did not have sufficient efficacy in obtaining diagnostic tissue. Transbronchial fine needle aspiration for nodal staging was found to have a sensitivity of 57% for lymph nodes greater than 10 mm with a specificity of 99% [73]. In a meta-analysis performed by Holty et al., the pooled sensitivity for TBNA mediastinal staging was even lower, at 39% (95% CI, 17–61%), with a pooled specificity of 99% [74]. Electromagnetic navigation bronchoscopy (ENB) allows for guidance of the bronchoscope to the solitary pulmonary lesion through a reconstructed CT image. Overall sensitivity of this technique was shown to be 71% [75]. The ENB system is still very expensive and so its use is naturally restricted.

In early 1980s, the first mechanical radial instruments for endoscopic ultrasound were introduced in gastroenterology [76]. The first dedicated endobronchial ultrasound system was made commercially available in 1999. It consisted of a balloon catheter with a rotating ultrasonic head. As with any other ultrasound device it consists of a system of piezoelectric crystals—transducer and a processor. The current widespread use of endobronchial ultrasound (EBUS) is due to an easier-to-interpret and more user-friendly device which was developed in Japan in 2005. This linear EBUS has the ability to facilitate real-time transbronchial needle aspiration under direct ultrasound guidance through the working channel of the endoscope [77]. However, during the last 5 years we have witnessed continuous return of slightly remastered radial EBUS miniprobes to clinical practice.

All interventional bronchoscopies and an increasing number of diagnostic bronchoscopies are currently performed under general anesthesia for the comfort of the patient and the convenience of the operator. Supraglottic airway devices such as laryngeal masks [78] or i-gel [79] may be used instead of rigid bronchoscope insertion.

4.1. Radial EBUS—in the Search of SPNs. With the above-mentioned increase in frequency of radiologically diagnosed SPNs, physicians are creating an increased demand for tissue diagnosis of indeterminate nodules. It is important to be both accurate and efficient in the preoperative diagnostic evaluation of SPN because rapid resection of malignant tumor can be life-saving. In patients with resected malignant nodules, the 5-year survival rate may be as high as 80%. With the widespread use of fluoroscopic guidance for TBB, endoscopists need a device for real-time point monitoring, a device which would give clear positive or negative information. Main issues with the technique are if the catheter is correctly located in the node and if the biopsy should be taken from this area.

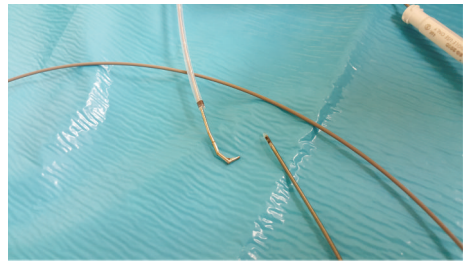


Figure 7: A radial EBUS miniprobe.

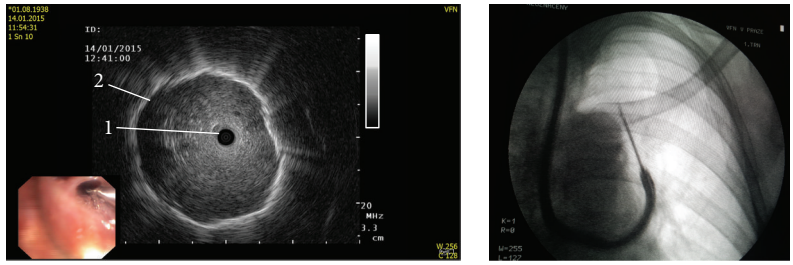
EBUS miniprobes are currently offered with outer diameters of 1.4 mm and 1.7 mm and are therefore available for the use in the periphery of the lung (Figure 7).

These are introduced through the working channel of a bronchoscope and offer a 360 degrees' view. A 20 MHz working frequency is commonly used in lung tissue. The probe can be reused up to 80 times if used with care. The navigation is a rather tricky procedure consisting of introducing the steerable guiding device through the Teflon catheter which is then inserted through the working channel of the endoscope. After ideal positioning of the catheter in SPN according to fluoroscopy, the guiding device is replaced by a radial EBUS probe and its positioning inside the nodule is confirmed. Subsequent biopsy is carried out with forceps or using a cryotechnique. This is a complicated and inaccurate method and as such it can be quite time consuming.

According to the literature data, radial EBUS dramatically improves the success rate of fluoroscopically navigated transbronchial procedures for diagnosing SPNs [80]. In a randomized trial which compared routine bronchoscopic transbronchial biopsy under fluoroscopy with radial probe EBUS facilitated TBB, the yields were 52% and 76%, respectively [81]. From a therapeutic perspective, navigational bronchoscopy has been utilized to place fiducial markers in order to carry on stereotactic body radiation therapy (SBRT) [82].

Nowadays, EBUS is perceived as irreplaceable tool by most bronchoscopists. The principal reason for this is the ability of EBUS to help physicians in many difficult situations.

4.2. Accessing the Extent of Airway Invasion. EBUS has enabled the bronchoscopist to extend his vision beyond the tracheobronchial wall. As stated before, CT is usually unable to predict the extent of pathologic tumor invasion into the airway wall. For many therapeutic purposes it is crucial to know



(a) (b)

Figure 8: Endobronchial ultrasound-navigated lung biopsy. (a) Bronchoscopic and ultrasound image, (1) bronchus, and (2) external border of the tumor. (b) X-ray control of the procedure.

if the tumor is extending beyond the cartilaginous layer or if it remains within the submucosal layers. This finding is crucial for differentiation between early and invasive lung cancer. The extent of tumor invasion can provide important information about the resectability of a lesion. EBUS has a specificity of 100%, a sensitivity of 89%, and an accuracy of 94% in differentiating external compression of the airway from tumor infiltration, in comparison to CT, which has a specificity of 28%, a sensitivity of 75%, and an accuracy of 51% [77].

4.3. Diagnosis of Mediastinal and Hilar Lesions. Linear probe EBUS (Figure 8) is an efficient device allowing real-time ultrasonography guidance during needle insertion into a suspected nodal area.

Preoperative EBUS-TBNA biopsies can be obtained from all following lymph node locations—2L, 2R, 3, 4R, 4L, 7, 10R, 11R, and 11L. 2013 ACCP guidelines for the diagnosis and management of lung cancer [83] clearly state that EBUS-TBNA should be used in primary staging of lung cancer whenever possible. However, a low negative predictive value still necessitates surgical staging before deciding on thoracotomy.

5. Conclusion

More prospective randomized studies are needed to confirm the position of conventional ultrasound in prediction of difficult airway management. Future research should be focused on patients with potentially difficult airway, such as pregnant or obese patients or those with anatomical changes in the maxillofacial and neck regions. Modern applications such as 3D ultrasound may be useful in the complex evaluation of upper and lower airway anatomy with accurate prediction of difficult intubation and correct calculation of tracheal tube size and validation of tube position. Acute airway interventions under real-time ultrasound guidance may become standard procedures in emergency and intensive care settings due to their relative ease of use. Endobronchial ultrasound is becoming widely used by pulmonary physicians. Its place in the diagnostic armamentarium is already firmly stated, and its applications are evolving. Its accuracy and good safety profile facilitate its further spread. Radial probe EBUS is used to navigate to SPNs and to evaluate airway invasion and linear EBUS is a powerful tool for primary staging and restaging of lung cancer and for sampling of all indeterminate mediastinal lesions.

Some of the ultrasound techniques described above are already well established in perioperative practice. The simple reliable evaluations with short learning curve involve ultrasound location of the cricothyroid membrane prior to expected difficult airway management, confirmation of endotracheal tube placement, and perhaps postoperative examination of vocal cords. Other techniques have shown varying reliability and are still more or less at experimental stage. Main limitation of ultrasound examination lies in the fact that it is significantly user-dependent technique and its overall reproducibility is lower than in that of other radiological methods.

Abbreviations

ACCP: American College of Chest Physicians
BACT: Bougie-assisted cricothyrotomy
BMI: Body mass index
CT: Computed tomography
EBUS: Endobronchial ultrasound
ENB: Electromagnetic navigation bronchoscopy
ICU: Intensive care unit
MRI: Magnetic resonance imaging
PDTS: Percutaneous dilatational tracheostomy
PET/CT: Positron emission tomography/computed tomography
SBRT: Stereotactic body radiation therapy
SPN: Solitary pulmonary nodule
TBB: Transbronchial biopsy
TBNA: Transbronchial needle aspiration
TRUE: Tracheal rapid ultrasound exam
US: Ultrasound.

Disclosure

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Conflict of Interests

Jiri Votruba, Petra Zemanová, Lukas Lambert, and Michaela Michalkova Vesela declare no conflict of interests regarding the publication of this paper.

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Review Article

Complications Associated with the Use of Supraglottic Airway Devices in Perioperative Medicine

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Supraglottic airway devices are routinely used for airway maintenance in elective surgical procedures where aspiration is not a significant risk and also as rescue devices in difficult airway management. Some devices now have features mitigating risk of aspiration, such as drain tubes or compartments to manage regurgitated content. Despite this, the use of these device may be associated with various complications including aspiration. This review highlights the types and incidence of these complications. They include regurgitation and aspiration of gastric contents, compression of vascular structures, trauma, and nerve injury. The incidence of such complications is quite low, but as some carry with them a significant degree of morbidity the need to follow manufacturers' advice is underlined. The incidence of gastric content aspiration associated with the devices is estimated to be as low as 0.02% with perioperative regurgitation being significantly higher but underreported. Other serious, but extremely rare, complications include pharyngeal rupture, pneumomediastinum, mediastinitis, or arytenoid dislocation. Mild short-lasting adverse effects of the devices have significantly higher incidence than serious complications and involve postoperative sore throat, dysphagia, pain on swallowing, or hoarseness. Devices may have deleterious effect on cervical mucosa or vasculature depending on their cuff volume and pressure.

1. Introduction

Supraglottic airway devices (SGAs) are tools used for airway management in anesthesia and also in certain situations outside the operating room [1]. They are less invasive than endotracheal tubes, which is attributed to their positioning outside of the larynx. Several classifications of these devices have been proposed: based on the absence or presence of a drainage channel, site and mechanism of sealing, or other features [2, 3]. The most commonly used classification divides the SGAs into 1st-generation devices containing only a breathing lumen (Figure 1) and 2nd-generation SGAs (Figure 2), which possess an additional channel for drainage of gastric contents.

Another logical classification relates the sealing site of SGAs and may be divided into base-of-tongue (BT) or pharyngeal sealers and perilaryngeal (PL) sealers [3]. Base-of-tongue sealers were invented more than 65 years ago, when Leech introduced his "pharyngeal bulb gasway" in 1937 [4]. The second line of SGAs, perilaryngeal sealers, was derived from the classical laryngeal mask airway (LMA Classic, cLMA), invented by Brain and patented in the UK in 1982 (GB2111394A) [5]. Various devices, described in Table 1, have been invented and introduced into clinical practice since 1992. Modern SGAs are disposable, withstand high seal pressures, are easy to insert with a high success rate more than 95%, and possess a mechanism for separation of respiratory and gastrointestinal tracts [4].

Initially, SGAs were used mainly for maintenance of a patent airway during elective procedures under general anesthesia but, during years following the release of

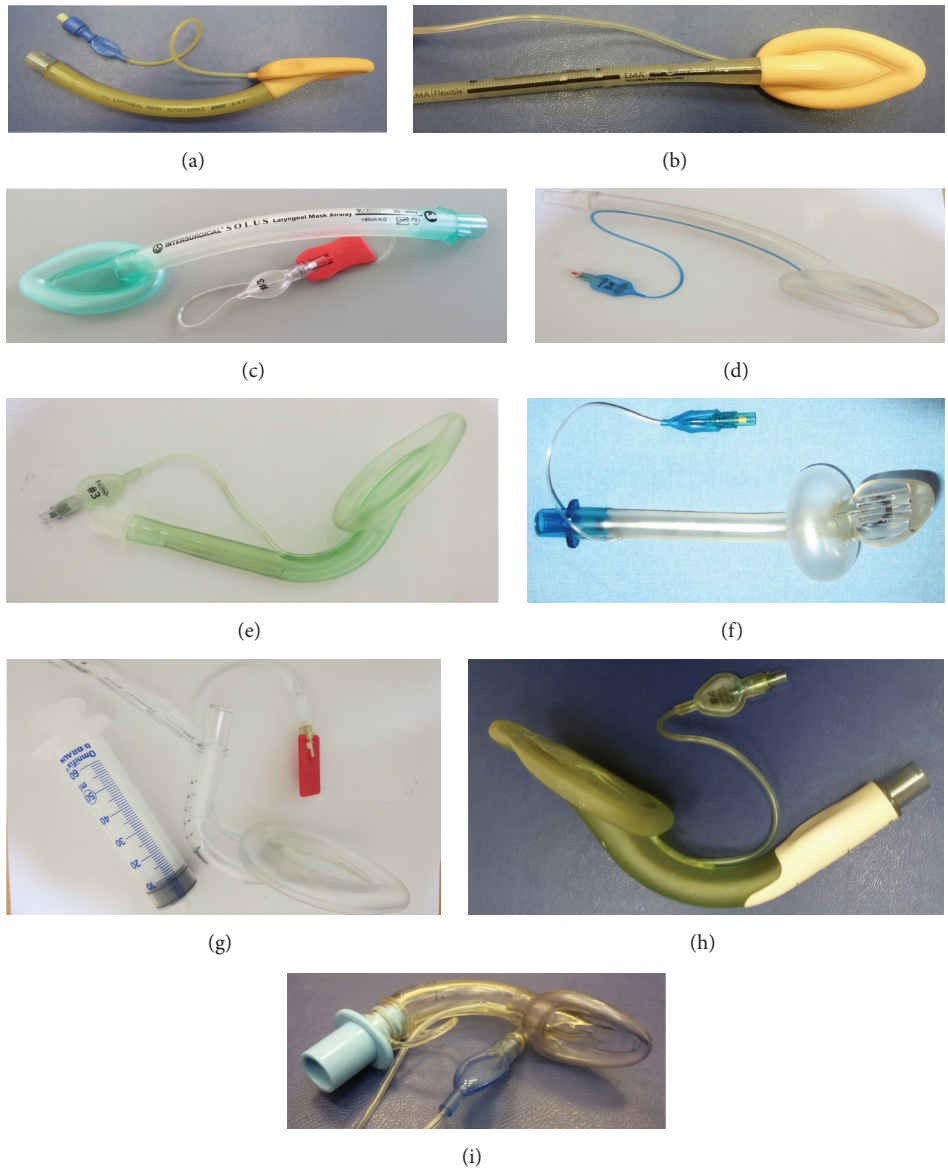

Figure 1: Main commercially available SGA devices without separated gastric channel (1st generation). (a) LMA Classic, (b) LMA Flexible, (c) LM Solus, (d) LM Portex Soft Seal, (e) LM AuraOnce, (f) Cobra PLA, (g) LMA Fastrach, (h) LM Aura-i, and (i) air-Q intubating laryngeal airway. Last three devices are designated as conduits for tracheal intubation.

the prototypical cLMA, these devices have also found other areas of utilization, for example, as conduits for tracheal intubation in difficult laryngoscopy scenarios [6] or as airway adjuncts in cardiac arrest or in prehospital medicine [7]. Several review articles have focused on individual devices and particular clinical indications for their use but none has been targeted specifically at complications associated with their insertion.

2. Complications

The use of supraglottic airway devices (SGAs) in perioperative medicine is now widespread. The 4th National Audit Project (NAP4), which was conducted in the United Kingdom, estimated that 56% of general anaesthetics performed were carried out using SGAs to manage the airway [8]. This project, led by the Royal College of Anaesthetists, looked into complications of airway management in general in the United Kingdom. In all, 33 of the events that were reported to NAP4 involved SGAs [9]. These events included aspiration, airway trauma, loss of the airway on insertion, failed insertion, displacement after insertion, loss of airway during maintenance, and extubation-related problems. In most cases, multiple factors such as obesity, comorbidities, traumatic insertion, inappropriate use of the devices, low operator experience, nonstandard patient positioning, or shallow anesthesia contributed significantly to these complications.

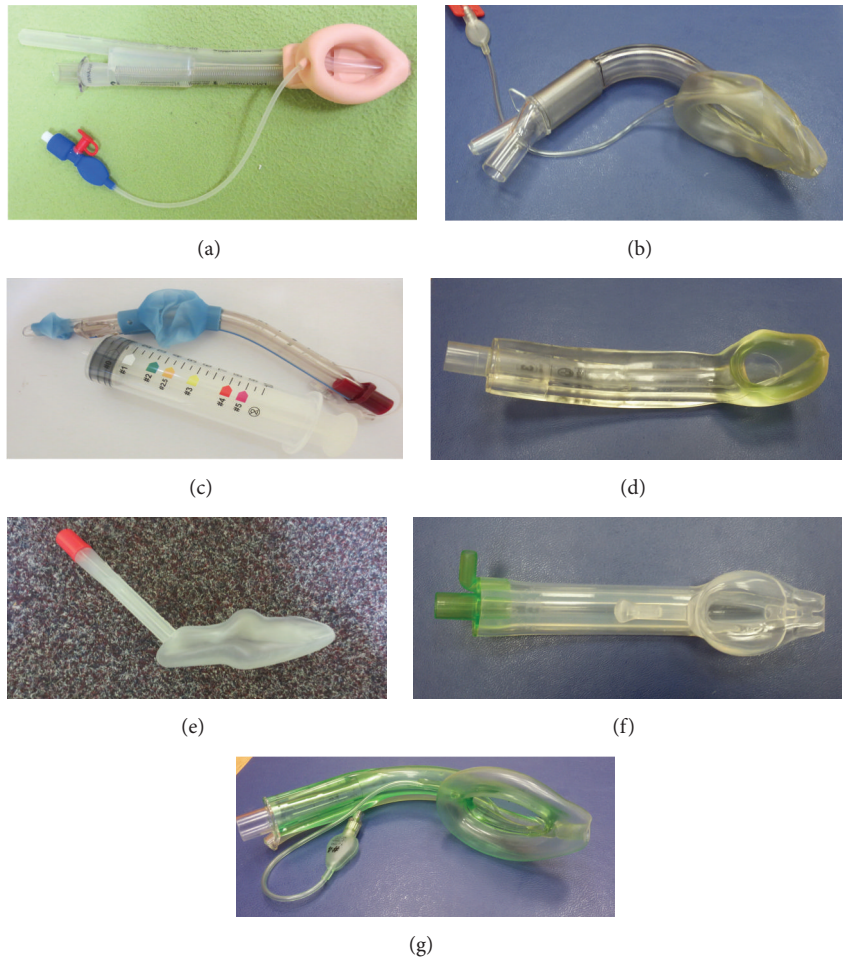

Figure 2: Main SGA devices with a mechanism for drainage of gastric contents (2nd generation). (a) ProSeal LMA, (b) Supreme LMA, (c) Laryngeal Tube Suction-D, (d) i-gel, (e) SLIPA, (f) Baska mask, and (g) AuraGain LM.

Cheon et al. found that the overall incidence of complications depends on a patient's body mass index (BMI) and also on their age—obese patients with a BMI over 30 $kg \cdot m^{-2}$ and those older than 46 years have a significantly higher chance of developing difficulties with ventilation and intraoperative laryngospasm [10].

Most reports dealing with the complications associated with the SGAs come from their use in elective procedures. However, the SGAs are also integral part of difficult airway management and recommended back-up plan in failed intubation according to the guidelines of various societies (Difficult Airway Society, American Society of Anesthesiologist, French National Society of Anesthesiology). These scenarios involve emergency procedures in nonfasted patients and in those with significantly increased risk for aspiration of gastric contents and therefore the incidence of complications should be theoretically multiplied to the elective use of these devices. Nevertheless, any of large cohorts describing the use of ILMA [11] or other SGAs [12] in difficult airway patients did not look specifically at the complication rate.

Complications discussed in this paper include those with serious sequelae such as aspiration of gastric contents, trauma, nerve injuries, and compression of vascular structures and also minor adverse effects such as hoarseness, sore throat, or swallowing difficulties.

2.1. Aspiration of Gastric Contents. Regurgitation of gastric contents is a process that can occur under anesthesia and which may lead to pulmonary aspiration. Pulmonary aspiration of gastric content can be defined as the inhalation of material into the airway below the level of the vocal cords. Depending on the nature, volume, and pH of the material inhaled patients can suffer morbidity and even mortality. The prevention of aspiration is one of the hallmarks of safe practice in anesthesia.

The incidence of regurgitation under anaesthesia is unknown but the incidence of pulmonary aspiration has been described as between 0.01 and 0.06% in general [14]. Aspiration during anesthesia accounts for between 2.6% and 3.5% of cases in surveillance studies and closed claims analyses [15, 16] with no such claims relating to aspiration during LMA anesthesia [17]. NAP4 featured aspiration as the primary event in 17% of cases and was the commonest etiology for death and brain damage [9].

Table 1: Main commercially available SGAs divided into the devices without and with aspiration protection mechanism and according to the sealing mechanism [4], (I)—may be used as a conduit for an insertion of tracheal tube. LTS-D: Laryngeal Tube Suction device, PLA: perilaryngeal airway, LMA: laryngeal mask airway, LM: laryngeal mask, ILA: intubating laryngeal airway, and SLIPA: Streamlined Liner of Pharyngeal Airway. SALT: Supraglottic Airway Laryngopharyngeal Tube.

Aspiration protection	Base-of-tongue (BT) sealers	Perilaryngeal (PL) sealers
None (1st generation)	VBM Laryngeal Tube (VBM, Germany) King Laryngeal Tube (King System, USA) Cobra PLA (Pulmodyne, USA) Cobra Plus (Pulmodyne, USA)	LMA Classic (LMA Co., Seychelles) LMA Unique (LMA Co., Seychelles) LMA Flexible (LMA Co., Seychelles) LMA Classic Excel (I) (LMA Co., Seychelles) AuraOnce LM (Ambu, Denmark) Aura-i LM (I) (Ambu, Denmark) Portex Soft Seal (Smith Med., UK) Solus LM (Intersurgical, UK) Sheridan LM (Teleflex, USA) La Premiere Plus LM, LaEncore Plus LM (Armstrong Medical, UK) Vital Seal LM (GE Healthcare, USA) Ultra CPV (AES, USA) Intubating LMA, Fastrach (I) (LMA Co., Seychelles) CTrach LMA (I) (LMA Co., Singapore) Air-Q ILA (I) (Mercury Medical, USA)
Gastric channel or storage container (2nd generation)	Combitube (Covidien, USA) Rusch Easy Tube (Teleflex, USA) VBM LTS II (VBM, Germany) King LTS-D (King System, USA) SLIPA (CurveAir, UK) SALT (I) (Ecolab, USA)	LMA ProSeal (LMA Co., Seychelles) LMA Supreme (LMA Co., Seychelles) i-gel (I) (Intersurgical, UK) Aura Gain LM (I) (Ambu, Denmark) Guardian LMA (Ultimate Medical, Australia)
Gastric channel + self-energizing mechanism of seal		Baska mask (I) (Logikal Health Products, Australia) 3gLM (I) (CurveAir, UK)

2.1.1. Aspiration and the 1st-Generation Perilaryngeal Sealers. The LMA Classic (cLMA) is the most studied SGA with over 2500 publications. A publication resulting from evaluation of one of the prototypes noted that there were no signs of regurgitation in 100 patients [18].

The first published case of significant aspiration leading to pneumonia was reported in 1990 [19]. This prompted a series of similar cases [20]. In reply to Nanji and Maltby's case report and an accompanying editorial, Dr. Brain—the inventor of the cLMA—pointed out that the patient described in the case report was unsuitable for use of the cLMA and also highlighted tips for reducing the risk of regurgitation, recognizing the problem and a treatment algorithm [21].

A large meta-analysis of publications describing aspiration and the cLMA by Brimacombe reported that the incidence of pulmonary aspiration with the cLMA was 2.3 per 10000 cases, which was comparable to the rates with endotracheal intubation or facemask anesthesia [22]. Two large studies also report low rates of aspiration with the device: 1 case in 11910 patients [23] and 3 cases in 35620 patients in a study which showed a similar incidence when compared with endotracheal intubation [24].

The mortality associated with aspiration and anesthesia is estimated to be 5% [25, 26]. Despite this, before completion of NAP4, only two deaths had been reported following aspiration with a cLMA [9, 27, 28].

Overall, the risk of aspiration for the cLMA is low and comparable to that seen with anesthesia using other devices to maintain the airway. No relevant data is available for the other laryngeal masks of the 1st generation such as the LMA Flexible, Intubating LMA Fastrach, AuraOnce, Aura-i, and La Premiere.

2.1.2. Aspiration and the 1st-Generation Base-of-Tongue (Pharyngeal) Sealers. These devices include the Laryngeal Tube (King LT) and Cobra Perilaryngeal Airway. Other devices from this group, Combitube and Easy Tube, are used mainly in prehospital medicine. Miller and Light suggested that the storage capacity of the Laryngeal Tube for regurgitated gastric contents inside the pharynx is higher than in cLMA, which may decrease the risk for aspiration with this device [29]. The safety of another SGA from this group (Cobra PLA) was questioned in a report by Cook and Lowe—they had to halt their study after two cases of aspiration (with an incidence of 6.9%) [30]. They highlighted that the device does not possess any mechanism for aspiration protection or obstruction of the esophagus. One of these two aspirations of gastric contents was reported during rotation of a malpositioned device during laparoscopic surgery.

2.1.3. Aspiration and the 2nd-Generation Devices. These devices fall into two subcategories: devices with a dedicated second gastric channel (LMA ProSeal (PLMA), LMA Supreme (SLMA), Laryngeal Tube Suction II (LTS II), i-gel, Baska Mask, AuraGain, and 3gLM) and devices designed to trap and store regurgitated material (SLIPA).

Table 2: Sites, types, and mechanisms of traumatic injuries caused by SGAs (modified from Michalek and Donaldson [13]).

Site of injury	Type(s) of injury	Mechanism(s) of injury
Pharyngeal mucosa	Laceration Bruising	Forceful insertion, inadequate lubrication Prolonged insertion, too high cuff pressures
Laryngeal apparatus	Arytenoid dislocation Recurrent laryngeal nerve injury	Direct trauma Compression of the nerve in piriform fossa
Uvula	Trauma leading to ischemia and necrosis	Direct trauma Prolonged compression
Epiglottis	Bruising Laceration	Incorrect or forceful insertion, anatomical abnormalities
Tongue	Frenular injury Lingual nerve injury	Incorrect or forceful insertion Compression of inferior or lateral surface of the tongue by cuff or tube of SGA
Teeth	Displacement Fracture of roots	Direct trauma Biting on SGA/bite block
Lips	Laceration Nerve injury	Direct trauma Compression by device, taping to device

The PLMA has been described in several cases where it served to protect the airway from regurgitated content [31]. Despite this, there exist a number of cases describing aspiration associated with use of the device [32–34].

The ProSeal requires careful positioning in order to function correctly, and if this is not the case then the device may actually increase the risk of regurgitation by contributing to gastric insufflation [33]. It is recommended that the position should be checked by following the manufacturer's recommendations or by the passage of a gastric tube. Novel techniques have been described for insertion using the gum-elastic bougie [35], gastric tubes [36], and suction catheters [37]. Less experienced users may benefit from the gastric tube-guided insertion of the PLMA [38].

The Laryngeal Mask Airway Supreme (SLMA) is a newer device with very little evidence of regurgitation associated with its use and no described cases of aspiration. A recent meta-analysis showed very low incidence of complications [39] and a large observational study of 700 patients undergoing caesarean section found no cases of aspiration [40].

The i-gel differs from the devices described above in that it has a cuff that does not require inflation. The i-gel also possesses a separate gastric channel. Despite, and in some cases because of, these features there have been cases described in the literature of both regurgitation and aspiration of gastric contents: Gibbison et al. described a case series of three patients who regurgitated under anesthesia [41]. In two of these cases, the authors stated that the i-gel protected the patients from aspiration. The third case did aspirate, but with no complications, and was discharged the same day. The authors state that the drain tube allowed recognition of regurgitation, which they suggest may have gone undiscovered with the use of a first-generation device. They conclude that the incidence of regurgitation and aspiration for the device is low and noted that—at the time—no patients appeared to have come to harm from such episodes. This phenomenon of "recognition of regurgitation" is also described in a case by Liew et al. [42].

The i-gel has been found to have a lower esophageal seal than both the cLMA and PLMA, but together with the PLMA it was found to drain away regurgitated fluid effectively [43]. The lower esophageal seal is likely due to the fact that the tip of the i-gel is narrower—which was a deliberate design intended to decrease dysphagia associated with SGAs [3].

The SLIPA, LTS-II, and its disposable version LTS-D have no published reports referring to either regurgitation or aspiration.

There is still a lack of high-quality evidence associated with those SGAs with an incorporated gastric channel with regard to their ability to deal with the risk of regurgitation and aspiration and large, well-conducted trials are needed in this area. Despite this lack of evidence, the authors of NAP4 made recommendations regarding the use of 2nd-generation SGAs, including the following: "If tracheal intubation is not considered to be indicated but there is some (small) increased concern about regurgitation risk a second generation supraglottic airway is a more logical choice than a first generation one." Similar recommendation has been also published in a recent editorial [44].

2.2. Trauma. Microscopic trauma associated with insertion of SGAs is thought to be relatively common but of little consequence and, in any case, difficult to detect. Macroscopic trauma, however, may lead to significant morbidity. It may occur at a number of sites and be caused by a number of mechanisms (Table 2). The main areas are the lips, teeth, pharyngeal mucosa, tongue, uvula, epiglottis, and the laryngeal apparatus [45]. Trauma may be caused directly by forceful placement or indirectly by compression and can result in laceration and bleeding, ischemic injuries, or neurological injuries as a result of compression of nerves [46], which will be discussed separately.

2.2.1. Minor Trauma. Dental injuries occur in about 1% of anesthetics and make up a significant proportion of legal claims against practitioners [47]. Dental injuries occur less frequently with SGA insertion than they do with direct laryngoscopy [48], but they may be also associated with removal of these devices.

There is only one publication mentioning dental damage in association with either the cLMA [49] or intubating LMA [50]. Few studies have looked for or mentioned dental damage in association with the i-gel but the incidence was almost zero [51–53].

The cLMA has been reported as the victim of trauma in one report: a sharp crown exposed by decay tore the cuff of two devices during insertion [54].

The presence of blood on the device upon removal of a SGA often indicates minor trauma associated with device insertion. The reported incidence of this for the cLMA is between 12 and 15% [55] and 9 and 22% in association with the PLMA [56, 57], depending on insertion technique. An incidence of blood staining of 20% has been described with the Guardian CPV laryngeal mask [57]. The typical incidence of blood on the i-gel at removal is between 4% and 13% [58–60] but has been reported to be as high as 20%, albeit in novice users [61]. The AuraOnce laryngeal mask was associated with a very low (2%) incidence of blood staining after its removal [62] but reached 10% in another study [63]. The presence of blood on the Cobra airway may be as high as 50% [64]. Aydogmus et al. reported a 7.5% incidence of blood staining on the LMA Supreme in pediatric patients, which was significantly lower than with the LMA ProSeal [65]. Insertion of the SLIPA may be associated with minor trauma in more than 20% of patients [66, 67]. Insertion of a novel SGA, the Baska mask, has been associated with significantly higher incidence of oropharyngeal trauma than the single-use cLMA, as reported by blood staining observed on the device after removal. However, this fact was not associated with an increased incidence of laryngospasm or postoperative complaints [68]. Five different 2nd-generation SGAs were inserted by inexperienced operators in another study [69]. SLMA, PLMA, i-gel, and LTS-D showed lower incidence of blood staining on removal than SLIPA. However, their patients were not surveyed postoperatively for symptoms of pharyngolaryngeal morbidity.

Theiler et al. analyzed complications associated with the use of i-gel in 2049 patients. They experienced 1.2% incidence of laryngospasm, 3.9% incidence of blood staining on the device, 2 cases of transient nerve damage, and one case of glottic hematoma after uncomplicated device insertion [70].

Injury to the lingual frenulum during insertion has been reported with use of the LMA ProSeal [71, 72] and the i-gel [73]. The mechanism of injury is usually backward folding of the tongue on insertion [74], thus stretching the lingual frenulum.

Trauma to the uvula or uvulitis has been described following insertion of laryngeal mask airway [75].

Ischemia of the tongue has been described in association with the intubating LMA after prolonged insertion [76] and also with the cLMA—again after a period of prolonged insertion [77]. A vacuum-like effect has been suggested to cause a hematoma on the lateral edge of the tongue following insertion of the 3gLM airway [78].

Pharyngeal lacerations have also been reported in association with the cLMA and in one case this led to the pulmonary aspiration of blood [79]. A different site of injury (aryepiglottic fold) led to massive hemorrhage after withdrawal of an i-gel [80].

Arytenoid dislocation has been reported after airway maintenance with a cLMA [81] which could be caused by direct contact with arytenoids, insertion with inflated cuff, or device rotation during placement. Despite strictly recommended methods of insertion, both uvular [82, 83] and epiglottic injuries [84] have been associated with use of the laryngeal mask. Arytenoid cartilage dislocation, as well as recurrent laryngeal nerve trauma with subsequent unilateral vocal cord palsy, has been described in association with the SLIPA [85]. Both complications led to persistent hoarseness.

2.2.2. Major Trauma. Severe damage to the pharyngeal structures or esophagus leading to life-threatening complications is extremely rare with SGAs. However, a few cases have been described in the literature. Blind insertion of a tracheal tube through the intubating laryngeal mask airway (ILMA) probably caused perforation of the esophageal diverticulum in an elderly patient which led to development of a pneumomediastinum [86]. The patient died nine weeks later due to multiorgan failure. Deep neck abscess and mediastinitis following pharyngeal perforation caused by cLMA insertion have been described in a low-risk elective procedure [87]. A similar complication causing a prolonged ICU and hospital stay was described following traumatic cLMA insertion for an elective urology procedure [88]. Both patients survived but required thoracic surgery intervention and prolonged mechanical ventilation. A posterolateral lesion of the pharyngeal wall after an uncomplicated insertion of cLMA was described in another elective patient [89]. Subsequent subcutaneous emphysema, pneumomediastinum, and pneumoperitoneum resolved spontaneously after several days. A recent report presented serious oropharyngeal trauma associated with the use of i-gel [90]. An elderly patient with multiple osteophytes on the cervical spine developed an airway obstruction few weeks after the procedure. Extensive hypopharyngeal mucosal erosions with denudation of the cricoid cartilage and subsequent supraglottic edema resulted in emergency tracheotomy and prolonged artificial ventilation. The authors suggested that age, duration of surgery, and pathology of the cervical spine contributed to this trauma.

2.3. Nerve Injuries. Innervation of the structures which SGAs come into contact with is complex. There are risks associated with device insertion and fixation and with the device in situ. Lesions to the lingual nerve have been repeatedly described with use of the cLMA [91–93], the PLMA [94], SLMA [95, 96], and i-gel [95, 97]. Injuries to the hypoglossal nerve have been described in association with using the cLMA [98, 99], PLMA [100], and SLMA [101]. Injuries to the recurrent laryngeal nerve have been described in association with the cLMA in adults [102–105] or children [106] and with insertion of the SLIPA [85].

Table 3: Possible factors implicated in the development of postoperative sore throat with SGAs.

Factor	Mechanism
Insertion technique	Leading edge of deflated cuff may cause trauma Inflated cuff causes more epiglottic downfolding, which increases POST Repeated attempts are associated with increased POST
Size of device	Smaller sizes of SGAs are associated with less POST
Use of lubricants	Adequate lubrication is essential Lidocaine gel is associated with an increase in POST
Overinflation of the cuff	Some studies have shown decreased POST with intracuff pressure monitoring
Duration of surgery	Increased POST in operations of over 60 min duration
Airway gases	Lack of humidification can dry mucosal surfaces and increase POST

Whilst the etiology of neurological injury by SGAs is multifactorial, in many of these cases the inflatable cuff of the devices was implicated—either by causing the device to be too rigid during insertion or by direct compression of nervous structures whilst the device was in place.

Despite its lack of a cuff, nerve injury in association with the i-gel has been described; Theron described a case of likely mental nerve injury [107]. In a reply to this letter, Chapman stresses the importance of taping the device correctly and of correct size selection, lubrication, and insertion technique [108].

Renes presented a case of bilateral lingual nerve injury in association with the use of an i-gel [97]. Another letter also refers to symptoms, which are consistent with an injury to the lingual nerve [73].

In their cohort study, Theiler et al. reported two instances of neurological damage [70]. The authors emphasise that device selection should involve choosing the smallest device that provides an adequate airway seal—particularly in those patients who are overweight or who are anesthetized for longer procedures.

2.4. Minor Complications. These mainly include sore throat, swallowing difficulties, and hoarseness lasting for up to several days after anesthesia. The etiology of postoperative sore throat (POST) is unclear. Factors associated with its increased incidence include female sex, use of suxamethonium, younger patients, and patients undergoing gynecological surgery [109]. Trauma to different areas by different devices (SGAs and endotracheal tubes) causes a similar incidence of sore throat postoperatively [110].

The incidence of sore throat associated with use of the cLMA ranges from 5.8% to 34% compared with 14.4% to 53% in association with endotracheal intubation [109]. There are differences in the sites of forces applied by a supraglottic airway (posterior pharynx) and endotracheal tubes (glottic entrance) which explain the different nature of complaints associated with them; dysphonia is more common with an endotracheal tube, and dysphagia more common with SGAs [111]. The incidence of sore throat after the use of other SGAs is not very different—AuraOnce LM up to 22%, the i-gel between 5% and 17% [62, 112]. Kihara et al. do not recommend using ILMA instead of cLMA for routine procedures due to its significantly higher pharyngolaryngeal morbidity including sore throat (34–59%) and swallowing difficulties (up to 31%) [113]. Limited evidence is available to show that those SGAs with a gastric channel (2nd generation) may cause less sore throat and swallowing difficulties than the 1st-generation devices [112]. SLIPA has demonstrated a very low incidence (2%–8.6%) of postoperative sore throat and swallowing difficulties [66, 67]. The incidence of minor postoperative complaints has also been studied in other base-of-tongue sealing devices. The Cobra PLA airway may cause sore throat postoperatively with the incidence rising up to 31% as the cuff volume and pressure are increased [114]. Turan and colleagues found a significantly higher incidence of POST in patients managed with the Cobra PLA airway—50%—compared to those who had the PLMA or Laryngeal Tube inserted [64]. The incidence of sore throat and dysphagia following insertion of the LT or LTS II (LTS-D) has been reported at between 8% and 20% [115, 116]. The LTS-D showed a significantly higher incidence of postoperative sore throat and dysphagia than both the i-gel and SLMA [117].

There are several factors that may lead to the development of a sore throat with SGA use and they are highlighted in Table 3.

3. Effect of SGAs on Cervical Vascular Structures

Supraglottic airway devices may cause distortion of anatomical structures in the neck. The inflated cuff of laryngeal mask airways lies at the level of the cricoid cartilage and its expansion may change the position and/or diameter of the common carotid artery and internal jugular vein.

The clinical effects of cuff inflation on neck vessels were first studied by Colbert et al. [118]. They initially performed a pilot evaluation of carotid artery diameter and flow in a patient who was scheduled for elective surgery under general anesthesia. The cross-sectional area of both carotid arteries significantly decreased after inflation of the LMA cuff which was compensated for by an increase in flow velocity and carotid blood flow. In their subsequent study, the authors evaluated carotid artery hemodynamics in seventeen patients who had cLMA inserted for routine elective cases under general anesthesia [119]. The cross-sectional area of the carotid arteries significantly differed between cuff inflation and deflation. Carotid blood flow was also significantly lower

during cuff inflation whereas no difference was observed in flow velocity. Reduction in the carotid artery diameter was more marked in patients older than 60 years where the cross-sectional area dropped after inflation by more than 60% when compared with the area measured during cuff deflation. The results of this study suggest a potential deleterious effect of the laryngeal mask airway on brain perfusion in older patients, which can be further potentiated by a presence of sclerotic plaques inside the carotid arteries.

The significance of these findings in patients with normal perfusion parameters remains debatable. Compression of neck vessels may have deleterious effects on brain perfusion in patients with low-flow conditions, such as resuscitation in cardiac arrest or hypovolemia. Segal et al. studied the relationship between three SGAs (King Laryngeal Tube Suction-D, Laryngeal Mask Airway Flexible, and Combitube 41F) and carotid artery blood flow in an experimental swine model of cardiac arrest [120]. The authors found that insertion and cuff inflation of each of the three SGAs caused a significant reduction in carotid blood flow as compared with the control group, which was managed with tracheal intubation. Postmortem arteriograms were performed for each airway device and showed that all three SGAs were associated with a compression of the common, internal, and external carotid arteries.

Laryngeal mask insertion may change the anatomical relationship of the common carotid artery and internal jugular vein [121]. This changed in 8.3% of children following inflation of the laryngeal mask cuff [122]. Intracuff pressures of the LMA should be measured regularly during general anesthesia because an overinflated cuff may cause congestion of the neck veins [123].

There is no evidence available regarding the effect of other or newer SGAs such as the SLMA, i-gel, SLIPA, Cobra PLA, or Laryngeal Tubes on carotid cross-sectional area or carotid blood flow.

4. Pressures Exerted by SGAs on Pharyngeal Mucosa

Tracheal tubes may cause damage to the tracheal mucosa which can manifest itself as postintubation edema, narrowing or, in prolonged intubation, as tracheal stenosis [124]. The inflated cuff of the tracheal tube may also damage the recurrent laryngeal nerves, more commonly in children [125]. Supraglottic airway devices do not have any effect on the tracheal mucosa. Marjot raised the first concerns about a negative effect of SGAs on oropharyngeal mucosa in 1993 [126]. He measured the intracuff pressures inside the bowl of the cLMA in ten patients under general anesthesia and found them to range between 103 and 251 mmHg. He suggested that transmitted mucosal pressures might potentially exceed capillary perfusion pressure in the hypopharynx. Similar concerns were also raised by O'Kelly and colleagues [127].

Subsequent studies were performed by Keller and Brimacombe's group. These researchers put microchip sensors on the outer surface of various SGAs and measured the pressures exerted by these devices on various parts of pharyngeal and perilaryngeal areas. The findings of their initial studies suggested that the actual pressures are probably much lower than those calculated and do not exceed the capillary perfusion pressures [128].

The same authors showed, on a cadaver model, that pressures exerted by the tracheoesophageal Combitube on pharyngeal and esophageal mucosa are quite high and that they may exceed mucosal perfusion pressures [129]. Another type of base-of-tongue sealer, the Laryngeal Tube, also showed a potential for pressure trauma to pharyngeal structures [130]. Extended insertion of supraglottic airway devices may significantly contribute to the pharyngeal mucosa hypoperfusion. LMA ProSeal inserted over a period of 12 hours was associated with a significantly increased incidence of mucosal injury in an animal model when compared with shorter periods of time [131]. Nitrous oxide, which is still used by some anesthesiologists, diffuses into the cuff of any inflatable SGA, expanding its size and increasing the intracuff pressures [132]. However, these higher pressures caused only mild histological signs of pharyngeal mucosal injury in an animal model for procedures of up to 2 h of duration [132, 133].

Human studies have been carried out for most currently used SGAs. The cLMA was compared with the intubating LMA in anesthetized and paralyzed adults. The intubating LMA was associated with significantly higher seal pressures but pressures exerted on the mucosa in the distal oropharynx were more than 157 cm H_2O, exceeding mucosal perfusion pressures in that area [134]. Pressures exerted on the pharyngeal mucosa with the intubating LMA were even higher than in devices employing base-of-tongue or pharyngeal sealing as their primary mechanism (Laryngeal Tube, Easy Tube, or Combitube) [135]. The i-gel airway and LMA Supreme were compared in regard to pressures exerted onto the oropharyngeal and perilaryngeal mucosal tissue [59]. Both devices exhibited very low pressures (not exceeding 10 cmH_2O). The i-gel did not show any pressure differences but pressures exerted by LMA Supreme were lower at the base of the tongue and distal oropharynx than in the hypopharynx. No data about their effect on mucosa are available for the SLIPA, Cobra airway, or novel devices such as the Baska mask, AuraGain LM, Guardian LM, or 3gLM.

Two studies confirmed an increase in the cuff volume, intracuff pressures, and transmitted mucosal pressures, depending on the increasing altitude, in tracheal tubes and SGAs when cuffs were filled with air [136, 137]. These findings raised concerns as whether to fill these cuffs with saline, to check the intracuff pressures at regular intervals, or to use SGAs with a noninflatable cuff such as the i-gel [138].

5. Conclusions

In many indications, such as for elective procedures outside of the thorax and abdomen in patients without increased risk for gastric content aspiration, SGAs have already replaced tracheal intubation. These devices are still developing in order to overcome their limitations and to minimize the incidence of complications or minor adverse events associated with their insertion.

Complications associated with the correct use of the SGAs are relatively rare and most of them are not life-threatening. They are often associated with a deviation from the manufacturers' advice on usage of their devices. Aspiration remains a problem, which can have serious and even fatal consequences. Its incidence is extremely low, comparable with the incidence of aspiration in tracheal tube anesthesia [25]; however, its real occurrence may be underreported [9]. Although there is some limited evidence that newer devices with an additional gastric channel may offer greater protection from regurgitation and aspiration this still requires robust studies to be carried out. Assessment of the risk of aspiration is a key component of the preanesthetic evaluation and should be used to guide device selection.

Nerve injuries may be avoided by careful insertion and by limiting cuff inflation pressure in accordance with advice from the manufacturer. Limiting cuff pressures may also decrease the incidence of sore throat.

The effects of SGAs on cervical vascular structures and microcirculation of the pharyngeal mucosa are not yet completely explored. It appears that negative effects are directly related to cuff volume and its internal pressure.

Abbreviations

BMI: Body mass index
ILMA: Intubating laryngeal mask airway
LM: Laryngeal mask
LMA: Laryngeal mask airway
LTS: Laryngeal Tube Suction
NAP: National Audit Project
PLA: Perilaryngeal airway
POST: Postoperative sore throat
SGA: Supraglottic airway device
SLIPA: Streamlined liner of the pharyngeal airway.

Disclosure

Pavel Michalek has lectured for several companies manufacturing supraglottic airway devices including Intersurgical Ltd., AMBU Ltd., and Intavent Orthofix Ltd. William Donaldson has delivered lectures on the i-gel for Intersurgical Ltd.

Conflict of Interests

Eliska Vobrubova and Marek Hakl declare no conflict of interests regarding the publication of this paper.

Authors' Contribution

Pavel Michalek and Eliska Vobrubova performed the literature search, Pavel Michalek and William Donaldson designed the paper, Marek Hakl created the tables and revised the paper, and Pavel Michalek and William Donaldson prepared final version of the paper. All authors have approved the final version of the paper.

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Review Article

Controversies in Pediatric Perioperative Airways

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Pediatric airway management is a challenge in routine anesthesia practice. Any airway-related complication due to improper procedure can have catastrophic consequences in pediatric patients. The authors reviewed the current relevant literature using the following data bases: Google Scholar, PubMed, Medline (OVID SP), and Dynamed, and the following keywords: Airway/s, Children, Pediatric, Difficult Airways, and Controversies. From a summary of the data, we identified several controversies: difficult airway prediction, difficult airway management, cuffed versus uncuffed endotracheal tubes for securing pediatric airways, rapid sequence induction (RSI), laryngeal mask versus endotracheal tube, and extubation timing. The data show that pediatric anesthesia practice in perioperative airway management is currently lacking the strong evidence-based medicine (EBM) data that is available for adult subpopulations. A number of procedural steps in airway management are derived only from adult populations. However, the objective is the same irrespective of patient age: proper securing of the airway and oxygenation of the patient.

1. Introduction

Managing the airway is crucial and the cornerstone of pediatric anesthesia. Airways in children are developing and changing during growth. They differ from adult airways in several aspects: they are narrower and the risk of swelling is greater and this can lead to increased airway resistance and breathing in a spontaneously breathing child in the postoperative period. The narrowest part of the airway is located at the level of cricoid cartilage in contrast to adults where we can choose the ETT (endotracheal tube) depending on the space between the vocal cords. The results of several MRI (magnetic resonance imaging) studies however indicate that the narrowest part can be the glottis [1]. To the best of our knowledge, this is the first airway management review article which summarizes all current controversies related to pediatric airway management.

2. Methods

We searched https://scholar.google.com, http://www.ncbi.nlm.nih.gov/pubmed/, Medline (OVID SP), and Dynamed for keywords: Airway/s, Children, Pediatric, Difficult Airways, and Controversies. We searched for data published between 2000 and 6/2015. After data collection, we identified several controversies related to pediatric airway management: difficult airway prediction, difficult airway management, cuffed versus uncuffed endotracheal tubes for securing pediatric airway, RSI (rapid sequence induction) in pediatric anesthesia, laryngeal mask (LM) versus endotracheal tube, and extubation timing.

3. Results and Discussion

The review is derived from the data of review articles ($n = 35$), prospective trials ($n = 6$), guidelines ($n = 3$), retrospective trials ($n = 1$), and meta-analysis ($n = 1$). The paucity of randomized controlled trials and meta-analyses included are a limitation of the paper but this is due to the lower number of randomized controlled trials (RCTs) related to the topic.

3.1. Difficult Airway Prediction. The airway management should be planned and the anesthesiologist should have a back-up plan for the scenario "when things can go wrong." The airway evaluation needs to include the patient's medical history: birth complications, history of trauma, previous surgery, and airway management during previous anesthesia. During the clinical examination, the anesthesiologist should seek for signs of stridor, dysphonia, swallowing disorders, difficulty in breathing, difficulty in speaking, and hoarseness. There are currently a number of difficult airway predictors, but their sensitivity and specificity vary in clinical practice. The predictors with good performance are mandibular protrusion, Mallampati's classification, movement of atlantooccipital joint [2], reduced mandibular space, and increased tongue thickness [3]. Other published risk factors are age less than one year, ASA (American Society of Anesthesiologists) status III and IV, obesity (BMI, body mass index, ≥35), and patients undergoing oromaxillofacial, ENT (ear, nose, and throat), and cardiac surgery [4, 5]. The thyromental distance can be used for difficult airway prediction: the normal value should be at least 3 finger breadths (patient's 3 finger breadths) [6]. The reported incidence of difficult airway in pediatric population however is lower than that for adults and predictable in the majority [7]. Unexpected difficult face mask ventilation (inadequate mask seal, excessive gas leak, or excessive resistance) in children varies from 2.8 to 6.6% [8] and the incidence of difficult endotracheal intubation (defined as Cormack and Lehane greater than grade 3) varies between 0.06% and 1.34% [4, 9, 10]. Difficult airway should be anticipated in several congenital syndromes: Pierre robin sequence, Goldenhar syndrome, Treacher Collins syndrome, Apart syndrome, Hunter and Hurlet syndrome, Backwith-Wiedermann syndrome, Freeman-Sheldon syndrome, Down syndrome, Klippel-Fail syndrome, Hallermann-Streiff syndrome, Arthrogryposis, Cri-du-chat syndrome, Edwards syndrome, and Fibrodysplasia ossificans progressiva [11–13].

Perioperative respiratory complications still remain one of the main causes of pediatric perioperative morbidity [14] and are the second most common cause of perioperative cardiac arrest in children [15]. In clinical practice, it is advisable to combine predictors with good performance and clinical examination to predict possible difficult airway. The best way to avoid airway-related complications is regular training for the cannot intubate cannot ventilate (CICV) scenario and stepwise difficult airway protocol implementation in routine clinical practice [7].

3.2. Expected Difficult Airway. In case of elective surgery, the pediatric patient with known or expected difficult airway should be treated in a tertiary center [7]. Currently, there are no guidelines on how to proceed in this scenario and the majority of anesthesiologists attempt to preserve the patient's spontaneous ventilation during the period of airway securing [8]. In adulthood, the recommended clinical practice is relatively clear and the fibreoptic awake intubation with spontaneous ventilation under local anesthesia or under mild sedation can be considered as a golden standard in case of expected difficult airway [9]. This is not easy to adopt in children due to lack of cooperation of pediatric patients and, in the vast majority of pediatric patients, the airways can be managed only after anesthesia induction or under deep sedation [16]. There are conflicting data on the role of muscle relaxants in the case of expected difficult airway in children. Some authors permit their use in case of possible facemask or supraglottic device ventilation with the exception of a patient with anterior mediastinal mass [17, 18]. Flexible fiberscopic intubation can be performed directly, using the special designed face mask [19] or supraglottic device as a conduit for flexible intubation [20]. It seems reasonable to preserve the spontaneous ventilation in patients with expected difficult airway. Supraglottic airway devices can resolve the situation or can be helpful as a route for fiberscopic intubation.

3.3. Unexpected Difficult Airway. There are currently published guidelines and reviews that summarize the recommendations in clinical situations of difficult mask ventilation, difficult tracheal intubation, and the cannot intubate cannot ventilate scenario in pediatric population [7, 10, 21]. Anatomically based problems can arise due to inadequate head position, airway collapse, inappropriate face mask handling, large tonsils, and/or adenoids. This can be overcome with proper positioning of the head, chin lift, jaw thrust, and two-hand manual ventilation via facemask [22]. However, functional airway obstructions are far more frequent and these can be caused by inadequate depth of anesthesia, laryngospasm, and opioid-induced glottic closure [14, 23, 24]. Laryngospasm is often treated with deepening the level of anesthesia although this may lead to significant hypotension in pediatric patients [25, 26]. Muscle paralysis for treating functional airway obstruction especially in case of cardiovascular instability is a more appropriate option [27]. The Difficult Airway Society (DAS) published guidelines for proceeding in emergency situations: unexpected difficult intubation during routine induction, difficult mask ventilation, and the cannot intubate cannot ventilate scenario in pediatric patients aged between 1 and 8 years (Figures 1–3) [28]. This stepwise protocol is demonstrative and provides the proper directions for proceeding in life-threatening situations: difficult mask ventilation, unexpected difficult tracheal intubation, and the cannot intubate cannot ventilate scenario.

3.4. Cuffed or Uncuffed ETT? Historically, uncuffed ETTs were used in pediatric patients under 8 years, to achieve a larger internal diameter of the tube, reducing flow resistance [29], and to minimalize possible oedema formation due to cuff caused mucosal damage. Currently, it is well documented that the narrowest part of the airway at the level of cricoid

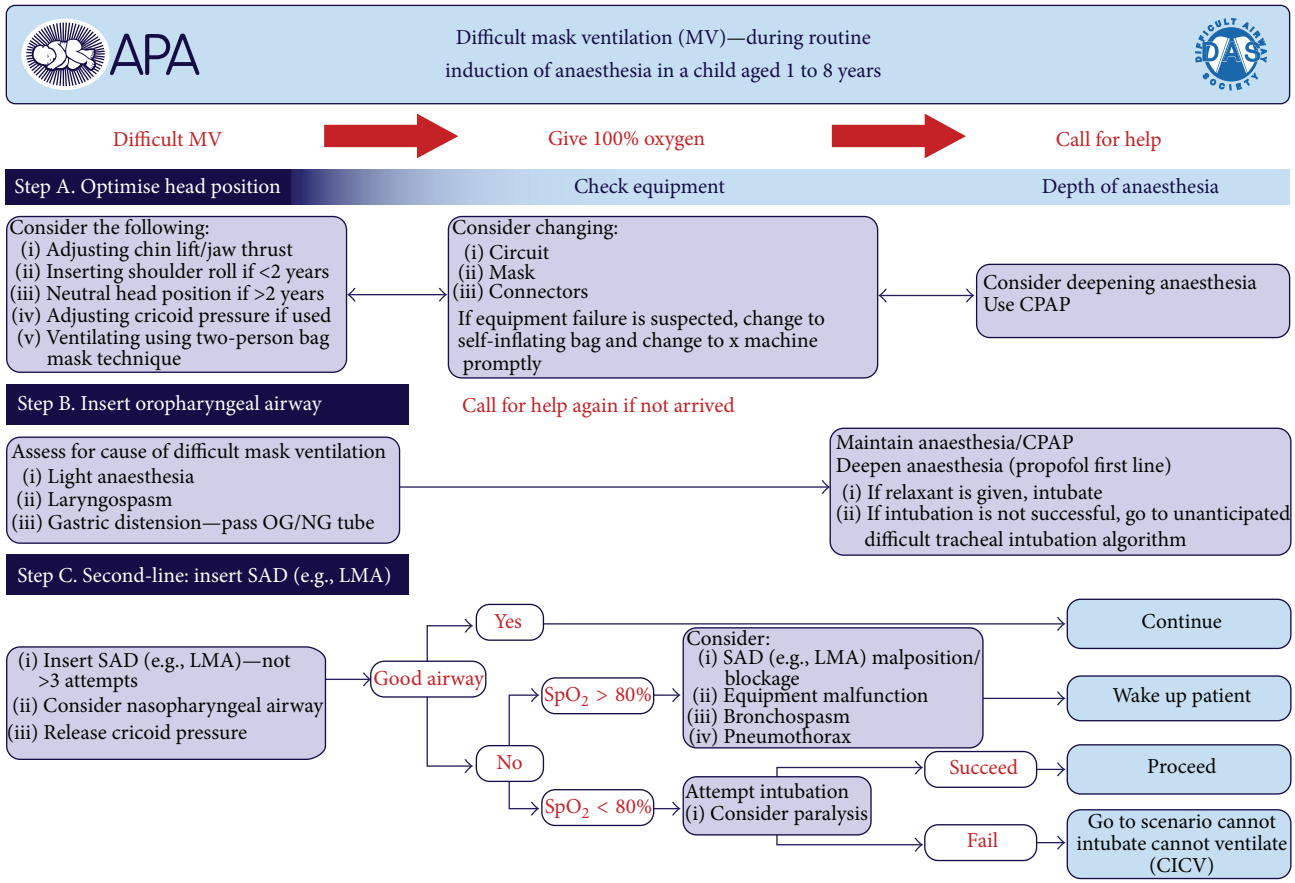

FIGURE 1: Guidelines for the management of difficult mask ventilation in children aged 1–8 years, published by DAS (Difficult Airway Society) at http://www.das.uk.com/guidelines/paediatric-difficult-airway-guidelines.

cartilage is elliptical. For this reason, there is the possibility of causing airway trauma also if the uncuffed tube with an acceptable leak pressure was used [12]. A higher incidence of laryngospasm with the use of uncuffed tubes has also been reported [12, 30]. The size of ETTs remains age-related [31]. It can be estimated using Cole's formula for uncuffed tube selection [32]: inner diameter (mm) = (16 + age)/4, although it has been reported that it can overestimate the actual tube size [33]. For cuffed tubes, Cole's formula results can be used, reduced by 0.5 or 1.0 mm [29], or another formula [34]: inner diameter (mm) = (age in years/4) + 3. The data show that accurately chosen and properly placed newly designed cuffed tubes (Microcuff) do not result in more airway-related complications than uncuffed ETT [34, 35] and can be used in infants [30]. One of the largest advantages of cuffed tubes is that they significantly reduce the exchange rate (from 25% to 2%) of ETTs after intubation in pediatric anesthesia [34]. No increase in morbidity has been reported with the latest cuffed ETT use in pediatric intensive care unit (ICU) patients [36] and according to the ILCOR (International Liaison Committee on Resuscitation) guidelines (2005), cuffed tubes are accepted as an alternative to uncuffed tubes [37]. Improper placement or excessive cuff pressure can lead to mucosal damage. It is highly recommended to periodically, ideally continuously monitor the cuff pressure to avoid potentially damaging pressures [38]. Newly designed (Microcuff) pediatric cuffed tubes are considered safe and effective in perioperative care for pediatric patient.

3.5. Rapid Sequence Induction (RSI). RSI in adults is a standard procedure in patients with high risk of gastric aspiration (unfasted, trauma, GERD, gastroesophageal reflux, etc.). The most frequently used neuromuscular blocking agent during RSI is suxamethonium. The cricoid pressure (known as Sellick's Maneuver, SM) was subsequently added to the sequence to prevent gastric aspiration [39]. The cricoid pressure can also be effective in pediatric patients [40], but it can worsen intubation conditions [41–44]. It can also lead to a fall in lower esophageal sphincter tone [45]. The efficacy of this maneuver has been widely discussed over the past 20 years, with conflicting results. Another question is the proper performance of SM and the pressure that should be applied to the cricoid cartilage [43, 46, 47]. The data analysis showed

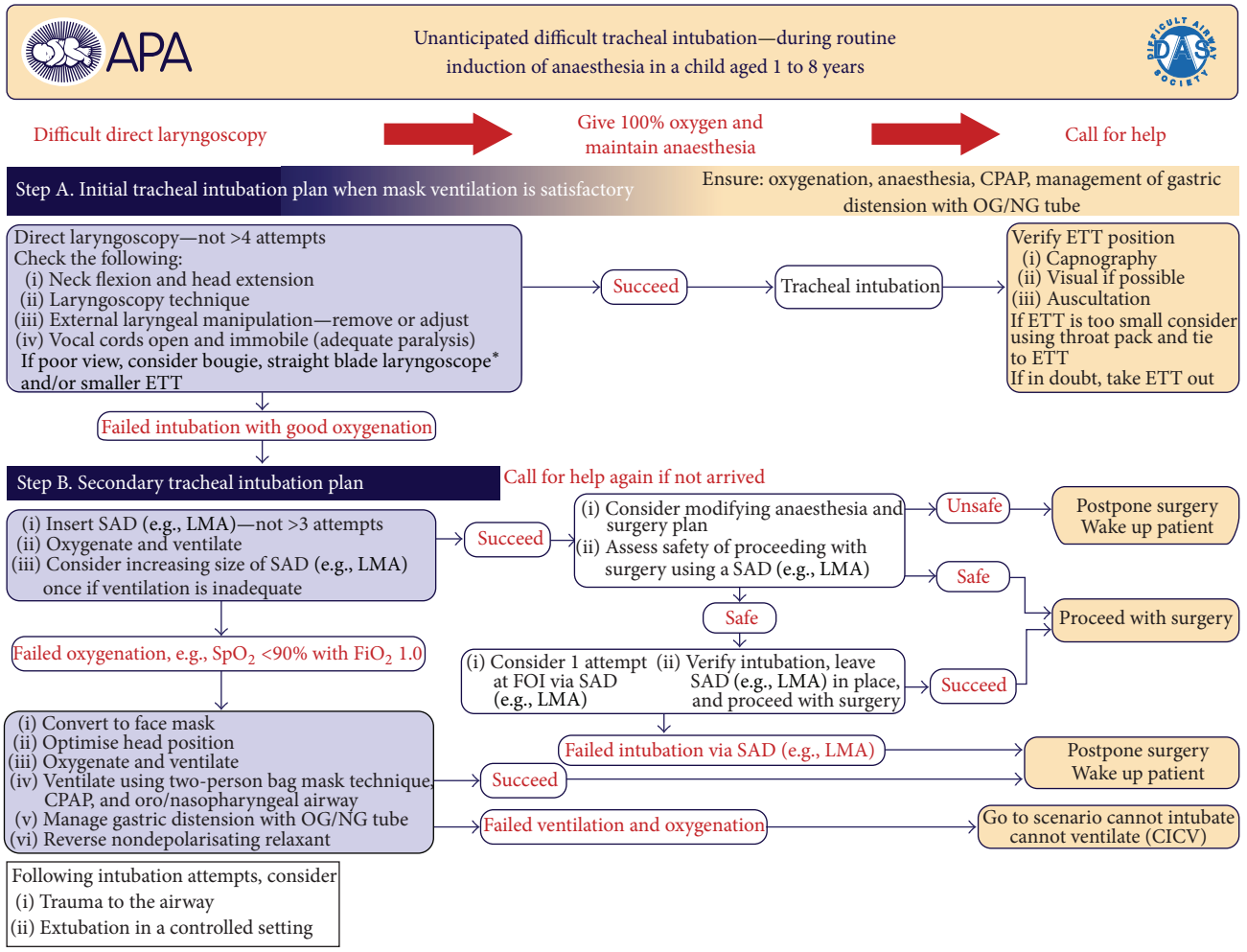

Figure 2: Guidelines for the management of unexpected difficult tracheal intubation in children aged 1–8 years, published by DAS (Difficult Airway Society) at http://www.das.uk.com/guidelines/paediatric-difficult-airway-guidelines.

that sufficient pressure to prevent aspiration is 10 N in awake patients and after induction the pressure should be raised to 30 N [48]. However, these data are derived from the adult population. During the past decade, SM has gradually been vanishing from routine anesthesiology practice. The results of its efficacy remain conflicting. It should be noticed that in Germany the routine use of SM in case of RSI in pediatric patients is no longer recommended [49] and in 2010 only 1.1% of pediatric anesthesiologists reported that they use SM during RSI in pediatric anesthesia [50].

Another conflicting issue is the use of suxamethonium in childhood. According to the Food and Drug Administration (FDA) recommendations, suxamethonium should be reserved only for emergency situations due to published adverse events and even deaths both in pediatric patients [51–53] and in adults [54–57]. Should we all abandon suxamethonium in pediatric anesthesia as it can be seen in some centers [58]? The authors recommend the well-known strategy "always have it (suxamethonium), never use it." We can look at RSI from different points of view: do we need RSI? And do we have any alternative? The reported aspiration incidence in pediatric patients is low (0.4–1 per 1000), with a very low rate of serious complications [59, 60], and also we are able to measure gastric volume by ultrasound imaging [61, 62]. We definitely need to perform RSI in bowel obstruction or posttonsillectomy bleeding. However, some conditions routinely considered to be indications for RSI are today questionable as can be seen in a recent publication on gas induction in pyloromyotomy [63].

Do we have any alternative to suxamethonium? Rocuronium is the only neuromuscular blocking agent with comparable onset rapidity to suxamethonium. It provides good intubation conditions at 60 seconds [64]. The major break was the introduction of sugammadex, a chelating agent with high

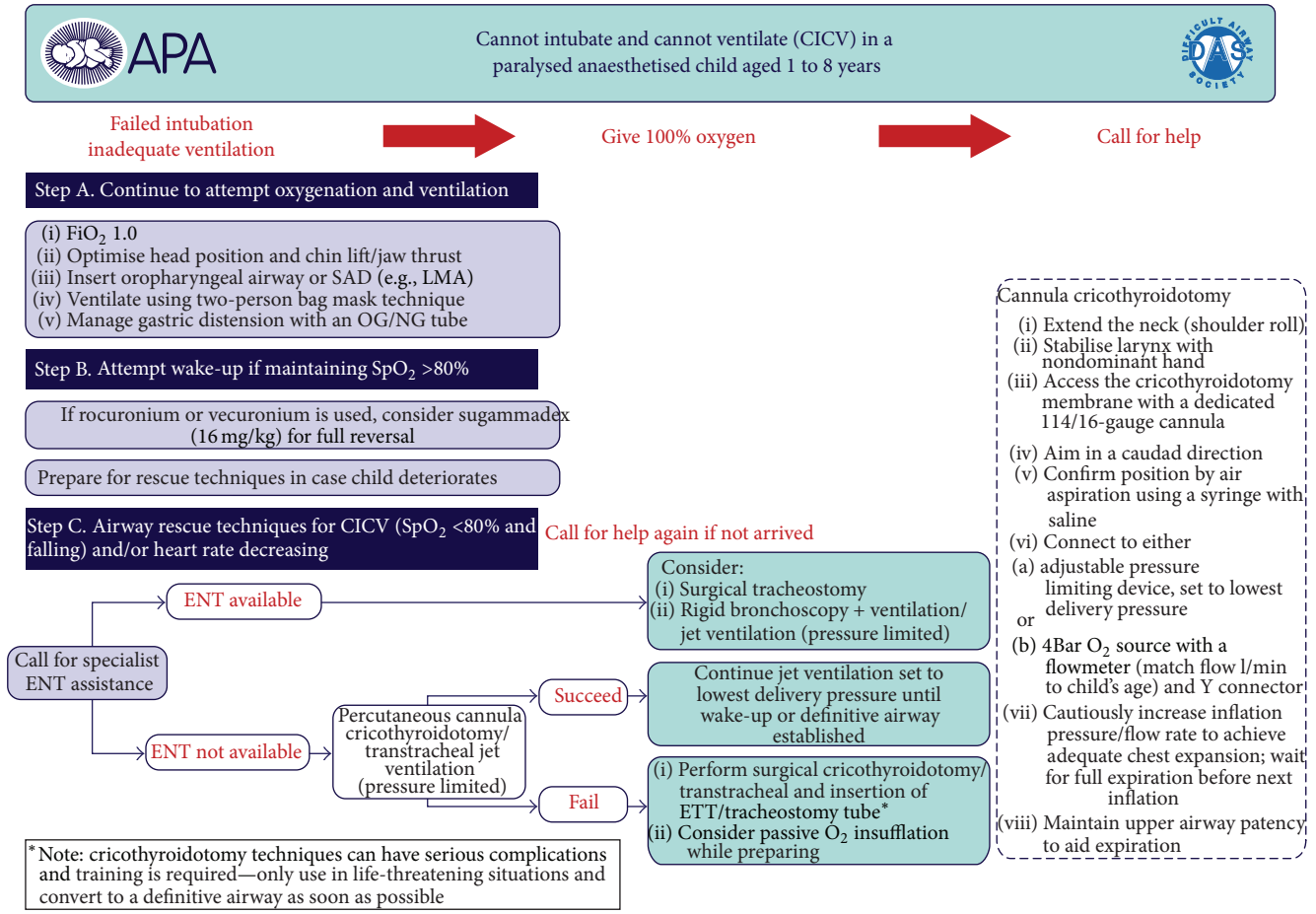

FIGURE 3: Guidelines for the management of CICV scenario in children aged 1–8 years, published by DAS (Difficult Airway Society) at http://www.das.uk.com/guidelines/paediatric-difficult-airway-guidelines.

specificity for rocuronium reversal. Sugammadex is currently licensed in children over 2 years [65] but still not registered by the FDA (concerns about possible allergic reactions). Rocuronium and sugammadex can be used in difficult airway scenarios [66]; however, it should be noticed that successful reversal of neuromuscular blockade does not always lead to a successful end [67, 68], while the reason for CICV (cannot intubate cannot ventilate) can be multifactorial. The main RSI principle is the absence of manual hand-bag ventilation during the induction. The majority of children cannot be sufficiently preoxygenated before the induction and due to their low functional residual capacity and higher oxygen consumption, they will desaturate much faster than adults in the absence of ventilation and oxygenation. The classic-adult RSI will lead to hypoxia, bradycardia, and hypotension during induction [69]. Therefore, many authors recommend RSI adapted for childhood or "controlled RSI" [70] with deep anesthesia, muscle relaxation, and intermittent face mask ventilation [71–73].

3.6. Tracheal Intubation versus Laryngeal Mask. Laryngeal masks (LMs) are today commonly used in routine pediatric anesthesia practice in a whole spectrum of surgical procedures [74–76]. Laryngeal mask can be effectively used in difficult airway management [77] and also in a large number of elective procedures [78, 79]. The LM use can lead to significant reduction of postoperative desaturation, laryngospasm, and cough and reduction in postanesthetic unit stay compared to ETTs [80]. The reason for the widespread use and high popularity of LMs by anesthesiologists may be the low failure rate and rapid learning curve [78, 79]. In case of insufficient seal, reposition, reinsertion or head flection, and rotation can lead to minimizing the air leak [81, 82]. However, even achieving a good seal does not guarantee the proper position of the LM [83]. For this reason, it is highly recommended to monitor cuff pressure during the anesthesia [84]. Possible gastric acid reflux is a question when using LM. The rate of reported aspiration appears to be very low although silent gastroesophageal reflux can often occur.

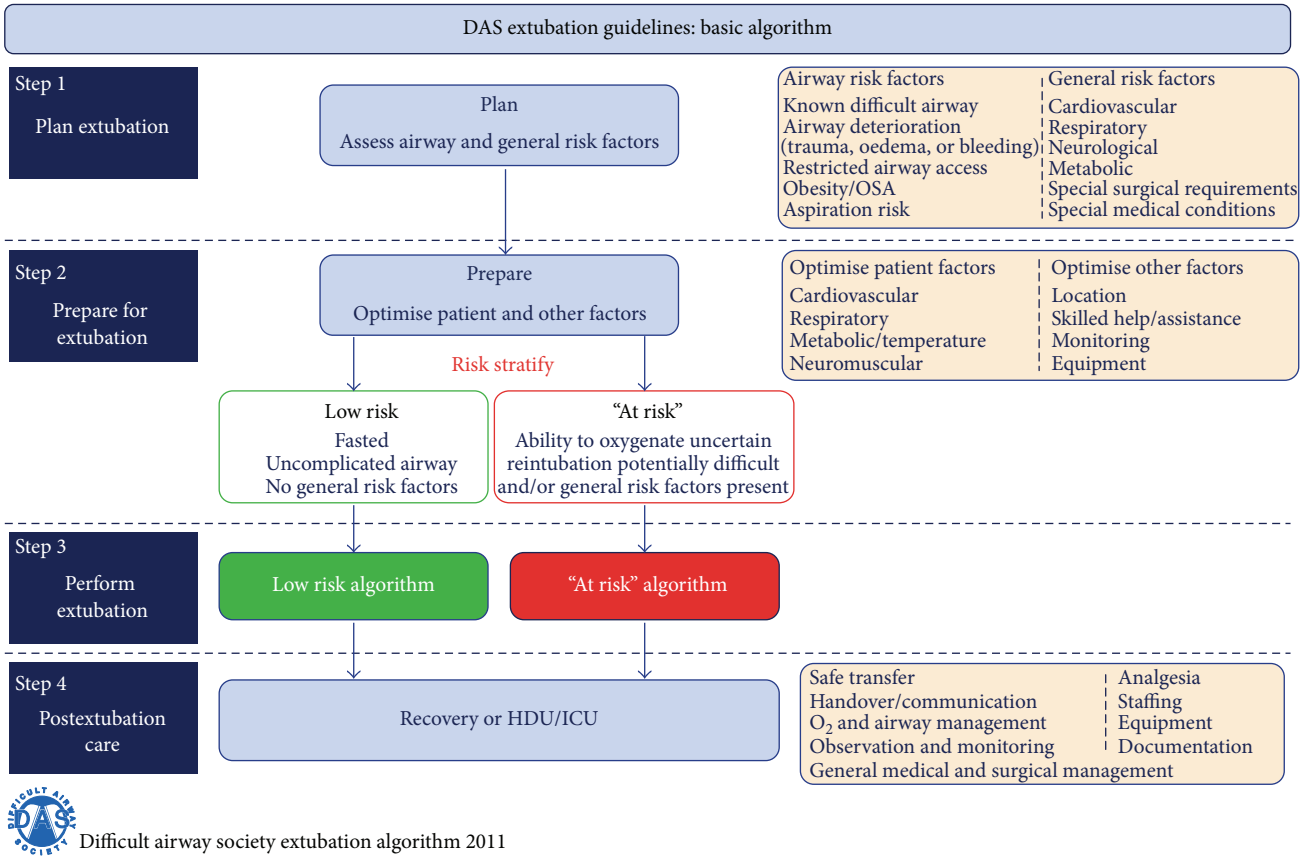

FIGURE 4: Guidelines for the management of tracheal extubation, basic algorithm, published by DAS (Difficult Airway Society) at http://www.das.uk.com/guidelines/paediatric-difficult-airway-guidelines.

It appears that, in reported cases, the diagnosis of reflux had no clinical consequences and compared to facemask ventilation and anesthesia with intubation, the incidence was similar [85, 86]. Laryngeal masks have been used for airway management during adenotonsillectomy, tonsillectomy, and adenoidectomy [87], laparoscopic surgeries (with comparable intragastric pressure to ETT [88]), during fibreoptic bronchoscopy [89, 90], eye surgery [91], during difficult airway management as a conduit for ETT placement [92, 93], and during resuscitation (also in neonates) with no documented difference in outcome compared to ETT use. LMs have earned their reputation for superior performance, simplicity, and low rate of failure also in pediatric anesthesia. Limitation of LMs can be seen in conditions such as Pulmonary alveolar Proteinosis (PaP) where the lung separation for invasive treatment is inevitable [94]. LMs have saved many lives and anesthesiologists' careers. We must also bear in mind, however, the limitations of this device (leak pressure, failure rate, and regurgitation risk) and the risk versus benefit ratio should always be considered in deciding between ETT and LM for pediatric patient's airway management. These data should not be interpreted as the uselessness of ETT and RSI in patients with high risk of aspiration (unfasted, major trauma, etc.), because in light of current EBM data it would be non lege artis practice.

3.7. When to Extubate the Pediatric Patient? The emergence from anesthesia is another risky situation during the perioperative period. The anesthesiologist should decide whether to extubate the child in deep anesthesia or awake with sufficient spontaneous ventilation or whether to proceed with the mechanical ventilation in ICU because of surgery duration, hypothermia, hemodynamic instability, respiratory distress, massive blood loss, and other conditions should be considered prior to extubation. The operator must consider two questions: intubation conditions and the risk of aspiration. In the case of difficult airway and in patients with high risk of aspiration, it is generally recommended to extubate them when awake with sufficient spontaneous ventilation with appropriate protective airway reflexes. In pediatric patients, it has been reported that the routine practice is extubation during deep anesthesia [95]. This can lead to minimizing cardiovascular system stimulation and reducing the incidence of cough; however, some data reported a higher

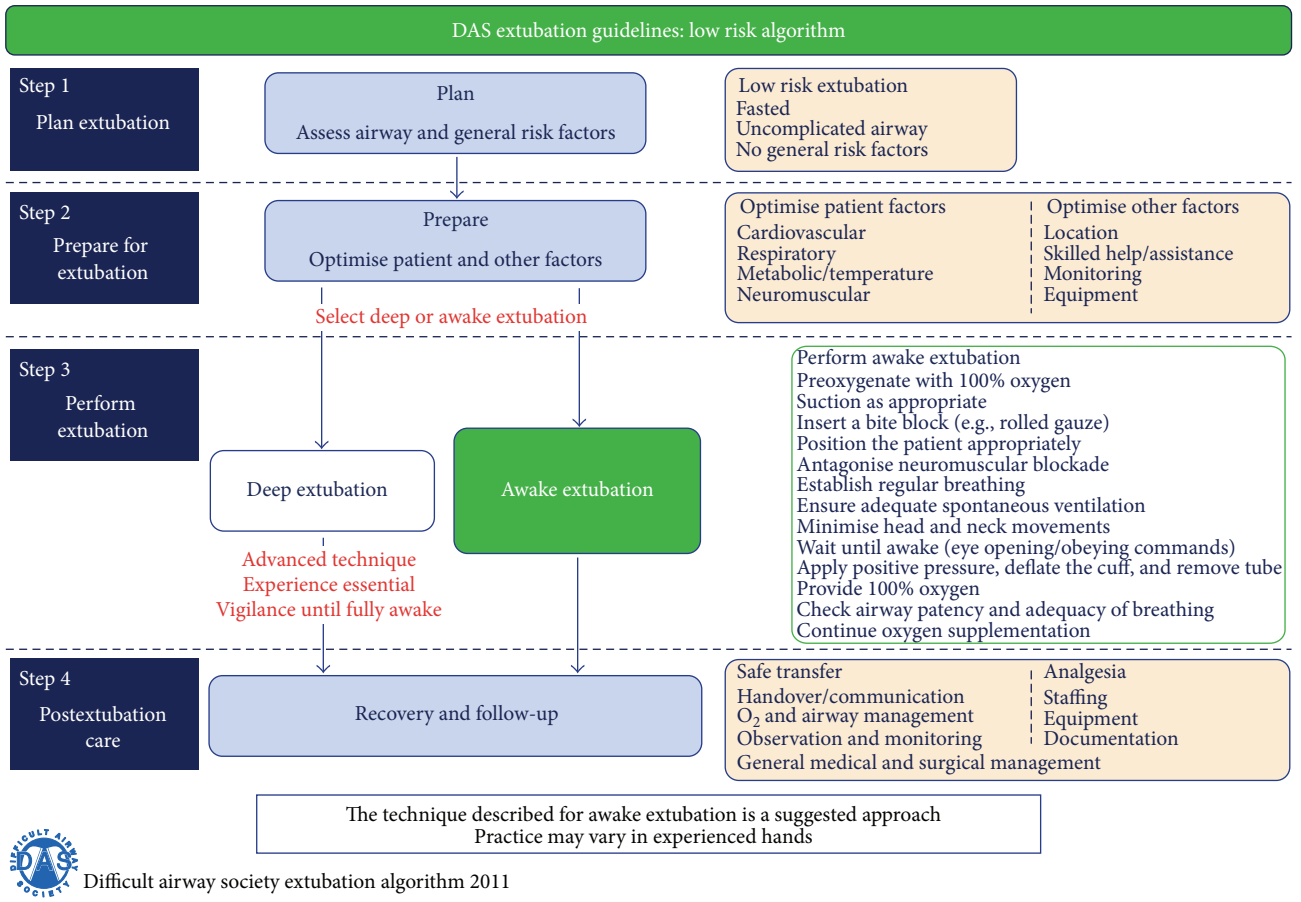

Figure 5: Guidelines for the management of tracheal extubation, low risk algorithm, published by DAS (Difficult Airway Society) at http://www.das.uk.com/guidelines/paediatric-difficult-airway-guidelines.

incidence of respiratory complications with this practice [96]. Extubation at the moment of end-inspiration can minimize the risk of laryngospasm [97] and experienced anesthesiologist is associated with lower risk of laryngospasm [98]. In conclusion, the difference in both practices (awake or in deep anesthesia intubation) is not associated with impact on outcome [99]. The main exception is the child with difficult airway and the child with high risk of aspiration, where the consensus is clear, extubating them awake with sufficient spontaneous ventilation. Compendious extubation guidelines have been published by DAS (Figures 4–6) [28]. The guideline is primarily for adult patients; however, with respect to differences in pediatric anesthesia, they could be implemented in pediatric extubation management.

4. Conclusion

The majority of difficult airway in childhood can be predicted and the best method for prediction seems to be the combination of clinical examination with predictors with good performance: mandibular protrusion, Mallampati's classification, movement of atlantooccipital joint, and thyromental distance. In case of anticipated difficult airway, it is advisable to preserve spontaneous ventilation. The classic RSI is not suitable for children and the mild (airway pressures under 20 cm H_2O) hand-bag ventilation is considered a safe method during pediatric RSI that provides oxygenation and minimizes possible hypoxia. Although we can see an increasing number of RCTs dedicated to pediatric airway management, there is still need to perform well designed large RCTs in pediatric subpopulation to formulate the airway management guidelines based on pediatric EBM data.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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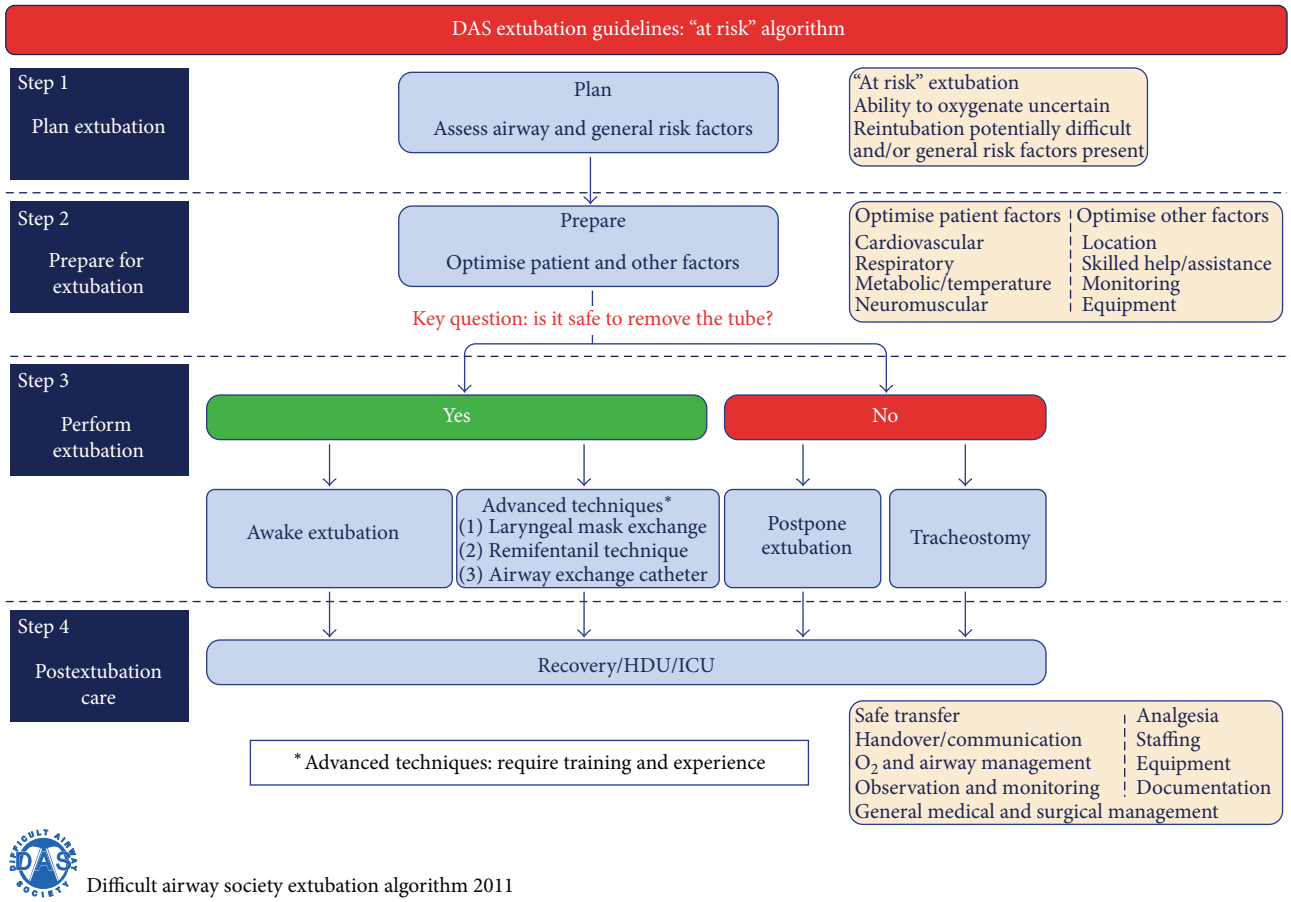

Figure 6: Guidelines for the management of tracheal extubation, high risk algorithm, published by DAS (Difficult Airway Society) at http://www.das.uk.com/guidelines/paediatric-difficult-airway-guidelines.

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Research Article

Comparison of Direct and Indirect Laryngoscopes in Vomitus and Hematemesis Settings: A Randomized Simulation Trial

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Background. Videolaryngoscopes may not be useful in the presence of hematemesis or vomitus. We compared the utility of the Macintosh laryngoscope (McL), which is a direct laryngoscope, with that of the Pentax-AWS Airwayscope (AWS) and McGRATH MAC (McGRATH), which are videolaryngoscopes, in simulated hematemesis and vomitus settings. *Methods.* Seventeen anesthesiologists with more than 1 year of experience performed tracheal intubation on an adult manikin using McL, AWS, and McGRATH under normal, hematemesis, and vomitus simulations. *Results.* In the normal setting, the intubation success rate was 100% for all three laryngoscopes. In the hematemesis settings, the intubation success rate differed significantly among the three laryngoscopes ($P = 0.021$). In the vomitus settings, all participants succeeded in tracheal intubation with McL or McGRATH, while five failed in the AWS trial with significant difference ($P = 0.003$). The intubation time did not significantly differ in normal settings, while it was significantly longer in the AWS trial compared to McL or McGRATH trial in the hematemesis or vomitus settings ($P < 0.001$, compared to McL or McGRATH in both settings). *Conclusion.* The performance of McGRATH and McL can be superior to that of AWS for tracheal intubation in vomitus and hematemesis settings in adults.

1. Background

The European Resuscitation Council (ERC) cardiopulmonary resuscitation (CPR) guidelines emphasize the importance of rapid and definite tracheal intubation [1]. The guidelines also suggest that skilled rescuers should be able to secure the airway without interrupting chest compressions to visualize the vocal cords and allow the passage of the tracheal tube [2].

The Pentax Airwayscope (AWS; Hoya, Tokyo, Japan) is a videolaryngoscope reported to provide an indirect view of the airway [3]. Studies indicate that AWS is useful not only for difficult airway management but also for emergent tracheal intubation during resuscitation by simulation analysis [4, 5]. The McGRATH (McGRATH; Aircraft Medical Ltd., Edinburgh, UK) is a device that has been developed with a high-resolution video camera, providing direct and indirect views of the glottis, and is reportedly useful for intubating several difficult airways [6]. While AWS and McGRATH are both considered convenient tools for difficult or emergent airway management, their indirect monitors may not be useful in the presence of hematemesis or vomitus in the pharynx [7]. In such patients, direct laryngoscopes such as the Macintosh laryngoscope (McL) may be superior to videolaryngoscopes for definite tracheal intubation.

The utility of direct (McL) and indirect laryngoscopes (AWS and McGRATH) for tracheal intubation has not yet been validated; therefore, we decided to compare the utility of McL with that of AWS and McGRATH in hematemesis and vomitus settings. Because direct clinical evaluation is unethical, we hypothesized that AWS and McGRATH would improve intubation in simulated hematemesis and vomitus settings and compared them with McL in terms of the ease of tracheal intubation by nonanesthesiologists using an adult manikin with hematemesis and vomitus simulations.

2. Methods

From November to December 2014, 17 doctors with more than a year of experience in anesthesiology or critical care medicine were recruited from medical personnel taking an airway management or sedation training course at the Osaka

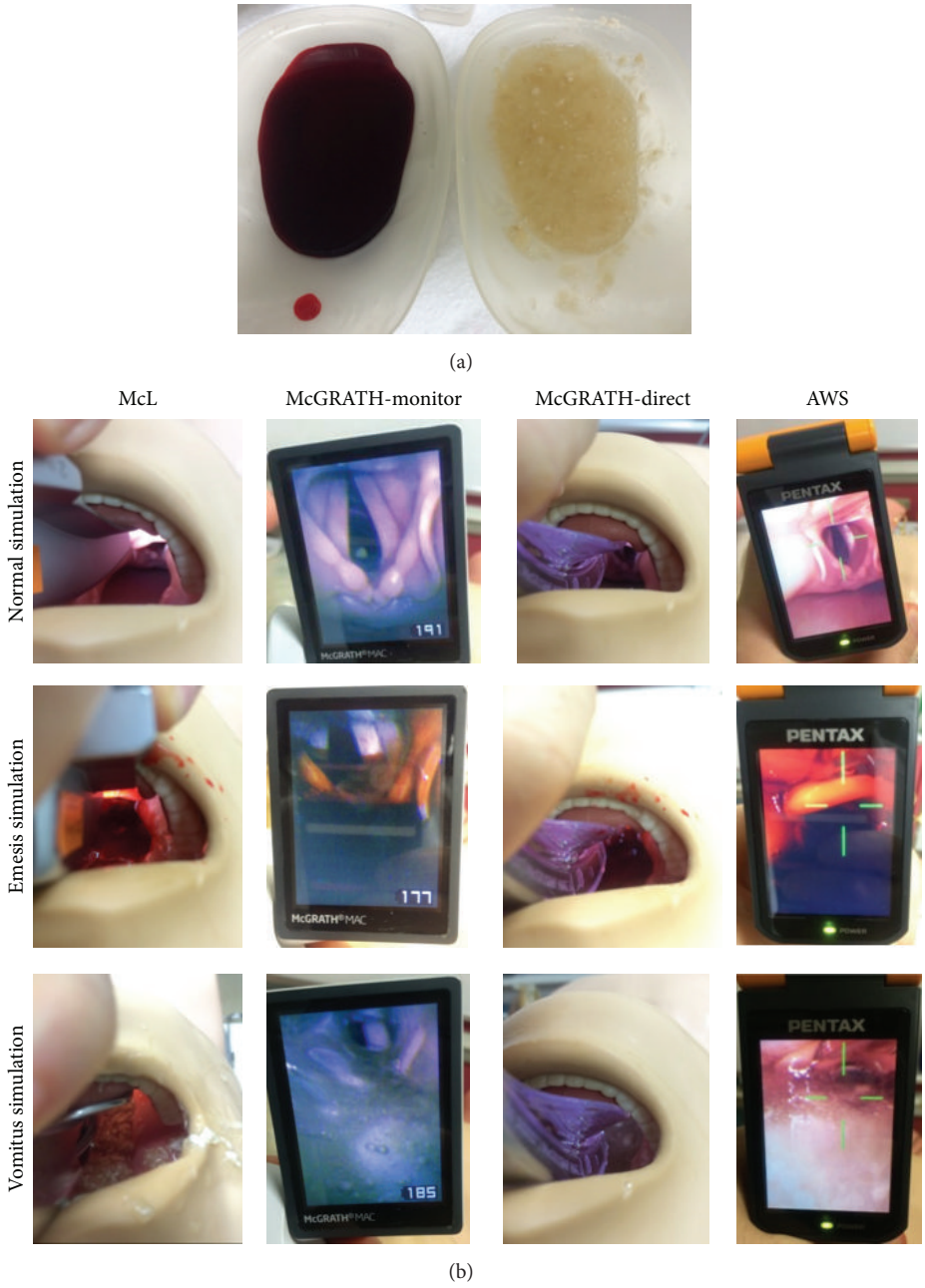

Figure 1: Simulated hematemesis and vomitus settings. (a) Simulated hematemesis and vomitus. (b) A representative laryngoscopic view with three laryngoscopes in each simulation condition (normal, hematemesis, and vomitus).

Medical College. Written informed consent was obtained before the study. This study was approved by the Osaka Medical College Research Ethics Committee (Approval number 1321).

The Airway Trainer (Laerdal, Stavanger, Norway), designed to accurately represent an adult male, was used for the study simulations and intubations. Participants used a tracheal tube (Portex, St. Paul, MN, USA) with an internal diameter of 7.5 mm.

Simulated stomach contents (vomitus; simulated stomach contents, Laerdal, Norway) or simulated blood (hematemesis; simulated blood, Kyoto-Kagaku, Japan) were added to the pharynx of the manikin. The contents were prepared by dissolving 10 g of powder in 200 mL of water according to the manufacturer's instructions and were poured into the pharynx to the level of covering the epiglottis to simulate vomitus or hematemesis. The lower esophagus was clamped with forceps to keep these liquids in the pharynx. We also clamped both bronchi instead of the trachea because clamping the trachea impedes smooth tracheal intubation. The different views (normal, hematemesis, and vomitus setting) of the three devices are shown in Figure 1.

Table 1: Tracheal intubation success rates for McL, AWS, and McGRATH in normal, hematemesis, and vomitus settings.

	Normal simulation (successful/total)	Hematemesis simulation (successful/total)	Vomitus simulation (successful/total)	*P* value
McL	17/17	15/17	17/17	0.125
AWS	17/17	10/17	12/17	<0.001
McGRATH	17/17	16/17	17/17	0.361
P value	0.978	0.021	0.003	

AWS, Pentax-AWS Airwayscope; McGRATH, McGRATH MAC; McL, Macintosh laryngoscope.
Numerator: number of participants who were successfully intubated.
Denominator: number of participants for whom tracheal intubation was attempted.
Differences were analyzed using chi-square test.

The manikin was placed on a hard, flat table for "on the resuscitation bed" simulation. Each participant was instructed to insert the tracheal tube with the three laryngoscopes (McL, AWS, and McGRATH), attach a bag valve mask, and attempt to ventilate the lungs of the manikin. In McL and McGRATH trials, participants used size 4 blade. In AWS trial, standard Introck (ITL-SL, HOYA, Japan) was used. Participants were given 10 min to practice intubation, with the instructor available for advice. The appropriate equipment for each trial was placed in a box next to the manikin's head. Intubation started when the participant picked up McL, AWS, or McGRATH and ended at the point of manual ventilation after tube insertion. The number of intubation sessions was recorded for both tracheal and esophageal intubations. At the end of the study, participants rated the difficulty of using each device using a visual analog scale (VAS) from 0 mm (extremely easy) to 100 mm (extremely difficult).

Statistical analysis was performed utilizing JMP 11 (SAS Institute Inc., Cary, NC, USA). Results obtained from each trial were compared using one-way repeated measures analysis of variance for intubation time and VAS and chi-square test for the success rate. Data are presented as means ± standard deviations (SDs). A P value of < 0.05 was considered statistically significant.

The study was designed as a randomized crossover trial to minimize the order effect. In each McL, AWS, and McGRATH trial, participants performed tracheal intubation in all three simulations (normal, hematemesis, and vomitus). The order of intervention was randomized for each participant using the random number table, resulting in a total of nine interventions per participant.

The sample size was calculated on the basis of our preliminary study on the time required for intubation with McL and McGRATH in the vomitus setting in eight participants. The mean (SD) time was 11.1 ± 3.3 s for McL and 5.9 ± 3.6 s for McGRATH. Using an α error of 0.05 and a β error of 0.2, we estimated that 15 participants would be adequate for each group. Therefore, we planned to recruit 17 participants for each group to adjust for missing data.

3. Results

The mean clinical experience of the 17 participants (11 male, 6 female) was 6.4 ± 3.6 years. The number of times the participants had worked before participating in the trial with McL, AWS, and McGRATH was 911.8 ± 501.1, 128.8 ± 94.2, and 68.2 ± 66.0, respectively.

3.1. Endotracheal Intubation Success with McL, AWS, and McGRATH. The number of successful tracheal intubations for each device is displayed in Table 1. In McL or McGRATH trial, the intubation success rate did not significantly differ among the three settings ($P = 0.125$ for McL trial, $P = 0.361$ for McGRATH trial). Contrastingly, in the AWS trial, the intubation success rate differed significantly among the simulated situations ($P < 0.001$).

In the normal setting, the intubation success rate was 100% for all three laryngoscopes. In the hematemesis settings, the intubation success rate differed significantly among the three laryngoscopes ($P = 0.021$). In the vomitus settings, all participants succeeded in tracheal intubation with McL or McGRATH, while five failed in the AWS trial with significant difference ($P = 0.003$).

3.2. Intubation Time with McL, AWS, and McGRATH. The intubation time in each setting is shown in Figure 2. In the normal setting, the intubation time did not differ significantly among the three laryngoscopes, while in the hematemesis and vomitus settings the intubation time was significantly longer with AWS than with McL and McGRATH ($P < 0.001$, compared to McL or McGRATH in both settings). There was no significant difference in the intubation time between McL and McGRATH in both the hematemesis and the vomitus settings.

3.3. VAS Scores for Difficulty of Tracheal Intubation with McL, AWS, and McGRATH. As shown in Figure 3, the subjective difficulty of tracheal intubation did not differ in the normal setting, while it was significantly higher with AWS than with McL and McGRATH in the hematemesis and vomitus settings ($P < 0.001$, compared to McL or McGRATH in both settings). The VAS score was not significantly different between McL and McGRATH in both the hematemesis and vomitus settings.

4. Discussion

Airway management is considered an essential element, particularly for in-hospital CPR. While conventional direct-view laryngoscopes such as McL are the most widely used for

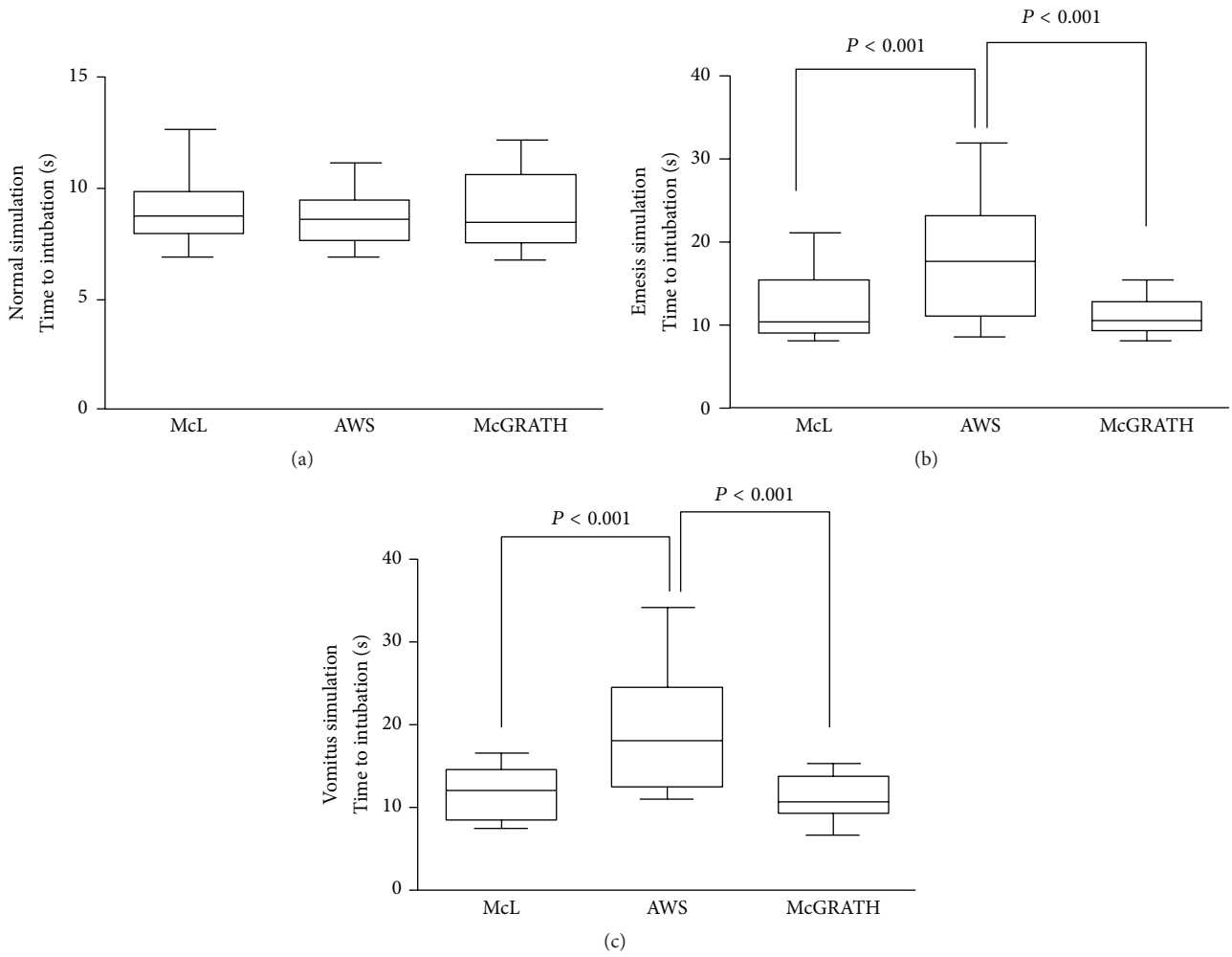

Figure 2: Box-and-whisker plot (median, IQR, and range) of time required for simulated tracheal intubation in hematemesis and vomitus settings using each laryngoscope. Results are expressed as means ± SDs and were analyzed using one-way analysis of variance. (a) Normal setting, (b) hematemesis, and (c) vomitus setting. AWS, Pentax-AWS Airwayscope; McGRATH, McGRATH MAC; McL, Macintosh laryngoscope.

tracheal intubation, it is difficult to master the skills required for use, and the incidence of inaccurate intubation can be unacceptably high for occasional operators [8, 9]. There are several reasons for the difficulty in airway management during resuscitation, such as chest compression, position of the rescuer or victim, and restriction of the airway management device [10]. A major problem encountered during airway management is vomitus or blood in the pharynx and neck fixation with the cervical collar. A nonnegligible number of patients exhibit vomiting or hematemesis during sudden cardiac arrest, leading to difficulty in tracheal intubation during resuscitation [11, 12]. In such situations, Easy Tube or combitube may be safe against aspiration and can therefore be used in vomiting or bleeding patients unless the glottis cannot be visualized. However, these devices usually do not complete protection of the trachea, and definite tracheal intubation is preferable in some circumstances [2].

Pentax-AWS Airwayscope is a videolaryngoscope for tracheal intubation designed to provide a clear view of the glottis and its surrounding structures. It improves the laryngeal view, and its tube guide facilitates rapid and reliable tracheal intubation under vision, even in difficult situations such as cervical neck immobility or morbid obesity [3]. Increasing evidence indicates that AWS is suitable for tracheal intubation during various difficult airway management and simulated emergency situations [13]. However, one clinical study showed that AWS did not show superiority to McL in prehospital settings, as opposed to simulated in-hospital situations [14]. We speculate that vomitus or hematemesis may have contributed to the lower success rate of AWS in the prehospital situations.

McGRATH is a portable videolaryngoscope that provides excellent laryngoscopic views in patients with normal airways and patients in whom direct laryngoscopy is difficult or fails [15]. While AWS provides only an indirect view of the glottis, McGRATH provides both direct and indirect views. There are several reports on the utility of these devices for airway management during resuscitation.

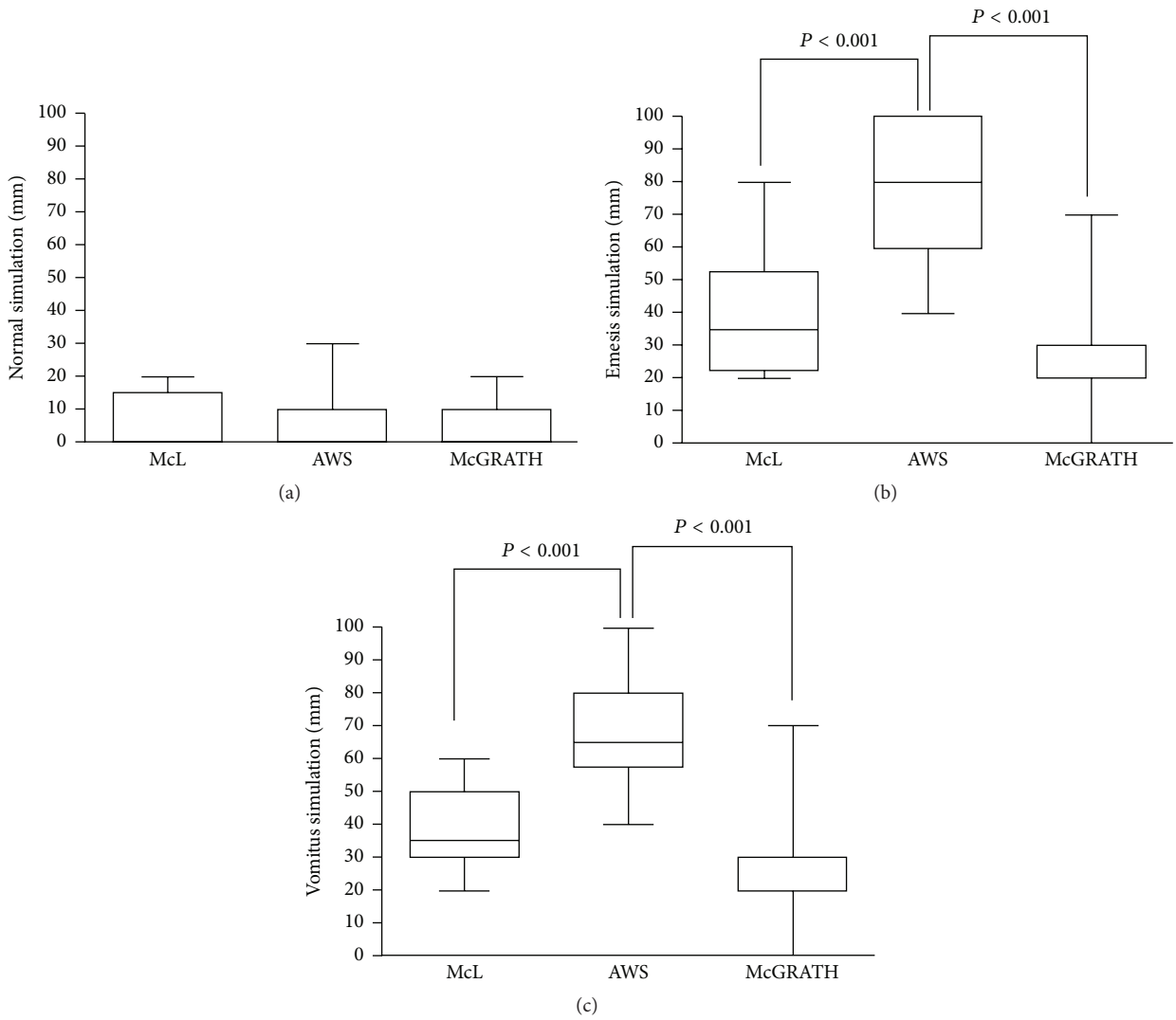

Figure 3: Box-and-whisker plot (median, IQR, and range) of visual analog scale scores for difficulty of simulated tracheal intubation in hematemesis and vomitus settings using each laryngoscope. (a) Normal setting, (b) hematemesis setting, and (c) vomitus setting. Results are expressed as means ± SDs and were analyzed using one-way analysis of variance. AWS, Pentax-AWS Airwayscope; McGRATH, McGRATH MAC; McL, Macintosh laryngoscope.

The present study found that the intubation time with AWS was significantly longer in the vomitus and hematemesis settings than in the normal setting, accompanied by a significant intubation success rate difference. In contrast, the intubation time did not significantly increase with McL and McGRATH. Only one or two participants failed in the hematemesis setting and all anesthesiologists were successful in intubating in the vomitus settings with McL or McGRATH. One probable reason for the difficulties experienced with AWS is that the video monitor is severely disturbed by vomitus and hematemesis. In contrast, as McGRATH can provide not only an indirect video monitor view but also a direct laryngeal view, participants could perform definite tracheal intubation, even in vomitus and hematemesis settings. Furthermore, because McGRATH provides a better laryngeal view compared with the conventional McL [15], it may be useful for emergent tracheal intubation in vomitus and hematemesis settings.

This study has several limitations. First, intubation was performed on a manikin, which leads to shorter airway intervention times than those required for actual patients [16, 17]. Second, the use of these three devices may be less than ideal in patients with difficult airways, such as those with a severely restricted mouth opening or a small jaw. Third, the simulations do not account for other factors related to resuscitation, such as chest compression and cervical stabilization [18]. Finally, the homogeneity of hematemesis and vomitus cannot completely simulate clinical situations.

For future directions, there is a controversy whether securing the airway using tracheal intubation is the best way of airway management during out-of-hospital cardiac arrest [7, 19]. Thus, in the next study, it may be interesting to evaluate

the efficacy of supraglottic devices such as laryngeal mask, laryngeal tube, or combitube for airway management in the hematemesis or vomitus settings.

5. Conclusion

Within the limitations of our study, we conclude McGRATH and McL can show superior performance compared with AWS for tracheal intubation in adults with vomitus or blood in the pharynx. Future studies examining accumulated evidence of clinical experiences and randomized trials of McL, AWS, and McGRATH in actual patients with hematemesis or vomitus are required to clarify the findings of this simulation study.

Abbreviations

CPR:	Cardiopulmonary resuscitation
ERC:	European Resuscitation Council
AWS:	Pentax-AWS Airwayscope
McGRATH:	McGRATH MAC
McL:	Macintosh laryngoscope.

Conflict of Interests

The authors have no affiliation with the manufacturers of any of the devices described in the paper and declare no financial interest in the material described in it. Financial support for the study was provided by our institution and department.

Authors' Contribution

Ryosuke Mihara, Nobuyasu Komasawa, and Sayuri Matsunami were involved in the study design, study implementation, data analysis, and paper preparation. Toshiaki Minami was involved in the study design and paper preparation.

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Clinical Study

Comparison of Pressure Changes by Head and Neck Position between High-Volume Low-Pressure and Taper-Shaped Cuffs: A Randomized Controlled Trial

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The present study compared changes in cuff pressure by head and neck position between high-volume low-pressure (HVLP) and taper-shaped (taper) cuffs in a prospective randomized clinical trial. *Methods*. Forty patients were intubated using tracheal tubes with either HVLP ($n = 20$; HVLP group) or taper-shaped ($n = 20$; Taper group) cuffs. Initial cuff pressure was adjusted to 15, 20, or 25 cmH_2O in the neutral position. Cuff pressure was evaluated after changing the head and neck positions to flexion, extension, and rotation. *Results*. Cuff pressure significantly increased with flexion in both HVLP and Taper groups at all initial cuff pressures. It significantly increased with extension in the HVLP group, but not in the Taper group. Cuff pressure did not significantly differ with rotation in either group and was significantly smaller in the Taper group during flexion and extension than in the HVLP group, regardless of initial cuff pressure. *Conclusion*. Cuff pressure changes with head and neck flexion and extension were smaller in the Taper group than in the HVLP group. Our results highlight the potential for taper cuffs to prevent excessive cuff pressure increases with positional changes in the head and neck. This trial is registered with UMIN000016119.

1. Introduction

The safety margin of tracheal tube cuff pressure lies between excessive and insufficient pressure. Specifically, insufficient pressure can lead to air leakage, which lessens the effect of mechanical ventilation and results in the leakage of inhalation anesthetics [1], while excessive pressure can cause serious injury and affect blood flow to the tracheal mucosa, resulting in tracheal stenosis, fistula, or tracheal rupture [2, 3]. Movement of the head and neck and the resulting displacement of the tracheal tube can alter cuff pressure [4].

Cuff shape design has advanced substantially in recent years. For example, the taper-shaped cuff was developed with a cylindrical shape to seal the trachea better than existing cuffs such as the high-volume low-pressure (HVLP) cuff [5, 6].

We hypothesized that the taper-shaped cuff would prevent cuff pressure changes due to head and neck position changes more effectively than the HVLP cuff. To this end, we compared cuff pressure increases with different head and neck positions between the HVLP and taper-shaped cuffs in a prospective randomized controlled trial.

2. Methods

The Research Ethics Committee of Osaka Medical College approved this study. Figure 1 shows the CONSORT flowchart for participant recruitment. This study was registered in the UMIN Clinical Trials Registry (registration number: UMIN000016119). From January to April 2015, eligibility was assessed for 50 patients, of whom two refused and eight were excluded in accordance with the eligibility criteria. After obtaining written informed consent, 40 patients aged 20 to 75 years who were to undergo general anesthesia in a supine position were randomly assigned (envelope method) to one of two groups: intubation by a tracheal tube with the HVLP

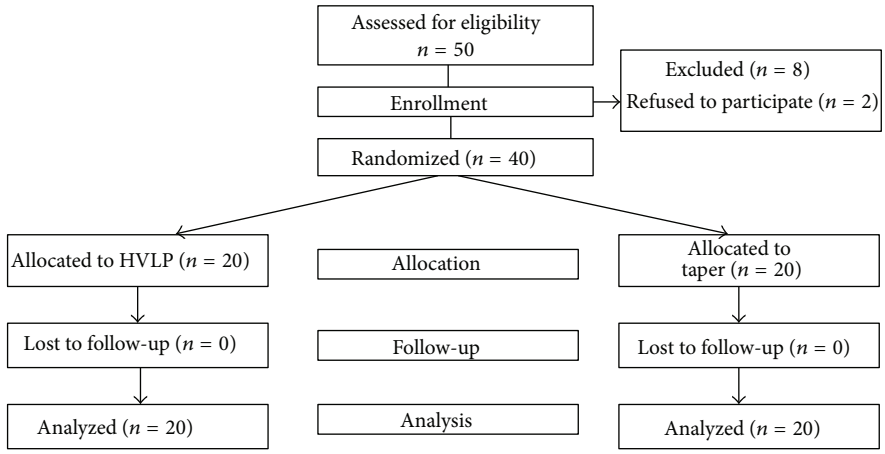

Figure 1: CONSORT flowchart for patient recruitment.

cuff (HVLP group, 20 patients) or the taper-shaped cuff (Taper group, 20 patients). Exclusion criteria were morbid obesity defined by a body mass index >35, cervical disease or cervical movement restriction, gastroesophageal reflux, previous upper abdominal surgery, and a recent (within seven days) history of upper respiratory tract infection [7].

Percutaneous oxygen saturation, noninvasive blood pressure, heart rate, electrocardiography, and end-tidal carbon dioxide tension were monitored for each patient [7]. Without any premedication, anesthesia was induced with a bolus infusion of propofol 1-2 $mg \cdot kg^{-1}$ and remifentanil 0.3–0.5 $\mu g \cdot kg^{-1} \cdot min^{-1}$. Rocuronium 0.8–1.0 $mg \cdot kg^{-1}$ was administered as a muscle relaxant. Anesthesia maintenance was performed with continuous inhalation of sevoflurane, and no nitrous oxide was used. A McL blade of either size 3 or size 4 was used according to the anesthesiologist's preference. Anesthesiologists performed intubation using a tracheal tube with a HVLP cuff (Portex Soft Seal, Smith Medical Co., Ltd., Kent, UK) or taper-shaped cuff (Mallinckrodt TaperGuard, Covidien, Dublin, Ireland) according to the randomization. The shapes of the cuffs are shown in Figure 2. The size of the tracheal tube was determined by the anesthesiologist based on the formula of height/20 mm to standardize study conditions. The number of intubation trials and Cormack's classification were assessed. The tip of the tracheal tube was placed about 2 cm into the trachea and fixed at the center of the mouth with cohesive tape Durapore [8]. Mechanical ventilation was performed in a volume-controlled manner at a rate of 10–12 mL/kg and 8–10 times/min.

Cuff pressure adjustments and measurements were performed with an automated cuff pressure controller (Mallinckrodt Pressure Control, Covidien, Dublin, Ireland), which is accurate to 1 decimal place, according to the manufacturer. The cuffs were initially inflated to a pressure of 15, 20, or 25 cmH_2O. The head and neck were placed in the neutral position, such that the external ear canal is level with the top of the shoulder and the ear-eye line (from the external ear canal to the superior orbital margin) is vertical, and then repositioned randomly in the following positions: maximal extension, maximal flexion (about 45 degrees), or maximal rotation (about 70–90 degrees) to the right. Cuff pressure

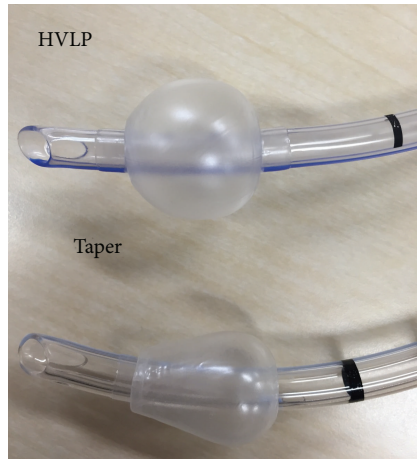

Figure 2: Shapes of high-volume low-pressure (HVLP) and taper-shaped (taper) cuffs.

was recorded by an independent observer in each position. We measured cuff pressure changes at the expiratory pauses for roughly 30 seconds at each position. After each cuff pressure measurement, the participant was returned to a neutral position. All participants experienced three initial cuff pressures for neutral, flexion, extension, and rotation, for a total of 12 patterns [9].

Statistical analysis was performed using JMP 11 (SAS Institute Inc., Cary, NC, USA). A two-way repeated measures analysis of variance was used to compare cuff pressure changes. Data are presented as either mean ± standard deviation or median ± interquartile range. $P < 0.05$ was considered statistically significant.

Sample size calculation was based on data from five participants in a pilot study in which cuff pressures were measured in the four flexion positions. The largest difference in mean oropharyngeal leak pressure between the positions was 4 ± 4.9 cmH_2O. Eighteen patients were needed to detect a difference in oropharyngeal leak pressures between positions with a type I error of 0.05 and a power of 0.8. Hence, 20

Table 1: Patient characteristics of each group presented as mean ± SD or number of patients. HVLP group: trachea was secured with a high-volume and low-pressure cuffed tracheal tube; Taper group: trachea was secured with taper cuffed tracheal tube.

	HVLP group $N = 20$	Taper group $N = 20$
Age (years)	61.8 ± 12.9	64.9 ± 12.7
Gender (male/female)	10/10	10/10
Body weight (kg)	59.4 ± 13.7	57.3 ± 7.9
Height (cm)	161.6 ± 7.5	159.5 ± 9.9
BMI (kg/m^2)	22.6 ± 4.6	22.5 ± 2.5
Mallampati score (1/2/3/4)	8/11/1/0	7/12/1/0
Cormack-Lehane grade (1/2/3/4)	11/8/1/0	9/11/0/0
Tracheal tube size (7.0/7.5/8.0/8.5)	2/11/6/1	3/7/8/2

BMI: body mass index.
ASA: American Society of Anesthesiologists.

Table 2: Cuff pressure changes by head and neck position with HVLP and taper-shaped cuffs. HVLP group: trachea was secured using a tracheal tube with a high-volume low-pressure cuff; Taper group: trachea was secured using a tracheal tube with a taper-shaped cuff. Data are presented as median [interquartile range]. $^*P < 0.05$.

(a) Initial cuff pressure 15 cmH_2O

	Flexion	Extension	Rotation
HVLP	5.3 [3.9–7.7]	3.4 [2.4–4.2]	0.3 [−0.8–1.1]
Taper	2.6 [1.5–3.5]	0.2 [−0.2–0.4]	0.1 [−0.7–0.6]
P value	<0.001*	<0.001*	0.41

(b) Initial cuff pressure 20 cmH_2O

	Flexion	Extension	Rotation
HVLP	8.4 [7.6–9.4]	4.7 [3.9–5.4]	0.4 [−0.4–1.2]
Taper	5.4 [4.0–6.5]	0.9 [0.4–1.8]	−0.6 [−1.5–0.4]
P value	<0.001*	<0.001*	0.12

(c) Initial cuff pressure 25 cmH_2O

	Flexion	Extension	Rotation
HVLP	10.3 [8.5–13.1]	5.0 [2.7–7.0]	−0.1 [−0.4–0.5]
Taper	4 [2.6–5.3]	0.5 [−0.4–1.4]	0.1 [−1.0–0.9]
P value	<0.001*	<0.001*	0.91

patients were enrolled in this study in order to allow for any methodological difficulties that could lead to exclusion from the study.

3. Results

Patient characteristics are summarized in Table 1. None of the patients were lost to follow-up during the trial.

3.1. Cuff Pressure Changes according to Changes in Head and Neck Positions for the HVLP and Taper Groups. Table 2 shows the cuff pressure changes according to initial cuff pressures. During flexion and extension, cuff pressure changes were significantly higher in the HVLP group than in the Taper group, regardless of initial cuff pressure ($P < 0.001$ for both flexion and extension). In contrast, cuff pressure changes did not differ significantly between the two cuff types during rotation, regardless of initial cuff pressure.

3.2. Cuff Pressure as Affected by Head and Neck Position in the HVLP and Taper Groups. Figure 3 shows changes in cuff pressure by head and neck position at the three initial cuff pressures. Cuff pressure significantly increased with flexion in both HVLP and Taper groups at initial cuff pressures of 15, 20, and 25 cmH_2O. Cuff pressure significantly increased with extension in the HVLP group, but not in the Taper group, regardless of initial cuff pressure. Cuff pressure did not significantly change with rotation in both HVLP and Taper groups. Cuff pressure in the Taper group was significantly smaller during flexion and extension than in the HVLP group, regardless of initial cuff pressure.

3.3. Number of Patients for Whom Cuff Pressure Exceeded 30 cmH_2O. At an initial cuff pressure of 20 cmH_2O, cuff pressure exceeded 30 cmH_2O for 5 patients in the HVLP group; this was not observed for any patients in the Taper group ($P < 0.001$). At an initial cuff pressure of 25 cmH_2O, cuff pressure exceeded 30 cmH_2O in 18 patients in the HVLP group and in 6 patients in the Taper group during flexion ($P < 0.001$). During extension, this was also observed in 10 patients in the HVLP group, but not in any patients in the Taper group ($P < 0.001$).

4. Discussion

Tracheal intubation during general anesthesia is essential for procedures that require changes in head and neck position. For example, sufficient extension of the neck is needed for thyroid or otolaryngology surgery, while neck flexion is often required for cervical spine, plastic, and cerebral surgery. Since head and neck movement changes the shape of the pharynx or compresses the trachea, cuff pressure management is important for preventing tracheal stenosis, necrosis, and postoperative pharyngeal pain [10, 11].

Introduction of a cuffed endotracheal tube with improved tracheal sealing characteristics over existing cuffed tubes may encourage the regular use of these tubes in the clinical setting. The pressure exerted by HVLP cuffs, popularized in the 1970s, is almost equal to the cuff inflation pressure. HVLP cuffs can be used for positive pressure ventilation with a cuff inflation pressure of less than 30 cmH_2O [12]. In this study, cuff pressure exceeded 30 cmH_2O in roughly 90% of patients during flexion and in 50% during extension, at an initial cuff pressure of 25 cmH_2O, demonstrating the potential inherent risk of increased cuff pressure leading to tracheal wall ischemia by using HVLP cuffs.

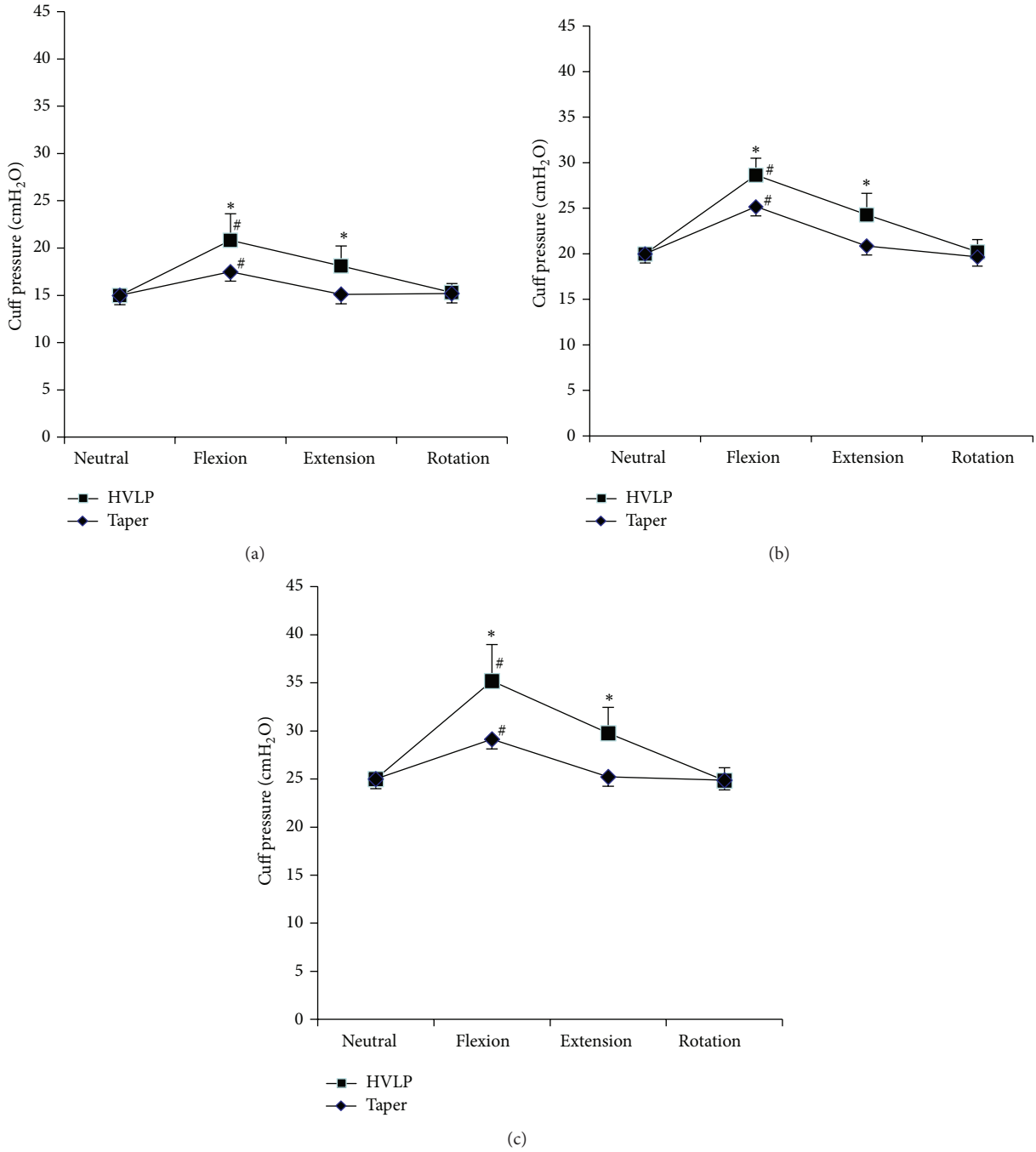

Figure 3: Cuff pressure by head and neck position with HVLP and taper cuffs. HVLP group: trachea was secured using a tracheal tube with a high-volume low-pressure cuff; Taper group: trachea was secured using a tracheal tube with a taper-shaped cuff. $^{*}P < 0.05$ compared to taper. $^{\#}P < 0.05$ compared to neutral position. (a) Initial cuff pressure of 15 cmH_2O, (b) initial cuff pressure of 20 cmH_2O, and (c) initial cuff pressure of 25 cmH_2O.

The taper, a newly developed endotracheal tube, has a cylindrical cuff that seals the trachea better than existing endotracheal tubes. This tube is shaped for effective prevention of leakage via longitudinal folds. Previous studies have assessed the sealing ability of taper-shaped cuffs using water or viscous fluids in adult airway simulation models [13, 14]. Our study revealed that the taper had significantly smaller cuff pressure increases during flexion or extension relative to those observed when using the HVLP. Moreover, cuff pressure exceeded 30 cmH_2O in only 30% of patients during flexion.

We found that cuff pressure with flexion was significantly smaller in the Taper group compared to the HVLP group, regardless of initial cuff pressure, and that cuff pressure

increased with flexion and extension in the HVLP group. In the Taper group, cuff pressure increased significantly with flexion but did not increase with extension or rotation. The cuff pressure was also significantly smaller in the Taper group than in the HVLP group with flexion and extension at all initial cuff pressures. We surmise that the taper prevents excessive cuff pressure increases when changes occur in head and neck positioning. One probable reason for the differences observed between the taper-shaped and HVLP cuffs may be differences in the cuff attaching area [15]. Since the area of the cuff that attaches to the tracheal wall is smaller with taper-shaped cuffs than with HVLP cuffs, the attachment pressure of taper-shaped cuffs may be higher than with HVLP cuffs under the same cuff pressure. Given these advantages and the cylindrical shape, taper cuffs are expected to reduce the incidence of excessive cuff pressure increases.

Notably, we did not observe any cuff pressure increases with rotation in either the HVLP or the taper, which differed from other study findings [4]. This inconsistency may be partially due to anatomical differences between children and adults. While the tracheal tube may rotate smoothly in the trachea and not elicit pressure changes in adults, pediatric tracheal tube cuffs can become compressed even by head rotation.

The present study has a number of limitations. Data were collected by unblinded observers. Blinding was unrealistic in this study because the position of the head and neck was difficult to hide from the observer who recorded the data [16]. However, the measured variables in this study were clearly defined. Thus, the lack of blinding is unlikely to have skewed our results. Second, as this study was conducted at a single institute, a large-scale multicenter study or meta-analysis will be needed to clarify the utility of taper-shaped cuffs for use in situations involving changes in head and neck position [17].

In conclusion, we demonstrated that changes in cuff pressure with head and neck flexion and extension were smaller in the Taper group than in the HVLP group. Our results highlight the potential for taper cuffs to help prevent excessive cuff pressure increases upon changes in head and neck position.

Conflict of Interests

The authors declare no conflict of interests regarding the publication of this paper.

Authors' Contribution

Nobuyasu Komasawa and Ryosuke Mihara contributed to the study design, study implementation, data analysis, and paper preparation. Kazuo Hattori and Kentaro Imagawa contributed to the study design, data collection, data analysis, and paper preparation. Toshiaki Minami contributed to the study design and paper preparation. All authors discussed the results and approved the final paper.

Acknowledgments

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Review Article

Respiratory Strategies and Airway Management in Patients with Pulmonary Alveolar Proteinosis: A Review

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Background. Pulmonary alveolar proteinosis is a rare disorder characterized by a large accumulation of lipoproteinaceous material within the alveoli. This causes respiratory failure due to a restriction of gas exchange and changes in the ventilation/perfusion ratio. Treatment methods include noninvasive pharmacological approaches and invasive procedures, such as whole-lung lavage under general anesthesia. *Methods*. Based on the literature search using free-term key words, we have analyzed published articles concerning the perioperative management of adult and pediatric patients with pulmonary alveolar proteinosis. *Results and Discussion*. In total, 184 publications were analyzed. Only a few manuscripts were related to anesthetic, respiratory, and airway management in patients suffering from pulmonary alveolar proteinosis. Airway should be strictly separated using a double-lumen tube. Respiratory strategies involve the use of manual clapping, continuous positive airway pressure, high-frequency jet ventilation of the affected lung, and employment of venovenous extracorporeal membrane oxygenation in the most serious of cases. *Conclusion*. The goal of this review is to summarize the current published information about an anesthetic management strategy with a focus on airway management, ventilation, and oxygenation techniques in PAP patients.

1. Introduction

Pulmonary alveolar proteinosis (PAP) is a rare disorder first described by Rosen and colleagues in 1958 [1]. This disease is characterized by an accumulation of phospholipoproteinaceous material inside the alveoli due to a disruption in surfactant homeostasis. The prevalence of PAP is estimated to be around 4 cases per 1 million. Male gender, smokers, and adults between 30 and 50 years are most commonly affected. The symptoms due to a restriction in gas exchange and changes in the ventilation/perfusion ratio include shortness of breath (dyspnea), cough, and, in one-third of cases, also nail clubbing. The disease course may be complicated by opportunistic bacterial and fungal infections. There is a variable interindividual progression of this disease which can range from spontaneous recovery to terminal cardiorespiratory failure. Diagnosis is based on the findings from bronchoalveolar lavage (BAL), histology, and immunohistochemical tests and on the presence of granulocyte-macrophage colony stimulating factor (GM-CSF) antibodies and computed tomography (CT) or high resolution computed tomography (HRCT) results which typically shows areas of patchy ground-glass opacification and interlobular thickening which together produce the characteristic, "crazy paving pattern" [2, 3]. PAP can also occur as an acquired disease (primary or idiopathic PAP), characterized by the production of GM-CSF antibodies, which is therefore autoimmune in origin. Congenital forms of PAP are less frequent and they are caused by a mutated gene responsible for surfactant production or by a mutated receptor for GM-CSF. Secondary forms of PAP are associated with other illnesses, mainly hematooncological diseases, exposure to inorganic materials (e.g., silicone), or caused by side-effects of medication, such as immunosuppressive drugs or amiodarone. Rarely, PAP can be a part of the acquired immune deficiency syndrome (AIDS) [4].

2. Therapeutic Approaches

There are two possible methods of the treatment of PAP depending on the etiology and severity of respiratory difficulties. Congenital, primary (idiopathic), and mild forms of PAP characterized by sufficient spontaneous breathing may be treated using a noninvasive, medical approach [4, 5]. The GM-CSF substitution is applied subcutaneously or inhalationally; other methods include biological treatment with monoclonal antibodies, plasmapheresis, or hyperbaric oxygen therapy [5]. Acquired or severe cases are associated with impairment of ventilation, dyspnea, development of severe hypoxemia, and hypercapnia and in these cases the only plausible treatment is lung lavage. In bronchoalveolar lung lavage, the lungs are flushed out with large quantities of saline. This procedure can be performed on individual lung segments, on lobes or on the whole lung with the option for longer periods between each lavage treatment. Whole-lung lavage (WLL) has been described as the most effective method of treatment [5–7]. The ultimate treatment for PAP is lung transplantation. Some published case reports suggest a successful treatment plan starting with WLL and continuing to GM-CSF application and/or other pharmacological treatment [5]. The first segmental washout was performed in 1963 by Ramirez et al. [8] and over the following five decades this procedure has been refined through the routine use of general anesthesia (GA) [4, 8], increasing lavage volumes and the use of warm saline and additional concomitant chest percussion and bilateral sequential WLL in the same treatment session [4]. In extreme situations, oxygenation can be supported using extracorporeal oxygenation (ECMO) [9]. In spite of the superiority of WLL as an interventional therapy for PAP, this procedure has not been yet standardized: it is not yet clear whether saline is superior to other solutions that are used, and each medical centre modifies its own practice [4].

3. Anesthetic, Respiratory, and Airway Management

Since 1965, WLL is routinely provided under general anesthesia (GA). GA presents a challenge due to the preexisting respiratory failure (with PaO_2 being commonly lower than 6 kPa on room air) and the limited functional reserve of PAP patients [5, 6]. Anesthesiologists can take advantage of short acting anesthetics with the minimum of side-effects, analgesics, which are well tolerated by the patient, and reliable neuromuscular blockade recovery agents, which are all available for routine use in the operating theatre. Application of total intravenous anesthesia (TIVA) is recommended in these patients as it does not require the uptake of volatile anesthetics by the affected lungs and it enables the accurate conduction of GA during WLL [10]. Routine monitoring should include electrocardiography (ECG), invasive arterial blood pressure (IABP) measurement, and peripheral blood saturation (SpO_2). Central venous line can be useful in blood gases analysis, intravascular volume assessment, and inotropic and vasoactive drugs administration. The CVP measures during pouring and draining the fluid in lateral position have limited value. Insertion of permanent urinary catheter with a temperature probe is recommended in procedures exceeding 4 hours. Point-of-care testing (POCT) of blood gases, sodium, potassium, chloride, magnesium, and osmolarity is recommended. Patients undergoing WLL can become hypothermic during these long procedures and therefore the appropriate management of body temperature is beneficial [11]. We also recommend transesophageal echocardiography (TEE) assessment prior to this procedure to evaluate cardiac function and during WLL for assessment of the lung tissue [12]. The manipulating TEE probe can move the DLT; therefore, immobilizing and fastening both the DLT and the probe are recommended. Based on our experience, PAP patients can suffer from pulmonary hypertension and symptoms of long-term right heart failure with an impact on left ventricular function. During WLL, an unpredictable volume of saline can be absorbed which may also overload the circulation.

3.1. Airway Management. Separation/isolation of lungs using double-lumen endotracheal tubes (DLT) for selective lavage of each lung and ventilation of the "dry" lung are necessary together with flexible bronchoscopy to confirm appropriate tube placement [11]. The use of double-lumen fiberoptic tubes (Vivasight ETView) have no superiority because bronchoscopic control of the lung tissue should be done by pneumologists prior to WLL. We have found that the optical lens can get smudgy immediately after the first wash cycle, thus becoming unusable for the remainder of the procedure.

Several case reports have described the use of serial lobar lavages with the use of a flexible bronchoscope together with endobronchial intubation of the healthy lung [13]. Davis et al. reported serial lavage in an awake patient under local anesthesia only [14].

Techniques for anesthetic management for WLL in children with PAP are determined by their age, weight, and severity of the disease. Pediatric airway management for WLL differs slightly from those techniques used in adults. Cuffed double-lumen tubes may be used for adolescents and school-age children. The smallest size of cuffed double-lumen tube which is available on the market has a diameter of 8.7 mm (26 F) [10]. This size may be used for pediatric patients older than 8 years of age [15]. Airway management techniques for younger children are usually very challenging. These include insertion of two separate narrow cuffed tracheal tubes inserted alongside into each bronchus or one of them endobronchially and the other one endotracheally [10, 16], insertion of a cuffed endobronchial tube into the healthy lung, with the lavage being performed with a flexible fibrescope inserted alongside into the other lung, and insertion of a standard cuffed tracheal tube with a cuffed bronchial blocker inserted into the affected main bronchus and the lavage performed via a gastric tube inserted alongside the bronchial blocker [17].

A special Marrano double-lumen tube which is available for smaller children cannot be used for WLL. This tube is uncuffed and therefore cannot protect the ventilated lung [10]. Neonates and infants undergoing WLL for pulmonary alveolar proteinosis are routinely managed with an endotracheal tube sitting above the carina and pulmonary artery

flotation catheter inserted into the mainstem bronchus of the affected lung. The balloon of the catheter is then inflated and the lung is lavaged through it [18].

Some centers use the support of venovenous extracorporeal oxygenation (v-v ECMO) in the most difficult pediatric patients [19, 20]. Alternatively, WLL utilizing cardiopulmonary bypass (CPB) can be used in small children with severe form of PAP to support ventilation during lavage [17].

3.2. Respiration and Ventilation. Volume-controlled ventilation is preferred due to the higher rigidity and lower compliance of the affected lungs. Pressure-controlled modes would not guarantee the adequate ventilation. PAP patients suffer from hypercapnia and further elevation of CO_2 partial pressure could affect microcirculation (the risk of brain oedema) and could provoke arrhythmias. The tidal volumes for each lung vary according to the condition of the pulmonary tissue, usually 200–350 mL at a rate of 12–16 breaths per minute in adults. In children, a sophisticated ventilatory regimen is not available due to the differences in age-based physiology and the degree to which the pulmonary tissue is affected [10, 12, 17]. The adjustment of end-tidal PCO_2 or better $PaCO_2$ (due to a restriction of gas exchange and changes in the ventilation/perfusion ratio in PAP) is recommended [21, 22]. Positive end-expiratory pressure is usually set between 5 and 7 cmH_2O. The FiO_2 in the inspired gas mixture is adjusted according to PaO_2 values, with fractions higher than 0.6 often required [6, 12]. In one case report, the authors applied continuous positive airway pressure (CPAP) ventilation into the washed lung, aiming to improve oxygenation [23]. Manual clapping performed by a respiratory physiotherapist during WLL can help to clear out the protein-rich alveolar material from the affected lung tissue [24]. This technique has been found to be superior to mechanical chest percussion or to WLL without any chest percussion. Several case reports have described the successful perioperative use of a novel system for clearance of the airway secretions in patients with PAP. The vest employs complex technology in which increased airflow velocities are generated, thus creating shear forces similar to spontaneous coughing while simultaneously reducing viscosity of secretions including the lavaged material [25, 26]. Oxygenation in the most severely affected adult and pediatric patients may be achieved with the aid of extracorporeal oxygenation techniques, v-v ECMO, or even full cardiopulmonary bypass (CPB), regardless of the risk of significant morbidities [10, 17].

Other methods supporting ventilation and oxygenation during this procedure have been tested only in experiments. Partial liquid ventilation (PLV) using perflubron improved oxygenation only temporarily and had no positive effect on protein removal in an infant with PAP scheduled for WLL [27]. Hyperoxygenated saline solution was found to improve oxygenation in five patients undergoing WLL for PAP in comparison with normal saline [28].

The duration of WLL is usually several hours and the accumulated phospholipoproteinaceous material is washed out of the lungs with 0.5–2.0 L of body temperature warmed saline in aliquots for 10–30 wash cycles per each lung. The total volume of saline can reach 30 liters [11, 29]. The patient must be positioned step by step into the right decubitus position and subsequently onto the left side according the protocol recommended by the American College of Chest Physicians in 2009 [11]. The aliquots of saline are subsequently loaded into the inferiorly placed lung following 4–6 minutes of percussion postural massage of the chest wall with the aim of evacuating the maximal amount of accumulated material. Afterwards, the effluent is drained with the help of gravity by placing the patient into the Trendelenburg position ("head down"). This procedure has to be repeated until the rinsed fluid is clear. The same algorithm is applied to the other lung [11, 12]. The volume of solution is essential. If the volume of solution was high enough, pulmonary blood flow shifts to the ventilated lung, and as a result the oxygenation improved. This shift of blood flow became smaller during the drainage phase, and oxygenation became worse. The nature is the hypoxemic pulmonary vasoconstriction effect and the bypassing of the affected lung. The adequate volume also facilitates effectiveness of the WLL. Validated data about the absorbed volume of saline is missing in the published cases. Extensive suction of the residual solution is required for the better oxygenation after procedure. The amount of chloride absorbed has not also been evaluated in any published report. We noted the development of significant facial soft tissue oedema during WLL as a possible result of absorption of electrolytes into the third space. The WLL procedure can be accompanied by derangements of acid-base

and electrolyte balances or hypervolemia. The type of crystalloid to be used in this procedure has not yet been standardized. Therefore, hourly electrolyte assessment can be recommended in WLL cases with extensive NaCl lavage considerations. Derangement of the electrolyte homeostasis causing cardiac arrhythmias might be avoided using Ringer's solution [30].

3.3. Management of Severe PAP. Whole-lung lavage can also be performed with ECMO or CPB support in adult and pediatric patients. The decision depends on the severity of clinical symptoms [31]. Most commonly, the cannulae used in v-v ECMO are placed such that the infusion cannula is inserted in the right internal jugular vein and the drainage cannula in the right femoral vein [32]. In the case of heart failure, it is possible to choose venoarterial ECMO [33]. Cannulae for venoarterial ECMO are then placed using either a percutaneous or surgical technique. In the literature, there is a case of WLL and lung resection being performed simultaneously, although the operation was complicated by cardiac arrest due to hypoxia. After successful CPR, the procedure was continued with the support of v-v ECMO [34]. Adequate oxygenation with the support of ECMO allowed the completion of the procedure and prevented cardiac arrhythmias and hemodynamic instability. It also avoided the complications that may occur in the interval from the end of procedure to the restoration of the lung tissue with traditional techniques of mechanical ventilation [9, 31]. v-v ECMO cannulation is an invasive technique with many possible complications such as bleeding, arterial puncture, vessel rupture, or development of pseudoaneurysms. WLL may be also complicated by pneumothorax. However, it

remains the only possible technique that prevents serious hypoxia during WLL. Even when taking into account all of the risks connected with WLL and v-v ECMO support, this technique is very effective [32, 35].

4. Conclusions

This review has aimed to present an anesthetic management strategy with a focus on airway management, ventilation, and oxygenation techniques for easier perioperative decision-making in patients scheduled for whole-lung lavage under general anesthesia due to pulmonary alveolar proteinosis. Further prospective studies or larger cohort studies are needed to obtain more robust data from which it is hoped that further guidelines could arise.

Abbreviations

AIDS:	Acquired immunodeficiency syndrome
BAL:	Bronchoalveolar lavage
CPAP:	Continuous positive airway pressure
CT:	Computed tomography
ECMO:	Extracorporeal membrane oxygenation
GA:	General anesthesia
GM-CSF:	Granulocyte-macrophage colony stimulating factor
HRCT:	High resolution computed tomography
PAP:	Pulmonary alveolar proteinosis
PEEP:	Positive end-expiratory pressure
POCT:	Point-of-care testing
TEE:	Transesophageal echocardiography
TIVA:	Total intravenous anesthesia
VCV:	Volume-controlled ventilation
v-v ECMO:	Venovenous extracorporeal membrane oxygenation
WLL:	Whole-lung lavage.

Conflict of Interests

The authors declare that there is no financial, personal, and nonfinancial conflict of interests.

Authors' Contribution

Tomas Vymazal has made substantial contributions to conception and design and analysis and interpretation of data, has been involved in drafting the paper and revising it critically for important intellectual content, and has given the final approval of the version to be published. He agrees to be accountable for all aspects of the work, ensuring that the questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Martina Krecmerova has made substantial contributions to conception and design, acquisition, analysis, and interpretation of data, has been involved in drafting the paper, or revising it critically for important intellectual content. She agrees to be accountable for all aspects of the work, ensuring that the questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Research Article

Utility of a Gum-Elastic Bougie for Difficult Airway Management in Infants: A Simulation-Based Crossover Analysis

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Background. Direct laryngoscopy with the Miller laryngoscope (Mil) for infant tracheal intubation is often difficult to use even for skilled professionals. We performed a simulation trial evaluating the utility of a tracheal tube introducer (gum-elastic bougie (GEB)) in a simulated, difficult infant airway model. *Methods.* Fifteen anesthesiologists performed tracheal intubation on an infant manikin at three different degrees of difficulty (normal [Cormack-Lehane grades (Cormack) 1-2], cervical stabilization [Cormack 2-3], and anteflexion [Cormack 3-4]) with or without a GEB, intubation success rate, and intubation time. *Results.* In the normal and cervical stabilization trials, all intubation attempts were successful regardless of whether or not the GEB was used. In contrast, only one participant succeeded in tracheal intubation without the GEB in the anteflexion trial; the success rate significantly improved with the GEB ($P = 0.005$). Intubation time did not significantly change under the normal trial with or without the GEB (without, 12.7 ± 3.8 seconds; with, 13.4 ± 3.6 seconds) but was significantly shorter in the cervical stabilization and anteflexion trials with the GEB. *Conclusion.* GEB use shortened the intubation time and improved the success rate of difficult infant tracheal intubation by anesthesiologists in simulations.

1. Background

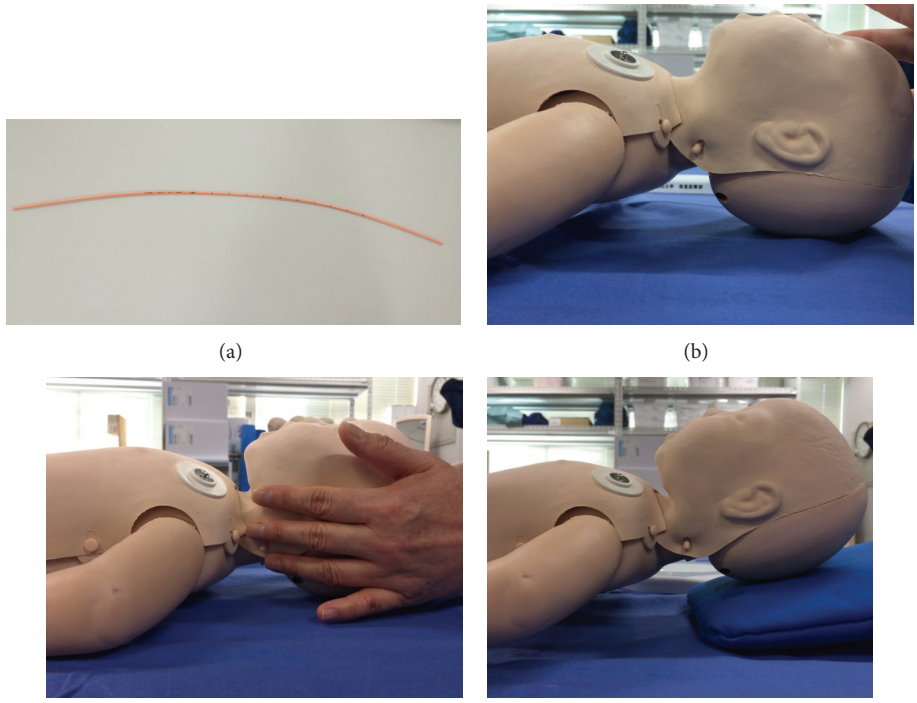
Difficulty with airway management in pediatric patients is a major reason for cardiac arrest, brain injury, and death [1, 2]. Fewer studies have been conducted regarding difficult pediatric airway management, particularly in infants, compared to adult studies. Although several videolaryngoscopes and supraglottic devices have been developed for infants [3, 4], direct laryngoscopy with the Miller laryngoscope (Mil) remains the most widely used technique for infant tracheal intubation. However, tracheal intubation with Mil is sometimes difficult due to its suboptimal laryngoscopy view [5].

The gum-elastic bougie (GEB), a tracheal tube introducer, is commonly used in airway management and its use is recommended by national guidelines at early stages of difficult intubation [6, 7]. Various studies have been published regarding the utility of the GEB for difficult adult airway management, particularly for addressing difficult laryngoscopy situations [8, 9].

Clinical reports and evaluations of infant-size GEBs have yet to be fully validated. Thus, in this study, we compared the utility of the GEB for use by experienced anesthesiologists. As direct clinical evaluations are unethical, we performed validations with manikins. We hypothesized that the GEB would improve intubation in simulated difficult infant airways. To this end, we evaluated the utility of the GEB with respect to ease of tracheal intubation by experienced anesthesiologists on an infant manikin.

2. Materials and Methods

This study was approved by the Research Ethics Committee of Osaka Medical College (number 1321). As the study was not performed on human subjects, the clinical trial registration was not required. In July 2014, we selected 15 anesthesiologists with more than 5 years of clinical experience (12.2 ± 4.0 years) who received simulation training at Osaka Medical College. Written informed consent was obtained prior to the study.



(a) (b) (c) (d)

Figure 1: Gum-elastic bougie and manikins used in the study. (a) 5 Fr gum-elastic bougie, (b) ALS Baby Trainer manikin for the normal trial, (c) ALS Baby Trainer manikin for the cervical stabilization trial, and (d) ALS Baby Trainer manikin for the anteflexion trial.

The ALS Baby Trainer manikin (Laerdal, Stavanger, Norway), designed to accurately represent a three-month-old infant (weight: 11 pounds), was used in this study to simulate tracheal intubation. Intubations were performed using a Mil with a size 1 blade and a tracheal tube (Portex, St. Paul, MN, USA) with an internal diameter of 3.0 mm without a cuff. A 5 Fr tracheal tube introducer (Portex, St. Paul, MN, USA) was used as GEB because there is no infant-size GEB with angle tip commercially available (Figure 1(a)).

The manikin was placed on a flat and hard table and fixed to the table firmly with cohesive tape to prevent movement during laryngoscopy. To simulate difficult laryngoscopy, three trials were designed: normal trial (Cormack-Lehane grades (Cormack) 1-2), manual cervical stabilization (grades 2-3), and anteflexion (approximately 15 degrees; grades 3-4) (Figures 1(b)–1(d)).

The instructor explained to each participant how to intubate the tracheal tube with or without the GEB, attach a ventilation bag, and ventilate the lungs of the manikin. Although all participants had clinical experience with GEB usage, they were given five minutes to practice insertion, with the instructor available to give advice [10].

Participants were instructed to perform tracheal intubation within 60 seconds for each trial. We measured the insertion time from the start-point, that is, when participants took the device in their hands, to the end-point, that is, when they performed ventilation with a respiratory bag following insertion. Ventilation success or failure was determined by a visible chest rise and was judged by the same observer. Intubation times were recorded for both tracheal and esophageal intubations. In cases where participants could not intubate the traceha within 60 seconds, the trial was considered a failure and the intubation time was recorded as 60 seconds.

At the end of the trials, participants rated the difficulty of each trial on a visual analog scale (VAS) from 0 mm (extremely easy) to 100 mm (extremely difficult) for laryngoscopic imaging (VAS-LI) and passage of the tracheal tube through the glottis (VAS-PT) [11].

Results obtained from each trial were compared using two-way repeated measures analysis of variance for intubation time, and the chi-square test for successful ventilation. Data are presented as mean ± SD. $P < 0.05$ was considered statistically significant. This study used a randomized crossover design to minimize the learning-curve effect. The order of intervention was randomized for each participant by a random number table, resulting in a total of six interventions per participant.

Results of a nine-doctor preliminary study showed that the time required for successful intubation in the cervical stabilization trial was approximately 10 ± 4 s. We considered 5 s to be a clinically meaningful difference. Thus, we estimated that 12 participants would be adequate for two independent groups using $\alpha = 0.05$ and $\beta = 0.2$.

3. Results

3.1. Success of Tracheal Intubation. Table 1 shows the number of successful intubations per trial. In the normal and cervical stabilization trials, all intubation attempts were successful with or without the GEB. In contrast, only one participant

Table 1: Number of successful intubations.

	Without GEB (success/total)	With GEB (success/total)	P value
Normal (Cormack 1-2)	15/15	15/15	N.S.
Cervical stabilization (Cormack 2-3)	15/15	15/15	N.S.
Anteflexion (Cormack 4)	1/15	8/15	0.005

Successful intubations with or without the gum-elastic bougie (GEB) in the three trials. Differences were analyzed with the chi-square test.

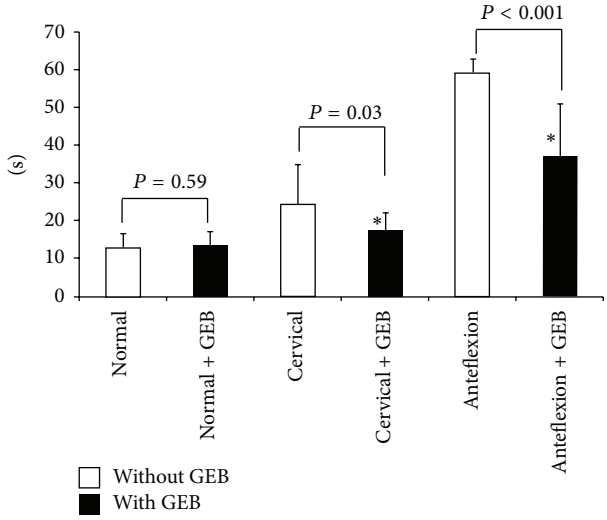


Figure 2: Intubation time with and without the gum-elastic bougie. White box: without GEB; black box: with GEB. Results are expressed as mean ± SD and were analyzed by two-way analysis of variance. NS: no significant difference; $^{*}P < 0.05$ compared to without GEB.

succeeded in tracheal intubation without the GEB in the anteflexion trial; success significantly improved with the GEB ($P = 0.005$).

3.2. Intubation Time. Results for intubation time are shown in Figure 2. Intubation times did not significantly differ with or without the GEB in the normal trial (without GEB, 12.7 ± 3.8 seconds; with GEB, 13.4 ± 3.6 seconds). Intubation time was significantly shorter with the GEB in both the cervical stabilization and anteflexion trials (cervical stabilization: without, 24.2±10.6 seconds; with, 17.4±4.7 seconds; $P = 0.03$; anteflexion: without, 59.0 ± 3.8 seconds; with, 37.2 ± 13.7 seconds; $P < 0.001$).

3.3. VAS for Laryngoscopic Imaging and Tube Passage through the Glottis. VAS-LI and VAS-PT scores are shown in Figure 3. VAS-LI scores did not significantly differ with or without the GEB in the three trials (Figure 3(a)). However, the VAS-LI score of the anteflexion trial was significantly higher than those of the cervical stabilization and normal trials. The VAS-LI score of the cervical stabilization trial was also higher than that of the normal trial.

The VAS-PT score did not significantly differ with or without the GEB in the normal trial. However, VAS-PT scores with the GEB were significantly lower than without GEB in the cervical stabilization and anteflexion trials (Figure 3(b)).

4. Discussion

Respiratory and airway problems are the most frequent causes of perioperative cardiac arrest in infants and children, highlighting the paramount importance of definite airway management [1, 12]. There have been only small evidences about pediatric difficult airway prediction factor, especially in infants [13]. In recent years, although many airway devices have been developed to address difficult intubation situations, most have been used in the context of adults and may not be suitable for pediatric use [14]. Hence, advances in adult airway management are not always transferable to pediatric practice. For example, most infants would not be able to tolerate awake or sedated intubation. Thus, options are limited for securing the infant airway.

Although the most widely used laryngoscope for these situations is the Mil, its difficulty to operate without experience can lead to an unacceptable high incidence of inaccurate intubation [15]. The GEB is a commonly used airway adjunct in intubation and is recommended by several guidelines for use at an early stage in cases of difficult intubation [6, 7]. Evidence from adult patients suggests that anesthesiologists can secure the airway with a high success rate when using the GEB [16].

Our present study demonstrated that intubation time is significantly shortened with the GEB under conditions of cervical stabilization, which simulates Cormack grades 2-3. Our findings suggest that GEB insertion is a simple and effective method for difficult infant airway management. However, in the anteflexion simulations with Cormack grades 3-4, about half of the participants failed in tracheal intubation. When anesthesiologists cannot see the GEB entering the larynx in Cormack grades 3-4, it is important to be able to determine whether the GEB is located in the trachea or esophagus. However, these signs in adults may not be applied to infant cases. Click and hold-up signs are well described in adults using GEB with angled tip. Click signs are apparent in adults and older children if GEB is correctly placed in the trachea [6, 17]. In this study, we used straight tip GEB. We should be careful that click sign can be confirmed in actual infants. Furthermore, hold-up sign will definitely work and is safe on manikin but there are concerns in real infant from the viewpoint of avoiding airway trauma. Thus, clinical evaluation of infant GEB including complications is needed in the future.

This study has several limitations. First, we used a manikin rather than real infants. Manikin simulation cannot mimic certain factors encountered in the clinical setting, such as body temperature, tissue stiffness, or sputum in the oropharynx. Second, though we utilized ALS Baby Trainer as infant simulator, more sophisticated or high-fidelity one

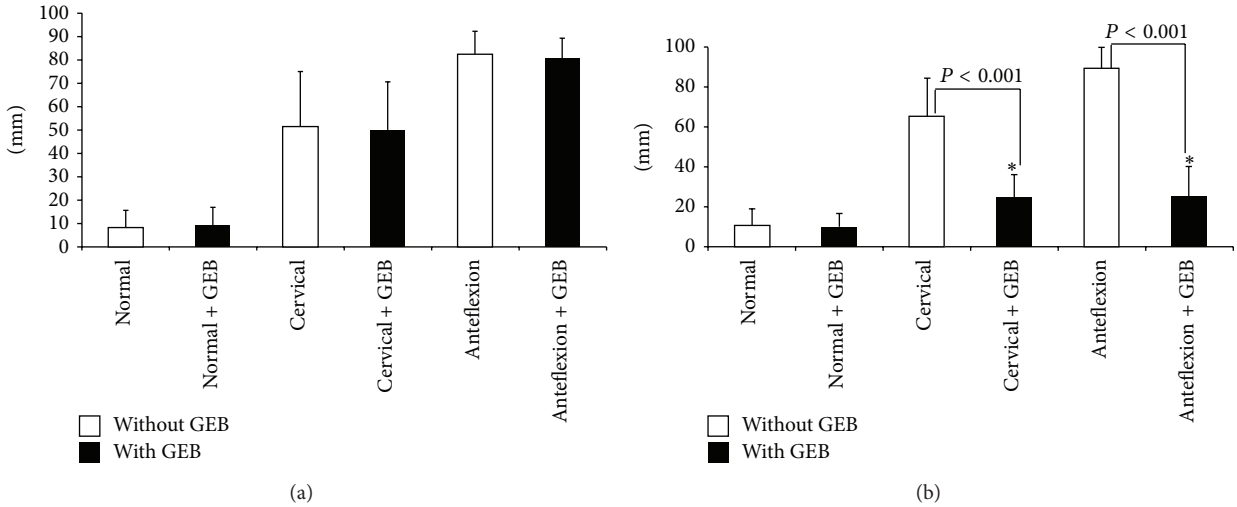


Figure 3: Visual analog scale for simulated tracheal intubation with and without gum-elastic bougie. (a) Laryngoscopic imaging and (b) tube passage through the glottis. White box: without GEB; black box: with GEB. Results are expressed as mean ± SD and were analyzed by two-way analysis of variance. NS: no significant difference; $^{*}P < 0.05$ compared to without GEB.

such as SimBaby may provide more precise data. Third, we used 5 Fr tube exchanger because GEB for infant resembling the shape of adult one is not commercially available now. It is desirable that the GEB with angled tip will be developed. Fourth, the time required for airway intervention in a manikin is generally shorter than that required in actual infants [18]. Thus, accumulation of clinical data on GEB use in infant airway management is necessary.

At present, there are only case series suggesting the utility of GEB for Pierre Robin syndrome [17]. In the future, it will be important to accumulate more data or perform randomized controlled trial to validate whether the GEB is equally useful in difficult congenital airway situations [19]. Next, since the present study was conducted with experienced anesthesiologists, trials targeting novice doctors may further clarify the utility of the GEB for difficult infant airway management [20]. Assessing the utility of the GEB in emergent simulations, such as with chest compression, is also warranted. Several reports have been published regarding the utility of videolaryngoscopes for difficult infant airway management [3]. Though there are reports about utility of videolaryngoscope and GEB combination for difficult intubation in adult cases [21–23], there are no case reports on this combination in infant or pediatric cases. Clinical accumulation of these videolaryngoscopes when used in conjunction with the GEB may help developing new strategies for infant difficult airway management.

5. Conclusions

Our simulation study demonstrated that GEB use shortened intubation time and improved intubation success rate with difficult infant airways (e.g., cervical stabilization and anteflexion (Cormack 3-4)). However, in anteflexion trial, the success rate of tracheal intubation with the GEB was significantly lower than in cervical stabilization and normal airway trials.

Notes

(a) The utility of tracheal tube introducers has previously been shown in adult cases, but not in pediatric cases, especially infants.

(b) GEB use shortened intubation time and improved the success rate of difficult infant tracheal intubation by anesthesiologists in simulations.

(c) GEB may be a useful device for difficult infant airway management.

Conflict of Interests

The authors have no affiliation with the manufacturers of any of the devices described in the paper and declare no financial interest with respect to the material described herein. Financial support for the study was provided by the authors' institution and department.

Authors' Contribution

Nobuyasu Komasawa and Akira Hyoda made the study design, conducted the study and data analysis, and wrote the paper; Sayuri Matsunami and Nozomi Majima conducted the study and data analysis; and Toshiaki Minami was responsible for the study design and paper preparation. All authors discussed the results and approved the final paper.

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Clinical Study

Comparison of Five 2nd-Generation Supraglottic Airway Devices for Airway Management Performed by Novice Military Operators

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Objectives. Five different second-generation supraglottic airway devices, ProSeal LMA, Supreme LMA, i-gel, SLIPA, and Laryngeal Tube Suction-D, were studied. Operators were inexperienced users with a military background, combat lifesavers, nurses, and physicians. *Methods*. This was a prospective, randomized, single-blinded study. Devices were inserted in the operating room in low light conditions after induction of general anesthesia. Primary outcome was successful insertion on the first attempt while secondary aims were insertion time, number of attempts, oropharyngeal seal pressure, ease of insertion, fibre optic position of device, efficacy of ventilation, and intraoperative trauma or regurgitation of gastric contents. *Results*. In total, 505 patients were studied. First-attempt insertion success rate was higher in the Supreme LMA (96%), i-gel (87.9%), and ProSeal LMA (85.9%) groups than in the Laryngeal Tube Suction-D (80.6%) and SLIPA (69.4%) groups. Insertion time was shortest in the Supreme LMA (70.4 ± 32.5 s) and i-gel (74.4 ± 41.1 s) groups ($p < 0.001$). Oropharyngeal seal pressures were higher in the Laryngeal Tube Suction-D and ProSeal LMA groups than in other three devices. *Conclusions*. Most study parameters for the Supreme LMA and i-gel were found to be superior to the other three tested supraglottic airway devices when inserted by novice military operators.

1. Introduction

Combat lifesavers in the Czech Army have already been trained for several years in easy and effective airway management during practicing medicine in the field. Generally, the algorithms of the Tactical Combat Casualty Care (TCCC) are applied [1]. The role of supraglottic airway devices (SADs) in these recommendations is not completely clear. As is well known from civilian prehospital medicine, tracheal intubation is a relatively complicated and risky procedure in the hands of nonanesthetic personnel such as paramedics [2, 3]. Similar conditions apply for combat lifesavers (CLS). SADs may provide a more patent airway than the nasopharyngeal airways currently recommended by the TCCC; however, they can be used only if they are tolerated such as in severely injured unconscious victims. In 2012, supraglottic airway devices were recommended for consideration in the TCCC [4]. Following a literature search, there currently is no comparison of currently available SADs which has been published for their use in military medicine. Theoretically, those SADs which can drain gastric contents using a separate channel or those with other aspiration protection mechanisms (compartment for storage of gastric contents), classified as 2nd-generation SADs, are more advantageous in prehospital medicine (with nonfasted patients) than the more simple 1st-generation devices, which do not possess any protective mechanism against aspiration [5]. Therefore we aimed to compare five different SADs with a protection

Table 1: Main features of tested supraglottic airway devices.

Device	Sealing site	Sealing mechanism	Aspiration protection	Disposable version	Conduit for intubation	Pediatric sizes
ProSeal LMA	Perilaryngeal	Inflatable cuff	H/obstruction, drainage	No	No	Yes
Supreme LMA	Perilaryngeal	Inflatable cuff	H/obstruction, drainage	Yes	No	Yes
i-gel	Perilaryngeal	Wedged sealing	H/obstruction, drainage	Yes	Yes	Yes
SLIPA	Base of tongue	Wedged sealing	Storage, H/obstruction	Yes	No	No
LTS-D	Base of tongue	Inflatable cuff	D/obstruction, drainage	Yes	No	Yes

H/obstruction: high esophageal obstruction, D/obstruction: deep esophageal obstruction.

mechanism against aspiration, ProSeal laryngeal mask airway (PLMA) [6], Supreme laryngeal mask airway (SLMA) [7], i-gel [8, 9], Streamlined Liner of the Pharyngeal Airway (SLIPA) [10], and Laryngeal Tube Suction-D (LTS-D) [11], in the settings of prospective randomized trial in simulated low light conditions performed by inexperienced military operators.

2. Methods

2.1. Study Design. This study was designed as randomized, prospective, and single-blinded (patient side). Ethical approval was obtained from the Local Ethical Committee (IRB), number 80-76/39-2012-UVN. The research was performed in full accordance with the Helsinki Declaration and the study was registered with a public database (R&D IS of the Czech Republic).

2.2. Study Setting and Population. All patients scheduled for elective procedures under general anesthesia during the study period and meeting the inclusion criteria were invited to participate in this study. The study setting was University Military Hospital in Prague, Czech Republic. Approximately 10 000 procedures under general anesthesia are performed in this hospital annually. The study period lasted from August 2012 till December 2013.

2.3. Study Protocol. All patients received the Study Information Pack and had the opportunity to discuss their participation with the researchers in advance. The inclusion criteria were elective surgery with an indication for an SAD insertion, age more than 18 years, and procedures with an expected duration of less than 2 hours. Exclusion criteria were increased risk of aspiration of gastric contents, emergency procedures, operations with an expected duration of more than 2 hours, obesity (BMI > 40 kg/m^2), history or prediction of difficult laryngoscopy, pregnancy, and edentulous subjects. The randomization process was performed using a randomization list created with the freeware http://www.psychicscience.org/ and patients were randomized after signing the informed consent with the code provided in sealed envelopes. The following SADs were used in patients, ProSeal laryngeal mask airway (Laryngeal Mask Company Ltd., Mahé, Seychelles), Supreme laryngeal mask airway (Laryngeal Mask Company Ltd., Mahé, Seychelles), i-gel (Intersurgical Ltd., Maidenhead, UK), Streamlined Liner of the Pharyngeal Airway (SLIPA) (Curveair Ltd., London, UK), and Laryngeal Tube Suction-D (VBM Medical, Sulz, Germany) (Figure 1), known as King LTS-D device in the United States. The main features of these SADs are highlighted in Table 1.

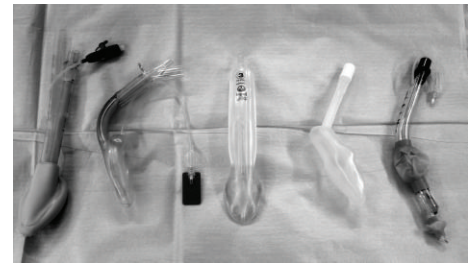
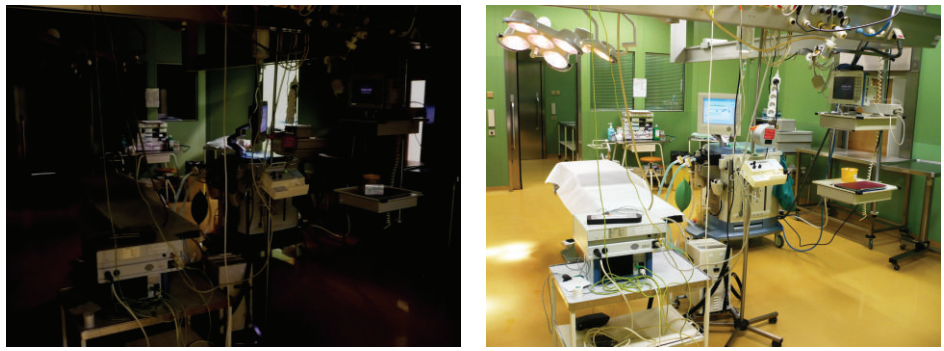


Figure 1: SADs used in the study. From the left: ProSeal LMA (PLMA), Supreme LMA (SLMA), i-gel, SLIPA, and LTS-D.

The primary outcome of the study was to evaluate the first-attempt insertion success rates of the devices and compare these between the groups. Secondary outcomes were evaluated as follows: time needed for successful insertion, number of insertion attempts, oropharyngeal seal pressure (OSP), ease of insertion, fibre optic check of the vocal cords through the devices, and presence of perioperative oropharyngeal trauma or gastric content aspiration/regurgitation. $etCO_2$ was controlled at 1, 5, and 10 minutes after insertion as a marker of efficient ventilation.

2.4. Anesthesia. All patients were premedicated using oral midazolam at a dose of 7.5 mg prior to surgery. Induction of general anesthesia was performed without the use of artificial light in gloomy conditions (Figure 2), using propofol (2–2.5 $mg \cdot kg^{-1}$) and a continuous infusion of remifentanil (1-2 $mcg \cdot kg^{-1} \cdot min^{-1}$) until the loss of verbal contact and eyelash reflexes. Anesthesia was maintained using isoflurane in an air : oxygen mixture whereas analgesia was maintained with a continuous infusion of remifentanil at a rate of 0.2–1.0 $mcg \cdot kg^{-1} \cdot min^{-1}$. No muscle relaxants were given as part of the study protocol.

2.5. Airway Management. SADs were inserted only by inexperienced operators working or undergoing training in a military hospital. They were defined as users who have not inserted an SAD more than five times in real patients. The operators included combat lifesavers, military paramedics,



(a) (b)

Figure 2: Conditions in the operating room without (a) and with (b) an artificial light.

nurses, surgical scrub nurses, or junior doctors at the beginning of their training. All participants were employed by the Czech Army and completed Basic Airway Skills Course according to their job competencies. The course agenda included bag-mask ventilation, insertion of oral/nasal airways, insertion of supraglottic airway devices, tracheal intubation, and surgical cricothyrotomy. Majority of training is performed on manikins or simulators. In regard of SADs all novice operators observed instructive insertion of these devices, had opportunity to insert them on manikins, and were apprized of each SAD prior to its insertion. A consultant anesthesiologist was always present in order to deal with failures or complications. The consultant performed a short presentation about the SAD to the operator prior to insertion, explaining its preparation, lubrication of the device, insertion technique, fixation, and evaluation of its efficacy. Size of the devices was selected according to the weight of patients and manufacturer recommendations. Level of consciousness was evaluated in all patients after induction of general anesthesia using the AVPU score and Glasgow Coma Scale. The devices were inserted only in patients who did not react to painful stimulus, forced jaw thrust. Failure to effectively insert an SAD was defined as impossibility to achieve tidal volumes of 4 mL·kg^{-1} and to eliminate CO_2 ($etCO_2$ over 6.5 kPa) at 10 minutes despite repeated insertion attempts. If the operator was not able to achieve successful ventilation on five insertion attempts, tracheal intubation was performed as a rescue procedure by a supervising consultant. Insertion time was defined as time needed for SAD preparation (removal from the package, lubrication), its insertion, cuff inflation (if applicable), and confirmation of effective ventilation with a visible $etCO_2$ tracking on the monitor and this started immediately after finishing initial bag-mask ventilation. The cuffs of inflatable devices (PLMA, SLMA, and LTS-D) were inflated according to the manufacturer recommendations. Correct position of PLMA, SLMA, and i-gel was also confirmed using "suprasternal notch" and "bubble" tests. Patients were artificially ventilated using pressure control ventilation (PCV mode) with a target tidal volume of 7 mL·kg^{-1}. Other parameters of ventilation were respiratory rate 12–16 per minute, inspiration/expiration ratio 1 : 2, and PEEP 4 cm H_2O. End-tidal CO_2 level was maintained between 4.7 and 5.3 kPa. An airway leak test was performed at 5 min after insertion; pressure limit was set to 40 cm H_2O, the APL valve was fully closed, and air flow was set to 3 L·min^{-1}. Oropharyngeal seal pressure (leak pressure) was defined as the pressure inside the system when the first sounds were audible above the larynx using a stethoscope [12].

2.6. Fibre Optic Evaluation. Fibre optic check of the SAD position was performed through the device using a flexible fibrescope. The following scoring system was used: (1) full view of glottis, (2) vocal cords, arytenoids, and inferior surface of epiglottis visible, (3) only superior surface of epiglottis visible, and (4) no part of epiglottis or larynx visible [13].

2.7. Ease of Insertion. This was a subjective evaluation performed by the operator, for which a five-point Likert scale was used ((1) very easy insertion, (2) easy insertion, (3) neither easy nor difficult insertion, (4) difficult insertion, and (5) very difficult insertion).

2.8. Airway Complications. The devices were carefully examined after removal for any signs of blood or gastric fluid. The oral cavity of patients was evaluated for bleeding or signs of regurgitation after removal of the SAD. Postoperative complaints were not evaluated.

2.9. Sample Size and Data Analysis. The sample size was calculated for an alpha-error of 0.05 and a power of 80% (beta-error of 0.2) to detect a 20% difference in insertion success rate on the first attempt. 65% success rate was considered as a baseline according to the study of Ragazzi et al. [14]. It was calculated that a minimum of ninety patients in each group should be enrolled. We have chosen to include at least one hundred patients in each group in order to compensate for patients lost to follow-up. In total 520 allocations were created using randomization freeware. Statistical analysis was performed by an independent consultant statistician. All data were first tested for their normal distribution using the Shapiro-Wilk test of normality. According to the data distribution, nonparametric (Kruskal-Wallis and Mann-Whitney tests) or Fisher's exact tests were employed. SPSS 13.0 (SPSS Inc., Chicago, IL) statistical software was used

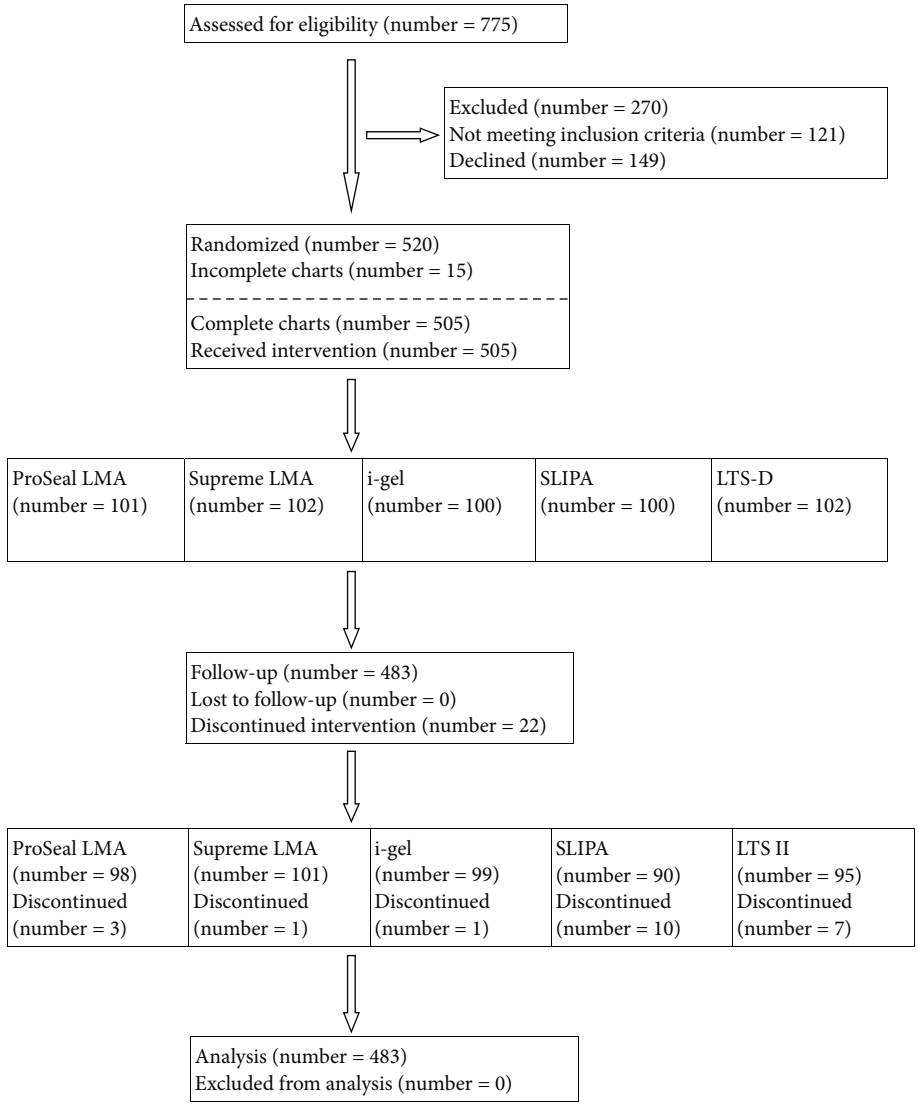


Figure 3: CONSORT 2010 flow diagram of the study.

for data analysis. p values less than 0.05 were considered as significant.

3. Results

3.1. Sample. In total 520 randomization codes were created and finally 505 patients were included in the study. Fifteen patients dropped out during the study period or their charts were incomplete. Figure 3 demonstrates flow of the study. There were no statistical differences in demographic parameters between the groups.

3.2. Primary Outcome. Insertion success rate on the first attempt varied between the devices (Table 2). These success rates were highest in the SLMA group (95.1%), followed by i-gel (87%), PLMA (84.2%), and LTS-D (77.5%). SLIPA demonstrated the lowest first-attempt insertion success rate at 66%. First-attempt insertion success rate of the SLMA was significantly higher than in the PLMA ($p = 0.012$), SLIPA ($p = 0.0001$), or LTS-D ($p = 0.0004$) groups. Similarly, both PLMA and i-gel showed higher insertion success rate on the first attempt than SLIPA device ($p = 0.003$ and $p = 0.0007$, resp.).

3.3. Secondary Outcomes. The total insertion success rate was similarly high for the SLMA (99%), PLMA (97%), and i-gel (99%), whereas the LTS-D (93.1%) and SLIPA (90%) showed slightly lower numbers. However, statistically significant difference was achieved only between SLMA and SLIPA ($p = 0.005$), i-gel and SLIPA ($p = 0.01$), and PLMA and SLIPA ($p = 0.049$), respectively.

Time for successful insertion was shortest in the SLMA (70.4 ± 32.5 s) and i-gel (74.4 ± 41.1 s) groups in comparison with the other three devices (Table 3). Insertion of the PLMA, SLIPA, and LTS-D was significantly prolonged ($p < 0.001$) when compared with the SLMA and i-gel. The highest oropharyngeal seal pressures were achieved with the PLMA

Table 2: Insertion success rates on the first attempt.

(a)

Device	First-attempt success rate			
	Successful	Unsuccessful	Total	(%)
PLMA	85	16	101	84.2
SLMA	97	5	102	95.1
i-gel	87	13	100	87.0
SLIPA	66	34	100	66.0
LTS-D	79	23	102	77.5

(b)

	PLMA versus SLMA	PLMA versus i-gel	PLMA versus SLIPA	PLMA versus LTS-D	SLMA versus i-gel	SLMA versus SLIPA	SLMA versus LTS-D	i-gel versus SLIPA	i-gel versus LTS-D	SLIPA versus LTS-D
p	0.012*	0.689	0.003*	0.285	0.081	0.0001*	0.0004*	0.0007*	0.098	0.086

Differences marked with (∗) are statistically significant.

Table 3: Insertion times and oropharyngeal seal pressures (OSP).

Device	Insertion time (s, ±SD)	Oropharyngeal seal pressure (cm H_2O, ±SD)
PLMA	109.6 (61.5)	29.2 (6.8)
SLMA	70.4 (32.5)	24.8 (6.1)
i-gel	74.4 (41.1)	25.3 (6.9)
SLIPA	98.5 (59)	23.7 (6.1)
LTS-D	107.3 (67.9)	29.5 (8.9)

Insertion time:
SLMA versus PLMA, SLMA versus SLIPA, and SLMA versus LTS-D: $p = 0.001$.
i-gel versus PLMA, i-gel versus LTS-D: $p = 0.001$, and i-gel versus SLIPA: $p = 0.01$.
Oropharyngeal seal pressures:
PLMA versus SLMA, PLMA versus i-gel, and PLMA versus SLIPA: $p = 0.001$.
LTS-D versus SLMA, LTS-D versus i-gel, and LTS-D versus SLIPA: $p = 0.001$.

Table 4: Coverage of the glottic opening (fibre optic assessment).

Device	Fibre optic assessment			
	1	2	3	4
PLMA	60 (64.5%)	14 (15.1%)	16 (17.2%)	3 (3.2%)
SLMA	53 (54.1%)	19 (19.4%)	22 (22.4%)	4 (4.1%)
i-gel	70 (72.2%)	16 (16.5%)	10 (10.3%)	1 (1%)
SLIPA	48 (58.5%)	9 (11%)	20 (24.4%)	5 (6.1%)
LTS-D	39 (41.1%)	20 (21.1%)	13 (13.7%)	23 (24.2%)

PLMA versus LTS-D: $p = 0.001$.
i-gel versus SLMA: $p = 0.05$, i-gel versus SLIPA: $p = 0.05$, and i-gel versus LTS-D: $p = 0.001$.
SLMA versus LTS-D: $p = 0.001$.
SLIPA versus LTS-D: $p = 0.001$.

Table 5: Ease of insertion (1: very easy, 2: easy, 3: neither easy nor difficult, 4: difficult, and 5: very difficult).

Device	Ease of insertion				
	1	2	3	4	5
PLMA	34.3%	44.4%	15.2%	5.1%	1%
SLMA	61.4%	30.7%	7.9%	0%	0%
i-gel	37.4%	48.5%	6.1%	6.1%	2%
SLIPA	7.1%	38.8%	24.5%	17.3%	12.2%
LTS-D	16.3%	43.9%	23.5%	13.3%	3.1%

SLMA versus PLMA, SLMA versus SLIPA, and SLMA versus LTS-D: $p = 0.001$, and SLMA versus i-gel: $p = 0.01$.
PLMA versus SLIPA: $p = 0.001$, PLMA versus LTS-D: $p = 0.05$.
i-gel versus SLIPA, i-gel versus LTS-D: $p = 0.001$, and SLIPA versus LTS-D: $p = 0.05$.

and LTS-D devices. The remaining three devices exhibited significantly lower seal pressures: $p < 0.001$ (Table 3).

Best view of the glottis, as confirmed by fibre optic evaluation, was achieved with the i-gel airway (88.7% of grade 1 or 2) while this was lowest in the LTS-D group (only 62.2% of grade 1 or 2): $p < 0.001$. Significant differences in the view of the glottis were also found between the i-gel and SLMA ($p < 0.05$) or SLIPA ($p < 0.05$) (Table 4). Fibre optic evaluation was performed in 465 patients (96.3%); the remaining 18 devices were not assessed due to unavailability of the fibrescope. The efficacy of ventilation was evaluated as better in the PLMA, SLMA, and i-gel groups as compared with the remaining two devices ($p < 0.05$).

Regarding ease of insertion, the participants reported that the SLMA was the easiest device to insert, 62% very easy and 31% easy, while the LTS-D and SLIPA were most difficult to introduce, less than 50% of very easy or easy insertions (Table 5).

Perioperative complications such as blood on the device on removal or regurgitation/aspiration of gastric contents occurred only in 18 patients (3.8%). Blood on the device after removal was found in one patient in the PLMA (1%), SLMA (1%), and i-gel (1%) groups, in five patients managed with the LTS-D (4.9%), and in ten patients in the SLIPA group (10%). One patient significantly regurgitated through the gastric lumen of the PLMA but did not aspirate. Insertion

of the i-gel was associated with one case of soft palate trauma which presented as minor bleed lasting for four hours. There was no significant difference between the PLMA, SLMA, i-gel, and LTS-D groups in the incidence of blood traces on the device. SLIPA was associated with significantly higher airway morbidity than PLMA, SLMA, and i-gel ($p = 0.005$).

4. Discussion

This study compared the performance of five different supraglottic airway devices with an additional mechanism for drainage/storage of gastric contents (2nd-generation SADs) in simulated field scenario when all devices were inserted by nonexperienced military personnel. The main findings are that the most suitable devices for use in this scenario are the Supreme LMA and i-gel airway and that the LTS-D and SLIPA have less favorable insertion parameters as well as other features. Important parameters for use in the field are the insertion success rate and speed of insertion. Both the SLMA and i-gel airway not only showed a high first-attempt insertion success rate and faster insertion times than other SADs but also were evaluated by the participants as most "easy to insert." PLMA has a reasonable insertion profile but it possesses significant disadvantage compared to the other studied devices. The device is not available as a disposable version and the use of reusable device in the field is difficult. The i-gel may offer another potential advantage against the rest of these SADs. It can be used as a conduit for a tracheal tube placement such as with an intubating LMA [15].

The results of our study may be compared with other evidence related to 2nd-generation SADs. Ragazzi et al. compared insertion success rates and other parameters between the SLMA and i-gel when inserted by novice operators [14]. They found a significantly higher first-attempt insertion success rate in the SLMA group as well as a shorter insertion time and higher oropharyngeal seal pressures. They recommended the SLMA as the first-choice device in emergency situations. SLMA also showed faster insertion times than the classical LMA during a simulated CPR scenario [16]. Our results did not confirm this superiority of the SLMA over the i-gel, which is similar to the results of another study comparing these two devices in gynecological laparoscopies [17]. There is no data available comparing the LTS-D device with other supraglottic airways inserted by novices. One case series considered the LTS-D as a promising device for out-of-hospital emergency management when the operators were inexperienced in tracheal intubation [11]. These same authors reported a 96.8% total success rate when using this device in the prehospital setting, with a first-attempt insertion success rate of 78.3% [18]. LTS II showed significantly lower first-attempt success rate than the ProSeal LMA in anesthetized and paralyzed patients [19]. A manikin study compared performance and skill retention of airway management using various supraglottic airway devices versus tracheal intubation [20]. The novice operators showed better performance and retention of insertion skills at 3 months with the i-gel, laryngeal tube device (LT-D) than with the tracheal intubation. However, the results of manikin studies cannot be extrapolated to humans because they do not accurately reflect human anatomy. SLIPA showed similar insertion parameters when inserted by inexperienced operators to the 1st-generation SADs [21]. However, in another study, the SLIPA showed a significantly lower insertion success rate on the first attempt than those for the PLMA [22].

ERC guidelines [23] recommend that airway should be secured within 30 sec but this interval would be probably significantly longer in the field due to various factors such as single-handed lifesaver, difficult combat conditions, ban on the using of artificial light, or other unpredictable factors.

5. Limitations

This study has several limitations related mainly to its emphasis on military medicine. Simulated conditions differ significantly from real situations in the field. Field conditions are very stressful for military paramedics, unconscious victims may struggle, and there is often orofacial or neck trauma with bleeding present, causing airway management to be more difficult. The victims are also often found in various positions although they are subsequently moved to supine position for airway management procedures.

Furthermore other factors such as light conditions, neck immobilization, quality of training, or device insertion technique affect success rate significantly in out-of-hospital scenarios. Gastric tubes were also not inserted through the devices to drain gastric contents. We have decided against their insertion because one of the devices (SLIPA) does not allow gastric tube insertion and also because gastric tubes are not part of the emergency equipment carried by combat lifesavers. We also allowed participants to perform more than usual three attempts on the placement of device. Other limitations of the study include that postoperative airway morbidity and other patient complaints were not assessed. However, there has been no study to date published comparing these 2nd-generation supraglottic airway devices, with supposed lower incidence of gastric content aspiration in relation to airway management in the field, and the results of this study could become a starting point for further research projects evaluating the role of these devices in military medicine. Finally, few new devices, such as the 3gLM airway [24] or CPV Guardian Laryngeal Mask [25], have been invented in the last years and they may be used for similar comparative studies in the future.

6. Conclusions

The Supreme LMA and i-gel supraglottic airway seem to be the most convenient of the 2nd-generation supraglottic airway devices for insertion by relatively inexperienced military healthcare providers in a simulated low light scenario. Other devices tested showed either lower success rates of insertion or a significantly longer insertion time.

Abbreviations

APL valve: Adjustable pressure limiting valve
BMI: Body mass index
CLS: Combat lifesaver

CPR: Cardiopulmonary resuscitation
ERC: European Resuscitation Council
$etCO_2$: End-tidal carbon dioxide
GCS: Glasgow Coma Scale
LTS-D: Laryngeal Tube Suction-Disposable
OSP: Oropharyngeal seal pressure
PCV: Pressure controlled ventilation
PEEP: Positive end-expiratory pressure
PLMA: ProSeal laryngeal mask airway
SAD: Supraglottic airway device
SLIPA: Streamlined Liner of the Pharyngeal Airway
SLMA: Supreme laryngeal mask airway
TCCC: Tactical Combat Casualty Care.

Disclosure

Pavel Michalek has lectured for several companies manufacturing supraglottic airway devices including Intersurgical Ltd., AMBU Ltd., and Intavent Orthofix Ltd. This study was presented as a free paper on the LIVES 2014, ESICM's 27th Annual Congress, Barcelona, Spain, 29 September 2014.

Conflict of Interests

Tomas Henlin, Michal Sotak, Petr Kovaricek, Tomas Tyll, and Lukas Balcarek declare no conflict of interests regarding the publication of this paper.

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