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ORIGINAL INVESTIGATION

A prospective validation and comparison of three multivariate models for prediction of difficult intubation in adult patients☆

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Abstract
Purpose: Several bedside clinical tests have been proposed to predict difficult tracheal intubation. Unfortunately, when used alone, these tests show less than ideal prediction performance. Some multivariate tests have been proposed considering that the combination of some criteria could lead to better prediction performance. The goal of our research was to compare three previously described multivariate models in a group of adult patients undergoing general anesthesia.
Methods: This study included 220 patients scheduled for elective surgery under general anesthesia. A standardized airway evaluation which included modified Mallampati class (MM), thyromental distance (TMD), mouth opening distance (MOD), head and neck movement (HNM), and jaw protrusion capacity was performed before anesthesia. Multivariate models described by El-Ganzouri et al., Naguib et al., and Langeron et al. were calculated using the airway data. After anesthesia induction, an anesthesiologist performed the laryngoscopic classification and tracheal intubation. The sensitivity, specificity, and receiver operating characteristic (ROC) curves of the models were calculated.
Results: The overall incidence of difficult laryngoscopic view (DLV) was 12.7%. The area under curve (AUC) for the Langeron, Naguib, and El-Ganzouri models were 0.834, 0.805, and 0.752, respectively, (Langeron > El-Ganzouri, $p = 0.004$; Langeron = Naguib, $p = 0.278$; Naguib = El-Ganzouri, $p = 0.101$). The sensitivities were 85.7%, 67.9%, and 35.7% for the Langeron, Naguib, and El-Ganzouri models, respectively.
Conclusion: The Langeron model had higher overall prediction performance than that of the El-Ganzouri model. Additionally, the Langeron score had higher sensitivity than the Naguib and El-Ganzouri scores, and therefore yielded a lower incidence of false negatives.
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Introduction

The field of airway management during anesthesia has recently experienced great advances, especially with the introduction of videolaryngoscopes[1] and better understanding of the importance of awake intubation techniques with optical devices in high-risk patients.[2] Despite these recent advances, difficult airway is still an important cause of anesthesia-related morbidity and mortality,[2] and conventional laryngoscopy is still the most widely used method to secure the airway during anesthesia.

The current guidelines for difficult airway management focus on good planning and execution of airway strategies with special emphasis on oxygenation and ventilation of the patient.[3] These guidelines strongly advocate that the airway should always be evaluated before administration of anesthesia.[3,4] This evaluation can be used to develop a primary plan to approach the airway and plan a rescue approach in case of failure of the primary plan.

Several bedside clinical tests have been introduced in practice to predict difficult tracheal intubation during anesthesia, such as the original Mallampati classification, modified Mallampati (MM), thyromental distance (TMD), mouth opening distance (MOD), presence of receding mandible, neck circumference diameter, etc.[5–8] Unfortunately, these tests, when used alone, frequently demonstrate a lower than ideal accuracy for confident use in clinical practice.[9,10]

To improve the prediction performance, some multivariate tests have been proposed. The rationale is that the combination of different parameters could lead to better prediction performance. These tests generally combine different criteria into a scoring system to predict difficult intubation. They include the multivariate models described by El-Ganzouri et al.,[11] Naguib et al.,[12] and Langeron et al.[13]

To our knowledge, only few studies have compared the multivariate models in the same patient population.[12,13] Therefore, we conducted this study to compare the prediction performance of these three multivariate models for difficult tracheal intubation in the same patient population and to determine the most accurate prediction model in our patient population.

Methods

The study was approved by the local Medical Ethics Committee (CEP 053/11), and is registered at ensaiosclinios.gov.br (RBR-493n4m). Written informed consent was obtained from all patients. The study population consisted of 220 adult patients scheduled for elective surgery under general anesthesia with tracheal intubation. The study was conducted in a single tertiary center. Inclusion criteria were patients scheduled to undergo elective surgical procedure under general anesthesia, age $\geq$ 18 years, American Society of Anesthesiologists (ASA) physical status $\leq$ 3. Exclusion criteria were emergency surgery, ASA physical status > 3, cervical or facial trauma, and refusal to participate. This manuscript adheres to the applicable Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) guidelines.

Experimental protocol

During the preoperative anesthetic evaluation conducted prior to hospital admission, an anesthesiologist participating in the study collected the patient data and completed the study protocol. Data collected included the type of surgery scheduled, sex, ASA physical status (I–III), age (years), weight (kg), and height (cm).

Airway evaluation was performed in a standardized manner. All airway evaluations were performed by an anesthesiologist participating in the study and previously trained to collect airway data. The airway evaluation included the following:

Visualization of pharyngeal structures according to the MM classification:[8] Class 1, soft palate, fauces, uvula, and pillars visible; Class 2, soft palate, fauces, and uvula visible; Class 3, soft palate, base of uvula visible; Class 4, only hard palate visible.

The MM evaluation was performed with the patient seated, without phonation, and with the aid of a flashlight.

TMD: measured in cm using a rigid translucent ruler from the thyroid notch to the mandibular mentum with mouth closed and head in full extension.

MOD: distance from the edge of the upper incisors to the edge of the lower incisors measured in cm using a plastic caliper with a 1-mm grading

Head and neck movement: The patient was asked to fully flex the head and neck and then fully extend the head and neck. The angles obtained between these two positions were categorized as follows: < 79°, 80–90°, 91–100°, and > 101°. The angle was measured using a digital goniometer.

Jaw protrusion capacity – the capacity to bring the mandible forward was graded as: > 0, if the patient could bring the lower incisors in front of the upper incisors; 0, if the patient could bring the lower incisors only up to the edge of the upper incisors; < 0, if the patient could not bring the lower incisors even up to the edge of the upper incisors.

History of difficult intubation was obtained by interviewing the patient, and the anesthesiologist categorized it as ''no,'' ''questionable,'' or ''definite''.

Receding mandible: the anesthesiologist performing the evaluation recorded the presence of receding mandible as present or not present.

After this airway data collection in the preoperative anesthetic evaluation, an anesthesiologist, who was also participating in the study, calculated the three multivariate models to be studied as follows:

The first score calculated was according to El-Ganzouri et al.[11] (Table 1), and a score $\geq$ 4 was considered positive for difficult intubation. The second score studied was that described by Naguib et al.[12] using the following mathematical formula:

$$l = 0.2262 - 0.4621 \times \text{TMD} + 2.5516 \times \text{MM} - 1.1461 \times \text{MOD} + 0.0433 \times \text{height}$$

Here, TMD, MOD, and height are in cm, and the MM value is considered as 0 (class 1 or 2) or 1 (class 3 and 4). A result < 0 (i.e., negative value) indicates an easy intubation, while that > 0 (i.e., positive value) indicates a difficult intubation.

The third score studied is the one described by Langeron et al.[13] (Table 2). In his original study, this score was called

Table 1 El-Ganzouri et al. Score.

Variable	Values	Points
MOD (mm)	≥ 40	0
	< 40	+1
TMD (mm)	> 65	+0
	60 - 65	+1
	< 60	+2
Modified Mallampati	1	0
	2	+1
	3	+2
	4	+2
HNM (degrees)	> 90	0
	80-90	+1
	< 80	+2
Ability to prognath	yes	0
	no	+1
Body weight (kg)	< 90	0
	90-110	+1
	> 110	+2
History of difficult intubation	none	+0
	questionable	+1
	definite	+2

MOD, mouth opening distance; TMD, thyromental distance; HNM, head and neck movement.
El-Ganzouri et al. Score; range: 0-12 points.

Table 2 Langeron et al. Clinical Score.

Variable	Values	Points
BMI (kg.m^{-2})	< 25	0
	25-34	0
	≥ 35	+1
Modified Mallampati	1	0
	2	+2
	3	+4
	4	+6
MOD (mm)	> 50	0
	36-50	+1
	≤ 35	+2
TMD (mm)	≥ 90	0
	61-89	+1
	≤ 60	+2
Sex	Woman	0
	Man	+1
Receding mandible	No	0
	Yes	+2

BMI, body mass index; MOD, mouth opening distance; TMD, thyromental distance.
Langeron's et al. Clinical Score; range: 0-14 points.

''Score Clinic''. In the present study, a score ≥ 5 was considered positive for difficult intubation.

On the day of surgery, the patients were admitted to the operation theater and standard monitoring was performed with an electrocardiogram, pulse oximeter, and non-invasive blood pressure device. After obtaining peripheral venous access, the patients breathed 100% oxygen for 3 minutes. Anesthesia was induced by administering fentanyl (3–4 mcg.kg^{-1}), propofol (1.5–2 mg.kg^{-1}), and cisatracurium (0.15 mg.kg^{-1}). The patients were then ventilated using a bag and face mask with 100% oxygen. All patients were monitored with a peripheral nerve stimulator (TOF – Watch, Organon, Boxtel, Netherlands).

An anesthesiologist who was participating in the study but not involved in the prior standardized airway evaluation of the patient performed laryngoscopy after the loss of the last muscle twitch in the train-of-four (TOF) stimulation. Laryngoscopy was performed with an English Macintosh blade with the patient lying supine on the surgical table at 0° tilt and the head placed on a head pad (7.0 cm height), with the head in full extension and no external laryngeal manipulation. The main outcome of our study was to grade the laryngeal view according to the Cormack-Lehane classification[14]: grade 1, full view of the glottis; grade 2, partial view of the glottis or arytenoids; grade 3, only epiglottis visible; and grade 4, neither glottis nor epiglottis visible. In this study, grades 1 or 2 were considered as easy laryngeal view (ELV), and grades 3 or 4 as difficult laryngeal view (DLV).

After this initial laryngoscopy classification, if the attending anesthesiologist judged necessary, he could use external laryngeal manipulation to improve the laryngeal view and, in case of necessity, he could use an alternative device to complete the tracheal intubation. The devices available included an intubation bougie, a videolaryngoscope (McGrath MAC, Aircraft Medical, Edinburgh, United Kingdom), and a lighted stylet (Surch-Lite, Bovie Medical, Clearwater USA).

Statistical analysis

The measured variables were expressed as the median and interquartile ranges. A univariate analysis was performed for anthropometric and airway measurement data to assess the association with DLV. The continuous variables were assessed for normality using the Kolmogorov-Smirnov test which demonstrated a non-normal distribution ($p = 0.036$). For continuous variables, the Mann-Whitney test was used, and the chi-square test was used for categorical variables.

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for the three multivariate models studied.

Receiver operator characteristic (ROC) curves were plotted for each of the multivariate models studied, and the area under the curve (AUC) was calculated for each.

The sample size necessary to compare two ROC curve areas was calculated using the Delong method.[15] Considering an AUC difference of 0.1, a significance of 0.05, and power of 80%, at least 10 patients with DLV would be required. Therefore, considering the incidence of DLV of 5%, a sample size of 200 patients would be necessary. Therefore, we chose to collect data from 220 patients to compensate for eventual dropouts. All statistical analyses were performed using R software (version 3.5.0).

Results

This study enrolled 242 patients during the preoperative anesthetic evaluation, of which 22 were excluded due to surgical scheduling changes. None of the patients refused to participate. Finally, 220 patients were included in the

Table 3 Comparison of Patients with ELV and Patients with DLV.

	ELV (n = 192)	DLV (n = 28)	*p* value
Age, year – median (Q1; Q3)	38.0 (31.5; 51.5)	54.5 (47.5; 65.0)	< 0.001[a]
Gender			
Men, n (%)	54 (28.1)	19 (67.9)	< 0.001[b]
Women, n (%)	138 (71.9)	9 (32.1)	
Weight, kg – median (Q1; Q3)	77.0 (67.0; 93.1)	79.5 (69.0; 96.5)	0.385[a]
Height, cm – median (Q1; Q3)	166.0 (160.0; 173.0)	167.0 (165.0; 172.5)	0.206[a]
BMI, kg.m^{-2} – median (Q1; Q3)	26.8 (24.2; 34.0)	28.0 (24.2; 33.9)	0.585[a]
TMD, mm – median (Q1; Q3)	85 (75; 90)	80 (70; 90)	0.009[a]
MOD, mm – median (Q1; Q3)	46 (42; 51)	41 (39; 45)	< 0.001[a]
Mallampati, n (%)			
Class 1 or 2	136 (70.8)	11 (39.3)	0.002[b]
Class 3 or 4	56 (29.2)	17 (60.7)	

BMI, body mass index; TMD, thyromental distance; MOD, mouth opening distance.
[a] Mann-Whitney test.
[b] Chi-square test.

Table 4 Diagnostic Profile of Three Multivariate Methods for predicting Difficult Laryngoscopy.

Methods	Sensitivity	Specificity	PPV	NPV
Langeron et al. clinical score[a]	85.7 %	62.5 %	25.0 %	96.8 %
Naguib et al. model[b]	67.9 %	77.1 %	30.2 %	94.3 %
El-Ganzouri et al. score[c]	35.7 %	89.1 %	32.3 %	90.5 %

PPV, positive predictive value; NPV, negative predictive value.
[a] Score ≥ 5.
[b] Score ≥ 0.
[c] Score ≥ 4.

study, and 28 patients were found to have DLV (i.e., Cormack Lehane grade 3 or 4) with overall incidence of 12.7%. There were no failed intubations. Intubation aids were used in 9 patients in the DLV group (videolaryngoscope, n = 6; intubation bougie, n = 2; and lighted stylet, n = 1).

Older age and male sex were associated with a higher incidence of DLV ($p < 0.001$ and $p < 0.001$, respectively; Table 3). Lower TMD, lower MOD, and higher MM classes (3 and 4) were associated with DLV ($p = 0.009$; $p < 0.001$; $p = 0.002$, respectively; Table 3).

The sensitivity, specificity, PPV, and NPV for each test are shown in Table 4. The Langeron score had the highest sensitivity and NPV, while the El-Ganzouri method had the highest specificity. The ROC curves of the models are shown in Figure 1. The AUC for the Langeron, Naguib, and El-Ganzouri models were 0.834 (95% CI: 0.768–0.900), 0.805 (95% CI: 0.725–0.885), and 0.752 (95% CI: 0.670–0.835), respectively. The AUC value was significantly higher in the Langeron model than that of the El-Ganzouri model ($p = 0.004$), but not when compared with the Naguib model ($p = 0.278$). The Naguib model's AUC value was not significantly higher than that of the El-Ganzouri model ($p = 0.101$).

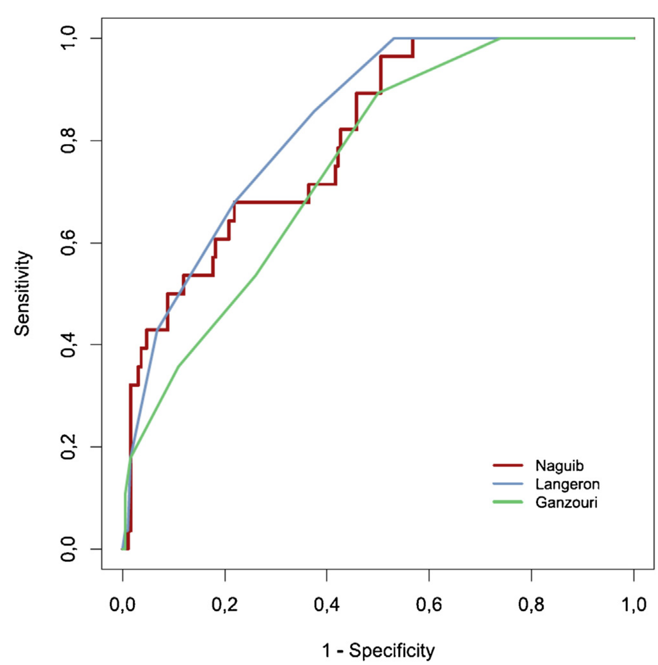

Figure 1 ROC curves of the three multivariate models studied.

Discussion

The incidence of difficult intubation during anesthesia is highly variable ranging from 1.8–20.2%.[9] This wide range can be attributed to the different definitions used across studies (e.g., difficult intubation vs. difficult laryngoscopy), different population subsets (e.g., obese vs. non obese[7]), or different laryngoscopic blades.[16] Our study used difficult laryngoscopy (i.e., Cormack-Lehane class 3 or 4) as a surrogate marker of difficult intubation, because it is a more objective and measurable endpoint used widely in difficult airway research.

In our study, the incidence of DLV was 12.7%, which corroborated with a previous meta-analysis that showed the incidence of DLV ranging from 6–27%.[10] Interestingly, in another study[17] using a similar method, where an experienced anesthesiologist performed the laryngoscopy after loss of fourth twitch in TOF stimulus using a Macintosh blade and the patient's head was placed on a 6-cm head pad the DLV incidence was 12.2%. Therefore, in more controlled settings, the range of DLV incidence could be considerably narrower.

Our study showed that low TMD and MOD were associated with DLV as in other studies.[12,13,17] This is in accordance with the fact that most multivariate difficult intubation scores include these criteria. In our study, older age was associated with DLV. Although not a common finding in difficult intubation studies, it is a definite marker of difficult mask ventilation associated with difficult intubation.[18] Moreover, our study showed an association between male sex and DLV. Notably, the Langeron score includes the male sex as a predictor of difficult intubation.[13]

We opted to compare these specific multivariate difficult airway prediction models (El-Ganzouri,[11] Naguib[12] and Langeron[13]) because they presented one or more of the following aspects. The model was easy to perform at the patient bedside with no need of complex diagnostic tools or complex measurements. The model had shown promising diagnostic capacity in previous or original studies and was described more recently in the anesthesiology literature. Also, a model which integrated various patient airway measurements and other data in one single result that could be easily obtained and interpreted.

When comparing airway prediction tests, two different approaches can be used. First, look at the overall test ability to discriminate patients with or without the condition using ROC curves.

An AUC $\leq$ 0.5 would indicate no discriminating power, while that of 1.0 would equate the diagnostic test to the gold standard. Second, compare the airway prediction tests by choosing a cut-off value, and calculate the test sensitivity and specificity for this specific point. For a given test, sensitivity and specificity are inversely related, hence a change in the test cut-off value would change both values in opposite ways.[19]

Considering the ROC curve analyses, the Langeron model showed the highest AUC (0.834) and the El-Ganzouri the lower (0.752) ($p < 0.001$). The Naguib AUC value (0.805) did not differ from that of Langeron or El Ganzouri ($p = 0.278$ and $p = 0.101$, respectively). This El-Ganzouri AUC value is in accordance with another study that tested this score in patients intubated with a Macintosh blade (AUC = 0.74).[20]

In our study, the Naguib AUC value of 0.805 differed from that shown in Naguib original study (AUC = 0.90).[12] We believe that this difference could be attributed to differences in the study design. While Naguib's study had a case-control design and the patients' airway data were collected after the event of difficult laryngoscopy, our study was a prospective evaluation where all data were collected beforehand. Furthermore, when a test is derived from a sample population, it tends to perform better in the same sample population than with another external sample.[19]

Our Langeron AUC value of 0.834 also differed from the original Langeron study[13] (AUC = 0.74), probably due to the different study designs. Langeron's study used difficult tracheal intubation as an endpoint, which differs from our DLV endpoint. Additionally, our study had more controlled conditions – only few experienced anesthesiologists performed airway evaluation and tracheal intubations, specific neuromuscular blockade intensity – while Langeron's study was multicentrical with anesthesia providers of different expertise levels. Langeron's study also tested the Naguib model and found an AUC value of 0.66, which differs from our study (AUC = 0.805). The aforementioned factors could explain this discrepancy.

Considering the specified cut-off values, the Langeron score showed the highest sensitivity (85.7%), while Naguib (67.9%) and El-Ganzouri (35.7%) scores showed moderate to poor sensitivities. In difficult airway prediction, high sensitivity is of utmost importance[12] because it leads to a lower occurrence of false negatives, which in this situation means that a patient deemed easy to intubate during airway evaluation proves to be difficult to intubate after anesthesia induction. This could lead to a potentially catastrophic situation of inability to intubate the patient who is already unconscious and apneic.

High sensitivity also favors a high NPV, which is also important in difficult airway prediction. In this scenario, a high NPV means that a patient deemed easy to intubate during airway evaluation will prove to be easy during the actual intubation. In our study, the Langeron model showed the highest NPV (96.8%) followed by the Naguib (94.3%) and El-Ganzouri models (90.5%). Therefore, a Langeron score ≤ 4, a Naguib score ≤ 0, and an El-Ganzouri score ≤ 3 would correctly indicate ELV approximately 97, 94, 91% of the time and would miss a DLV 3, 6, 9% of the time, respectively.

In our study, the sensitivity and specificity of the El-Ganzouri score (cut-off value 4) were 35.7% and 89.1%, respectively. This is in accordance with a previous study, where for the same cut-off point, the El-Ganzouri score showed a sensitivity and specificity of 31.8% and 95%, respectively.[20] In our study, the Naguib method's sensitivity (67.9%) differed markedly from that of the original study (82.5%).[12]

Our study has some limitations. First it was conducted by few experienced anesthesiologists. While this could have led to lower inter-observer variability and potentially to better prediction results, our results may not be applicable to a broader spectrum of clinical scenarios. Second, the use of strict criteria for patient intubation procedure – with predetermined neuromuscular block intensity, use of a standard head pillow, and lack of external laryngeal manipulation – could have led to accurate predictions, but it could also not be applied to broader intubation situations.

Thus, our study showed that the Langeron model had a higher overall prediction performance than the El-Ganzouri model. Furthermore, the Langeron model had higher sensitivity than the Naguib and El-Ganzouri models and therefore yielded a lower incidence of false negatives.

In clinical practice, a difficult airway prediction model with high sensitivity, like the Langeron model, is greatly desirable. This is because it minimizes the occurrence of false negatives, in this context, a critical scenario where a patient appointed as easy to intubate during the airway evaluation proves to be difficult to intubate after anesthesia induction. A simplified difficult airway prediction model, like the Langeron model, is also desirable since it can be easily done at the patient bedside with no need of complex measurements or calculations.

We believe that future research should aim to evaluate multivariate airway prediction models in the era of the indirect laryngoscopy, nowadays made possible with the increasing use of videolaryngoscopy.

Conflicts of interest

The authors declare no conflicts of interest.

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