Clinics in Surgery

Research Article
Published: 30 Jul, 2021

Ultrasound Assessment of Difficult Airways Applying the Cormack-Lehane Scale: A Prospective, Observational, Interventional, Blind Study

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Abstract

Background: A difficult airway cannot be effectively evaluated due to the lack of non-standardized clinical tests. The need to identify new tests with the aid ultrasound has recently been proposed as a useful, simple, non-invasive tool that can be performed in addition to the clinical method. The aim of this study is to assess the efficacy of ultrasound to identify a difficult airway according to objective, assessable parameters capable of predicting difficult intubation.

Methods: This study was prospective, observational, monocentric, interventional and blind, conducted on 250 patients undergoing major abdominal elective surgery under general anesthesia. Preoperative clinical and ultrasound assessment were conducted bedside by two anesthesiologists different from the ones who conducted the intraoperative phase. At the end of the tracheal intubation, we differentiated the "easy" laryngoscopy (Cormack and Lehane [C-L] grades 1, 2a and 2b) from the "difficult" laryngoscopy (C-L grades 3a, 3b and 4) and compared it to previous ultrasound measurements. Results: The univariate and multivariate analysis showed that the ultrasound parameters able to predict the patients with easy (C-L grade ≤ 2b) and difficult (C-L grade ≥ 3) laryngoscopy was the thickness of the soft tissues anterior to the epiglottis in hyperextension of the head and protrusion of the tongue (STTep).

Conclusion: Ultrasounds have been widely used as a diagnostic and a therapeutic tool, including to evaluate difficult airway and predict difficult intubation. Specifically, the ultrasound measurement of the STTep at 2.5 cm correlates with difficult laryngoscopy. Further studies are necessary to confirm this correlation.

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Received Date: *05 Jul 2021*
Accepted Date*: 27 Jul 2021*
Published Date*: 30 Jul 2021*

Citation:
Laici C, Bianchini A, Cavicchi S, Serra C, Dormi A, Siniscalchi A. Ultrasound Assessment of Difficult Airways Applying the Cormack-Lehane Scale: A Prospective, Observational, Interventional, Blind Study. Clin Surg. 2021; 6: 3266.

Introduction

The primary goal of the anesthesiologist-resuscitator is to identify the Difficult Airway (DA) as early as possible to reduce or eliminate potential risks linked to incorrect management. Inadequate airway protection or insufficient oxygenation of the patient during interventional procedures is associated with an overall increase in mortality and morbidity [1,2]. There isn't a single definition of DA in the literature. The American Society of Anesthesiologists (ASA) guidelines identify the DA as a clinical situation in which an experienced anesthesiologist encounters difficulties in facial mask ventilation and/or tracheal intubation [3,4]. A recent Cochrane review defines DA as difficult face mask ventilation, difficult laryngoscopy, difficult tracheal intubation, and failed intubation [5]. The definition can also include circumstances in which it is necessary to use advanced instruments for the management of the airways, such as extra glottic devices and cannulas for direct tracheal access [6]. This variability in the definition of DA, as well as the use of non-standardized clinical tests, which can comprise of different clinical situations, operator experiences and factors related to the patient, means that the incidence of the phenomenon cannot be effectively evaluated. The need to identify new tests with the aid of imaging techniques is therefore evident. The evaluation of the airways using ultrasound has recently been proposed as a useful, simple, non-invasive tool that can be performed at the patient's bed in addition to the clinical method. However, because the various studies on the subject have not all conformed to the same methods and have not uniformly applied the same measurements, their results regarding the potential role of ultrasound use in the assessment of airways cannot be considered definitive and therefore the efficacy of ultrasound measurements to predict DA has not been sufficiently validated. The aim of this study is to assess the efficacy of airways ultrasound parameters to identify DA according to objective, assessable parameters capable of predicting difficult intubation.

Methods

Clinical trial design

The study was designed to be prospective, observational, monocentric, interventional and blinded. The study was conducted at the University of Bologna in the S. Orsola-Malpighi Polyclinic (Bologna, Italy) and approved by the Institutional Research Ethics Board (Protocol No. 58/2017/O/Sper) on March 14, 2017. Written informed consent was obtained from the enrolled patients and from the person photographed for all the images displayed among the figures. The study conformed to the Declaration of Helsinki and Good Clinical Practice guidelines.

All participants in the study were consenting adults over 18 years of age anticipating major abdominal surgery between 2017 to 2019, during which they would require general anesthesia and orotracheal intubation.

Patients requiring emergency surgeries or rapid-sequence induction were excluded from the study. Patients currently pregnant, patients with a history of difficult intubation or laryngoscopy, or patients likely to require a bronchoscopy were also excluded from participating in the study. The clinical design was divided into two different phases.

Phase 1: Preoperative phase

During the preoperative clinical period the patient underwent ultrasound evaluation by two anesthesiologists. Both anesthesiologists received a theoretical training course and 20 senior-assisted bedside scanning tests as proposed in other similar recent studies [7]. The ultrasound measurements were performed using Esaote My Lab™ Alpha ultrasound machine. A convex probe (1 MHz to 8 MHz) was used for measurements proximal to the hyoid bone (suprahyoid) whereas a linear probe (3 MHz to 13 MHz) for measurements distal to the hyoid bone (subhyoid); the subhyoid distances were detected by a convex probe in case of ossification of the laryngeal cartilages or in case of important thickness of the interposed tissue. The distances detected by the convex probe and linear probe are all linear distances. The patient was placed in a supine position with the head 30 degrees incline. The pre-set ultrasound used was always the same for all patients (musculoskeletal presets for both linear and curved array probes). Ultrasound measurements and the scanning techniques used are described.

Phase 2: Intraoperative phase

The intraoperative phase was conducted by expert anesthesiologists different from those who conducted the ultrasound preoperative evaluation. General anesthesia was conducted according to a standard protocol. The patient was positioned in a standard position (in “sniffing position” if Body Mass Index [BMI] <30 kg/m^2, in “ramped position” if BMI>30 kg/m^2) and he was monitored with Electrocardiography (ECG), Oxygen Saturation measured by pulse oximetry (SpO2,) non-invasive blood pressure, capnography and accelerometric neuromuscular monitoring of Train-of-Four (TOF). Depth of anesthesia was measured with Bispectrality Index (BIS). After 3 min of pre-oxygenating, the anesthesiologist administered Propofol (2 mg/kg) and Fentanest (1.5 mcg/kg). When the anesthetic plane was deep enough (state BIS below 60) the anesthesiologist started to ventilate the patient with a facial mask (AERObag®). After excluding the possible ventilatory difficulty, the anesthesiologist proceeded to the neuromuscular block of the patient (Rocuronium 1 mg/kg). When neuromuscular blockade was deemed as adequate (TOF=0), conventional direct laryngoscopy with a Macintosh blade was performed to assess the Cormack and Lehane (C-L) grading and achieve tracheal intubation. At the end of the tracheal intubation, the anesthesiologists reported on a dedicated data collection form the grade of visualization of the vocal cords according to the C-L grade before and after the external manipulation of the larynx with Backward, Upward, Rightward Pressure (BURP) maneuver. In accordance with Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) guidelines [8] we differentiated the "easy" laryngoscopy (C-L grades 1, 2a, 2b) from the "difficult" laryngoscopy (C-L grades 3a, 3b and 4). Afterwards in accordance with Falcetta et al. [7]. We differentiated the "easy" laryngoscopy (C-L grades 1 and 2a) from the "restricted/difficult" laryngoscopy (including all patients with C-L grades 2b, 3a, 3b and 4). No patient follow-up was foreseen, and the study was completed at the end of the surgery.

Statistical analysis

The ultrasound measurements were compared with the degree of visualization of the vocal cords according to the C-L scale before and after BURP maneuver.

Normality of the distribution of the data was examined with the Kolmogorov-Smirnov test. Continuous variables are expressed as mean ± Standard Deviation (SD) or median with Interquartile Range (IQR) as appropriate, and categorical variables are expressed as a percentage. For the continuous variables, comparisons between two groups were made using t-tests and test for paired data, for non-parametric variables Mann-Whitney U test and test of signs. For categorical variables, we used the chi-square test or Fisher test.

The ultrasound parameters were valued whit univariate and multivariate analysis. Univariate analysis was carried out by means of non-parametric statistics: Mann-Whitney U test and Kruskal-Wallis test.

Multivariable logistic regression analysis using the stepwise method was performed to assess factors related to C-L scale, $p \leq 0.05$ was considered statistically significant and we also used Odds Ratios (OR) and their 95% Confidence Intervals (CI). A Receiver Operating Characteristics (ROC) curve analysis was also performed to quantify the discrimination accuracy of the proposed measures and to assess the optimal cut-off scores. We are considered a good and an acceptable ROC AUC>0.5. All the analyses were conducted in IBM SPSS Statistics version 25 [SPSS Inc., Chicago, IL, USA], Microsoft Windows version.

Sample size was estimated on the basis of available literature review data from Vannucci and Cavallone [9], who reported an accuracy of 0.8 (AUC 95% CI: 0.63-0.95) for the conventional clinical exam, therefore, we estimated an overall increase of at least 10% obtained with the use of ultrasounds (AUC 0.9). On the basis of such difference, considering an alfa error of 0.05 and a beta error of 0.8 the estimated sample size was 219. Considering a dropout rate of 10%, 250 patients were recruited.

Results

Of the 250 eligible patients originally enrolled in the study, 15 did not end up receiving a direct laryngoscopy and were therefore excluded from the study. Furthermore, 6 did not require tracheal intubation due to a modification in their surgical program and 9 were intubated directly using video laryngoscope, which illustrates the patients' flow through the screening and enrolment process and number of patients divided per the degree of C-L during direct laryngoscopy). After excluding these patients that did not fit within the parameters of the study, the eligible patients included in the final study were 235; 117 males (49.8%) and 118 females (50.2%) aged between 18 and 88 years old (average years 54.6 ± 17.1 years). In accordance with SIAARTI guidelines [8] direct laryngoscopy in the absence of laryngeal manipulation was classified as "easy" (C-L grade ≤ 2b) in 220 (93.6%) patients and as "difficult" (C-L grade ≥ 3) in 15 patients (6.4%). In this cluster, a C-L grade 3 was visualized in 14 patients (6%); C-L grade 3b was observed in only one patient (0.4%) while C-L grade 4 wasn't found in any patient. After external manipulation of the larynx with BURP maneuver, the number of patients with difficult laryngoscopy (C-L grade ≥ 3) was reduced to 8 (3.4%), all categorized as C-L grade 3. In accordance with Falcetta et al. [7] direct laryngoscopy in the absence of laryngeal manipulation was classified as "easy" (C-L grade ≤ 2a) in 197 (83.8%) patients and as "restricted/difficult" (C-L grade ≥ 2b) in 38 patients (16.2%). In this cluster the 23 patients at the first laryngoscopy with a C-L grade 2b were reduced to 10 after BUPR maneuver. No failed intubations were recorded.

Table illustrates ultrasound measurements in patients with easy and difficult direct laryngoscopies in absence of laryngeal manipulation and after external manipulation of the larynx with BURP maneuver. The univariate and multivariate analysis showed that the ultrasound parameters able to predict the patients with easy (C-L grade ≤ 2b) and difficult (C-L grade ≥ 3) laryngoscopy with and without BURP maneuver was the thickness of the soft tissues anterior to the epiglottis in hyperextension of the head and protrusion of the tongue (STTep) (p=0.054 and p=0.028 before and after BURP maneuver respectively). In these patients the ROC curve analysis identified a cut-off of STTep equal to a value of 2.50 cm, above which the laryngoscopy is more likely to be difficult (C-L grade ≥ 3 before BURP: specificity 55.9%, sensitivity 73.3%; Area Under the Receiver Operating Characteristics Curve [AUC] 0.649, CI 0.537 - 0.762; p=0.053; C-L grade ≥ 3 after BURP: Specificity 55.9%, sensitivity 87.5%; AUC 0.726, CI 0.589-0.862; p=0.03.

With "easy" larygynoscopy as defined as C-L grade ≤ 2a and "restricted/difficult" as defined as C-L grade ≥ 2b, the univariate and multivariate analyses of the STTep value both before and after BURP maneuver was significant (p=0.001 and p=0.001 before and after BURP maneuver respectively). In these patients, the ROC curve analysis showed the cut-off value of 2.50 cm identified both before BURP (specificity 57.9%, sensitivity 65.8%; AUC 0.672, CI 0.579-0.764) and after BURP (specificity 57.9%, sensitivity 83.3%; AUC 0.738, CI 0.635-0.840).

No statistically significant differences were found between the two groups (easy and difficult laryngoscopy) for other ultrasound measurements.

Discussion

Various clinical criteria have been proposed in the literature to predict a DA, such as the Mallampati score, the interincisor distance, and the mental-thyroidal distance. These criteria are routinely applied in clinical practice; however, they have shown low sensitivity and poor predictive value Paix et al. [9-12]. Estimated that the use of clinical criteria for the preoperative evaluation of DA is able to identify only 50% of DA [13].

The use of ultrasound in airway management is quite recent but already common practice for certain procedures: To identify anatomical structures during cricothyrotomy and percutaneous tracheostomy, to verify the correct positioning of the orotracheal tube and the laryngeal mask, to predict the caliber of the tube based on the diameter of the airway, to verify the exclusion of a lung in mono-pulmonary ventilation, and to diagnose the obstruction of the upper airway [14].

According to a recent meta-analysis by Fulkerson [15], the iomental distance, the thickness of the soft tissues anterior to the hyoid bone and the thickness of the soft tissues anterior to the thyroid membrane are the most predictive indicators of DA [16-19]. However, the usefulness of this meta-study is limited by the fact that not all the studies included assessed patients according to the same parametrics, which varied from ASA scores, to BMI, to demographic data. Moreover, the lack of standardized protocols in performing ultrasounds and the range of operator expertise in ultrasound examination also propose inconsistencies within the studies included in the meta-analysis.

This study examined the correlation between various ultrasound measurements of the airway and the difficulty of intubation according to the classifications on the C-L. As in other related studies, all patients with a history of difficult intubation were excluded. This exclusion can potentially generate bias; however, as noted in Falcetta's hypothesis [7], the inclusion of subjects with a history of difficult can create bias as well, potentially influencing both the administration and the analysis of the ultrasound. The patients were analyzed using numerous ultrasound parameters, some of which have been taken into consideration in previous studies. However, the sample in this study consisted of patients within a more limited range of ASA score and BMI, therefore reducing the variation of other possible variables that can influence the efficacy of intubation. In addition, the study was performed blindly to maximize the validity of the analysis.

Our study examined the correlation between measured ultrasound parameters and the grade of C-L laryngeal visualization to direct laryngoscopy. Of the many parameters analyzed, the only significant ultrasound parameter able to effectively predict a difficult laryngoscopy was the thickness of the soft tissues anterior to the epiglottis measured with the head hyper extended and the tongue protruded (STTep). Tongue protrusion mimics the actual dislocation of the tongue during laryngoscopy and reduces the interference of the base of the tongue when measuring STTep.

The STTep was a predictive indicator for both laryngoscopies performed before and after laryngeal manipulation of BURP. The identified cut-off was 2.50 cm, beyond which intubation becomes extremely difficult. The positive correlation between the glottis visualization and the tissue thickness anterior to the epiglottis in predicting a difficult laryngoscopy could be explained by the anatomical model described by Greenland [20] and recently taken up by Falcetta [7]. According to the Greenland model, an adequate laryngoscopic visualization requires that both the curves that form the upper airway - the "oro-pharyngeal or primary" curve, and the "pharyngeal-tracheal or secondary" curve - are aligned within the visualization axis. It follows that an increase in the thickness of the tissues anterior to the epiglottis, which implies an increase in the distance between the skin and the epiglottis, could be due to a greater concavity of the oro-pharyngeal curve, making it therefore more difficult to align along the axis of visualization and thus impeding direct laryngoscopic visualization.

Contrary to the method proposed by other studies [7,19,21], the thickness of the soft tissues anterior to the epiglottis was most effectively measured in a longitudinal median scan. In accordance with the findings of Falcetta et al. [7]. A longitudinal median scan reduces error in measurement when compared to a transverse scan, in which the depth of the anterior tissues to the epiglottis can vary depending on the point from which the scan is performed, due to the oblique course of the epiglottis. In our study, therefore, the thickness of the soft tissues anterior to the epiglottis was detected in a longitudinal median scan at the midpoint between the thyroid cartilage and the hyoid bone. Furthermore, to reduce any error in measurement, the thickness of the epiglottis itself was included in the measurement since the posterior border of the epiglottis can be identified more precisely than the anterior margin. The cut-off of 2.50 cm is comparable to the value found by other authors whose ultrasound measurements were performed with the patient supine with the head in a neutral position without tongue protrusion [7,19].

The thickness of the anterior soft tissues of the epiglottis was measured after tongue protrusion as well, in order to imitate tongue dislocation during a laryngoscopy and therefore minimize the influence of the thickness of the tongue's base on the measurement of STTep. Lastly, in order to reduce the inference of the patient's weight on the results, the BMI was accounted for in a multivariate analysis that allowed it to be isolated as an independent variable from STTep.

Accounting for all these variables in the analysis, our findings confirm that STTep positively correlates not only with a restricted/difficult laryngoscopy, as proposed by Falcetta et al. (C-L grade ≥ 2b), but also with extremely difficult intubation (C-L grade ≥ 3), rendering it an applicable and practical point of reference for anesthesiologists for the management of DA.

In conclusion, the ultrasound STTep parameter, which can be measured at the patient's bed in less than two minutes, can be used to predict a difficult laryngoscopy.

The most effective ultrasound measurement to predict a difficult laryngoscopy is a STTep >2.50 cm.

Acknowledgement

The authors thank Alicia Potente for collecting the data and participating in writing of the manuscript and Francesca Scuppa for collecting the data.

Funding

Supports were provided from institutional and/or departmental sources.

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