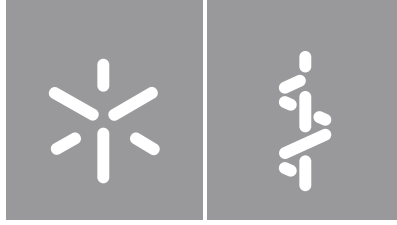




Universidade do Minho
Escola de Medicina

Sara Cláudia Santos da Hora Gomes

**Airway management using ultrasound
Best practices in teaching, training and
assessment**



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Tese de Doutoramento
Doutoramento em Medicina

Trabalho efetuado sob a orientação do
Professor Doutor Patrício Ricardo Soares Costa
e do
Professor Doutor Jorge Manuel Nunes Correia Pinto

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STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration.

I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

Manuseio da Via Aérea com Ultrassonografia – Melhores Práticas no Ensino, Treino e Avaliação

Resumo

O manuseio da via aérea é um componente central dos cuidados anestésicos. Todos os doentes submetidos a procedimentos anestésicos podem estar em risco de terem ventilação e oxigenação insuficientes, se não for conseguida uma via aérea segura. Existem indicadores clínicos que podem prever um manuseio difícil da via aérea, mas globalmente têm baixa sensibilidade e moderada especificidade, pelo que é relevante encontrar melhores preditores de forma a conseguir uma abordagem segura da via aérea a cada paciente. A recente divulgação da utilização da ultrassonografia (US) no cuidado do doente, inclui a sua aplicação à avaliação da via aérea. Numerosos parâmetros US têm sido estudados como preditores de via aérea difícil; no entanto, ainda não é claro quais os parâmetros que devem ser considerados para uso clínico. Na presente Tese, através dos resultados de uma revisão sistemática e meta-análise caracterizamos inicialmente o preditor US mais relevante na previsão de uma laringoscopia difícil. A distância hiomentoniana (DHM) em posição neutral revelou-se o preditor mais consistente para ser utilizado na clínica. Tratando-se de uma competência técnica, o uso da US é dependente do operador e requer treino e avaliação através de escalas objetivas e estruturadas. Assim, no segundo trabalho desta Tese criámos um programa de ensino e de treino da utilização da DHM por US. Simultaneamente, avaliamos a competência de participantes utilizando a escala *Objective Structured Assessment Ultrasound Skills* (OSAUS) e analisamos as suas propriedades psicométricas. Os resultados mostraram que a escala é válida e confiável na avaliação do desempenho técnico. Finalmente, testamos uma nova aplicação clínica para a US da via aérea na intubação/exclusão seletiva pulmonar, num modelo animal pediátrico. Este trabalho mostrou resultados promissores para a translação para a população pediátrica. Em conclusão, os trabalhos de investigação desta Tese permitiram identificar um preditor confiável de laringoscopia difícil, que pode ser avaliado clinicamente por US, para o qual é necessário o desenvolvimento e avaliação da competência. Simultaneamente, apresentamos a aplicação inovadora da US na intubação seletiva no modelo animal pediátrico que pode contribuir para uma mudança do paradigma da abordagem da via aérea nesta população.

Palavras-chave: Avaliação, Manuseio, Treino, Ultrassonografia, Via aérea

Airway Management using Ultrasound – Best Practices in Teaching, Training and Assessment

Abstract

Airway management is a core component of anesthesia care. Every patient submitted to anesthesia procedures is at risk of insufficient ventilation and oxygenation if a secure airway could not be achieved. Many clinical indicators can predict difficult airway but globally with low sensibility and moderate specificity. Therefore, is relevant to find better predictors to achieve a safe airway approach. The recent widespread use of ultrasound in patient care includes airway assessment. Numerous ultrasound measurements have been studied as predictors of difficult airway; nevertheless, it is still unclear which parameters should be considered for routine clinical use. In the present Thesis, we have characterized the most relevant ultrasound predictors of difficult laryngoscopy and difficult intubation throughout a systematic review and meta-analysis. Hyomental distance (HMD) was the most consistent factor in the clinical setting. As a technical skill that is operator dependent, ultrasound requires training and assessment with objective and structured scales. So, the second work of our Thesis, we created a teaching and training program to use ultrasound HMD. Simultaneously, we assessed participants' competence using the Objective Structured Assessment Ultrasound Skills (OSAUS) scale and analyzed the scale's psychometric properties. Results showed that OSAUS scale is a valid and reliable tool that can be used to assess performance. Finally, we tested a new clinical application of ultrasound in selective lung intubation/exclusion in a pediatric animal model. This work showed promising results for translation to the pediatric population. In conclusion, the research work of this Thesis allowed the identification of a reliable ultrasound predictor of difficult laryngoscopy, that can be trained and assessed. Simultaneously, we presented an innovative application of ultrasound in selective intubation in pediatric animal model that can contribute to change the paradigm of airway management in this population.

Keywords: Airway, Assessment, Management, Training, Ultrasound

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LIST OF ABBREVIATIONS

ASA – American Society of Anesthesiologists

BB – Bronchial blocker

CNS – Central nervous system

CO₂ – Carbon dioxide

DHM – Distância hiomentoniana

EBUS – Endobronchial ultrasound

ETI – Endotracheal intubation

FOB – Fiberoptic bronchoscope

HMD – Hyomental distance

KT – Knowledge translation

OLV – One-lung ventilation

OSATS – Objective Structured Assessment for Technical Skills

OSAUS – Objective Structured Assessment Ultrasound Skills

PoCUS – Point-of-care Ultrasound

SLT – Single lumen tube

US – Ultrasound

VATS – Video Assisted Thoracoscopic Surgery

VL – Videolaryngoscopy

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Amo-te para que subas comigo
à mais alta torre,
para que tudo em ti
seja verão, dunas e mar.

Eugénio de Andrade

Chapter 1

INTRODUCTION

1. INTRODUCTION

1.1. Airway Management

1.1.1. Anesthetic Procedures

The global volume of major and ambulatory surgeries has steadily increased throughout the years. In 2012, the estimated annual volume of surgeries was 312.9 million, which represents an increase of 33.6% since 2004 (Weiser, 2015). In most surgeries, patients are submitted to general anesthesia either because the surgical procedure demands or by lack of expertise in regional anesthesia. General anesthesia promotes depression of the central nervous system (CNS), with loss of conscience. It induces loss of airway patency and protective reflexes, conditioning the patient to hypoventilation, hypoxia, and pulmonary aspiration (Mendelson, 1946). So, during the induction of the general anesthesia, the anesthesiologist must provide adequate ventilation and oxygenation through mask ventilation and proceed to introduce airway devices that allow positive ventilation throughout a mechanical ventilator. The infra-glottic devices also protect the patient from pulmonary aspiration. This is a primordial part of the everyday work of an anesthesiologist.

1.1.2. Historic perspective of airway management

Historically, the airway management began in the early 18th century in the context of resuscitation (Matrioc, 2016). In those days, the reported airway interventions had little evidence support, such as Midwives' s rescue maneuvers for newborn resuscitation that empirically introduced the positive pressure (PPV) through mouth-to-mouth ventilation and Tossach's description of the use of his expired air to resuscitate James Blair (Trubuhovich, 2006).

The first concern with the airway patency was with the obstruction caused by the tongue recognized by Lister and Clover in 1871 (Clover, 1871; Lister, 1871). A few years later, in 1890, Fell proposed a solution for this problem with the intubation or the use of tracheostomy for longer surgical cases, achieving the proper airway patency during the procedure (Trubuhovich, 2007).

In the beginning of the 20th century, Frederic Hewitt (Hewitt, 1903) published a lecture about "The anesthetization of so-called "Difficult" and "Bad" subjects", where he emphasized the need to evaluate what he called the "respiratory pattern" of all patients before submitting to anesthesia, highlighting neck and jaw mobility limitations, the presence of sublingual and neck tumors or the enlarged nasopharyngeal tissue. Despite the limitations – for the most part, the airway approach was still unstructured and unplanned – Hewitt's work was the foundation of today's difficult airway predictors.

The first half of the XX century was characterized by a significant development of surgical complexity. The procedures are more invasive and technically demanding, requiring invasive and secure airway for positive pressure ventilation, which reduced patients' risk of aspiration and hypoxia (Matrioc, 2017). Tracheal intubation through a direct laryngoscopy became the technique of choice for airway management. With the widespread use of tracheal intubation, difficult experiences began to be published, creating the need to identify predictive factors. In 1956, Cass and co-workers (Cass, 1956) reported several difficult intubations in patients with facial and neck deformities. For each case, they described the successful approach for intubation, designing what should be considered as the scratch of guidelines for complex airway management.

1.1.3. Definitive Airway Definition

Airway management can be performed with supraglottic devices or with tracheal tubes to assure adequate ventilation. The most frequently used supraglottic devices in anesthesia are the laryngeal masks. These devices allow adequate ventilation although they do not ensure protection from the aspiration of gastric content since their final position is in the inlet of the glottis. A definitive airway is a cuffed tube positioned in the trachea below the vocal cords that allows simultaneously adequate ventilation and airway protection. (Henry S., 2018) This maneuver is called intubation. The procedure can be done through larynx or the skin of the neck (cricothyroidotomy or tracheostomy). The access through the larynx is done under direct or indirect visualization of the glottis with a laryngoscope or a videolaryngoscope, respectively. However, even with a definitive airway the tube can be displaced and compromise ventilation and oxygenation, if not promptly recognized. It is important to highlight that the most frequent cause of morbidity associated with anesthesia relates to airway management. Joffe et al. studied the closed claims from the Anesthesia Closed Claims Project related to managing difficult tracheal intubation from the year 2000 to 2012. This study revealed that death was the outcome for 73% of those closed claims (Joffe, 2019). Simultaneously, Crosby reviewed the closed claims from the Canada Medical Protection Association from 2007 to 2016 and found that 11% were airway-dependent (Crosby, 2021).

1.1.4. Difficult airway definition

The most recent guidelines of the American Society of Anesthesiologists (ASA) (Apfelbaum, 2022) define a difficult airway as a "clinical situation in which anticipated or unanticipated difficulty or failure is experienced by a physician trained in anesthesia care, including but not limited to one or more of the following: facemask ventilation, laryngoscopy, ventilation using a supraglottic airway, tracheal intubation,

extubation, or invasive airway.” Difficult or failure to manage a difficult airway has serious implications. The outcome of that situation depends on a variety of factors: (1) time until restoration of oxygenation; (2) presence of airway trauma; (3) erroneous intubation; (4) cardiovascular insult and (5) brain and neurological injury. And although the prevalence of difficult airway is very low, 0.06 per 1000 inhabitants (Schroeder, 2018), the risk of death cannot be neglected (1 in 180 000 general anesthesia) (Cook, 2016).

1.1.5. Predictive factors for laryngoscopy and tracheal intubation

The causes for a difficult airway have been studied since the beginning of the airway manipulation with laryngoscopy and tracheal intubation and they relate with distinct components from visualization of structures to application of the technical procedures (Vannucci, 2016).

Direct laryngoscopy is the most frequent technique used to achieve tracheal intubation. The technique aims to align the oral, pharyngeal, and laryngeal axis, so the anesthesiologist can directly see the inlet of the glottis and perform intubation (Miller, 2019). Since this procedure requires mobilization of the head, neck and oropharyngeal structures, the clinical evaluation of the patient that is going to be submitted to anesthesia is crucial and the clinical history has relevant information for airway evaluation. Previous history of neck radiotherapy or surgery can compromise the mobility of the neck and its soft tissues; obesity, especially with large and short neck; limitation in the mobility of the temporomandibular joint, with small mouth opening or long upper incisors; macroglossia or micrognathia; obstructive sleep apnea are clues to difficult laryngoscopy. Many clinical scores have been developed and implemented to aggregate physical characteristics that could predict a difficult airway. The Mallampati Score initially developed by Mallampati and co-workers (Mallampati, 1985) compares the relative size of the tongue to the cavity of the mouth, represented as the visualization of the faucial pillars, uvula, and the soft palate, when the patient is in the sitting position with the mouth completely opened and with the tongue protruded. The score has 4 grades; grade I represents the complete visualization of the structures, whereas grade IV only soft palate can be visualized. Although anesthesiologists use this score routinely, its accuracy as a predictor of difficult intubation is low. Therefore, the evaluation of the airway benefits from the combination with other predictors.

Difficult laryngoscopy and difficult tracheal intubation terms are used interchangeably used, although they have different meanings. Difficult laryngoscopy is defined as a situation when the glottis cannot be completely visualized after a correct technique of a direct laryngoscopy. In 1984, Cormack and Lehane developed and implemented a four-stage grading scale to describe the glottic views during the direct laryngoscopy (Cormack & Lehane, 1984). Both epiglottis and vocal cords are visible in grade I, in grade

IV, none of the structures is visualized. Later, Yentis proposed a division of the grade II in IIA for the laryngoscopy that allows the partial view of the glottis and the grade IIB where only the arytenoids or the posterior aspect of vocal cords are visible. Laryngoscopy with a IIB grade or more is considered difficult by most authors (Yentis, 1998). This scale remains the reference to classify direct laryngoscopy (Pearce AC, 2021).

Difficult tracheal intubation is when more than one attempt is necessary, requires a more experienced operator or when a change in technique or device is needed to achieve intubation (Apfelbaum, 2022; Law, 2021). In fact, a patient can have an easy laryngoscopy, but difficult intubation due to blood, secretions on the airway or when any infra-glottic or glottic deformity may prevent intubation.

However, there is no single predictor that can accurately anticipate a difficult airway. The everyday work of the anesthesiologist is to combine several bed-screening predictors; recognize a difficult airway and plan and prepare for the airway approach. Nevertheless, since some patients have difficult airway that is not recognized by the screening-tests, all anesthesiologists should have competence in technical and non-technical-skills in case of an unanticipated difficult airway. This competence has a considerable impact on patient safety.

1.1.6. Guidelines to approach a difficult airway

Practical guidelines for the approach to a difficult airway have been published with revisions and updates based on the current medical knowledge and technology by different national anesthesia societies (Frerk, 2015; Kornas, 2021; Law, 2021; Apfelbaum, 2022). These documents are structured recommendations that guide clinicians in safely managing a patient with a difficult airway. They focus in (1) definition; (2) evaluation of the airway; (3) preparation for a difficult airway; (4) anticipated difficult airway management; (5) unanticipated and emergent difficult airway management; (6) monitoring; (7) extubation of the difficult airway and (8) follow-up care. The different approaches are presented in the form of algorithms that are easy to understand and follow, which facilitates the process of decision-making, ultimately increasing patient safety.

1.2. The use of ultrasound in airway evaluation

In the last decades, we have witnessed the expansion of the use of Point-of-care ultrasound in many fields of medicine, including the lung, abdominal, cardiac, vascular, nerves and plexus, and airway in the context

of emergency, trauma, intensive and peri-operative care, in both adults and pediatric population (Gleeson, 2018; Su, 2018; Shaahinfar, 2021; Li 2020, Moore, 2011).

The ultrasound machine has a piezoelectric crystal and can produce and receive high-frequency sound waves that are inaudible to the human ear (2-13 MHz). The real-time images of the tissue are dynamic: (1) with the B-mode, structure movement can be seen; (2) with M-Mode the movement is analyzed over some time; (3) using the doppler effect the direction of the flow can be identified (Enriquez, 2014). Measurement of the dimensions of structures or distance between structures can also be determined with accuracy. The devices have become more portable and friendly to use in order to be accessible to all clinicians and patient care, even in complex environments, such as the emergency room. Nevertheless, since it is still highly operator-dependent, oriented, and structured training is needed to provide competence and excellent care (Souleymane, 2021; Chen, 2021; Nicholas, 2021).

The airway evaluation with ultrasound began with Carp and Bundy with their “preliminary study of the use of the ultrasound to examine of the vocal cords and larynx”, published in 1992 (Carp, 1992). The study presented ultrasound as a useful tool to visualize the vocal cords. Although it could not guide intubation, the work is considered the pioneer of the airway ultrasound for anesthesiologists. From this moment in time, several developments were published. Briefly, in 2003, Ezri and co-workers (Ezri, 2003) studied the thickness of the anterior neck soft tissue in obese patients as a predictor of a difficult laryngoscopy and found significant results; as far as we know to date, this is the first study that addresses difficult airway prediction. In 2007, although preliminary and with small a sample size, two studies deserve to be highlighted: (1) Lakhal and co-workers’ study (Lakhal, 2007) confirmed a strong correlation between ultrasound and magnetic resonance in measuring the transverse diameter of the airway at the cricoid level and (2) Werner and co-workers’ who study the ultrasound as useful to confirm the positioning of the tracheal tube during the intubation procedure (Werner, 2007). In the following years, many studies reported the ultrasound assessment of the upper airway as an useful tool to: (1) guide tracheal intubation in real-time (Kundra, 2021; Chou, 2013; Miss, 2014); (2) confirm endotracheal tube positioning in either adults, pediatric, pregnant or obese patients (Lin, 2016; Chen, 2020; Men, 2020; Descamps, 2020; Farrokhi, 2021); (3) determine the appropriated tracheal tube size in either adults, pediatric patients, pregnant and obese patient population (Gunjan 2020, Gupta 2012, Altun 2017); (4) guide cricothyroidotomy and tracheostomy procedures (Saritas, 2017; Suzuki, 2012; Lavelle, 2021; Kristensen, 2016; Gobatto, 2021; Hung, 2021) and (5) predict difficult airway (Alessandri, 2019).

In the last two decades, many ultrasound parameters have been studied as difficult airway predictors. Still, we found a high heterogeneity in the number of parameters, measurement methodologies and

patient population, which can compromise the accuracy of its clinical use. This calls for several actions, the training of professionals being one of the most needed and impactful.

1.2.1. Educational training and assessment of airway ultrasound competence

In the era of competence-based education, medical students and residents need adequate opportunities for education and training to achieve competent performance in their clinical tasks with autonomy. Ultrasonography (US) is a clinical competence that was recently integrated into medical schools' curricula worldwide (Tarique, 2018; Amini 2015; Nicholas, 2021). The possibility of performing a point-of-care ultrasonography at the patient's bedside is innovative and transforming. This individualized patient care is goal-directed, representing an increase in efficiency and patient safety.

The Point-of-care ultrasound (PoCUS) is a technical skill that needs an organized and structured training for imaging acquisition and image interpretation (Amni, 2015, Mamhood 2019). The creation of ultrasound learning opportunities for undergraduate medical students and postgraduate residents is beneficial since it (1) effectively facilitates the acquisition of knowledge and US skills (Beal, 2017); (2) increases self-confidence (Armson, 2021); (3) enhances retention of knowledge and skills (Kimura, 2016; Schott, 2021); (4) increases lifelong learning process (McCormick, 2018) and (5) facilitates the integration of the competence in clinical practice (Chen, 2021). PoCUS courses also create a chance for residents to practice, especially those whose residency programs do not contemplate sufficient time for training.

The technical skills assessment should be an integral part of the training program. The assessment should be objective, well structured, valid, reliable, feasible, and equivalent to previously validated. Ideally, it should provide feedback, stimulate further learning, and ultimately be accepted by all stakeholders (Norcinni, 2018). Many tools to assess technical skills competence have been developed in the last decade, with special highlights for Objective Structured Assessment for Technical Skills (OSATS). This tool is considered the goal standard for assessing technical skills in most surgical specialties (Vaidya, 2020). There is an ongoing need to develop scales that are adequate to the nature of technical skill. The Objective Structured Assessment Ultrasound Scale (OSAUS) scale was developed by Tolsgaard and co-workers (Tolsgaard, 2013) using the Delphy methodology to assess clinical ultrasound competency. It has recently been applied to many fields of ultrasonography such as gynecology/obstetrics (Grabdjean, 2021; Byford, 2021, Tolsgaard, 2014); head and neck ultrasonography (Todsens, 2018); surgery and trauma (Todsens, 2017) and lung (Di Pietro, 2021). OSAUS scale was not yet used for ultrasound airway evaluation which is a gap that we have addressed (at least partially) in this Thesis.

1.3. Airway management for one-lung intubation and special populations

One of the anesthesia milestones in the history of airway management was the development of intubation strategies for thoracic surgery. In 1931, Gale and Waters (Gale & Waters, 1931) described the one-lung intubation technique using a single-lumen, cuffed, tracheal tube for the first time. The tube was positioned with its lumen facing the lung to be ventilated and the tube cuff in the inlet of the bronchus to be excluded. Meanwhile, a rubber catheter with a balloon on the tip was used as the first bronchial blocker by Archibald (Brodsky, 2007). With the use of this device, direct endoscopic visualization of its positioning was necessary to guarantee the exclusion of the correct lung. Although many devices have been more recently developed such as the modern Arndt blockers, Univent™ tubes and Robertshaw double lumen tubes, its use continues to be challenging for anesthesiologist who need to control its placement and positioning by flexible fiberoptic bronchoscopy (FOB). This is particularly true in the pediatric population.

One lung ventilation in paediatric patients is a frequent demand for anaesthesiologists, due to the increasing use of thoracoscopic procedures. Since the use of double-lumen tube is limited to patients older than eight years, the bronchial blocker is the device recommended for younger children (Templeton, 2021; Downard, 2021; Lazar, 2022). For neonates and very small children, lung exclusion represents a challenge to the anaesthesia team, due to the reduced size, low respiratory reserves and the trachea and bronchial injury risk. For those patients, two approaches are possible (1) endobronchial intubation to the non-operating-lung with a single lumen tube or (2) single lumen tube positioned in the trachea with a bronchial blocker introduced in the operating-lung.

The bedside PoCUS in pediatric patients includes the assessment of the airway. Many studies confirmed the use of US to (1) identify adequate size (Lin 2016, Hao 2020) and positioning (Wani, 2021; Altun, 2017) of the tracheal tube; (2) confirm the localization of cricothyroid membrane (Hsu, 2020; Walsh, 2019); (3) prevent the post-extubation stridor (El Amrousy, 2018) and (4) identify the positioning of the laryngeal mask (Kim, 2015; Arican, 2021).

In the clinical scenario of one lung ventilation, US can be useful to identify the exclusion of the non-ventilated lung by the absence of lung sliding, since this image represents an indirect evaluation of a non-ventilated lung (Tognon, 2022). In neonates the low density of the ossified costal cage allows an adequate window for mediastinum, trachea, and carina ultrasound, opening new options to approach one-lung ventilation in these patients (Gottlieb 2021; Trinavarat, 2014; Joshi, 2019). These are certainly relevant clinical challenges that call for action to improve its safety and quality.

1.4. Aims of the study

Airway management is one foundation of anesthesia practice. Anesthesiologists need to be proficient and competent in all the available approaches to the airway, both invasive and non-invasive. The risk of a difficult airway should be assessed in every patient proposed to anesthesia, since the morbidity and mortality associated with a failed airway are relevant.

The use of US to assess the airway is introducing a profound change in the paradigm of airway evaluation. Many airway US parameters have been studied as predictors of difficult airway in the last decade. However, the results of the studies are diverse, and a clear definition of cut-off values for each parameter measured has not yet been established.

Medical education is driven by competence, where students and residents proceed in their learning processes depending on their clinical skills and achievements instead of the time spent in clinical rotations. Standardized tools should assess technical skills (Norcinni, 2018). Objective Structured Assessment Ultrasound Skill OSAUS is an assessment scale developed to evaluate competence using clinical ultrasound (Todsén, 2015). However, its use as a training and assessment tool was not yet studied in airway evaluation.

Concurrently, US for airway evaluation in neonates and pediatric patients is also becoming a routine. However, the studies published in this area used US in a static approach, meaning to evaluate the proper size and positioning of the tracheal tube and evaluation of the lung and pleura. Dynamic use of ultrasound, allowing real-time monitoring of the tracheal tube position and simultaneously guiding selective lung intubation or exclusion, has not yet been described.

The present work aims to:

- Identify and characterize the most relevant and clinically applicable ultrasound airway parameters that predict a difficult airway. Simultaneously find cut-off values for those ultrasound airway measurements that are aligned with the risk of difficult laryngoscopy and tracheal intubation. (Chapter 2.1)
- Investigate the psychometric properties of the Objective Structured Assessment Ultrasound Skill (OSAUS) Scale when assessing competency in ultrasound hyomental distance (HMD). (Chapter 2.2)
- Describe a new application of clinical airway ultrasound to pediatric selective lung intubation/exclusion in the animal model. (Chapter 2.3)

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Chapter 2

RESEARCH WORK

Chapter 2.1

Sara H. Gomes, Ana M. Simões, Andreia M. Nunes, Marta V. Pereira, Wendy H. Teoh, Patrício S. Costa,
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Useful Ultrasonographic Parameters to Predict Difficult Laryngoscopy and Difficult Tracheal Intubation—A Systematic Review and Meta-Analysis

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Gomes SH, Simões AM, Nunes AM, Pereira MV, Teoh WH, Costa PS, Kristensen MS, Teixeira PM and Pêgo JM (2021) Useful Ultrasonographic Parameters to Predict Difficult Laryngoscopy and Difficult Tracheal Intubation—A Systematic Review and Meta-Analysis. *Front. Med.* 8:671658. doi: 10.3389/fmed.2021.671658

Unexpected difficult airway management can cause significant morbidity and mortality in patients admitted for elective procedures. Ultrasonography is a promising tool for perioperative airway assessment, nevertheless it is still unclear which sonographic parameters are useful predictors of difficult laryngoscopy and tracheal intubation. To determine the ultrasonographic predictors of a difficult airway that could be applied for routine practice, a systematic review and meta-analysis was conducted. Literature search was performed on PubMed, Web of Science and Embase using the selected keywords. Human primary studies, published in English with the use of ultrasonography to prediction of difficult laryngoscopy or tracheal intubation were included. A total of 19 articles (4,570 patients) were analyzed for the systematic review and 12 articles (1,141 patients) for the meta-analysis. Standardized mean differences between easy and difficult laryngoscopy groups were calculated and the parameter effect size quantified. A PRISMA methodology was used and the critical appraisal tool from Joanna Briggs Institute was applied. Twenty-six sonographic parameters were studied. The overall effect of the distance from skin to hyoid bone ($p = 0.02$); skin to epiglottis ($p = 0.02$); skin to the anterior commissure of vocal cords ($p = 0.02$), pre-epiglottis space to distance between epiglottis and midpoint between vocal cords ($p = 0.01$), hyomental distance in neutral ($p < 0.0001$), and extended ($p = 0.0002$) positions and ratio of hyomental distance in neutral to extended ($p = 0.001$) was significant. This study shows that hyomental distance in the neutral position is the most reliable parameter for pre-operative airway ultrasound assessment. The main limitations of the study are the small sample size, heterogeneity of studies, and absence of a standardized ultrasonographic evaluation method [Registered at International prospective register of systematic reviews (PROSPERO): number 167931].

Keywords: airway ultrasound assessment, prediction of difficult intubation, prediction of difficult laryngoscopy, ultrasound predictors of difficult intubation, ultrasound predictors of difficult laryngoscopy

INTRODUCTION

Rationale

Airway management is a core component of anesthesia care (1). In any procedure that requires general anesthesia, anesthesiologists need to control the patient's airway in order to maintain adequate ventilation and oxygenation. This can be a high-risk task and lead to patient morbidity and mortality, due to inadequate/impossible ventilation, and/or intubation. Therefore, it is essential to optimize methods to anticipate a difficult airway and ensure the necessary means to intervene (1).

According to the *Practice Guidelines for Management of the Difficult Airway* by the American Society of Anesthesiologists (ASA), a difficult airway is present when “a conventionally trained anesthesiologist experiences difficulty with facemask ventilation of the upper airway (...) tracheal intubation or both,” a laryngoscopy is difficult when “it is not possible to visualize any portion of the vocal cords after multiple attempts at conventional laryngoscopy” and an intubation is difficult when it “requires multiple attempts” (2). The etiology of a difficult airway is multifactorial and should prompt a detailed clinical history and physical examination (2–7).

However, most clinical predictors have low sensitivity and moderate specificity. Difficult/failed intubation has a low prevalence in the general population, and hence the positive predicted values (PPV) are also low (8). Even though there are several multivariate scoring systems which increase PPV in comparison to single tests, prediction scores still remain poor and many failures are still unanticipated as all airway management techniques can fail (4, 9).

Ultrasonography (US) is a promising tool for airway assessment, as it is safe, quick, repeatable, portable, widely available, and gives real-time dynamic images (10, 11). Many studies have recently been published in this field, but it is still unclear which sonographic parameters and respective cutoff values are clinically useful predictors of difficult laryngoscopy and intubation (11, 12).

Objectives

This systematic review and meta-analysis was undertaken to identify and synthesize evidence from the existing literature (i) to determine the ultrasonographic predictors of difficult laryngoscopy and difficult tracheal intubation in anesthetized adult patients undergoing elective surgery, and to (ii) summarize the current knowledge and applicability of the sonographic measurements already trialed, in the hopes of contributing to establishing an ultrasonography standardized protocol for preoperative airway assessment.

METHODS

Registration

The present review and meta-analysis was elaborated according to the transparent reporting of systematic reviews and meta-analyses, PRISMA (13, 14) and the study was registered

at **International prospective register of systematic reviews (PROSPERO)**: number 167931.

Eligibility Criteria

The articles were considered when they fulfilled the following inclusion criteria: (1) Use of ultrasonography; (2) Prediction of difficult laryngoscopy or tracheal intubation; (3) Humans; (4) Primary studies; (5) English language. No time period was established, so all articles were included until search dates (12/04/2019 and 12/06/2019).

The exclusion criteria were: (1) Obstetric specialty; (2) Pediatric population; (3) Emergency context; (4) Laryngeal mask ventilation; (5) Gray literature. Reviews, editorials, conference abstracts and case reports were also excluded.

Information Sources and Search Methods

The primary search was conducted using the following databases: PubMed, Web of Science and Embase. Keywords and Boolean operators used were: (ultrasound OR ultrasonic OR ultrasonography OR ultrasonographical OR sonography OR ultrasonographic) AND (predict OR predictor OR predictors OR prediction) AND (intubation OR laryngoscopy OR “airway management”) AND difficult. The search results were organized using a Microsoft Excel datasheet with records of the exclusion rationale and duplicated citations.

Study Selection

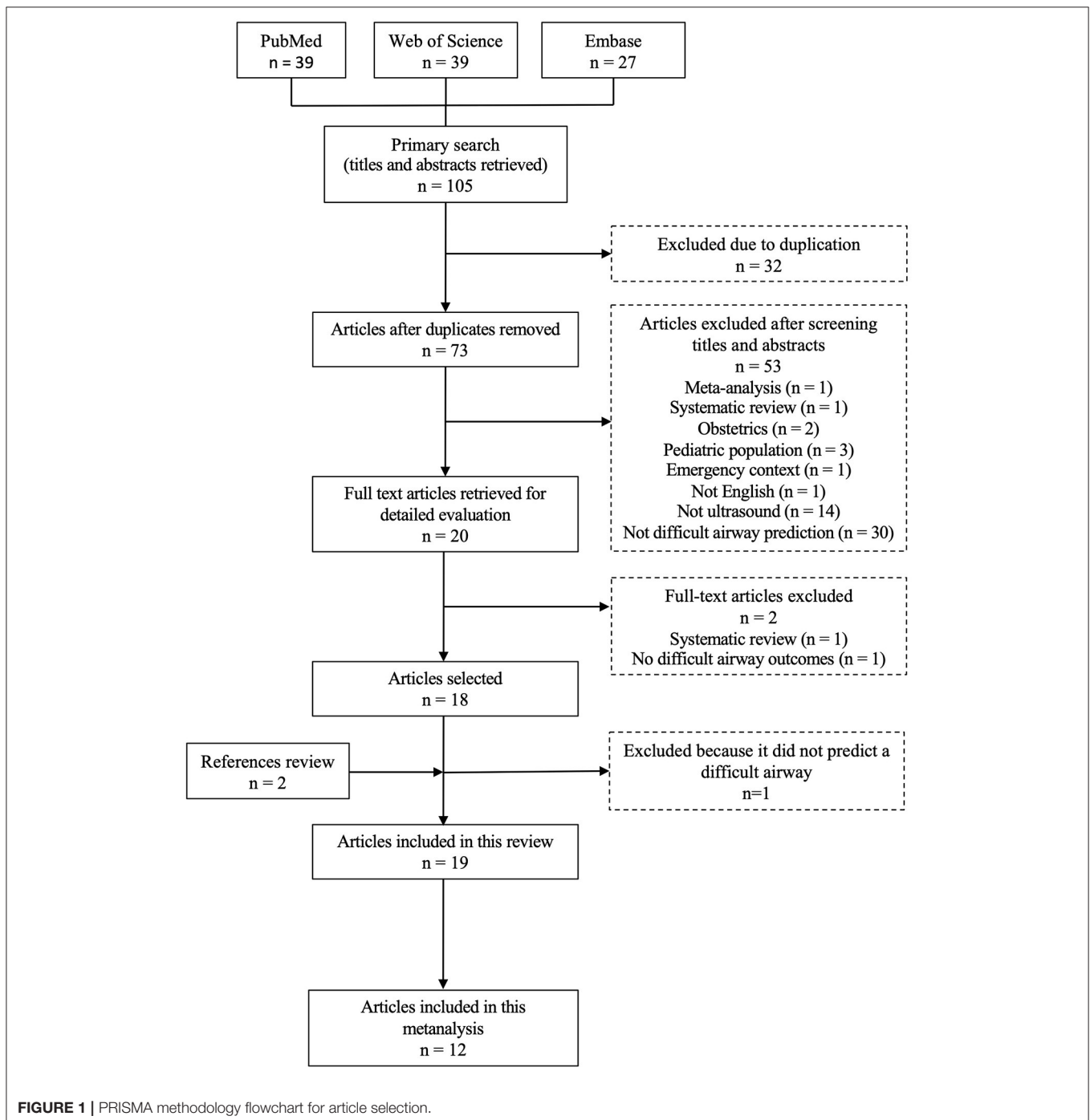
Three independent reviewers (AMS, AMN, MVP) screened studies on the basis of title and abstract to identify duplicates. The next step for screening was done by the same reviewers analyzing by title and abstract for eligibility and dissimilarities were solved by consensus after a review of full text publication by SHG. A full text analysis of the remain articles, for detailed information, was done by (AMS, AMN, MVP, SHG) and lead to article exclusion. The percent concordance value was calculated. In order to reduce the risk of publication bias, a reference list search of included studies and previous systematic review on the same topic was done (**Figure 1**).

Data Collection Process

AMS, AMN, MVP extracted the data from each study and collected in a word file locally developed (similar to Cochrane Consumers and Communication review Group's data extraction template). SHG reviewed each data and supervised the process. Disagreements were resolved by discussion between authors. We contacted two authors for further information. One author responded and provided relevant information. No double counting was found. This study includes only two articles from the same author, but a different ultrasound parameter was studied in each article.

Data Items

From each study, information was extensively extracted and included: (1) study design and methods (objective, study design, anesthesiologist blinding process, standard characteristics—age, sex, BMI, clinical evaluation, US measurements, position for US



measurements and laryngoscopy technique); (2) sample selection (number of participants, BMI, demographic characteristics, inclusion criteria, and setting—Hospital and/or country); (3) Exclusion criteria; (4) Variables and data type (dependent and independent); (5) Statistical analysis (data normality test, numerical, ordinal, nominal, correlation, regression, ROC curve, ...); (6) US results; (7) Conclusions and (8) Limitations. The data was extracted and organized in **Supplementary Table 1** and the relevant cutoff values, means and standard deviations

from the predictors were gathered in **Supplementary Table 2**. To standardize the presentation of results, all distance measurements were converted into centimeters.

Risk of Bias in Individual Studies

The quality assessment of each study was done using the “Checklist for Analytical Cross Sectional Studies” tool, by *The Joanna Briggs Institute* (JBI), by four independent reviewers (AMS, AMN, MVP, SHG) (15) (**Appendix 1**).

Summary Measures and Planned Methods of Analysis

The analysis of the obtained data is presented in forest plots developed using Review Manager 5.3 software (16).

Considering the heterogeneity of the studies, random effect modeling was chosen, and the effect size measured by Standardized Mean Difference to allow comparison of the results. Authors tested heterogeneity using the method proposed by Higgins et al. (17) to measure inconsistency (I^2). An value of I^2 superior to 50% was considered significant which indicated a lower reliability of results.

In order to enable comparison with the other results, a study that presented results as mean and confidence interval, the standard deviation was calculated using the following formula: $(\text{SQRT}(n) \times (\text{Upper CI} - \text{Lower CI}) / t_{\alpha, df} \times 2)$ being the mean and n values relative to the difficult group of each specific parameter (18).

To allow the comparison with other studies, the 4 categories of Cormack-Lehane classification, was dichotomized as easy and difficult by calculating the weighted average of the mean and standard deviation for each group (grades 1 and 2 vs. grades 3 and 4) (19–21).

Ethics

Ethical approval for this study was not required because no animals or patients were involved.

RESULTS

Study Selection

The flowchart in **Figure 1** describes the search method implemented, following PRISMA statement. Primary search on PubMed and Web of Science occurred at 12/04/2019 and Embase at 12/06/2019. PubMed's search was sorted by the "most recent" results and filtered by humans, English and adults (≥ 18 years), obtaining 39 articles. Web of Science's search was sorted by "topic" and filtered by articles and English, excluding the following filters: obstetrics and gynecology, and pediatrics, obtaining 39 articles. The following filters were used in Embase's search: young adult, adult, middle aged, aged, very elderly and articles, and the results were sorted by "all fields," obtaining 27 articles.

One hundred and five articles were identified through database search. Thirty two duplicates were identified. Seventy three studies were analyzed by title and abstract by reviewers for eligibility and dissimilarities were solved by consensus after a review of full text publication by SHG. Due to the particular inclusion/exclusion criteria of this study, this step of screening was possible to do only with title and abstracts analysis, without significant bias, and 53 articles were excluded (see reasons in **Figure 1**). After a full text analysis of 20 articles, for detailed information, two papers were excluded, with a percent concordance value of 1. In order to reduce the risk of publication bias, we search reference list in included studies and previous systematic review on the same topic and one more article was included. Therefore, 19 articles were included in the systematic review and 12 in the meta-analysis (**Figure 1**).

Studies Characteristics

This review included 4,570 adult patients undergoing elective surgery with general anesthesia and tracheal intubation. A summary of the main characteristics, conclusions, and limitations of each article included in the present systematic review and meta-analysis is presented in **Supplementary Table 1**.

All studies analyzed were cross-sectional observational studies. Most of them were prospective (94.7%), except Wojtczak's (12) study where previous anesthesia records were reviewed (5.3%). Blinding was assured in 73.6% of studies, not mentioned in 21.1% (12, 21–23) and "not guaranteed" in 5.3% (24).

The most common exclusion criteria reported were limited neck mobility secondary to cervical spine fractures or tumors (18–22, 24–30), limited neck extension (21, 22, 29, 31, 32), including arthritis (24). Patients with maxillofacial fractures or deformities (18, 21, 22, 24, 27–29, 31, 32) or upper airway abnormalities (19, 25, 26, 28, 30, 33–35), including epiglottic surgery (24), limited interincisal distance (20, 22, 29, 31, 32), subglottic stenosis (35), or thyroid disease (27, 30) were also eliminated from the reported samples.

Although upper teeth removal or absence (20–22, 24, 26) can improve the interincisal distance and facilitate the introduction of the laryngoscope and the direct laryngoscopy view, only (20–22, 24, 26) excluded these patients from their studies.

Previous history of difficult intubation (25, 26, 28, 32, 33, 35) and pregnancy (19, 25–27, 30, 32) were disqualifiers in 32% of the studies.

Patients with full stomach (21, 22), diaphragmatic hiatus hernia (21, 22), gastroesophageal reflux disease (GERD) (25, 26), and planned rapid sequence intubation (19, 23, 32) were excluded in some studies. Only Wojtczak (12) didn't mention exclusion criteria.

Ninety percent of studies reported standard characteristics of age, sex, body mass index; with Reddy et al. (19) only considering the body mass index and no mention of this parameter in Gupta et al. (21) study. Two studies recorded the race of the patients (15, 34).

A population of obese patients were specifically studied in 21.1% of the articles (12, 23, 25, 26). Pinto et al. (27), Mohammadi Soltani (22), Parameswari's et al. (31), and Rana et al. (20) excluded this population from their studies, however in Reddy's study (19) a population with a heterogenous weight was included.

Difficult airway, clinically relevant history and objective signs from the physical examination were collected by the majority, except for Falcetta et al. (32) who did not mention which clinical screening evaluation was used.

A history of Obstructive Sleep Apnea Syndrome (OSAS) was collected in 21.1% of the studies (18, 25, 26, 30); teeth pathology (18, 25, 26, 30, 34) and neck mobility problems (18, 25, 26, 30, 34) in 26%, and neck circumference (12, 18, 25–27, 31) in 32% of the studies.

The mobility of the temporomandibular joint was directly evaluated in only 10.5% of studies (18, 26), though many other authors evaluated parameters related to that joint's kinesis, for example interincisal distance (IID) (18, 20, 24–28, 30, 31, 33–35),

upper lip bite test (ULBT) (23, 28, 30, 33), mandibular protrusion (28), and condyle-tragus distance (28).

The evaluation of the clinical predictors was done by the same practitioner in a minority of the studies (19, 25, 26), with only (28, 33, 35) stating that the evaluation was done by clinicians with competency for the task.

In 53% of the studies (19, 20, 23, 24, 28, 30, 32–35), laryngoscopy was reportedly performed by experienced anesthetists with more than 2 years of training, although most of the authors (53%) omitted mentioning the number of anesthetists who performed the technique (12, 19, 20, 22, 23, 27, 29, 31, 32, 35).

In all studies a direct laryngoscopy was used and the Cormack-Lehane (CL) grade was defined as the outcome variable (CL 1&2 = easy vs. CL 3&4 = difficult). In order to facilitate the laryngoscopy view, a backward, upward, and rightward pressure (BURP) was applied on the thyroid cartilage during all laryngoscopies in Ezri et al. (25) study. In Komatsu et al. (26), Yao and Wang (35), and Falcetta et al. (32) studies this maneuver was also allowed, however Prestrisor et al. (23) excluded patients when an external laryngeal manipulation was necessary.

Ultrasound measurements were done by the same sonographer in 58% of the studies (18, 21, 24, 24–28, 30, 31, 34), and in 42% the experience of the ultrasound practitioner was not declared (12, 19, 20, 22–24, 27, 30).

Another essential aspect of the studies is the positioning of the patient in which US parameters were evaluated. All US measurements were conducted in supine position, except in Hui and Tsui (34) and Yao et al. (28) studies (sitting position) (10.5%) and Ezri et al. (25) did not specify this feature (5.3%).

The majority of the measurements of the skin to structure distance were undertaken in the central axis of the neck, but Erzi et al. (25), Komatsu et al. (26), Adhikari et al. (18), Pinto et al. (27), and Falcetta et al. (32) presented averaged values from the measurements taken in the central midline and 1.0 or 1.5 cm to each side.

Risk of Bias Within Studies

Quality assessment of the studies included in the systematic review and the meta-analysis was done using the “Checklist for Analytical Cross Sectional Studies” tool, by *The Joanna Briggs Institute* (JBI), by four independent reviewers (15) (**Appendix 1**).

All studies have clearly defined the criteria for sample selection except for Wojtczak (12) that does not mention exclusion criteria. Ezri et al. (25), Komatsu et al. (26), Gupta et al. (21), Parameswari et al. (31), Wojtczak (12), Rana et al. (20), and Petrisor et al. (23) did not describe in detail the demographics, location, or time period of their studies; whereas, Wu et al. (24), Pinto et al. (27), Andruszkiewicz et al. (33), Reddy et al. (19), Yao et al. (28), and Chan et al. (29) left some of these parameters unclear.

The description of the study subjects, setting, and time was presented in detail in Adhikari et al. (18), Andruszkiewicz et al. (33), Yao et al. (28), Yao and Wang (35), Falcetta et al. (32), Mohammadi Soltani et al. (22), and Alessandri et al. (30).

In relation to the validity of the studies performing US evaluations, almost every study described in detail the technique implemented to obtain the measurements, with the exception

of three (25, 26, 34). Furthermore, Yao et al. (28) and Yao and Wang (35) studies assessed inter-rater reliability by comparing the measurements of at least two independent sonographers, and (29) assessed both inter and intra-rater reliability.

All studies selected only patients undergoing elective surgery, therefore standard criteria were used to evaluate the referred condition. Although none of the studies has listed eventual confounding factors, (12, 23, 25, 26) selected only obese patients; (20, 32) excluded patients with clinically predicted difficult airway; (19, 21, 22, 24, 30) performed a correlation analysis between the considered variables and (26, 28, 33, 35) studies performed a multivariate logistic regression analysis to assess the potential effect of each variable while controlling the effect of others.

Regarding the laryngoscopy classification method, there are some important differences between studies since Chan et al. (29) analyzed anesthesia records after surgeries (12), analyzed anesthesia records from previous surgeries, and (18, 21, 22, 28) did not have an anaesthesiologist specifically assigned for this task. Furthermore, Wu et al. (24) did not blind the US results and (12, 21–23) did not mention blinding.

With regards to statistical analysis, the majority of studies used appropriate methods. However, not all results were reported in Adhikari et al. (18), Parameswari et al. (31), Mohammadi Soltani et al. (22), and Falcetta et al. (32) studies. Some presented unclear statistical data, such as Gupta et al. (21), Rana et al. (20), Parameswari et al. (31), and Petrisor et al. (23). Finally, Ezri et al. (25), Komatsu et al. (26), Wu et al. (24), Pinto et al. (27), Mohammadi Soltani et al. (22), Wojtczak's (12), Yao et al. (28), and Yao and Wang (35) studies did not mention the application of normality tests, which may compromise the results, especially in Wojtczak's (12) study, due to the small sample size.

Results of Studies by Ultrasound Parameter

To predict difficult laryngoscopy and difficult tracheal intubation, a total of 26 US parameters were investigated in the 19 studies.

Significant Ultrasound Predictors of Difficult Laryngoscopy

The following parameters were significant in predicting a *difficult laryngoscopy*: evaluation of the distance from skin to hyoid bone (24), skin to epiglottis (18, 23, 24, 27, 32), skin to vocal cords (VC) (19, 24–26), and skin to anterior aspect of trachea at the level of suprasternal notch (25); condylar translation (28); HMD in neutral (23, 33), ramped (23), and extended (27, 31) position; tongue cross-sectional area and volume (33), thickness and ratio of tongue thickness to TMD (35); Pre-E/aVC (29); Pre-E/mVC (20, 21); ratio between HMD ramped position and neutral position (HMDR1) (23); ratio between HMD in the extended position and neutral position (HMDR2) (12, 20, 23, 33); pre-epiglottic area (PEA) (32) and visualization of hyoid bone with sublingual US (34) approach.

By contrast, evaluation of the pre-epiglottic space (Pre-E) (22), distance from epiglottis to midpoint of the distance between vocal cords (E-VC) (22); skin to trachea at the level of the

thyroid isthmus (18, 25, 30); floor of the mouth muscle cross-sectional area (33); floor of the mouth muscle volume (12, 27); tongue width and tongue thickness-to-oral cavity height ratio (33) and Pre-E/pVC (22, 29) were not significant in predicting a difficult laryngoscopy.

Outcomes from each study was profoundly analyzed, we present the most relevant.

Hyoid Bone Visualization

Hui et al. (34) study concluded that sublingual ultrasound had a sensitivity of 73% and a specificity of 97% for predicting difficult intubation ($p < 0.0001$) when hyoid bone visualization was not possible.

Skin to Hyoid Bone

At the level of the hyoid bone, patients with a difficult laryngoscopy had a significantly larger distance from skin to hyoid bone of 1.08 ± 0.41 cm (30), 1.69 ± 0.62 cm (18), and 1.51 ± 0.27 cm (24) compared with easy laryngoscopy. Wu et al. (24) concluded that a distance more than 1.28 cm predicts a difficult laryngoscopy (Se: 85.7%, Sp: 85.1%). By contrast, findings in Reddy et al. (19) study were not statistically significant. The overall effect of this measurement was significant ($p = 0.02$) (Figure 2).

Skin to Epiglottis

At the level of the thyrohyoid membrane, patients with a difficult laryngoscopy displayed mean measurements over 2.8 cm (18), 1.78 cm (24) (Se: 100%, Sp: 66.2%), 2.54 cm (32) (Se: 82%, Sp: 91%), and equal or superior to 2.75 cm (27) (Se: 64.7%, Sp: 77.1%). Even a mere 0.91 ± 0.28 cm (30) was found to be associated with difficult laryngoscopy. By contrast, findings in Petrisor et al. (23) study were not statistically significant. The overall effect of this measurement was significant ($p = 0.02$) (Figure 3).

Skin to Vocal Cords

At the level of the vocal cords, studies showed significant discrepancies. While Ezri et al. (25) reported that patients with a difficult laryngoscopy presented a significantly bigger distance from skin to vocal cords (2.80 ± 0.27 cm compared to easy laryngoscopy, 1.75 ± 0.18 cm), Komatsu et al. (26) reported an inverse relationship between difficult and easy laryngoscopy patients (2.04 ± 0.3 and 2.23 ± 0.38 cm, respectively). A distance superior to 1.10 cm (Se: 75%, Sp: 80.6%) (24) and even 0.23 cm (Se: 85.7%, Sp: 57%) (19) predicted a difficult laryngoscopy in other studies. By contrast, findings in Adhikari et al. (18), Falcetta et al. (32), and Alessandri et al. (30) studies were not statistically significant. However, the overall effect of this measurement was significant ($p = 0.02$) (Figure 4).

Pre-epiglottic Area (PEA)

The pre-epiglottic area analyzed by Falcetta et al. (32) measures the area from skin to epiglottis 10 mm each side of the midline should be not confused with the pre-epiglottic distance used by Gupta et al. (21), Chan et al. (29), Rana et al. (20), or Mohammadi et al. (22) (see definition above). Falcetta et al. (32) concluded that

if this measurement was superior to 5.04 cm^2 (Se: 85%, Sp: 88%), it predicted a difficult laryngoscopy.

Pre-epiglottic Space (Pre-E) and Distance From Epiglottis to Midpoint Between Vocal Cords (E-VC)

Only Mohammadi Soltani (22) evaluated Pre-E and E-VC in isolation and concluded that the correlation between Pre-E and E-VC with Cormack-Lehane grade 1–3 were weak.

Pre-epiglottic Space to Distance Between Epiglottis and Midpoint Between the Anterior and Posterior Vocal Cords Ratio (Pre-E/mVC)

Rana et al. (20) established that a Pre-E/mVC ratio superior to 1.77 (Se: 82%, Sp: 80%) predicts a difficult laryngoscopy and (21) described a strong positive correlation with a regression coefficient of 0.495 (95% CI 0.319–0.671; $p < 0.0001$) even though (19) did not obtain a statistically significant result for this parameter. The overall effect was significant ($p = 0.01$) (Figure 5).

Pre-epiglottic Space to Distance Between Epiglottis and Anterior Vocal Cord Ratio (Pre-E/aVC)

Chan et al. (29) found that a Pre-E/aVC ratio superior to 1 (Se: 79.5%; Sp: 39.2%) (29) predicts a difficult laryngoscopy.

Skin to Anterior Aspect of Trachea at the Level of Thyroid Isthmus

This was not statistically significant in the individual studies (18, 25, 30) that considered this measurement. Its overall effect was also not significant ($p = 0.06$) (Figure 6).

Skin to Anterior Aspect of Trachea at the Level of Suprasternal Notch

At the suprasternal notch, patients with a difficult laryngoscopy had significantly deeper skin to the anterior aspect of trachea distance of 3.30 ± 0.43 cm (25). By contrast, findings in Adhikari et al. (18) and Alessandri et al. (30) studies were not statistically significant. The overall effect of this measurement was also not significant ($p = 0.06$) (Figure 7).

Hyomental Distance in Neutral Position

Patients with shorter hyomental distances in neutral position [3.99 ± 0.56 cm (33)] were found to be significantly associated with difficult laryngoscopy. Although Petrisor et al. (23) and Wojtczak (12) did not obtain statistically significant results for this parameter, the overall effect of this measurement was significant nonetheless ($p < 0.0001$) (Figure 8).

Hyomental Distance in Ramped Position

Petrisor et al. (23) concluded that an HMD in ramped position equal or inferior to 4.97 cm (Se: 100%, Sp: 61.9%) predicts a difficult laryngoscopy.

Hyomental Distance in Extended Position

Patients with a difficult laryngoscopy had significantly decreased HMD in the extended position, of 4.28 ± 0.64 cm (33) and 5.26 ± 0.58 cm (12), compared to patients with easy laryngoscopy.

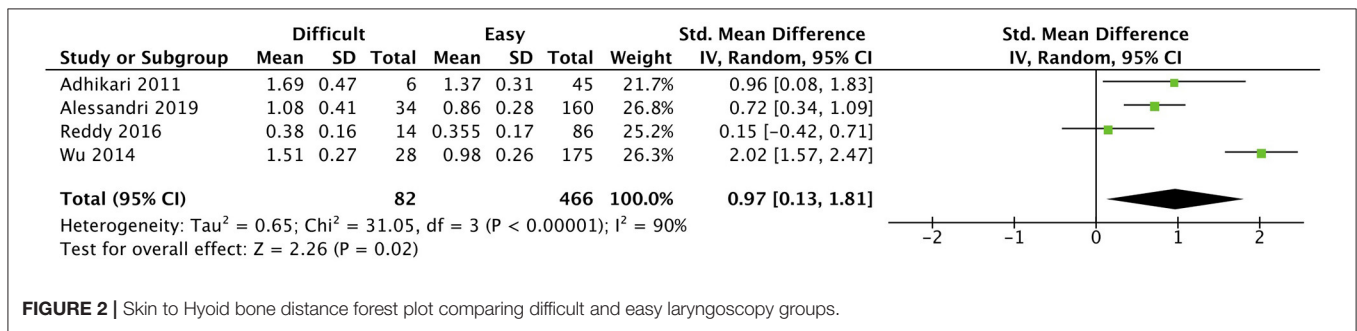


FIGURE 2 | Skin to Hyoid bone distance forest plot comparing difficult and easy laryngoscopy groups.

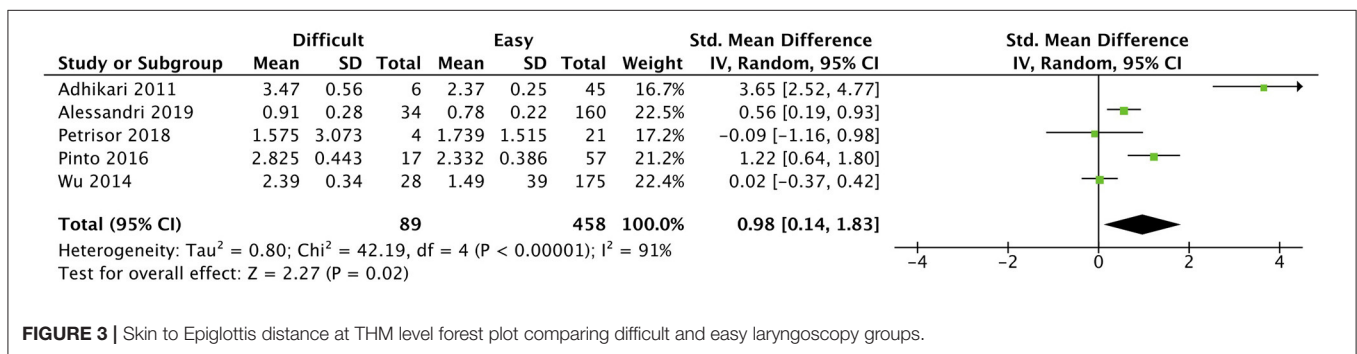


FIGURE 3 | Skin to Epiglottis distance at THM level forest plot comparing difficult and easy laryngoscopy groups.

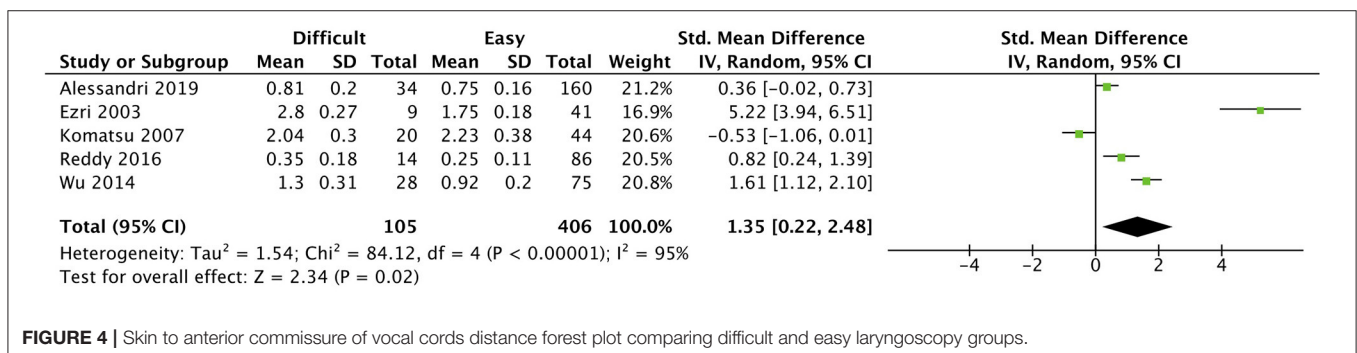


FIGURE 4 | Skin to anterior commissure of vocal cords distance forest plot comparing difficult and easy laryngoscopy groups.

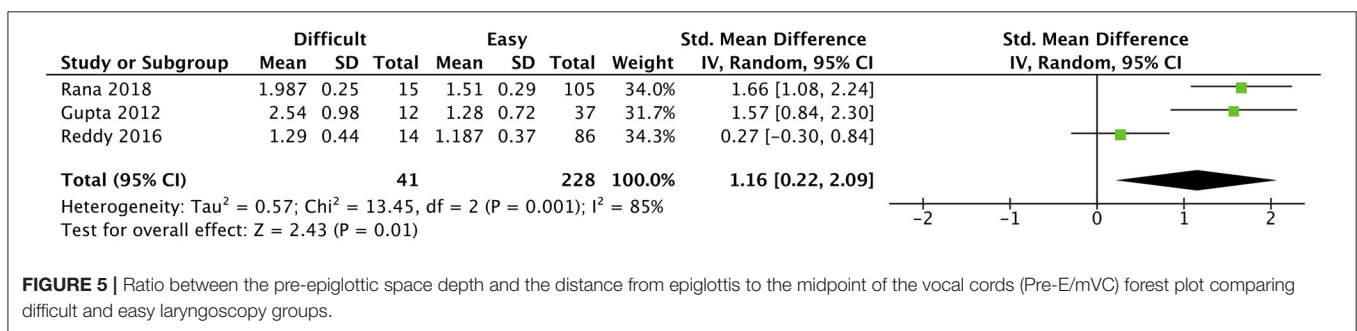


FIGURE 5 | Ratio between the pre-epiglottic space depth and the distance from epiglottis to the midpoint of the vocal cords (Pre-E/mVC) forest plot comparing difficult and easy laryngoscopy groups.

Petrisor et al. (23) established that values equal or inferior to 5.50 cm (Se: 100%, Sp: 71.4%), predicted a difficult laryngoscopy. The overall effect of this measurement was significant ($p = 0.0002$) (Figure 9).

Hyomental Distance in Ramped to Neutral Position Ratio (HMDR1)

Petrisor et al. (23) found that HMDR1 equal or inferior to 1.12 (Se: 75%, Sp: 76.2%) predicts a difficult laryngoscopy.

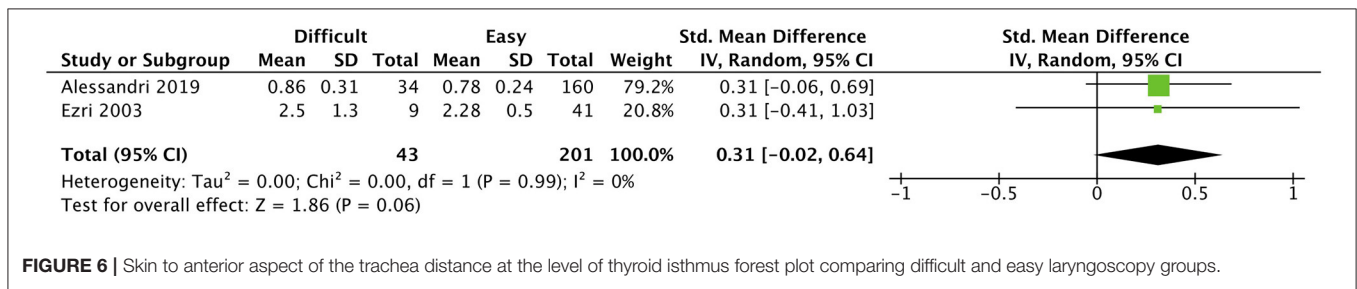


FIGURE 6 | Skin to anterior aspect of the trachea distance at the level of thyroid isthmus forest plot comparing difficult and easy laryngoscopy groups.

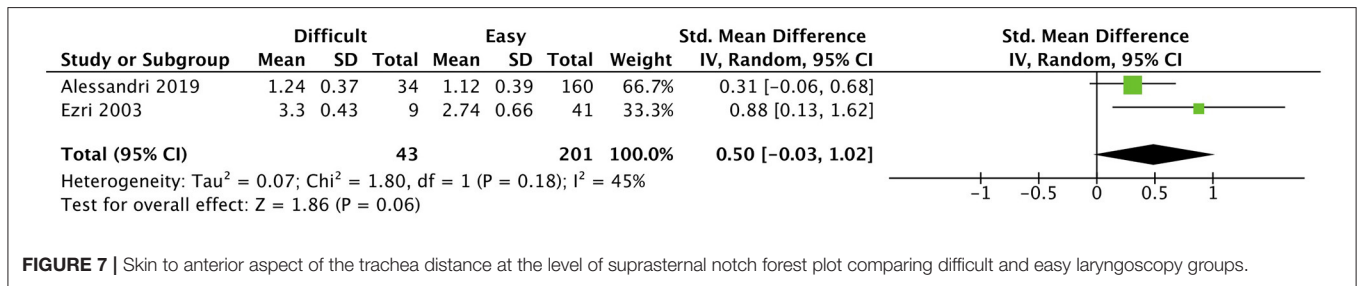


FIGURE 7 | Skin to anterior aspect of the trachea distance at the level of suprasternal notch forest plot comparing difficult and easy laryngoscopy groups.

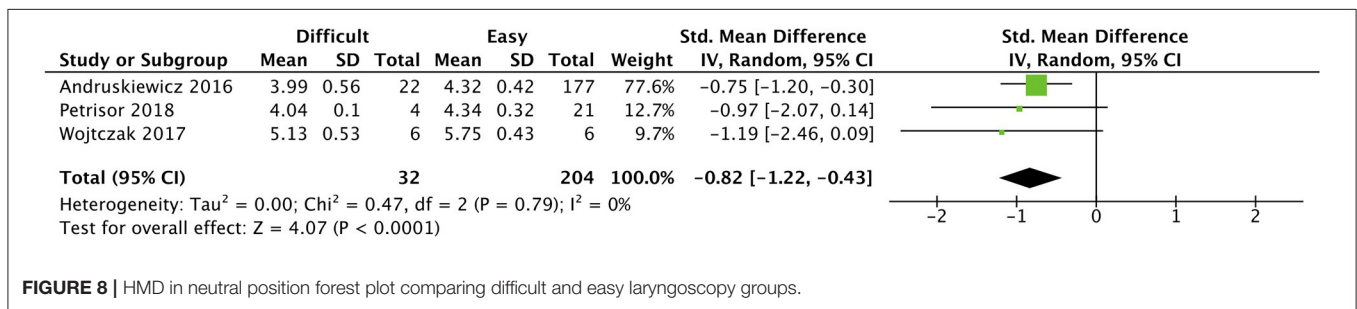


FIGURE 8 | HMD in neutral position forest plot comparing difficult and easy laryngoscopy groups.

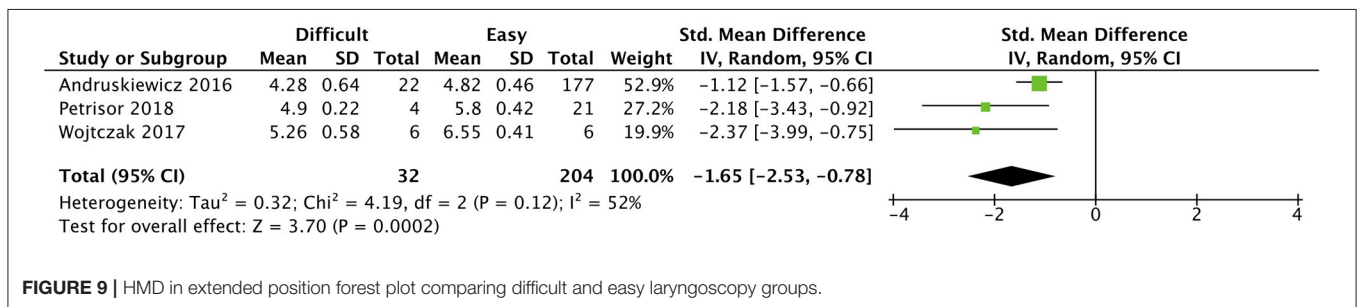


FIGURE 9 | HMD in extended position forest plot comparing difficult and easy laryngoscopy groups.

Hyomental Distance in Extended to Neutral Position (HMDR2)

Patients with a difficult laryngoscopy presented with a significantly shorter HMDR2 [1.07 ± 0.08 (33) and 1.02 ± 0.01 (12)] compared with patients with easy laryngoscopy. HMDR2 equal or inferior to 1.085 (Se: 75%, Sp: 85.3%) (20) and to 1.23 (Se: 100%, Sp: 90.5%) (23) predicted a difficult laryngoscopy. The overall effect of this measurement was significant ($p = 0.001$) (Figure 10).

Tongue Volume

The group of difficult laryngoscopy patients in Andruskiewicz’s study (33) had significantly larger tongue volumes ($121.7 \pm$

27.1 cm) compared with patients with an easy laryngoscopy. Wojtczak (12) did not obtain a statistically significant result for this parameter. The overall effect of this measurement was also not significant ($p = 0.88$) (Figure 11).

Floor of the Mouth Muscle Volume

The floor of the mouth muscle volume parameter was not statistically significant in individual studies (12, 31); its overall effect was not significant as well ($p = 0.55$) (Figure 12).

Tongue Thickness

Yao and Wang (35) concluded that in difficult laryngoscopy patients had larger tongue thickness, a value superior to 6.0 cm

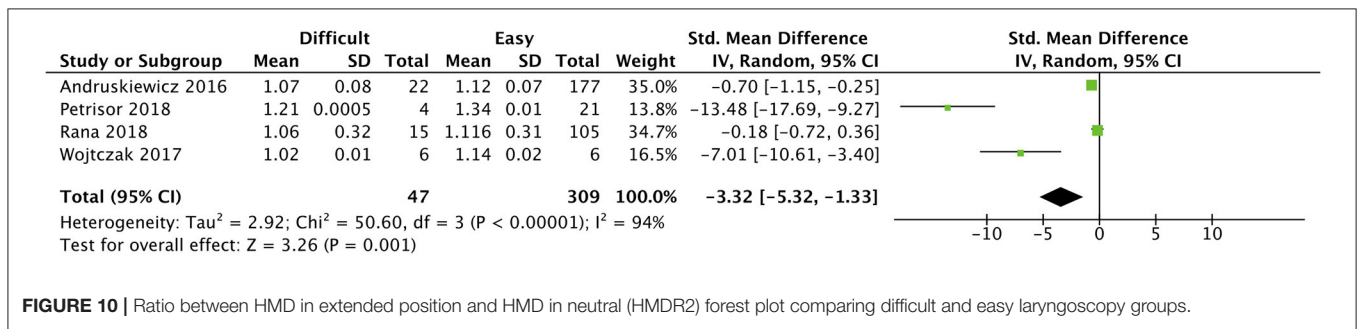


FIGURE 10 | Ratio between HMD in extended position and HMD in neutral (HMDR2) forest plot comparing difficult and easy laryngoscopy groups.

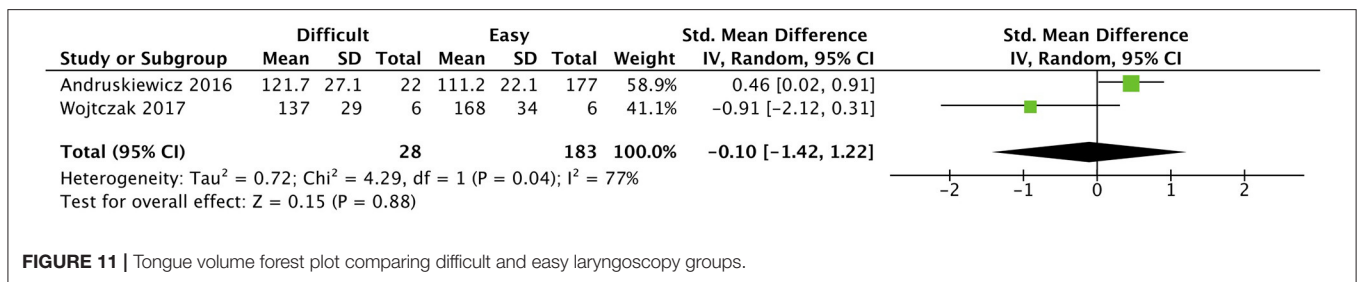


FIGURE 11 | Tongue volume forest plot comparing difficult and easy laryngoscopy groups.

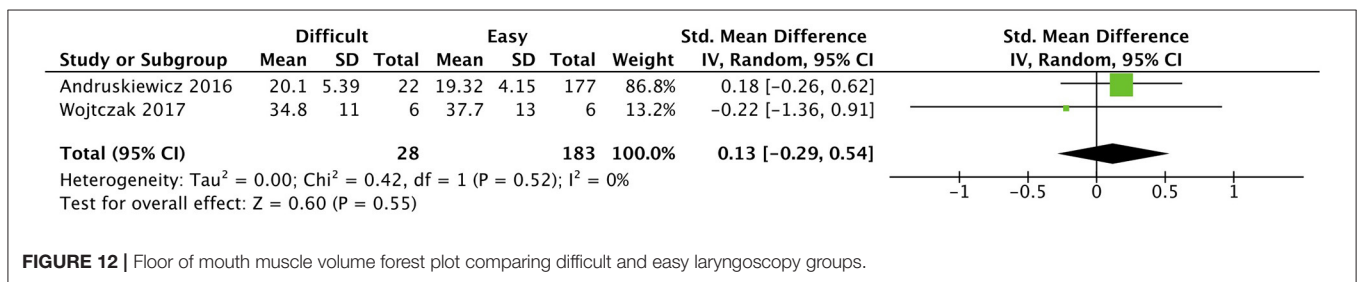


FIGURE 12 | Floor of mouth muscle volume forest plot comparing difficult and easy laryngoscopy groups.

(Se: 63%, Sp: 66%) predicts a difficult laryngoscopy. By contrast, in Adhikari et al. (15) study the parameter was not considered statistically significant, although the values were not presented.

Tongue Cross-Sectional Area

Only Andruskiewicz et al. (33) evaluated tongue cross-sectional area and concluded that patients with a difficult laryngoscopy had a larger tongue cross sectional area ($23.1 \pm 3.57 \text{ cm}^2$) compared with the easy laryngoscopy group ($21.6 \pm 3.09 \text{ cm}^2$).

Condylar Translation

Only Yao et al. (28) evaluated condylar translation and concluded that if this measurement was equal or inferior to 1 cm [sensitivity (Se): 81%, specificity (Sp): 91%] it predicted a difficult laryngoscopy.

An overall view of the results of the difficult laryngoscopy group from the studies included in the meta-analyses is presented in **Supplementary Table 2**.

Significant Ultrasound Predictors of Difficult Tracheal Intubation

As predictors of difficult tracheal intubation, only three parameters were analyzed. Tongue thickness (35) was a **significant** predictor, whereas the distance from skin to anterior

commissure of vocal cords (26) and tongue thickness to TMD ratio were not significant. Yao et al. (35) determined that a measurement of tongue thickness superior to 6.1 cm (Se: 75%, Sp: 72%) and tongue thickness to TMD ratio superior than 0.87 (Se: 84%, Sp: 79%) predicted a difficult tracheal intubation. On the other hand, Komatsu et al. (26) did not obtain a statistically significant result when analyzing the distance from skin to the anterior commissure of vocal cords. Therefore, Yao and Wang study (35) is the only one that obtained a statistically significant result for difficult tracheal intubation.

No forest plot was done for difficult tracheal intubation predictors since for each ultrasound parameter studied only one paper was published.

Syntheses of Results

To predict a difficult laryngoscopy, 12 articles were analyzed and 11 ultrasound parameters were included in the meta-analysis, 7 of which had a significant overall effect.

Concerning the distance from skin to the hyoid bone, the positioning of patients may explain why (19) was the only study without significant results [head in extended (19) vs. neutral position (18, 24, 30)]; a sample of Asian population could have also contributed to this outcome. Even though the meta-analysis

had a significant result, the high heterogeneity (I^2 of 90%) means it is less reliably applied in clinical practice.

Adhikari et al. (18), Pinto et al. (27), Wu et al. (24), Alessandri et al. (30), and Petrisor et al. (23) studies analyzed the distance from skin to epiglottis and had different results from their studies.

The methodology adopted by Adhikari et al. (18) and Pinto et al. (27) were very similar. Both excluded morbidly obese patients and the ultrasound images were collected by the same sonographer with the same transducer (Sonosite M-Turbo, 10 MHz linear). The positioning of the patients was also comparable (neutral position without a pillow). The CL categorization was equal (CL 1&2 easy vs. CL 3&4 difficult). In Adhikari et al. (18) reported values that corresponded to the average of three measurements (one made in the central axis and two measurements distanced 1 cm from the central axis on either side) while Pinto et al. (27) reported similar methodology except that the lateral measurement was made at the lateral border of the epiglottis.

Eighty and 76% of the difficult airway patients were males and a cut-off of >2.8 and ≥ 2.75 cm was established in Adhikari et al. (18) and Pinto et al. (27), respectively. Although the methodology was quite similar to the studies referred above (i.e., transducer, patient positioning), Wu et al. (24) study selected patients from Chinese Han population, that were less heavy than in Pinto et al. (27). This fact can explain why its cut-off value of 1.78 cm (Se: 100%, Sp: 66.3%) is less than the studies mentioned above (>2.8 cm in Adhikari's and ≥ 2.75 cm in Pintos's study).

Skin to epiglottis distance showed significant differences between the difficult and the easy laryngoscopy groups in all studies except in Petrisor's study (23). The study population was morbidly obese (i.e., BMI >40 kg/m²), 75% of the difficult airway patients were female, and the patient position for collecting this measurement was omitted. Those facts can explain the differences from Adhikari et al. (18), Pinto et al. (27), Wu et al. (24), and Alessandri et al. (30). Although its significant value in meta-analysis, strong evidence of heterogeneity ($I^2 = 91\%$, $p < 0.00001$) was observed.

The distance from skin to the anterior commissure of the vocal cords studied by Ezri et al. (25), Komatsu et al. (26), Wu et al. (24), Reddy et al. (19), and Alessandri et al. (30) had a significant overall effect but a low reliability.

The study design, methods and sample selection were very similar in Ezri et al. (25) and Komatsu et al. (26) which can explain the similarity of results (2.8 ± 0.27 vs. 2.04 ± 0.3 cm). Although Wu et al. (24) adopted the same methodology and study design, their sample of lighter Chinese Han population may have resulted in a lower cut-off and lower mean (>1.1 cm, 1.30 ± 0.31 cm). Reddy et al. (19) yielded the most discrepant result (cutoff >0.23 cm) compared to the studies above, mostly secondary to a specific population (only 6% of patients were obese) and the extended cervical position adopted for the US evaluation. Alessandri et al. (30) was the only study without significant results and with the lowest mean value measured. This authors adopted a different CL categorization (CL grade 2B as difficult laryngoscopy), which may have unintentionally placed patients in the difficult laryngoscopy group, that in other studies would belong to the

easy group. A strong heterogeneity was reported ($I^2 = 95\%$, $p < 0.00001$).

Rana et al. (20) and Gupta et al. (21) found significant results concerning Pre-E/mVC. In Gupta et al. (21) study the mean value for the Pre-E/E-VC was much higher (2.54 cm \pm 0.98) when compared with Reddy et al. (19) (1.29 cm \pm 0.44) and Rana et al. (20) (1.987 cm \pm 0.26) results. This can be partially explained by a small sample size, an incomplete investigator training and by the unknown demographics from Gupta et al. (21) study. Rana et al. (20) included patients with a BMI <25 kg/m² and Reddy (19) between 14.2 and 39 kg/m², which may explain the distinct results and indicate that this parameter might be more useful in normal weighted patients. Although the overall effect was significant, the heterogeneity ($I^2 = 85\%$) was high.

Only Andruskiewicz et al. (33) found significant differences measuring HMD in neutral position. This parameter had, however, a significant overall effect, with 0% heterogeneity, since this author and co-workers had a considerably higher weight in the analysis due to the sample size (199 patients). This US parameter was the most reliable measure of a difficult laryngoscopy.

Both HMD in extended position (12, 23, 33) and HMDR2 (12, 20, 23, 33) had significant overall effects as all studies had significant differences. All authors implemented the same methodology, study design and US measurement technique, for both HMD extended and HMDR2. Although Petrisor et al. (23) and Wojtzak (12) studied obese and morbidly obese patients, the population body mass index in Andruszkiewicz et al. (33) study had the lowest BMI while in Rana et al. (20) patients had variable BMI (14.2–39 kg/m²). This fact suggests that this predictor may be applied to the general population. However, HMD in extended position had a heterogeneity of 52%, meaning that their relevance for clinical practice is still unclear.

DISCUSSION

Summary of Evidence

Despite its widespread use, ultrasonography is not yet routinely used for airway assessment and management (36–39) and its use for prediction of a difficult airway is still limited.

In the literature, several ultrasound measurements of cervical anatomic structures have been assessed and used as indicators of difficult airway, but there is still debate about the best parameter and the need for higher level of evidence (40).

The present analysis revealed that 7 US measurements have a significant overall effect as predictors for a difficult laryngoscopy. We found that HMD in neutral position was the most consistent predictor. Other potentially useful measurements are HMD in extended position, HMDR2, Pre-E/E-mVC, as well as the distance from skin to hyoid bone, skin to epiglottis, and skin to the anterior commissure of vocal cords.

Limitations

One of the most important limitations of this systematic review and meta-analysis is the heterogeneity of the samples in the studies reviewed, namely BMI ranges, ethnic diverse populations, and female to male proportions. There is also significant

discrepancy in study characteristics, mainly in the sample size and blinding. Another limitation of the study is related to the concepts of difficult laryngoscopy and difficult intubation. Both words are used interchangeably in some cases. Therefore, the use of the Cormack-Lehane classification as a surrogate outcome measure for a difficult tracheal intubation may imply a bias in this study. However, it has been thoroughly utilized in the literature, and a CL grade 3 was associated with an 87.5% likelihood of a difficult tracheal intubation (41).

In the selected studies, there may be a selection bias as only articles related to elective surgeries were chosen, which can compromise external validity of the results. This resulted from the fact that only one article on the use of ultrasound in emergency surgery was identified and was not considered as representative sample. Additionally, our population study excluded pregnant (42, 43) and pediatric (44, 45) patients. Both groups of populations have airway anatomical and physiological specificities that could render a bias in the analysis and should be analyzed independently from the general population.

Finally, for the evaluation of each US parameter, a standardized US technique and positioning are missing, hence there may be a bias associated with the acquisition of the data, even though there was a significant effort to describe in detail the used technique and to train the sonographers to allow reproducibility of the results.

CONCLUSION

Our findings suggest that ultrasonography is a useful tool for prediction of a difficult laryngoscopy and that the best candidate to implement in clinical practice is the measurement of the hyomental distance with the head and neck in neutral position.

Recommendations for Future Studies

Future studies should include larger sample sizes with proportional standard characteristics and ensure a standardized US measurement technique and positioning. It would also be beneficial to assess inter and intra-rater reliability to ensure the validity of the results.

Assessing HMD in neutral position may be the direction to go as it is the most promising US parameter. It may be relevant to define a specific cut-off for ethnicity, obesity, pregnancy, and

pediatric patients and implement US airway evaluation in the context of emergency and intensive care.

Finally, it would be advantageous to introduce ultrasonography for the preoperative airway assessment in anesthesiology curriculum training (46), to ensure the acquisition of the skill as early as possible.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

SG and JP: study conception and design. SG, AS, AN, MP, PT, PC, and JP: acquisition of data, analysis and interpretation of data, and drafting the article. SG, WT, MK, PT, PC, and JP: in depth revising the manuscript critically for important intellectual content. SG, AS, AN, MP, WT, PC, MK, PT, and JP: final approval of the version to be published and all agree to be countable for all aspects of the work thereby ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors contributed to the study substantially.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fmed.2021.671658/full#supplementary-material>

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Chapter 2.2

Gomes SH, Trindade M, Petrisor C, Pêgo JM, Correia-Pinto J, Costa PS

Objective Structured Assessment Ultrasound Skill Scale for Hyomental distance competence – psychometric study

(Manuscript submitted)

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Rational of this Chapter

The current work followed the results from the first task of this Thesis - Systematic review and meta-analysis of ultrasound parameters that could predict a difficult laryngoscopy and a difficult tracheal intubation. The objective of this second work was to evaluate a reliable tool that could monitor learning, training, and assessment of the ultrasonographic measurement applied to airway management. This chapter comprehends the study of the psychometric properties of the previously validated Objective Structured Assessment Ultrasound Skills (OSAUS) Scale when used to assess competence in the measurement of ultrasound hyomental distance.

Objective Structured Assessment Ultrasound Skill Scale for Hyomental distance competence – psychometric study

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Supplementary material: 2 tables

Keywords: OSAUS, hyomental, distance, airway, ultrasound, assessment, psychometric properties

Abstract

Background: Ultrasound assessment of the airway recently integrates the point-of-care approach to patient evaluation since ultrasound measurements can predict a difficult laryngoscopy and tracheal intubation. Because ultrasonography is performer-dependent, a proper training and assessment tool is needed to increase diagnostic accuracy. An objective, structured assessment ultrasound skill (OSAUS) scale was recently developed for different medical fields. The study aims study the psychometric properties of OSAUS Scale when used to evaluate competence in ultrasound hyomental distance (HMD) measurement.

Methods: Prospective and experimental study. Fifteen volunteers were recruited and split into three groups depending on participants expertise in airway ultrasound. Each participant performed ultrasonographic HMD evaluation, with the patient in head neutral and extended position, in 3 standardized patients. The performance was videorecorded and anonymized. Five assessors blindly rated participants' performance using OSAUS scale and a Global Rating Scale (GRS). A psychometric study of OSAUS scale as assessment tool for ultrasound HMD competence.

Results: Psychometric analysis of OSAUS showed strong internal consistency (Cronbach's alpha 0.916) and inter-rater reliability (ICC 0.720; $p < 0.001$). The novice group scored 15.4 ± 0.08 (mean \pm SD), the intermediate 14.3 ± 0.33 and expert 13.5 ± 0.68 , with a significant difference between novice and expert groups ($p = 0.036$). The time in seconds to complete the task was evaluated: novice (90.40 ± 34.15) (mean \pm SD), intermediate (84.20 ± 22.88) and experts (82.60 ± 15.07), with no significant differences between groups. A strong correlation was observed between OSAUS and global rating scale (5-points Likert) ($r = 0.970$, $p < 0.001$).

Conclusion: The study demonstrated evidence of response process, internal structure, and relation to other variables. Further studies are needed to complete the Messick's criteria for validity and move forward to implement OSAUS scale in the clinical setting for training and assessment of airway ultrasound competence.

1. Introduction

In the last decades, the use of ultrasonography expanded from the laboratory to the patient bedside evaluation. Nowadays, almost all clinical medical specialties have developed a Point-of-Care Ultrasonography (PoCUS) approach to enhance patients' primary assessment, diagnostics, and treatment. In anesthesiology training curriculum and daily practice several PoCUS approaches to patient evaluation have been incorporated, namely cardiac, lung, gastric, abdominopelvic, regional anesthesia, vascular access, and airway ultrasound evaluation. (1)

Ultrasound can be applied to multiple aspects of airway management, such as tube size positioning, predicting successful extubation, guiding cricothyrotomy and predict difficult airway. (2) Several ultrasound parameters have been studied as predictors of difficult laryngoscopy, specifically hyomental distance in neutral and extended position (3), distance from skin to hyoid bone (4), to vocal cords (5), to epiglottis (6), tongue cross-sectional area and volume (7) and many others. Nevertheless, in a recent systematic review and meta-analysis, the most consistent predictor was hyomental distance (HMD) in a neutral position. (8)

Since ultrasound is an operator-dependent technique there is a need for structured training and standardized assessment to certify clinician's skills and competence. (9,10,11) However, there is no evidence-based guidelines for education or evaluation of airway ultrasound assessment.

Traditionally, skills competence was achieved after a subjective evaluation by tutors. The process was complex and was supported by knowledge assessment, gather information from third parties, structured supervision, and a direct practical observation of trainees' performance. (12,13,14) In the last two decades, many valid and reliable instruments were developed to improve the objectivity of assessment through the creation of checklists and global rating scales. (15,16)

In 2013, Tolsgaard and co-workers (17) led an international multispecialty consensus on the content of a generic ultrasound rating scale, using a Delphi technique. A total of 60 international ultrasound experts from different medical specialties (radiology, emergency medicine, obstetrics, surgery, urology, rheumatology and gastro-enterology) were invited to participate in three Delphi rounds. Since then, several authors have used this tool to train and assess proficiency for clinical ultrasound in a variety of fields, namely obstetric and gynecology (18-21), abdominal in trauma (eFAST) (22,23), lung (24), head and neck (25) ultrasound.

Global rating scales (GRS) have been globally used in medical education and in clinical training to assess competency in many technical skills. (15,26,27). In the present study, GRS was used as an "overall performance" scale based on 5-points of Likert.

This study explores the psychometric properties of OSAUS scale for hyomental ultrasound distance in neutral and extended position measurement.

2. Materials and Methods

2.1. Materials

2.1.1. Ethical approval

The study was carried out in accordance with relevant guidelines and regulations. The study was conducted after institutional review committee approval from Ethical Committee for Institute of Life and Health Sciences (CEICVS) of School of Medicine, University of Braga, Braga, Portugal (Chairperson Prof. Dr Cecília Leão) on 15th November 2020 (CEICVS15/2020) (available Supplementary material Ethical file). Participation in this study was absolutely voluntary and all participants and assessors gave an oral and written informed.

In addition, all were aware that they could leave the study at any time without any problem.

2.1.2. Study dates

The study was conducted at School of Medicine, University of Minho, Braga, Portugal, from November 2020 to June 2021.

2.1.3. Study Design

This is a prospective experimental, rater and principal investigator double-blinded study to determine OSAUS's psychometric properties when the scale is used for the ultrasound measurement of hyomental distance in head neutral and extended position.

Figure 1 represents the study design (Figure 1). The study has developed in 4 steps. In the first step an educational moment was organized with a theoretical presentation of 1 hour. Two experienced airway ultrasound anesthesiologists presented the OSAUS scale (17) and its applicability to measuring ultrasound hyomental distance in neutral and extended positions. The protocol for HMD measurement in neutral and extended position was very well-defined and given to participants and was available for consult as a guide for practice. After this session, 3 hours of practical training of the HMD ultrasound measurements were done, tutorized by the same trainers.

Two weeks later, in the second step, participants completed the ultrasound measurement of ultrasound HMD in neutral and extended position, and the performance was video recorded. Each participant evaluated ultrasound HMD from three standardized patients, generating a total of 45 videos.

In step 3, six assessors were recruited and received online guidance on the OSAUS scale and its applicability for assessing ultrasound HMD measurement. A concrete preparation analyzing a pilot video study was done.

In step 4, assessors blindly rated participants videorecords according to OSAUS and a global rating scale (GRS) with 5-Likert points (1 point - unacceptable; 2 points – weak; 3 points – acceptable; 4 points – Very good; 5 points – excellent performance). For further analysis, the time needed to complete participants' tasks was also collected. The assessors' evaluation was sent in an anonymous excel file.

2.1.4. Participants

Volunteer participants provided informed consent and self-reported their experience with airway ultrasound before their enrolment. According to participants experience, three categories were created: novices, intermediates and experts. A novice participant had up to six months experience in airway ultrasound, and an expert uses airway ultrasound for more than two years. The intermediate group enrolled participants within the two groups.

Standardized patients (SP) volunteers: Nine SP were recruited for the study and participated in both moments (training and validation) and provided informed consent before participating on the study.

2.1.5. Equipment and environment

Steps 1 and 2 were realized at School of Medicine, University of Minho, and the study equipment and environment was the same for the practical session and the assessment time. Ultrasound measurements were obtained using a SonoSite®, portable ultrasound machine (Fujifilm, SonoSite® Edge II and SonoSite® SII, Ultrasound System, Inc Bothell, WA, USA), using a curvilinear, multifrequency 3-8 MHz ultrasound transducer probe.

2.1.6. Procedure

Participant measurement of HMD in neutral and extended head position was video recorded. The angle of video records provided a global overview of the technique, including the face of the SP, both hands of the sonographer and the all ultrasound machine. In all recordings, both the practitioner's technique and the ultrasound were visible.

Physicians were anonymized by not recording their faces or voices. Once the procedure was finalized, the film clips were all stored and referenced by order of collection. An anonymous link to a folder with the videos was sent to each assessor.

2.2. Methods

2.2.1. Psychometric study

The analysis of OSAUS's psychometric properties was based on the Standards for Educational and Psychological Testing (American Educational Research Association AERA, American Psychological Association & National Council on Measurement in Education, 2014) (28), following the category framework articulated by Messick (29) (content, internal structure, relation to other variables, response process and consequences).

The internal structure or construct validity was analyzed by internal consistency and interrater reliability. The relation to other variables included the criterion-related analysis (concurrent validity), by comparing OSAUS with GRS, where raters were instructed to rate the overall participant's performance and by comparing time to complete the task from different experience levels (expert, intermediate and novice). The response process of OSAUS scale evaluation focused on data collection methods; rater instructions, training and performance; how scores were reported and summarized and, in the methods, responsible for the lack of bias in the process. (30)

2.2.2. Statistical analysis

The internal consistency was assessed through Cronbach's alpha for each item used (items 2, 3, 4 and 5). For each participant, we calculated the mean score of the 3 ultrasound measurements and the mean time in seconds to complete the task. Intraclass Correlation (ICC) estimates and their 95% confidence interval were calculated. The ICC two-way-random effect model was used to evaluate consistency between raters based on the mean value of the OSAUS score from 5 raters ($k=5$), consistency, 2-way random effects model. (31) An analysis of variance (ANOVA) for repeated measurements was also done. Convergent validity was assessed by a Pearson's correlation between OSAUS and Global Rating Scale. One-way ANOVA explored differences in OSAUS rating scores and differences in time to complete the task between different levels of competence.

The statistical analysis was done using SPSS version 27 (IBM Corp, Armonk, NY) with P values below 0.05 were interpreted as statistical significance and the strength of agreement were interpreted according to *Portney* and co-workers (31) where values under 0.5 represent poor reliability, values between 0.5 to 0.69 considered moderate, values between 0.7 to 0.9 indicate strong and over 0.9 represent excellent reliability.

3. Results

3.2. General results

3.2.1. Participants

Fifteen participants were enrolled on the study, 10 (66.6%) were female, and 5 (33.3%) were male. The mean age of participants was 30 ± 4.6 , mean \pm SD, (min 25, max 39) years old.

3.2.2. Assessors

A total of 6 assessors were recruited for the study. One assessor was excluded due to an incomplete assessment.

3.3. Psychometric Study

3.3.1. Content

The content analysis was not done since the development of OSAUS scale were done by Tolsgaard and co-workers (17). Due to the design of this study, the items: (1) Indication for the examination; (2) Documentation of the examination and (3) Medical decision making, were not adequate to investigate in the study. The item - Indication for the examination, is optional and in this study was an unvalued, since all participants were aware of the purpose of the study. The fifth item – Documentation of examination intends an image recording and a focused verbal or written documentation, so authors excluded this item since the participants could be identified by assessors and bias the results. The sixth item – Medical decision making is also optional and was out of the aim of the study.

3.3.1.1. Internal Consistency

The scale's internal consistency was achieved by analysing the use of each item of OSAUS scale (225 = 45 videos x 5 assessors). The internal consistency of OSAUS scale for ultrasound HMD measurement was evaluated by Cronbach's alpha was 0.916. Each item descriptive statistics is presented in table 1 and 2. (Supplementary table 1 and 2).

3.3.1.2. Inter-rater reliability

The inter-rater reliability was assessed using the Interclass Correlation Coefficient (model 2,5) when analysed the mean score of the three ultrasound measurements from each participant was 0.720 (95%CI 0.408 to 0.893), with a significance level inferior to 0.001 ($p < 0.001$).

3.3.2. Relation to other variables

To explore validity evidence for relations to other variables, we compared OSAUS scale with GRS, and compared the OSAUS scores and time to complete the task across different experience levels (novice, intermediate and expert).

3.3.2.1. OSAUS compared with GRS

OSAUS for HMD measurement was compared with a 5 points-Likert global rating scale (1- poor performance; 5 – perfect performance). The correlation between OSAUS and GRS was studied using the mean score of the three ultrasound measurements done by each participant.

The correlation between OSAUS-HMD and GRS was $r=0.970$ ($p<0.001$; with 94% of shared variance, $r^2=0.941$).

3.3.2.2. Group performance comparisons

3.3.2.2.1. Score performance

The mean value of OSAUS-HMD scores for each group was evaluated during the analysis of the mean of 3 ultrasound measurement from each participant (15). The novice group scored 15.5 ± 0.98 , mean \pm SD (95%CI 15.1 to 15.6), the intermediate 14.3 ± 0.33 , mean \pm SD (95%CI 13.0 to 14.90) and expert 13.5 ± 0.68 , mean \pm SD (95%CI 12.2 to 16.1). One-way ANOVA showed no significant differences between groups ($F(2,12)=4.42$, $p=0.036$). The novice group rated higher than the intermediate (mean difference of 1.14) and even higher compared with the expert group (mean difference of 1.84), with a significant result. The intermediate group rated a little higher than the expert group (mean difference - 0.7) also with no significant differences between groups. (Figure 2)

3.3.2.2.2. Time to complete the task

In the analysis of the mean time to complete the task for each participant (15), the novice, the intermediate, and the expert group spent in mean \pm SD (95%CI) respectively, 90.4 ± 34.1 (95%CI 47.9 to 132.8), 84.2 ± 22.88 (95%CI 55.78 to 112.61) and 82.6 ± 15.07 (95%CI 63.88 to 101.31) seconds to complete the task. No significant differences were found between different competency levels ($F(2,12)=0.133$, $p=0.877$, one way ANOVA). Novice group spend more time to complete the task when compared with the intermediate group (mean difference of 6.2 seconds) and when compared with the expert group (mean difference of 7.8 sec), with no significant difference between groups. The same was observed for the intermediate group when compared with the experts (mean difference of 1.6 seconds) with no significant differences between groups. (Figure 3)

3.3.3. Response process

The participants performances were done individually, with no external interferences, and the video was recorded without participant's faces or voices. With this approach we were able to blind the ratters. The videos were encoded by acquisition time.

The rater instructions and training consisted of an online meeting session with authors, where the OSAUS scale used for HMD measurement was presented, and an intermediate performance video was analyzed. All assessors agreed to use OSAUS to evaluate participants performance in ultrasound HMD measurement in neutral and extended head position.

4. Discussion

The authors decided to use the previously developed OSAUS scale to measure competence in ultrasound hyomental distance measurement. This approach allowed us to compare our results with previous work and contribute to a broader application of the scale.

Documenting evidence of validity and reliability are essential for any new educational tool before its implementation, to have confidence in the collected data. (30) In this study, we used the content, internal structure, relation to other variables and response process domains of validity evidence described by Messick (29). Because no social implication or impact of participant's scores was inherent to this study, the consequence domain was not investigated.

The content of OSAUS Scale was validated in the aforementioned study. (17) Three Delphi rounds were necessary to develop the scale, which represents a robust concern within its items.

The final version of the OSAUS scale has 7 elements, each with a 5-points Likert score. Due to the design of this study, items number 1, 6 and 7 were excluded from the analysis. The indication for the examination was clearly defined at the beginning of the study, so it was not adequate to evaluate this item. The examination of documentation was not done, since it could contribute to identifying participants, compromising the response process and the medical decision-making category is out of the aim of this study.

The evidence of reliability was documented through internal consistency and inter-rater reliability. The internal structure measures the "degree to which individual items fit the underlying construct of interest" (32). In our study its evaluation was based on each time an item was rated (45 videos x 5 assessors=225 evaluations) (33). A relevant internal validity was achieved (alfa-Cronbach 0.916) with no evidence of redundant items nor excessive scale length. Three elements from OSAUS were excluded from the original scale in our study: (1) "Indication for the examination", since all participants knew the purpose of the study; (2) "documentation", to ensure anonymity and (3) "medical decision making", since the study was done in a simulated environment without any clinical implications. The internal consistency achieved in this study is undervalued, since not all items were used in the present study.

Inter-rater reliability was evaluated using interclass correlation coefficient – ICC (2,5) with a model 2-way model random, since we selected 5 consistent ratters from a larger possible population. (32,34) A good reliability was achieved with an ICC of 0.720 (95%CI 0.408 to 0.893), with a significance level ($p < 0.001$), which reflects a strong correlation and agreement between measurements.

According to the relation to other variables, convergent evidence was achieved by a strong correlation ($r = 0.970$, $p < 0.001$) with Global Rating Scale with 5-points Likert.

The OSAUS scale was able to discriminate between novice and experts. We expected that experts had higher scores than the rest of the groups, but experts had the lowest values. These results can be explained by the fact that participants self-reported their level of experience in airway ultrasound based on experienced time. A previous objective evaluation by an independent expert panel could distribute participants differently. The study was developed in a simulated environment away from the clinical reality, so experts were not familiar with the settings nor commitment with the study, which could have compromised their performance. (35) Simultaneously, the novice participants were at a relatively early stage in their residency program, so that their appetency to learn new techniques and increase their knowledge can explain the higher scores achieved by this group. (36,37)

The comparison of scores from different competency groups does not represent an essential validity argument. (38-40) Similarly with the Cook's study (41) several methodological problems can explain the observed differences between groups not related with the construct of the scale: (1) lack of representativity of the population; (2) the novice group was the most homogenous and the group average score does not represent the individual performance and

Although no significant differences were found in the total time to complete the task, experts performed faster than intermediate and novice groups due to their familiar use of the ultrasound equipment.

Methods to obtaining evidence about the response process are difficult to develop. A meta-analysis published by Beckman et co-workers (32) and a literature review published by Padilla and co-workers (42) reported response process as one of the least represented sources of validity in clinical teaching and assessment tools.

In our study, a valid response process was guaranteed since: (1) all assessors participated in a training session; (2) assessors approved on the application of OSAUS scale to ultrasound HMD measurement after a training session; (3) participants performed individualized, with no external interferences; and (4) adequate quality and security control throughout the steps of the study blinding assessors and authors, reducing the risk for a halo effect.

4.1. Limitations

Our study has some limitations that need to be considered: (1) The different competence groups were done following participant's experience based on time of practice. Although this evaluation could be like the number of procedures done, an external expert panel that could rate participants by level of competency could be more adequate. (2) We use GRS with a single item, as an overall performance scale. Although it was used to simplify the process of assessment and to decrease the time spent by

assessors to complete the task it could influence the results. (3) The consequence domain of the Messick framework was not explored in this study, nevertheless our results express that this tool could be used in the in-training program. (4) Since this is the earliest study using OSAUS scale for airway ultrasound competence, it was not possible to compare with the methodology of similar studies.

5. Conclusions

The study demonstrated significant results in internal structure, relation to other variables and response process.

Further studies are needed to complement the Messick's framework for validity. The OSAUS scale should be used as assessment tool in other airway ultrasound parameters. Finally, we need to move forward and implement the use of OSAUS scale in the clinical setting for training and assessment of airway ultrasound competence.

6. Competing interests

The authors declare that the study was conducted in absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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8. Author's contribution

All authors contributed substantially to the study. Conceived and design the experiments: SHG, MT, JMP, JCP, PC. Performed the experiments: SHG, MT, DC. Analyzed the data: SHG, JMP, JCP, PSC. In depth revising the manuscript critically for important intellectual content: SHG, CP, JMP, JCP, PSC. Final approval of the version to be published and all agree to be countable for all aspects of the work thereby ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: SHG, MT, CP, DC, JMP, JCP, PSC.

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11. Figures

Figure 1 – Study design. Step 1 - theoretical presentation and practical session; Step 2 - participants evaluation of HMD in standardized patients, videorecord; Step 3 – assessors preparation to use OSAUS scale; Step 4 – evaluation of videorecord participants performance using OSAUS scale.

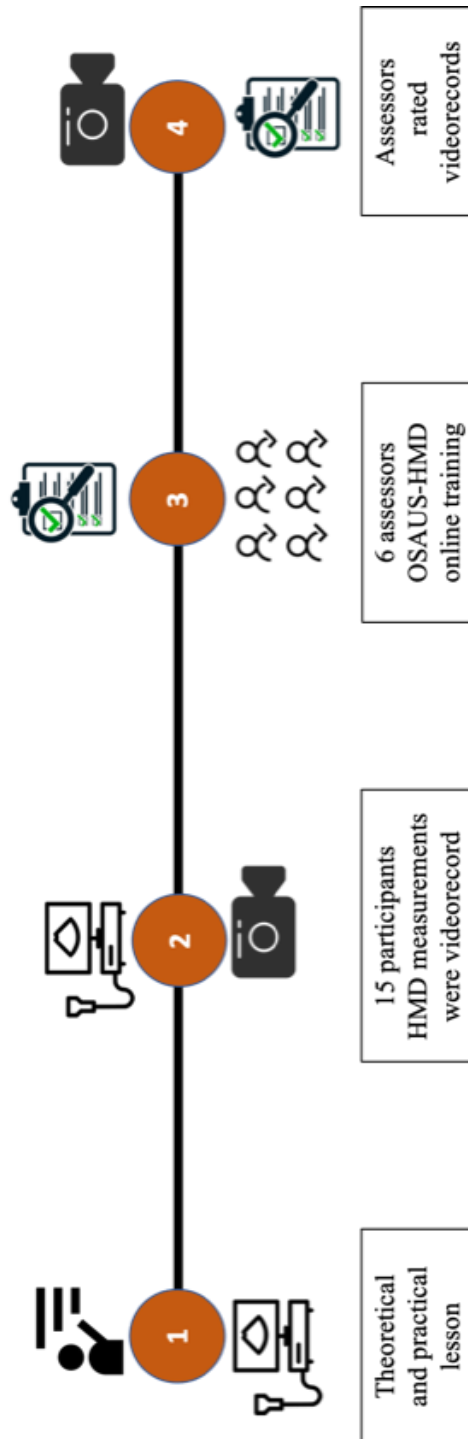


Figure 2 – Participants mean total score for each competency group. Mean and error bars 95% CI for each competency group. * - $p < 0.05$

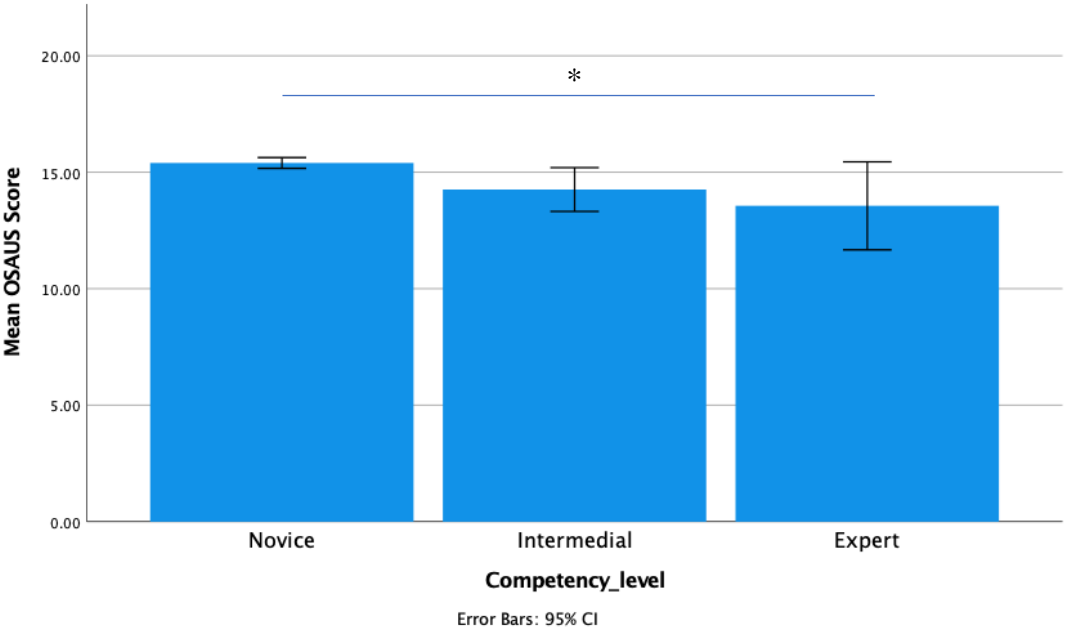
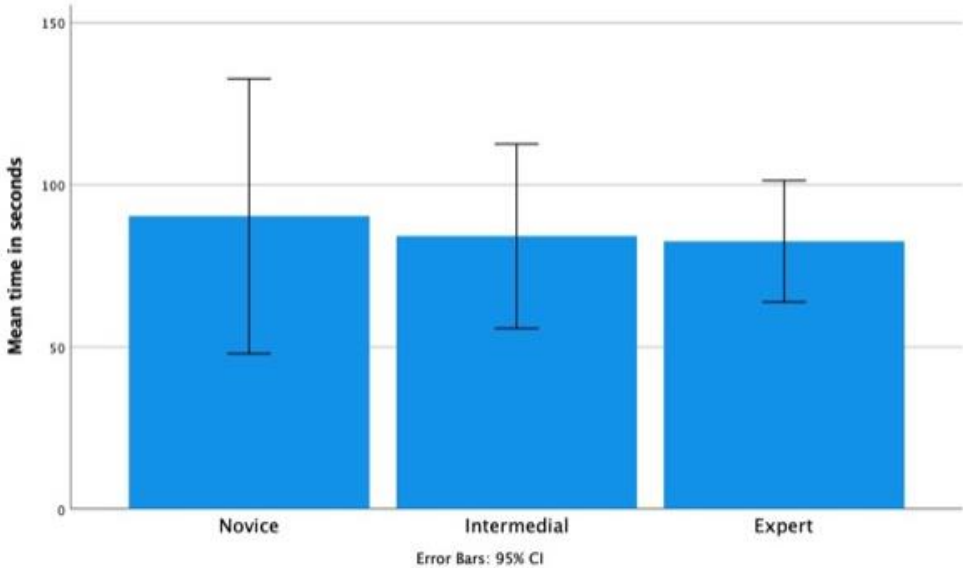


Figure 3 – Participants mean total time in seconds to complete the task measurement for each competency level. Mean and error bars 95% CI for each competency group.



12. Supplementary material

Table 1 – Descriptive statistics from 225 assessments of the OSAUS's Item 2, 3, 4 and 5.

OSAUS Item Statistics	Minimum	Maximum	Median	Mean	SD	kurtosis
Item 2	1	5	5	4.07	1.14	-.160
Item 3	1	5	3	3.11	1.05	-.363
Item 4	1	5	4	3.90	1.20	-.551
Item 5	1	5	3	3.32	1.23	-.585

Table 2 – Descriptive statistics from each assessor of the OSAUS's Item 2, 3, 4 and 5.

	Minimum	Maximun	Median	Mean	SD	Kurtosis
Assessor A						
Item 2	4	5	5	4.91	.28	7.26
Item 3	3	5	3	3.26	.65	3.3
Item 4	5	5	5	5	0	
Item 5	3	5	4	4	.90	-1.81
Assessor B						
Item 2	1	4	2	2.26	.75	-.12
Item 3	1	4	2	1.88	.80	-.5
Item 4	1	4	2	2.20	.81	-.10
Item 5	1	4	1	1.64	.88	-.39
Assessor C						
Item 2	4	5	5	4.8	.40	.42
Item 3	2	5	4	3.5	.75	-.17
Item 4	4	5	5	4.7	.42	-.09
Item 5	2	5	4	3.7	.76	-.14
Assessor D						
Item 2	3	5	4	4.2	.78	-1.15
Item 3	2	5	3	3.4	1.01	-1.03
Item 4	2	5	4	3.8	.83	-.003
Item 5	1	5	4	3.6	.97	.80
Assessor E						
Item 2	3	5	4	4.1	.80	-1.41
Item 3	2	5	3	3.4	1.01	-1.06
Item 4	2	5	4	3.6	.90	-.62
Item 5	2	5	3	3.4	.94	-.83

Chapter 2.3

Sara Hora Gomes, Alice Miranda, José Miguel Pêgo, Patrício Costa, Jorge Correia-Pinto

Ultrasound- Guided Selective Bronchial Intubation: A Feasibility Study in Pediatric Animal Model

(Manuscript accepted for publication, *Frontiers in Medicine*, 9:869771)



Ultrasound-Guided Selective Bronchial Intubation: A Feasibility Study in Pediatric Animal Model

Sara Hora Gomes^{1,2*}, Alice Miranda^{1,2}, José Miguel Pêgo^{1,2}, Patrício S. Costa^{1,2} and Jorge Correia-Pinto^{1,2,3}

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Objective: Selective one-lung ventilation used to optimize neonatal and pediatric surgical conditions is always a demanding task for anesthesiologists, especially during minimally invasive thoracoscopic surgery. This study aims to introduce an ultrasound-guided bronchial intubation and exclusion technique in a pediatric animal model.

Methods: Seven rabbits were anesthetized and airway ultrasound acquisitions were done.

Results: Tracheal tube progression along the trachea to the right bronchus and positioning of the bronchial blocker in the left bronchus were successfully done with consistent ultrasound identification of relevant anatomical structures.

Conclusion: The study provided a new application of ultrasound in airway management. More advanced experimental studies are needed since this technique has the potential for translation to pediatric anesthesia.

Keywords: ultrasound-guided, selective, bronchial intubation, bronchial exclusion, pediatric animal model

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INTRODUCTION

One lung ventilation in neonates and very small children is becoming an increasingly frequent demand for anesthesiologists, since the growing use of video-assisted thoracoscopic surgery (VAST) at this age (1, 2).

The reduced dimensions of the airway in neonates and very small children limit the airway management to two approaches, endobronchial intubation with a single lumen tube (SLT) to the non-operating lung or a bronchial blocker (BB) placed in the operating lung (3–5). There are limitations reported from the use of the first technique in children up to 2 years old since the use of a larger or cuffed tube can cause tracheobronchial mucosa damage (6–9), and the use of a smaller tube can increase airflow resistance, create auto-peep, limit suctioning or be unable to provide adequate sealing (10, 11).

The lower tracheobronchial anatomy favors the insertion of the endobronchial tube to the right mainstem bronchus but with the risk of right upper lobe occlusion. On the other

hand, the left main bronchus is smaller than the right, but the emergence of the upper left lobe is consistently more distal than the right side, reducing the risk of occlusion (5).

The use of a bronchial blocker is considered the technique of the choice for children under 6 years old (12). The Arndt Bronchial blocker has been the most popular device in the pediatric population due to its safety, high efficacy, and intuitive placement (12–16). In children under 2 years old, an extraluminal approach is preferred, since it allows the maintenance of driving pressure to ventilation, reducing the risk of a compromised oxygenation and ventilation during the device placement (2, 5, 17, 18). Although the complications of the airway instrumentalization with a bronchial blocker are rare, they can be potentially serious, including bronchial blocker entrapment (19), bronchial perforation and rupture (8, 20), and tip fracture (21, 22).

A flexible fiberoptic bronchoscope (FFB) is routinely recommended to guide the endobronchial intubation and the placement of the bronchial blocker to its final position (23–25).

The last decade is characterized by a significant dissemination of the use of ultrasound as a point-of-care methodology. In the pediatric population, with the arrival of small-size, high-frequency ultrasound probes a fast bed-sided examination of the airway can be done with efficiency and safety, reporting airway sonoanatomy and endotracheal tube position (26–28). The low mineral density and the incomplete fusion of the ossification centers of the sternum and ribs in neonates and small infants allow the use of ultrasound for mediastinum evaluation, including trachea and carina and provides a feasible window of observation (29–31).

Rabbits have been considered adequate models for experimental pediatric surgery and anesthesia, especially for neonatal and small children's airway and ventilation research (32–35).

The purpose of this study is to evaluate the upper and lower airway sonoanatomy and describe an ultrasound-guided approach to selective bronchial intubation using an SLT and a BB in a pediatric animal model.

MATERIALS AND METHODS

Ethical Approval

Ethical approval for this study was provided by EU Directive 2010/63/EU, under project authorization attributed by local ethics committee (*Subcomissão de Ética para as Ciências da Vida e da Saúde* – SECVS 004/2016, Chairperson Prof. Cecília Leão, on March 2016) and by the national authority for animal protection (*Direção Geral de Alimentação e Veterinária* - et al. DGAV 015296, Chairperson Dr. Fernando Bernardo, on June 2017). This manuscript adheres to the applicable EQUATOR guideline and was performed in accordance with ARRIVE guidelines (**Supplementary Document 1**).

Animals and Anesthesia

Seven adult rabbits (*Oryctolagus cuniculus*), 4 females and 3 males were used (2242 g \pm 151 g body weight average). Animals were anesthetized in their home pen with a

subcutaneous administration of a combination of Ketamine (25 mg/kg; Ketamidol, Richter Pharma AG, Austria), Medetomidine (0.4 mg/kg; Sededorm, VetPharma Animal Health, Barcelona, Spain) and Buprenorphine (0.03 mg/kg; Bupaq, Richter Pharma AG, Austria) and transported to surgical laboratory. A peripheral venous access in the ear was obtained for fluid (0.9% saline, 2 ml/kg/h) and anesthesia administration. General anesthesia was maintained using continuous intravenous administration of propofol (4.2 mg/kg/h). Oxygenation was monitored using an oximeter and oxygen therapy was provided to an animal in spontaneous ventilation in order to maintain oxygenation above 95%. After tracheal intubation, animals were ventilated in pressure support mode. Anesthesia depth was increased for signs of inadequate anesthesia such as increased heart rate, small movements, or lacrimation.

Animals were positioned supine with heads extended and were shaved from the neck to the xiphoid process in a median plane and bilaterally in the thorax until the medial axillary line.

At the end of the experiment, with the animals still under deep anesthesia, euthanasia was performed by an intravenous administration of Pentobarbital (200 mg/kg; Euthasol, Le Vet Beheer B.V., Netherlands).

Ultrasound Approach

The study included the animal upper and lower airway sonoanatomy evaluation and the real-time ultrasound scanning of the introduction of the SLT and the BB from glottis to right and left main bronchus, respectively.

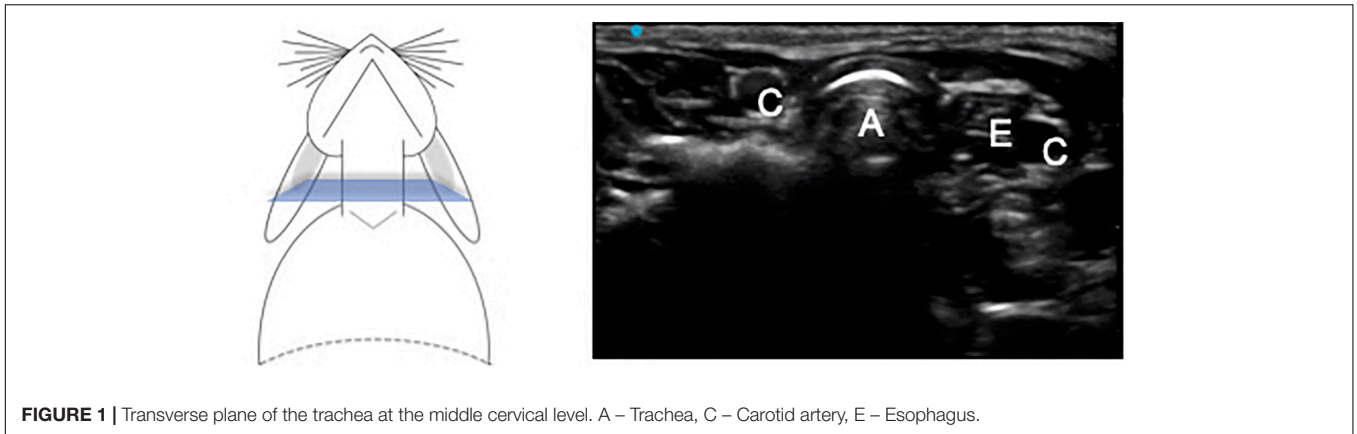
The scanning protocol for the study included a cervical anterior approach with longitudinal and transverse planes, sliding the probe from the mentum to the suprasternal notch. The probe was then moved to the thoracic level, with an oblique parasternal, midclavicular plane from the suprasternal notch to the anterolateral face of the right hemithorax. The ultrasound penetration used a range between 2.0 and 3.0 cm depth. Ultrasound image acquisition was performed by an experienced anesthesiologist in human airway ultrasound, using a SonoSite Edge II (FUJIFILM SonoSite®, Inc., Bothell, WA, United States) with a linear multifrequency 6–13 MHz transducer probes (HFL38xi) from FUJIFILM SonoSite®, Inc. (Bothell, WA, United States).

Procedure

After anesthesia and animal monitoring, a scanning protocol was done to identify and describe the animal airway sonoanatomy. Due to the small, dimensions of the glottis and its mucosa fragility, a flexible fiberoptic bronchoscope was used (Karl STORZ SE&Co, Tuttlingen, Germany, 5.2 mm \times 65 cm) to guide tracheal intubation and the extraluminal bronchial blocker insertion, only at the level of the glottis (**Supplementary Figure 1**).

During the fiberoptic procedure, local anesthetic – lidocaine 1%, was sprayed in the airway, though an epidural catheter (Perifix® Standard, Soft-tip; B.Braun Melsungen AG, Germany) in order to provide mucosa anesthesia and facilitate the procedure.

After SLT and BB introduction at the level of the glottis, two procedures were performed guided exclusively by ultrasound:



Right endobronchial intubation with a cuffless, reinforced, extra soft, single lumen tube, 2.5 mm (Mallinckrodt™, Covidien®, United States) with an internal and external diameter of 2.5 mm and 4.0 mm, respectively. The SLT was the same that provided tracheal intubation.

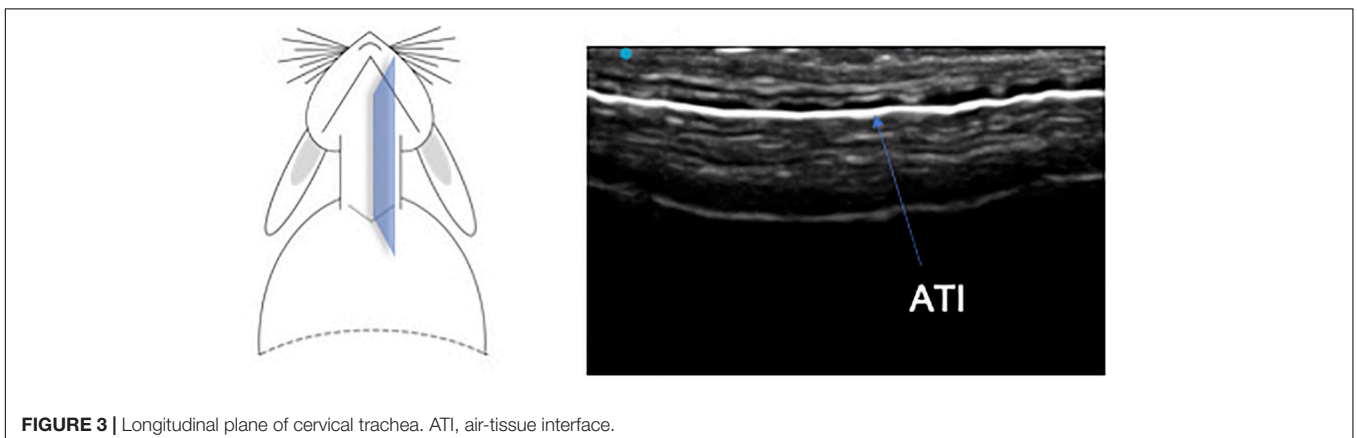
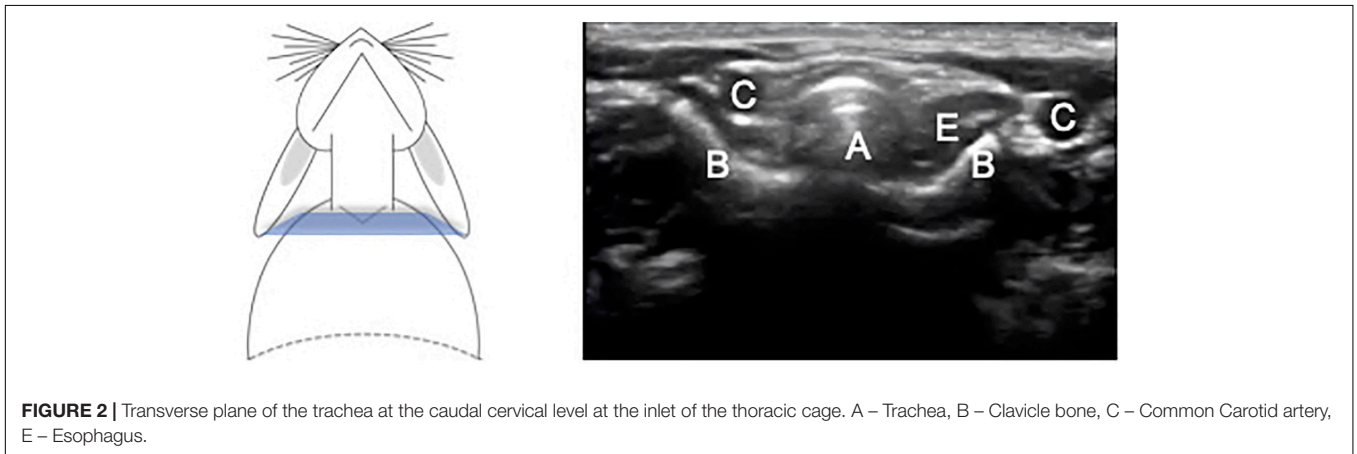
Left lung exclusion with a 5 Fr bronchial blocker (Uniblocker® MBA, Fuji Systems Corporation) with an external diameter of 1.7 mm (length 400 mm, effective length 300 mm, cuff length 8 mm, max. volume 3 ml), used with an extraluminal approach.

Confirmation of the side of the instrumented bronchi was done in post-mortem evaluation.

RESULTS

Sonoanatomy Study

The images from the cervical view in transverse and longitudinal planes are presented in **Figures 1–3**.



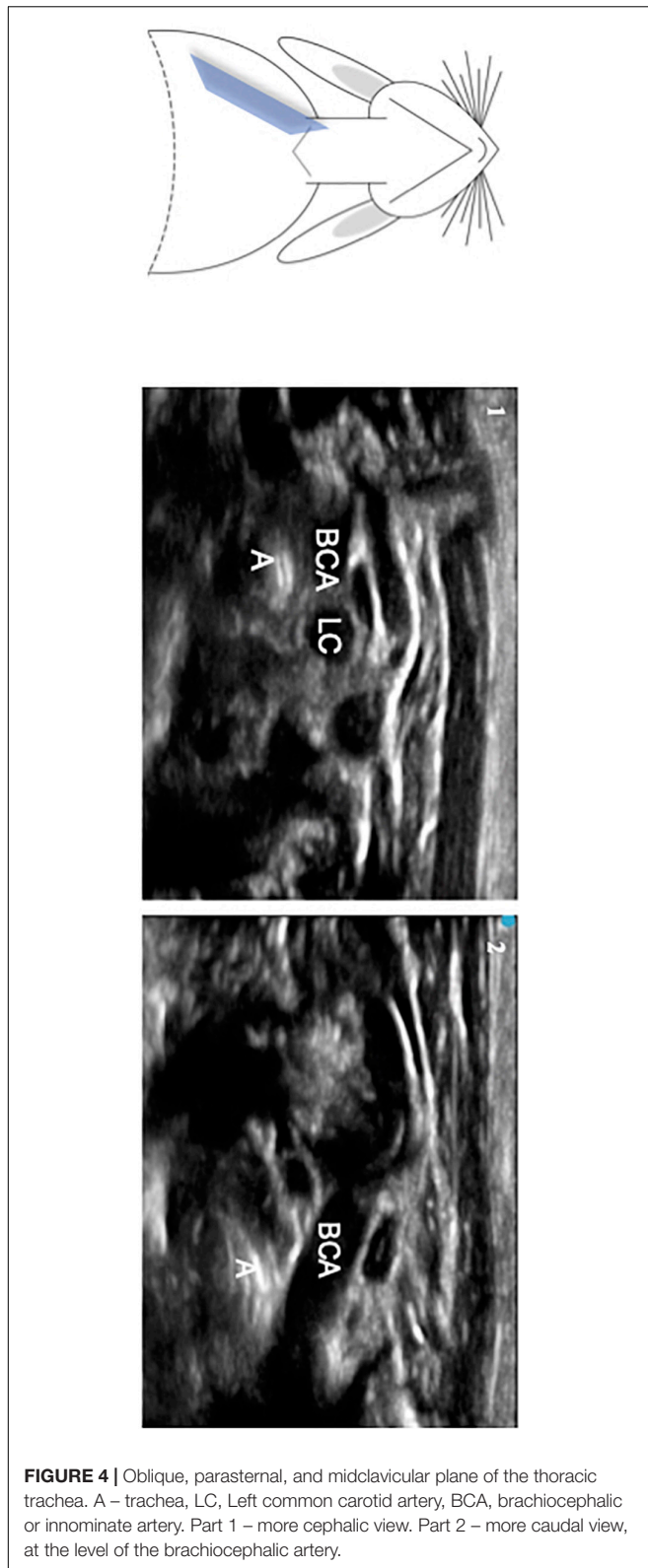


FIGURE 4 | Oblique, parasternal, and midclavicular plane of the thoracic trachea. A – trachea, LC, Left common carotid artery, BCA, brachiocephalic or innominate artery. Part 1 – more cephalic view. Part 2 – more caudal view, at the level of the brachiocephalic artery.

The relationship between cervical trachea, esophagus and right and left common carotid artery was easy to identify.

In the right oblique, parasternal, and midclavicular plan, it was possible to visualize the intra-thoracic trachea, represented as two hyperechogenic lines, and its relationship with the aorta and innominate artery (**Figure 4**). The tracheal bifurcation was located at the level of the 3rd thoracic vertebra. During the scanning movement of the probe from intrathoracic to cervical level, it was possible to notice the trachea's proximity to the aortic arch, innominate artery, right and left common carotid artery, and esophagus (**Supplementary Video 1**).

Ultrasound Images of Single Lumen Tube and Bronchial Blocker Positioning

It was possible to visualize in real-time, the progression of the SLT along the cervical trachea and its positioning in the right mainstem bronchus, with the probe moving from the cervical longitudinal to the oblique parasternal, midclavicular plane. Due to the artifact of the reinforced tube wire, a continuous ellipsis line was visible throughout the trachea extension (**Figure 5**).

The progression of BB until the main left bronchus was visible with the ultrasound probe oriented in the same right oblique, parasternal, and midclavicular plane. The BB was seen as a dense line visible throughout the thoracic trachea and left bronchus (**Figure 6** and **Supplementary Video 2**). Main right bronchus intubation was visualized with the probe in the same plane after a small probe tilts to the left. In this plane, the anatomic relationships between the right main bronchus and the right and left atrium were also identified.

In the first animal, with a fiberoptic view, a tracheal mucosa leak was identified during the first attempt at tracheal intubation. The animal was immediately euthanized and the experiment aborted. Considering that this animal was the smallest and the lightest of the sample, probably the size of the SLT (external diameter of 4 mm) was not appropriate for this animal. No other complications were reported.

All animals were euthanized after the experiments and the complementary anatomic study confirmed device positioning.

LIMITATIONS

One potential limitation of the study is the use of a SLT only to the right side and the BB only to the left side positioning. However, in the work of Loewen et al. (36), small rabbits (weigh between 2.0 and 2.5 kg) had an average of tracheal ventral-dorsal diameter of 4.2 (min 3.75- max 4.75), with the left bronchus significantly smaller than the right. This animal findings are consistent with human studies. Hammer et al. (23) concluded by using computerized tomography that the left main bronchia is consistently smaller than the right and in children younger than 3 month its diameter can be smaller than the size of a 3.0 uncuffed endotracheal tube. Therefore, the positioning chosen for each device was adequate and intended to reduce the risk of injury.

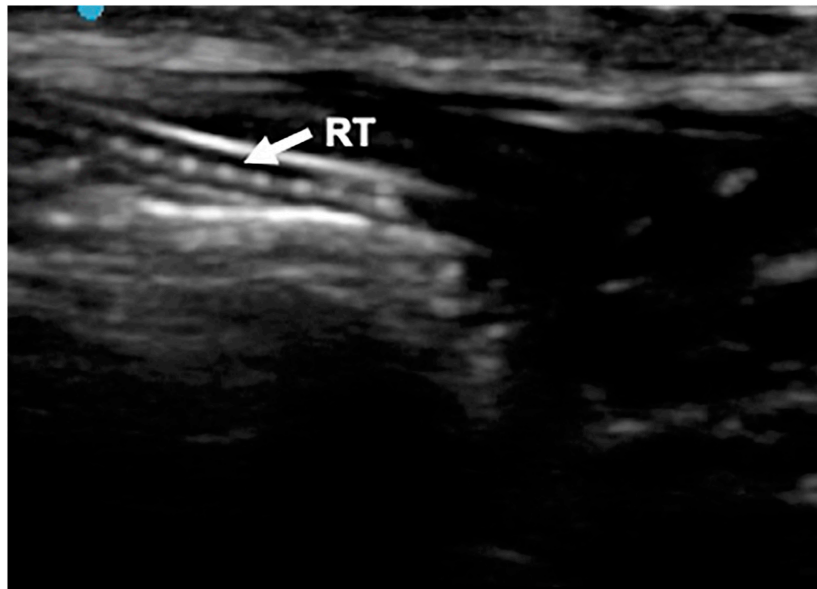


FIGURE 5 | Longitudinal anterior plane of the neck. RT, reinforced tracheal tub.

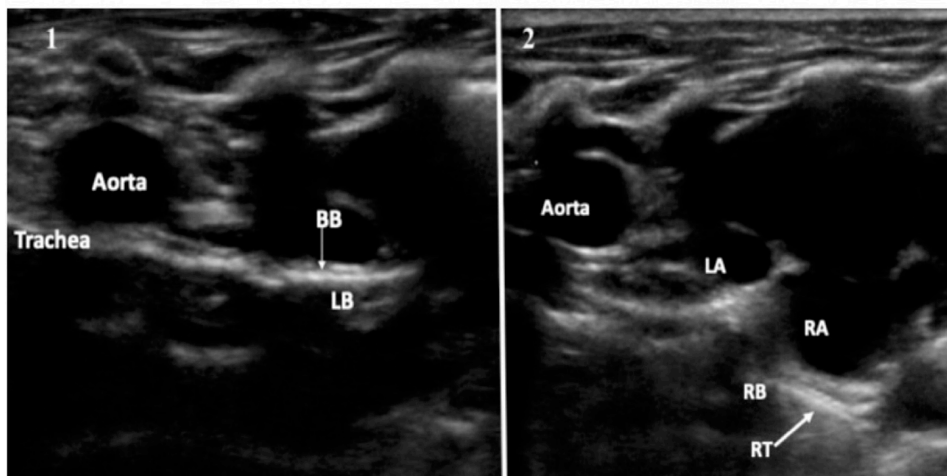
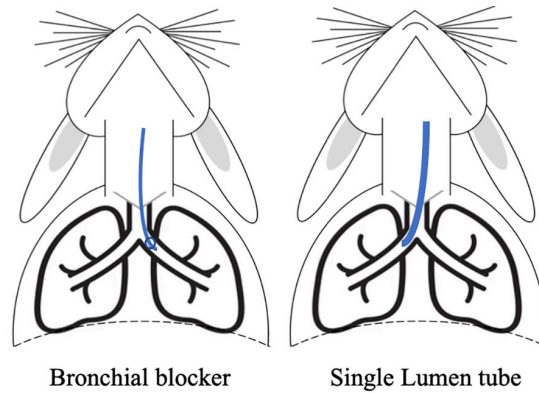


FIGURE 6 | Oblique, parasternal, and midclavicular plane 1. Bronchial blocker in the left bronchus. BB, Bronchial blocker, LB, Left bronchus. 2. Reinforced tube in the right bronchus. RT, Reinforced tube, RB, Right Bronchus, LA, left atrium, RA, right atrium.

The sample size of the study was small. Nevertheless, the study intended to be a proof-of-concept with evidence of feasibility and reproducibility of the results.

DISCUSSION

The study details the successful use of ultrasound to guide bronchial intubation with an SLT and exclusion with a BB, in the pediatric rabbit model (**supplementary Visual Abstract**).

Rabbits are an adequate and useful animal model for studies related to airway management in pediatric ages such as (1) subglottic stenosis, since their larynx dimensions are similar in size; (2) diaphragmatic hernia repair; and (3) one-lung ventilation management (32–35, 37).

The anatomical characteristics of the narrow and deep oral cavity and the lining mucosa's frailty make the management of the rabbit's airway challenging. According to recent studies (38) optimizing the view of the glottis with fiberoptics can facilitate the intubation of very small lab animals. The use of fiberoptics in our study was limited to the intubation at the level of the glottis, with no further need for the FFB.

The concept of the study was to dispense the use of FFB for pediatric one-lung intubation or exclusion. In this population, the glottis view is well achieved through direct laryngoscopy or video-laryngoscopy, meaning that the glottis intubation is not an issue. However, published studies described the use of ultrasound as an alternative technique to guide real-time tracheal intubation in children (39), in patients with cervical trauma (40), or with an anticipated difficult airway (41, 42).

Hereby, studies with the exclusive use of the US to achieve glottis intubation and to monitor the correct positioning of the SLT or BB can bring promising results to clinical application.

We used a reinforced endotracheal tube to reduce the risk of occlusion since the small airway was also instrumented with a bronchial blocker. As a result, we identified an ultrasound image pattern represented by a continuous ellipsis line. This specific sign facilitated the identification of the tube in the trachea and right main bronchi, reducing the vision limitations from the air interference. The development of new models of BB with a metal wire coil embedded in the wall of the tube shaft can be transformative and allow an easier recognition of the device by the ultrasound.

In the sonoanatomy study, the relationships observed with ultrasound between cervical and intrathoracic trachea with the aorta, innominate artery and common carotid arteries are in complete accordance with the anatomical study previously done by Souza et al. (43). The bifurcation of the trachea was identified by ultrasound at the level of the 3rd intercostal space and was confirmed in the post-mortem study.

This study introduced in an animal model a safe, non-invasive and non-radiant technique that could independently guide SLT and BB positioning for one-lung ventilation purposes. The authors believe that this technique can be particularly useful for premature, neonate, and small children under 2 years old with

a non-ossified thoracic wall. Nevertheless, this approach requires technical skills training to achieve competence, with its learning curve still to be defined.

CONCLUSION

The study introduced the use of ultrasound to guide selective bronchial intubation and bronchial exclusion in a pediatric animal model, providing a new ultrasound application to airway management. These preclinical findings can drive new perspectives of research, training and clinical application, such as in neonatal and small children's anesthesia.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The animal study was reviewed and approved by the Chairperson Prof. Cecília Leão, SECVS 004/2016 Chairperson Dr. Fernando Bernardo, DGAV 015296.

AUTHOR CONTRIBUTIONS

SG, JC-P, and JP: conception or design of the study. SG, AM, and JP: acquisition, analysis, and interpretation of data. SG, AM, JP, PC, and JC-P: manuscript reviewing, final approval of the version to be published, and agreement to be accountable for all aspects of the study in ensuring that questions related to the accuracy or integrity of any part of the study are appropriately investigated and resolved. SG and AM: figures and movies. All the authors contributed substantially to the study.

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We gratefully acknowledge: (1) Karl Storz® for the opportunity to use a flexible fiberoptic bronchoscope; (2) FujiFilm® for the support with the ultrasound equipment; (3) Covidien® for the cuffless, reinforced, single lumen tubes, 2.5 mm; (4) MBA® – Fuji

Systems Corporation for the bronchial blockers 5Fr; and (5) B.Braun® for the epidural catheter.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fmed.2022.869771/full#supplementary-material>

Supplementary Figure 1 | Flexible fiberoptic bronchoscope view with the glottis intubated with a single lumen tube and the extraluminal approach of the bronchial blocker.

Supplementary Video 1 | Ultrasound video visualizing trachea's proximity to the aortic arch, innominate artery, right and left carotid artery, and esophagus.

Supplementary Video 2 | Ultrasound video with the identification of the bronchial blocker in the main left bronchus.

Supplementary Document 1 | ARRIVE set document.

Supplementary Visual Abstract | The study introduced an exclusive ultrasound-guided bronchial intubation with a reinforced single lumen tube and bronchial exclusion with a bronchial blocker technique on rabbit pediatric model. Further advanced experimental studies are needed for translation to pediatric anesthesia.

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Chapter 3

DISCUSSION

3. DISCUSSION

Ultrasound airway management is one of the leading themes in anesthesia research. Current research relies on translational work, the use of new drugs or techniques, large-scale innovations implementation, and evidence of patient outcome improvement (Lane-fall, 2020). Airway research continues to be an interesting topic for future research since difficult airway management can cause serious complications, including death (Kendall, 2017).

The most recent use of US applied to airway has been transformative in the way anesthesiologists predict and monitor airway management in perioperative care (Kristensen, 2011). With the present thesis, we have clarified what are the best ultrasonographic indicators of a difficult airway, designed a reliable and easy to apply learning opportunity to training and assess competence in airway US and explored a new clinical application for US in lung exclusion for pediatric patients. The first study, a systematic review with meta-analysis, we established the most reliable ultrasonographic parameter to predict a difficult intubation in clinical practice – hyomental distance (HMD) in a head-neck neutral position. The second work explored the psychometric properties of a previous validated scale for ultrasound competency assessment (OSAUS Scale) when used to evaluate the performance of US HMD: this work opened the opportunity to implement the scale as a training and assessment tool. Finally, the third study described a new US approach to guide one-lung intubation/exclusion in an animal model of pediatric anesthesia. In the population of neonates and very small children, one-lung intubation/exclusion is still demanding for anesthesiologists, so we expect that the results of this study could be considered for further translation to human medicine. In summary, the results from this thesis add new information and new perspectives for the clinical use of US in airway management, therefore improving the safety in anesthesiology practice.

3.1. Ultrasound predictors of difficult laryngoscopy

Anesthesiologists are considered the experts in difficult airway management although consistent educational programs are needed to maintain proficiency (Brisard 2016). From the beginning of their training program, they learn how to control patient's airway and this competence is achieved by gradually facing opportunities for training in easy airway patients to practice in patients with predictable difficult airways progressively. In most anesthesia residency programs, tutors support these learning opportunities in a completely safe environment, frequently in a non-emergent scenario. The learning curve for endotracheal intubation (ETI) using a direct laryngoscopy was analyzed in a systematic review (Buis,

2016). Buis et al. found that to have a success rate of more than 90% within two attempts, at least 50 ETI are needed to be performed in elective and low-risk interventions. However, 10% of the unsuccessful ETI in a controlled environment is unacceptable since those patients face hypoxic risk, severe brain damage, or even death. In addition, many patients that need tracheal intubation are out of the context of an elective intervention and have an emergent airway situation due to in-hospital or pre-hospital medical conditions. The risk for a difficult airway is even higher for those patients due to their physiological condition. The primary operator is not always the most skilled or qualified for an emergent ETI (Brown, 2015). For those professionals several training opportunities are needed to achieve proficiency (Kornas, 2021).

To increase the first-attempt intubation success rate, in the last decades, numerous airway devices and techniques have been developed and implemented in the clinical setting of the operating room, emergency and intensive care departments and pre-hospital care. The most relevant technique is videolaryngoscopy (VL) (Healy, 2012). The videolaryngoscope has a high-resolution micro camera that allows an indirect view of the illuminated glottis on a screen. Unlike direct laryngoscopy, the vision from the VL is independent of the alignment of the oropharyngeal and laryngeal axis, increasing the Cormack-Lehane score, but the success of ETI can be compromised if the endotracheal tube orientation is out of the line of sight. Although this device proved to be highly efficient in the clinical setting proper training opportunities are needed to achieve competence (Lewis, 2017).

Several methods have been tried, but none is simultaneously accurate, reliable, and easy to apply objectively. Nevertheless, the most important decision-maker for the success of the first-attempt intubation is the anticipated screening for a difficult airway that allows patient preparation and team planning. Airway US is a complementary tool that can potentially add value to clinical predictors and uncover unexpected difficult airway patients in a more precise and reliable way. Its usefulness is indisputable in all clinical settings, but with a special role for uncollaborative, obese and patients in the context of emergency (Gottlieb, 2020).

The last decade has been characterized by the dissemination of the use of the US to assess the patient at the bedside. Regarding airway evaluation, US studies started to identify anatomic structures and the tracheal tube or laryngeal mask position. Still, they soon evolved to complex measurements such as cross-sectional areas and ratios between measurements. Numerous sonographic parameters have been studied individually and in association, through qualitative and quantitative evaluations of oropharyngeal and laryngeal structures such as distance from skin to laryngeal structures (Mohammadi, 2016; Wu, 2014; Addhikari, 2011; Reddy, 2016; Petrisor, 2018; Ezri, 2003; Falcetta, 2018) distance between

structures (Andruszkiewicz, 2016; Pinto, 2016; Rana, 2018; Gupta, 2012); ratio between different measurements (Yao, 2017; Petrisor, 2018; Wojtczak, 2012); cross-sectional area, volume and thickness (Wojtczak, 2012; Yao, 2017), identification of structures and degree of movement (Hui, 2014; Yao, 2017). Nevertheless, the precise value of each parameter as a predictor of difficult airway has not been established yet.

Our work identified that the most consistent and reliable US predictor to apply to clinical practice is the hyomental distance (HMD) with the patient's head and neck in a neutral position. HMD represents the distance between the hyoid bone and the symphysis menti, measured from the submandibular approach. The hyoid bone is a horseshoe-shaped bone with no osseous articulations but many ligamentous and muscle connections to the tongue, epiglottis, pavement of the mouth, pharynx, mandible, temporal bone, and styloid process, being structural support for tongue movement (Biby, 1981). The mandible position concerning hyoid bone directly relates to the oropharyngeal space (Cheng, 2020). The bigger the space, the easier it is to do a direct laryngoscopy, and correctly align the oropharyngeal and laryngeal axis. Therefore, patients with short HMD are expected to have small oropharyngeal space, consequently creating difficulties in direct laryngoscopy view.

Ultrasound HMD is measured with a curvilinear probe oriented longitudinally in the mid-sagittal plane, in the submandibular region. The measurement reflects the distance between the anterior border of the hyoid bone and the posterior portion of the symphysis menti. The procedure is simple, fast and easy to learn and perform. Although it is not time-consuming, proper training is needed to recognize the sonoanatomy of the structures and find the correct start and end points to measure HMD.

Notably, the variation of the HMD in general population is still to be defined. From the published studies, US HMD was especially relevant when an over-weight to morbid obesity population was considered (Andruszkiewicz, 2016; Wojtczak, 2017; Petrisor, 2018). Therefore, the role of this predictor in a normal to underweight population is yet to be established.

Other US parameters were expected to be relevant predictors of difficult laryngoscopy since they are related to clinical predictors. A patient's neck circumference is a predictor (Apfelbaum, 2022), so US measurement of cervical soft anterior tissue was expected to have an important role. Although, the results from studies with the distance from skin to hyoid bone, epiglottis, and vocal cords, had a significant overall effect, they display an elevated heterogeneity which can be explained by different population demography. We think that in future studies with standardized populations and protocols those parameters will be relevant US predictors of difficult airway.

Modified Mallampati score estimates the size relation between the tongue and oral cavity and is currently used as a predictor in clinical practice. Following the same reasoning, it was expected that tongue's cross-sectional area, thickness, volume and its relation to oral cavity size were US parameters with predictive value. Nevertheless, our meta-analysis did not find significant overall effects (Yao & Wang, 2017).

Determining the best clinical predictor of a difficult airway is still a concern. Ultrasound is a powerful complementary tool with the potential to increase the recognition of a difficult airway. HMD in a neutral position is to the best of our knowledge, the most reliable parameter to be used.

As a result of the above findings, a major challenge for the field is the need for increased standardization. This challenge involves several dimensions, namely (1) multicentric protocols; (2) study of different populations and contexts and (3) clinical implementation of research results. Next, we will discuss this in further detail.

3.1.1. Standardized protocols in multicentric studies

Lack of standardization is detrimental to establishing a reliable and reproducible marker of difficult airway. New studies are needed with standard protocols for US measurements that include definition of patient positioning, a consistent classification for laryngoscopy and prevision of the use of intubation aids. Enrolling in multicentric studies with a representative sample of the general population and training of the assessors is the direction to go. At the same time, studies combining clinical and US predictors can increase the sensibility and specificity of recognizing a difficult airway. All these recommendations for future research can reduce the heterogeneity of the studies and simultaneously determine cut-off values that represent thresholds to difficult airway that ultimately improve clinical decision making and patient safety.

3.1.2. Study different populations and context

There is also a need for studies in different contexts and populations, such as emergency, pediatric ages, pregnant women, and obese patients.

Outside the operating room, airway management has an increased risk because patients are critically ill with low reserve capacity and because of the limited number of specialized professionals and material resources (Bowles, 2011; Karamchandani, 2021). Simultaneously, some patients cannot collaborate with clinical evaluation of the screening tests that depend on the patient's participation (e.g. opening of the mouth, neck mobility, upper lip bite, mandible protrusion) or that are time-consuming. Although recent studies proposed using some US parameters (tongue base, tongue-to-skin, epiglottic width and thickness

and pre-epiglottic space) in the Emergency Department the predictive value of this approach is still unknown (Hall, 2018). The development of prospective observational studies on airway US predictors, applied to emergency contexts could bring new perspectives of approach and improve patients' outcomes. The difficult airway management in children is associated with significant morbidity and mortality (Fiadjoe, 2016). The pediatric population, especially the small children, have particular anatomic airway characteristics that, combined with limited cardiovascular and respiratory reserves, make this group particularly vulnerable to hypoxia during airway management. In different studies, the incidence of difficult airway in children can vary from 3.6% (Klucka, 2021) to 19.7% (Amaha, 2021), which may represent scarcity of data, the divergent definition of concepts or other realities of practice. In a recent multicentric European study, the incidence of difficult intubation in neonates and infants was reported to be 5.8%, where two-thirds being unanticipated (Disma, 2021). This means that there is an increased risk of difficulties in airway management at this specific age. In opposition to adults, few studies have assessed the use of clinical predictors (e.g., low body mass index, short lip to chin distance, previous difficult airway, maxillofacial surgery, short thyromental distance, mallampati III/IV, ASA III/IV) to anticipate a difficult airway in pediatric ages (Heinrich, 2012; Mansano, 2016; Malladi, 2018; Jagannathan, 2021). It is noteworthy that in this population, examining clinical predictors is often difficult since they depend on patient collaboration or because the child's health condition does not allow time-consuming procedures. Despite these results, few structured and specific guidelines for pediatric difficult airway management have been published, (Black, 2015; Komasa, 2020, Walas, 2019), increasing the need for a substantial preparation and training in pediatric anesthesia and intensive care. Several studies have been published on the pediatric population using US for upper airway management (Hao, 2020; Sharma, 2019; Wani, 2021), but none to evaluate difficult airway predictors. Standardized studies can highlight different US parameters to consider when airway management is needed in this population group.

Pregnant women are considered difficult airway patients due to anatomic and physiological modifications that occur during pregnancy, labor, and delivery. Edema, increased vascularity of the laryngeal structures and trachea, and the frequent increased weight are the main reasons for difficult laryngoscopy and intubation, with a higher risk of hemorrhage (Delgado, 2020). This fact also contributes to a higher Mallampati score observed in these patients, often increasing during labor (Kodali 2008). One of the advantages of using neuroaxis regional anesthesia during labor, delivery, and c-section, is to reduce the need for general anesthesia. So general anesthesia is restricted for emergent c-section, reducing the opportunities for training airway management which increases the risk of a difficult/failed intubation in this population. The incidence of difficult airway in this group is higher than in the general population.

The rate of failed intubation is 2.3:1000 in general anesthesia for c-section, in which the maternal mortality related to airway management is 2.3:100.000 compared with 1:180.000 in the general population (Kinsella 2015). There are standardized guidelines for managing difficult and failed tracheal intubation in this population (Mushami, 2015). Still, relevant clinical predictors of the difficult airway are not so well explored [(e.g., neck circumference, Mallampati score (Riad, 2018) and sternomental distance (Eiamcharoenwit, 2017)]. There are no published studies where US was used to find predictors of difficult airway, except for Zheng, who published a protocol and methods for a prospective observational study (Zheng, 2019). Results from this study promise a new approach to the airway of parturients.

The last recommendation in this domain is related to obesity. Obese patients are considered to have natural difficult airways due to anatomic and physiological conditions, and consequently the population is susceptible to airway events during general anesthesia (Shaw, 2021). Obese patients comprised of 26% of the studies used in the systematic review (Ezri, 2003; Komatsu, 2007; Wojtczak, 2012; Reddy, 2016; Petrisor, 2018), which may have contributed to the heterogeneity of results.

Subsequently, further studies are recommended to define cut-off values of each US parameter for each group population.

3.1.3. Research results dissemination and clinical implementation

In the most recent difficult airway guidelines from the American Society of Anesthesiologists (ASA) (Apfelbaum, 2022) there are few references to the relevant role of US measurements as predictors of difficult airway. Because the way to implement a behavior change in clinical practice depends on evidence-based results, mainly from systematic reviews and meta-analysis, the way to go is to start to highlight in the international guidelines the results from those studies and develop and validate new protocols of combined clinical and US screening predictors of difficult airway. This strategy can contribute to knowledge translation (KT).

3.2. OSAUS scale for HMD competence assessment

Systematic reviews and meta-analyses provide the best evidence of increased knowledge necessary to induce a behavioral change (Bero, 1998), and the one of the paramount strategies for clinical implementation is continuing medical education (Forsetlund, 2021). So, after our first study had identified the hyomental distance as the most consistent US measurement to predict a difficult laryngoscopy (Gomes & Simões et al., 2021), we developed a learning opportunity (theoretical and practical), in a

simulated environment and studied the psychometric properties of OSAUS scale to assess competence. Our secondary goal was to demonstrate the usefulness of the measurement, the technical ease of the execution, and the limited resources needed for the task. Simultaneously, we provide to participants with educational strategy and a structured competence assessment tool that could guide the acquisition of the competence and facilitate the implementation of the measurement in the clinical setting (Bramley, 2021). The Objective Structured Assessment Ultrasound Skills (OSAUS) scale has been used to evaluate US proficiency in many medical fields. The tool covers seven key elements (indication, applied knowledge of US equipment, image optimization, systematic examination, interpretation of the images, documentation, and medical decision-making), assessed with a five-point Likert scale. The choice of OSAUS scale relies on its broad coverage and applicability to US interventions ranging from obstetric, lung, neck, and other surgical fields. A newly designed scale specifically for airway US assessment could have been developed, nevertheless OSAUS scale was already validated and used in clinical US with good reliability (Todsén, 2015).

The research demonstrated that the OSAUS scale had a relevant internal structure and relation to other variables. The work was intended to be a pilot study and needs to be complemented by the consequence source of validity. The expert group had non-expected results with the lowest performance scores in our work. Although these results were surprising, it highlights some important issues related to expert participants and the design of the work, namely (1) simulated environment; (2) self-reported levels of previous experience; (3) experts' engagement with educational programs. (1) Since there is still a positive correlation between simulated performance and patient outcomes in the clinical setting (Brydges, 2015; Weersink, 2019), we decided to do the study in a controlled environment, out of the clinical field, so participants could practice without time limitation or disturbing factors (patients, clinical rounds, emergency calls). (2) Participants self-reported their level of expertise in US HMD and attending to the consistency of the inter-rater score's reliability, this group overvalued their experience. So, an objective and independent evaluation of participants' experience is the way to go, which could significantly improve the results. (3) In our perspective, experts' participants were not aware of the educational program's learning potential, which significantly compromised the secondary outcome of the study. This is not a new question within medical education. Numerous barriers have been described as impactful in results' translation from research to clinical practice (Wallace, 2014; Chapman, 2021).

3.3. Ultrasound-guided bronchial intubation

As described above, selective intubation in neonates and infants is considered difficult airway management since these patients have airways with reduced dimensions and are more sensitive to the consequences of hypoventilation and hypoxia in the case of prolonged or failed intubation attempts. They have very small chest cavities, which hinders thoracic interventions in a greater dimension when compared with adults (Huang, 2021). Nevertheless, the video-assisted thoracoscopic surgery (VATS) approach is recommended for many thoracic interventions in this population and has been largely used in the clinical setting. An artificial pneumothorax is created with carbon dioxide (CO₂) inflation, which promotes atelectasis of the operating lung and an adequate visualization of the surgical field. But, although the pneumothorax creates an “empty” thoracic cavity compressing the lung, proper airway management is necessary. The standard airway approach for many of those interventions is the use of one lung ventilation (OLV) achieved by the use of a single lumen tube (SLT) in the non-operating lung or a bronchial blocker (BB) in the operating lung (Tobias, 2004). Both techniques have been the gold standard for decades (Templeton, 2021).

Fiberoptic bronchoscopy (FOB) use for difficult neonatal airway management has been recently advocated as the recommended technique to guide and confirm the device’s final position (Cobo, 2020). However, proper training and experience are needed to achieve competence. The learning curve to proficiency in performing FOB is still to be established and should be tailored to each trainee (Dalal, 2011). A survey published in 2014 defined 50 FOB as the minimum threshold necessary to develop competence (Leong, 2014). However, due to the prevalence of the procedure in this population group, this number can be difficult for all residents and young consultants, even in referenced medical centers. The purpose of the study was to exclude the use of the FOB in the context of neonatal and infant patients proposed for VATS. Our work tested the hypothesis that US airway visualization was adequate for selective bronchial intubation. Using a reinforced endotracheal tube for endobronchial intubation allowed the description of a new US pattern and facilitated the recognition of the device. These findings opened the opportunity for a new area of research that involves high-resolution technology that can recognize anatomic structures and simultaneously allows the adequate positioning of airway devices.

A final note to discuss the recent technology that has been developed in other fields of medical care but can easily be applied to airway management for one-lung ventilation, which we next highlight. In the last decade, several innovations have been introduced to regional anesthesia, with navigation technology being the most studied approach. The increased US recognition of the needle tip throughout a signal-

processing that calculates and projects the needle position in the US screen has been used successfully for plexus and peripheral nerve blocks (McLeod, 2021). This kind of approach applied to the bronchial blockers or tracheal tubes could be transformative even for older patients, where the ossified sternum and thoracic rib cage can compromise US view.

Another potential approach perspective is to apply the technology inherent to endobronchial ultrasound (EBUS) with minimal ultrasonic probes adapted to the airway device (BB or SLT), which would allow the identification of the anatomic structures and guide the device position. EBUS is currently used for diagnosing, staging, and treating intrathoracic lesions (Gompelmann, 2012; Kuijvenhoven, 2020). However, minimal millimetric dimensions of the probe are needed given the reduced size of the trachea and bronchus in the pediatric airway.

The final remarks go to the future perspectives of work on knowledge translation (KT) in postgraduate medical education and assessment in anesthesia and critical care. Many barriers and limitations condition the implementation of the results from evidence-based research to clinical practice. Those barriers create gaps that ultimately compromise patient access to the best treatment or intervention. Working in KT can be transformative for patients and healthcare professionals, and the system. This will be the following path.

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Chapter 4

CONCLUSION

4. CONCLUSION

The present Thesis highlighted the importance of ultrasound in managing the airway in three complementary domains.

In summary, the results of the work indicate that:

1. The hyomental distance in neutral head and neck positioning is the most reliable ultrasonographic parameter to predict difficult laryngoscopy.
2. An objective structured scale to assess ultrasonography skills competence (OSAUS) has high internal consistency and reliability to measure hyomental distance and can guide the learning and training of this skill.
3. Selective bronchial intubation guided by ultrasound in a pediatric animal model can be applied to human translational research.

Chapter 5

FUTURE PERSPECTIVES

5. FUTURE PERSPECTIVES

Taken together, the conclusions were withdrawn from the research from this Thesis confirms the usefulness of ultrasound in airway management as a (1) way to identify reliable predictors of difficult airway to apply to clinical practice (2) which can be reliably assessed using OSAUS scale, and (3) US as a useful guide for selective intubation in small infants. Despite these advances, new questions emerge from the results.

Future work should be directed to clarify:

1. The most reliable ultrasonographic predictor for difficult airway will be similar using larger prospective and standardized studies in different populations.
2. The relevance of combining clinical and ultrasonographic predictors.
3. Usability of OSAUS scale in training and assessment of other difficult airway predictors in the clinical setting.
4. The best strategy to implement OSAUS in the airway management as a training and assessment tool in undergraduate and postgraduate medical curricula.
5. What are the best practices to translate the ultrasound-guided selective bronchial intubation to pediatric patients.
6. The impact of the using navigation technology and endobronchial ultrasound adapted to airway devices as a strategy to increase visibility.
7. The best practices to improve knowledge translation in postgraduate medical education and assessment.