Orginal Title: Evaluation of Anthropometric and Ultrasonographic Measurements With Different Machine Learning Methods in Predicting Difficult Intubation: A Prospective Observational Study

Brief Title: Anthropometric and US-Guided Difficult Intubation Prediction With ML Models

NCT Number: NCT06904586

UPDATE DATE: 20.04.2025

ETHICS APPROVAL DATE: 18.04.2022

Statistical Analysis Plan

It is reported in the literature that the rate of difficult intubation is approximately 17% (3). This study determined the minimum sample size required to detect a statistically significant difference (effect size= 0.1) as 273 individuals under 95% power and 5% type I error conditions. Power analysis was performed with the PASS v.15 demo program.

Machine Learning Algorithms

The data labeled with expert opinion on whether there was a difficult intubation was classified using 8 different machine learning algorithms, which are among the most widely used classification algorithms in the literature and have proven success in this field. These algorithms are; Logistic Regression (LR) , Support Vector Machine (SVM) , Random Forest (RF), K-Nearest Neighbors (KNN), Gaussian Naive Bayes (GNB) , CatBoost, XGBoost ve Decision Tree (DT). These algorithms were applied to the dataset, and the results were obtained.

The 15 most affecting features determined by the feature extraction method from the 30 parameters in the dataset were selected and the dataset was prepared for the classification process according to these features. In addition, different pre-processing methods, such as editing and categorizing the "null" values, were applied to the dataset.

Models were created for each algorithm. The data set was evaluated in 2 groups: 80% training and 20% testing. After training and testing each model with data, the results were obtained. K-fold Cross-validation, the training data is divided into k equal parts. The divided parts are used for both training and testing. 5-Fold cross-validation was performed on the training data. This prevented overfitting of the data.

INFORMED VOLUNTEER CONSENT FORM

This study you will participate in is a scientific research and the name of the study is Evaluation of Anthropometric and Ultrasonographic Measurements with Different Machine Learning Methods in Predicting Difficult Intubation: A Prospective Observational Study. Inherited physical characteristics make it difficult for patients to be connected to the machine for anesthesia. The purpose of this study is to identify people with these measurements through a computer program. In this study, some lengths in your neck will be measured and recorded with a tape measure and ultrasound. The expected period for you to take part in this study is 1 year and the number of volunteers to take part in the study is 278.

It is your responsibility to follow the researcher's recommendations regarding this study and to provide information if you have had previous operations. The use of gel while taking neck ultrasound in this study may cause discomfort; However, the possible benefits expected for you will be preliminary information in the future situations (surgery, accident) if you have a condition called Difficult Airway, and will ensure that the necessary precautions are taken.

In case of any harm related to the research, the treatment of this condition will be carried out by the responsible researcher, and the resulting expenses will be covered by Dr. Gizem Demir Şenoğlu (not mandatory for research that does not require permission from the Ministry of Health).

If there is new information/developments that may concern you regarding the research topic during the research and that may affect your desire to continue participating in the research, this situation will be immediately notified to you or your legal representative. You can always contact Dr. Gizem DEMİR ŞENOĞLU by calling +90 505 9313588 for additional information about the research or for any problems, undesirable effects or other discomforts related to the study.

No payment will be made to you due to your participation in this research; in addition, no fee will be charged from you or your affiliated social security institution for all examinations, tests, and medical care services within the scope of this research. Participation in this study is entirely voluntary. You may refuse to participate in the study or withdraw from the study at any stage; this will not result in any penalty or hindrance to your benefits. The researcher may remove you from the study with or without your knowledge for reasons such as failure to meet the requirements of the applied treatment scheme, disruption of the study program, or to increase the effectiveness of the

treatment, etc. The results of the study will be used for scientific purposes; if you withdraw from the study or are removed by the researcher, your medical data may also be used for scientific purposes if necessary.

All your medical and identity information will be kept confidential and your identity will not be disclosed even if the study is published; however, the audience of the study, those conducting the examination, ethics committees and official authorities may access your medical information when necessary. You may also access your own medical information if you wish.

The measurements that can be obtained from you will be used for scientific purposes and the analyses will not be conducted abroad.

Consent to Participate in the Study:

I have read and listened to all the information listed above that should be given to me before the start of the study. I have asked the researcher all the questions that come to my mind, and I have understood in detail all the explanations made to me by the researcher physician named below, both verbally and in writing. I have been given enough time to decide whether I want to participate in the study. I know that I am participating in this study voluntarily and that I can withdraw from the study at any time, with or without a reason. Under these conditions, I authorize the researcher to review, transfer and process the treatment and/or practices to be performed within the scope of this study and my personal medical information, and I agree to participate in the study with my own consent, without any coercion or pressure.

A signed copy of this form will be given to me.

The biological samples (blood, urine, etc.) taken within the scope of the study;

I only allow it to be used in the above-mentioned study

I allow it to be used in all future studies

I do not allow it to be used under any circumstances

Volunteer,

Name-Surname:

Address:

Tel.-Fax:

Date and Signature: The researcher who made the explanations,

Name-Surname:

Position:

Address:

Tel.-Fax:

Date and Signature:

For those under guardianship or tutelage, the parent or guardian,

Name-Surname:

Address:

Tel.-Fax:

Date and Signature: The organization official/interview witness who witnessed the consent process from

beginning to end,

Name-Surname:

Position:

Address:

Tel.-Fax:

Date and Signature:

PROTOCOL

Ethics committee approval numbered 2022/65 was received from the Düzce University Non Interventional Health Research Ethics Committee. Our study, which received project support numbered 2023.04.04.1402 from Düzce University Scientific Research Projects Coordinatorship, was designed as a prospective, observational study in the Anesthesiology and Reanimation Clinic of the Faculty of Medicine Hospital. Informed consent was obtained from all patients.

Patients over the age of 18 who underwent general anesthesia and had an American Society of Anesthesiologists (ASA) score between I-III were included in the study. Patients who had undergone or were planned to undergo head and neck surgery, who were scheduled to undergo thyroidectomy, who had congenital or acquired morphological disorders, and who had a history of difficult airways were excluded from the study.

It is reported in the literature that the rate of difficult intubation is approximately 17% .This study determined the minimum sample size required to detect a statistically significant difference (effect size= 0.1) as 273 individuals under 95% power and 5% type I error conditions. Power analysis was performed with the PASS v.15 demo program.

329 patients who met the inclusion criteria were included in the study. Following routine vital monitoring (ECG, SpO2, NIBP) in the preoperative evaluation room, age, gender, weight, height, body mass index (BMI), Modified Mallampati score, and upper lip bite test (ULBT) values were recorded. Anthropometric lengths were measured as described with the help of a tape measure;

1. Thyromental distance: the distance from the thyroid notch to the lower tip of the chin when the patient's head is in a neutral position
2. Neck circumference: the measurement around the entire neck with the help of a tape measure, just below the thyroid cartilage
3. Mouth opening distance: the distance between the upper and lower incisors at maximum mouth opening
4. Sternomental distance: the length from the sternal notch to the mentum when the neck is extended

The ultrasonic evaluation was performed with the 4- 15 MHz linear probe of the Esaote MayLab sevenR ultrasound in the supine position, with the head and neck in a neutral position. The distances

to the anterior neck surface were obtained by placing the linear probe in a transverse position at three different levels;

1. Minimum distance from the hyoid bone to the skin surface (DSHB) at the level of the hyoid bone
2. Distance from the skin to the epiglottis (DSE) at the midpoint between the hyoid bone and the thyroid cartilage at the level of the thyrohyoid membrane
3. Minimum distance from the skin to the vocal cord anterior commissure (DSAC) at the level of the anterior commissure
4. Distance between the skin and the trachea (DST) 2 cm above the sternal notch, with the trachea seen transversely
5. Maximum tongue thickness in the sagittal axis under the chin with a 1- 8 MHz convex probe while the patient was in the neutral position.
6. The distance from the hyoid bone shadow to the mentum via the convex probe while the patient's neck is in extension (DSHBE) and neutral (DSHBN) positions. All USG evaluations were performed by an independent trained anesthesiologist.

Patients were induced with 2-2.5 mg/kg propofol, 1 mcg/kg fentanyl and 0.6 mg/kg rocuronium. Mask-ventilated patients were intubated by direct laryngoscopy by an anesthesiologist with different professional experience after the count became 0 with neuromuscular monitoring using GE Healthcare's line of NMTR accessories. Cormack-Lehane score was recorded. Patients who could not be intubated were taken over by more experienced specialist physicians. Patients who could not be intubated by direct laryngoscopy by an anesthesiologist with 5 years or more experience, who used video laryngoscopy, fiberoptic bronchoscopy, and who required stylet, bougie, and cricoid pressure in addition to video laryngoscopy were evaluated as having difficult intubation.

The data obtained from the patients were subjected to various pre-processing steps to make them suitable for classification. Although there are many methods for pre-processing, the pre processing steps applied to the data set used in this study were the editing of null data, categorization of data, and feature extraction. After the completion of the null data, the textual data in the data set was converted to categorical data. Since there was little difficult intubation data in the data set, data augmentation was performed to prevent memorization in the data.

Data balancing was performed for the difficult intubation class, which was in the minority, using SMOTE (Synthetic Minority Over-Sampling Technique). SMOTE increased the samples of the minority classes and balanced the unbalanced classes.

Machine Learning Algorithms

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