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COMPARISON OF TOTAL AIRWAY SCORES AND INTUBATION DIFFICULTY SCORES IN DENTAL PROCEDURES PERFORMED UNDER GENERAL ANESTHESIA: A RETROSPECTIVE STUDY\*  
GENEL ANESTEZİ ALTINDA YAPILAN DENTAL İŞLEMLERDE; ENTÜBASYON ZORLUK SKORU İLE TOPLAM HAVAYOLU SKORUNUN KARŞILAŞTIRILMASI: RETROSPEKTİF ÇALIŞMA

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**ABSTRACT**

Total airway score determined by 8 bedside tests during the preoperative period. During intubation, difficult intubation score determined by the Intubation Difficulty Scale. Both values were compared with each other. The aim of this study is to investigate the correlation between the Total Airway Score and the Intubation Difficulty Scale. Two hundred, American Society of Anesthesiologists ASA 1-3 patients elective dental treatment, maxillofacial surgery under general anesthesia were included in the study. Airway evaluation was performed preoperatively by total airway score which were; Mallampati classification, thyromental and sternomental distance measurement, head and neck mobility, body mass index (BMI), presence of buck teeth, inter incisors gap, upper lip bite test. After endotracheal intubation, the patients were divided into two groups as a healthy group (intubation difficulty scale (IDS)<4) and difficult intubation (IDS ≥4) according to their estimated difficult intubation scores with seven variables and compared with patients with total airway score >3 in two groups. In this study, total airway score (> 3), thyromental distance (<6cm), upper lip bite test (class III), mallampati classification (≥ class III), inter incisors gap (<3 cm) and buck teeth (> 0.5) respectively 49.45 (95% CI = 4.75-515.45, P <0.05) 7.72 (95% CI = 1.81-32.9, P <0.05), 21.12 (95% CI = 2.31-192.27, P <0.05), 1.92 (CI 95% = 0.51-7.22), 3.54 (95% CI-) 2.31 (95% CI = 0.49-10.78) was evaluated in favor of difficult intubation. It is concluded that total airway score (>3), upper lip bite test (class III), thyromental distance measurement (<6 cm), which we use in predicting difficult intubation are the most useful preoperative evaluation factors.

**Keywords:** Dental care, general anesthesia, intubation

**ÖZ**

Toplam hava yolu skoru, preoperatif muayene sırasında 8 yatak başı testi ile belirlendi. Entübasyon sırasında, Entübasyon Zorluk Ölçeği ile zor entübasyon puanı belirlendi. Her iki değer birbiri ile karşılaştırıldı. Bu çalışmanın amacı Toplam Havayolu Skoru ile Entübasyon Zorluk Ölçeği arasındaki uyumu araştırmaktır. Çalışmaya genel anestezi altında elektif diş tedavisi, maksillofasial cerrahi olan 200 Amerikan Anestezistler Derneği (ASA) 1-3 hasta dahil edildi. Hava yolu değerlendirmesi ameliyat öncesi toplam hava yolu skoru; Mallampati sınıflaması, tiromental ve sternomental mesafe ölçümü, baş ve boyun mobilitesi, vücut kitle indeksi (VKI), tavşan dişlerin varlığı, kesici dişler arası boşluk, üst dudak ısırma testleri ile belirlendi. Endotrakeal entübasyon sonrası hastalar yedi değişkenli tahmini zor entübasyon skorlarına göre sağlıklı grup (entübasyon zorluk skoru (IDS)<4) ve zor entübasyon (IDS ≥4) olmak üzere iki gruba ayrıldı ve her iki grup toplam hava yolu skoru > 3 olan hastalarla karşılaştırıldı. Bu çalışmada toplam hava yolu skoru (>3), tiromental mesafe (<6cm), üst dudak ısırma testi (sınıf III), mallampati sınıflaması (≥ sınıf III), kesici dişler aralığı (<3cm) ve tavşan dişlerin öne protrüzyonu (>0.5cm) olması zor entübasyon lehine değerlendirildi. İstatistiksel olarak sırasıyla 49.45 (%95 GA = 4.75-515.45, p <0.05) 7.72 (% 95 CI = 1.81-32.9, p <0.05), 21.12 (%95 CI = 2.31-192.27, p <0.05), 1.92 (CI %95 = 0.51-7.22), 3.54 (%95 CI-) 2.31 (%95 CI = 0.49-10.78) saptandı. Zor entübasyonu öngörmede kullandığımız total hava yolu skoru (> 3), üst dudak ısırma testi (sınıf III), tiromental mesafe ölçümünün (<6 cm) en yararlı preoperatif değerlendirme faktörleri olduğu sonucuna varıldı.

**Anahtar kelimeler:** Diş bakımı, genel anestezi, entübasyon

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## INTRODUCTION

Delay or failure to achieve safe airway patency as a result of difficult endotracheal intubation under general anesthesia can cause fatal complications. Therefore, the issue has always been up to date for anesthesiologists. Many studies have been conducted on difficult airway (1-4). Thanks to these studies, clear criteria are being sought for the prediction of difficult intubation and taking necessary measures. Difficulty in intubation may be seen more frequently in patients who will receive general anesthesia for dental procedures. Especially mouth, teeth, jaw anomalies and facial defects may cause this (5). Difficult endotracheal intubation is defined by the American Society of Anesthesiologists (ASA) as intubation lasting more than 10 minutes with a standard laryngoscope or requiring at least three attempts (6). As can be understood from this definition, the definition of difficult intubation is subjective and does not contain precise data indicating the degree of difficulty. In a study in which difficult intubation was defined as Cormack and Lehane grades III and IV, the rate of difficult intubation ranged from 1 to 4%, while the rate of failed intubation was 0.05-0.35%. (2). According to the study conducted by Tüzüner et al. (5) found the rate of difficult endotracheal intubation rate of 15% in maxillofacial surgeries. Difficult laryngoscopy and difficult intubation are different definitions. According to the scale of Adnet et al. (7) intubation was defined as easy, difficult and very difficult. Also, facilitating the effects of intubation and equipment used during intubation was considered in this study. Thus, more objective criteria for difficult or easy intubation were determined, and intubation difficult scala (İDS) was created. However, the number of samples constitutes a severe limitation of the studies. Studies on difficult airway in pediatric patients are scarce. There are usually studies in neonatal intensive care units (8,9). Operating room studies are rare, and no guidelines have been developed in this regard as in adult patients. Congenital anatomic deformities and some syndromes are the conditions that make intubation impossible in children. Significant congenital anomalies may cause loss at an early age, but sometimes surgery may be necessary. General anesthesia may become mandatory. The number of these patients that we have not encountered for many reasons and rarely have to give anesthesia is not enough to carry out clinical studies. For this reason, information about airway management is frequently seen in the literature as case presentations. On the other hand, although it is healthy in the pediatric age group, intubation difficulties are not as frequent as in adult patients (9). Bedside tests are modified or formulated differently than adult patients (10). It is reported that, upper lip bite and mallampati tests have some more importance (9).

There may not be enough time to prepare for intubation in emergency services, intensive care units and some critical patients. Since bedside tests are time consuming, evaluation for intubation is usually performed by physical examination. If an emergency operation is not planned, the patient is evaluated preoperatively for difficult airway and difficult intubation. There are many studies of these patients, including, practical, results in reliable tests, or combinations of conventional tests. In a

study, a total of 7 airway evaluation tests were combined total airway score (TAS) was established (3). Before this, many studies have been carried out with different parameters of TAS. In our study, in addition to these tests, another airway test was added, and the total airway score was rearranged, and pediatric patients were included in the study. In this study, patients who were predicted to have difficult intubation according to the total airway score obtained in the preoperative examination was included. It was compare difficult and easy intubation according to IDS criteria. In addition, the duration of intubation, the lowest SpO<sub>2</sub> level, and systemic diseases were also noted and discussed in the light of the literature in terms of the causes and effects of difficult intubation. In this study, we aim to investigate the usefulness of the preoperative total airway score in predicting difficult intubation in patients undergoing general anesthesia for dental procedures. The preoperative total airway score is a clinical tool that combines several physical examination findings related to the patient's airway. These include parameters such as mouth opening, neck mobility, visibility of the uvula, and the thyromental distance. A higher score indicates a potentially more difficult airway to manage. However, the effectiveness of this scoring system in predicting difficult intubation, particularly in patients undergoing dental procedures, remains unclear. Thus, our hypothesis is that a higher preoperative total airway score is associated with an increased likelihood of difficult intubation in these patients.

Although failure to intubate is one in 5000-10000 patients, it is responsible for 25% of all anesthesia-related deaths (4). Preparing for difficult intubation is extremely important to prevent serious anesthetic complications.

## MATERIALS AND METHODS

### Ethical approval

Informed consent was obtained from all patients, and approval for the study was obtained from the Local Ethical Committee of the Süleyman Demirel University Faculty of Medicine (05.05.2021/206).

### Study population

This retrospective study examined the records of 200 patients who underwent dental treatment under general anesthesia between April 2017 and April 2018 at Disabled Hospital of the Faculty of Dentistry, Süleyman Demirel University.

### Study design

Inclusion criteria: ASA I, II and III patients between the ages 5 and 70 years, who were scheduled for dental treatment and maxillofacial surgery under general anesthesia.

Exclusion criteria: Patients with missing teeth, using removable dentures, having temporomandibular joint ankylosis, or having oral or laryngeal tumors, and disabled or healthy individuals who could not cooperate were excluded.

ASA value, demographic data (age, sex, weight, height) and existing secondary diseases (diabetes, hypertension and syndromes) were added to the study data before surgery.

After the purpose of airway assessment was explained to patients, their consent was obtained. Anesthesiology

residents with five years of experience visited the patients before surgery to evaluate the airway assessment factors, and all data were recorded.

The 8 airway assessment factors were included: Mallampati (MP) classification (1), the thyromental distance (TMD) (10), the head & neck movement (HNM), BMI, the severity of buck teeth (BT), the inter incisor gap (IIG), sternomental distance (SMD) and the upper lip bite test (ULBT) (11). Each factor was given a 0, 1 or 2 scores (for BMI, 0 or 1 score) and the total score was tallied and recorded as TAS (Table I). Pediatric patients and patients with syndrome were examined with the help of their parents or their guardians.

#### Intubation process

All patients received 0.05 mg/kg midazolam intravenously before being sent to the operating room. First of all, standard monitoring was performed according to the ASA guideline for the patients who came to the operating room. Preoxygenation was performed for 5 minutes before starting anesthesia. In all patients, 2 mg/kg propofol, 0.2 ug/kg/min remifentanyl, 0.8 mg/kg rocuronium were administered intravenously. Endotracheal intubation was performed when muscle relaxation was sufficient. The intubations were performed by an experienced anesthesiologist who had at least five years of practice after completing their anesthesiology residency. The lowest SpO<sub>2</sub> value during the period until the patient was intubated was recorded.

#### Measuring of the Intubation Difficult Scala

The difficulty of intubation was determined using the difficult intubation scale (7) in intubated patients (Table II) and noted. Difficult intubation was accepted as 4 points or more according to the scale (Group 1). Intubation below 4 points was noted as easy intubation (Group 2). In the airway assessment point system, a TAS

over 3 points was considered predictive of difficult endotracheal intubation. The TAS of more than 3 points in the two groups was compared to calculate the P-value and odds ratio.

In addition, in this study, patients with hypertension, diabetes mellitus, syndrome, the lowest SpO<sub>2</sub> values during intubation were noted and evaluated for their contribution to intubation difficulty.

#### Statistical analysis

SPSS program version 18.0 was used for statistical analysis of the data obtained in the study. The results of all parameters of the cases were given as numbers (percentages) mean ± standard deviation. Independent samples t-test was used to compare continuous variables between groups, and chi-square test was used to compare categorical variables. Multivariate logistic regression analysis was applied to find the odds ratio (OR), 95% confidence interval (CI) and P value to the data that showed a significant difference in the chi-square test. p<0.05 was considered statistically significant. In the study, skewness and kurtosis values were examined to understand whether the distribution was homogeneous or not, and it was determined that all parametric values were normally distributed. Normality tests were performed and it was determined that the entire study was distributed homogeneously (normally). Logistic regression analysis was performed.

#### RESULTS

There were 22 patients (11%) in the difficult intubation group (Group 1), and 179 patients (89%) in the Normal group (Group 2). There were no patients who could not be intubated in either group. TAS of the patients were between 1-5 points. Mean TAS was 3.64±2.12 in Group 1

**Table I.** Airway scores of the patients

Airway factors	Score 0	Score 1	Score 2
MP	Class I	Class II	Class III-IV
TMD (cm)	> 6.5	6-6.5	< 6
HNM (°)	> 90	90	< 90
BMI (kg/m <sup>2</sup> )	< 25	≥ 25	-
BT	No	Mild	Severe
IIG (cm)	> 5	4-5	< 4
ULBT	Class I	Class II	Class III
SMD (cm)	<12	12-13.5	>13.5

MP: Mallampati, TMD: Thyromental Distance, HNM: Head and Neck Mobility, BT: Buck Teeth, IIG: Inter Incisors Gap, BMI: Body Mass Index, ULBT: Upper Lip Bite Test, SMD: Sternomental Distance

**Table II.** IDS scores

Calculating method	
N1	Every additional attempt adds 1 point
N2	Each additional operator adds 1 point
N3	Each alternative technique adds 1 point: repositioning of the patient, change of materials (blade, ET tube, addition of a stylette), change in approach (nasotracheal/orotracheal) or use of another technique (fibroscopy, intubation through a laryngeal mask)
N4	Apply Cormack grade for 1st oral attempt. For successful blind intubation: N4 = 0
N5	Increased lifting force during laryngoscopy adds 1 point. For normal lifting force: N5 = 0
N6	External laryngeal pressure to improve glottic exposure adds 1 point
N7	Position of vocal cords during laryngoscopy (abduction: N7 = 0, adduction: N7 = 1)

ET: Endotracheal, IDS: intubation difficulty scale (IDS = 0: easy, 0 < IDS ≤ 4: slight difficulty, IDS > 4: moderate to severe difficulty).

and 1.43±1.27 in Group 2. There was a significant difference between the 2 groups (p<0.001) (Table III). There were only 1 (0.06%) patients in Group 2 with a TAS score above 3 and 22 (69.4%) patients in Group 1. In addition, the number of patients with a score above 6 was significantly higher in group 1 (p<0.001) (Table IV). According to these data, when TAS≤3 and TAS>3 were compared, the probability of difficult intubation was 49.45 times higher (95% CI=4.74-515.45, p<0.05) (Table V). When the tests that make up the TAS are compared within themselves; MP classification (≥class III, 2 groups: 15.2% against group 1: 40.9%) and TMD (<6 cm, group 2:6.7% and group 1:31.8%), CT (>0.5cm, 2nd group: 1.7% and 1st group: 0.9%, IIG (<4 cm, 2nd group: 0% vs. 1st group: 9.1%) and ULBT (class III), 2nd group: 1.1% and 1st group: 18.2%. In group 2, 5 factors were significantly higher (p<0.05) (Table IV). The 5 airway assessment factors were significantly different and the odds ratio for ULBT (class III) was 21.2 (95% CI = 2.32-192.27, p<0.05), TMD was 7.72 (95% CI = 1.81-32.9, p<0.05), 2.31 (95% CI = 0.49-10.78, P = 0.28), 1.92 for CT (>0.5cm), MP classification (≥class III) and IIG (<4cm), respectively (95% CI=0.51-7.22), p=0.33), 3.54 (95% CI = -, p=0.99) (Table V). Endotracheal intubation time was 29.87±11.41 seconds in group 1, which was 43.27±16.32 seconds longer than endotracheal intubation time in group 2. The lowest

SpO<sub>2</sub> value during extubation was 94.59±1.56 in group 1 and 98.71±1.45 in group 2. Group 2 showed a statistically significant difference (p=0.001). The mean age, gender, hypertension, diabetes mellitus and syndrome prevalence did not differ statistically between the 2 groups (Table III).

**DISCUSSION**

In many studies, especially using anatomical markers and measurements, the best predictor airway test has been estimated. The results of those studies have shown that these tests have high specificity but low sensitivity. The results suggest that difficult intubation will occur in patients, but unexpected intubation difficulty may occur in 20% of patients. There is no guarantee that the expected easy intubation will not be difficult. Although its reliability is discussed in the diagnosis, guidelines recommend bedside tests (4). MP was first described in 1985 to predict difficult laryngoscopy (1). MP evaluation initially included three classes based on the ability to see tonsil columns, uvula and palate with mouth open and tongue protruding. The more commonly used modified MP test have classified 4 groups. In addition to all the class I structures listed above, MP is described in class 0 where part of the epiglottin can be seen (12,13). MP evaluation is routinely performed in the sitting position. If the patient cannot sit, it is also done in the supine position. The patient should be done without talking.

**Table III.** Characteristics of patients in the normal and difficult intubation groups

	N (DIS≤4)	DI (DIS:5-7)	p value
Number of patient (%)	178 (89)	22 (11)	-
Age	20.02±18.21	30.95±27.64	0.080
Gender (M/F)	96/82	9/13	0.240
Associated disease (none, syndrome, systemic )	141/13/24	15/4/3	0.220
Intubation duration (Sec)	29.87±11.41	43.27±16.32	0.001
Lowest SPO <sub>2</sub> level(%)	98.71±1.45	94.59±1.56	0.001
TAS	1.43±1.27	3.64±2.12	0.001

TAS: Total Airway Score

**Table IV.** Comparison of predictive tests in normal and difficult intubation groups

Airway factors	N (DIS≤4)	DI(DIS:5-7)	p value
TAS (>3)	1 (0.6%)	8 (36.4%)	0.001
MP (≥3)	27 (15.2%)	9 (40.9%)	0.003
TMD (< 6cm)	12 (6.7%)	7 (31.8%)	0.001
HNM (< 90°)	5 (2.8%)	1 (4.5%)	0.650
BMI (≥ 25 kg/m <sup>2</sup> )	33 (18.5%)	5 (22.7%)	0.630
BT(>0.5cm)	3 (1.7%)	2 (9.1%)	0.030
IIG (< 4cm)	0 (0%)	2 (9.1%)	0.010
ULBT (= Clas III)	2 (1.1%)	4 (18.2%)	0.001
SMM(<12)	13 (7.3)%	3 (13.6%)	0.550

MP: Mallampati, TMD: Thyromental Distance, HNM: Head and Neck Mobility, BT: Buck Teeth, IIG: Inter Incisors Gap, BMI: Body Mass Index, ULBT: Upper Lip Bite Test, SMD: Sternomental Distance

**Table V.** Predictive tests for difficult intubation by logistic regression analysis

Airway factors	B	S.E.	Wald	p value	Odd ratio	95%CI
TAS (>3)	3.841	1.187	10.476	0.001	46.587	4.550-476.952
MP (≥3)	0.662	0.675	0.963	0.326	1.939	0.517-7.276
TMD (< 6cm)	0.986	0.371	7.065	0.008	2.679	1.295-5.541
BT(>0,5cm)	0.875	0.544	2.587	0.108	2.399	0.826-6.971
IIG (< 4cm)	8.753	12918.617	0.000	0.999	6328.675	-
ULBT (= Clas III)	1.526	0.571	7.136	0.008	4.599	1.501-14.088

MP: Mallampati, TMD: Thyromental Distance, HNM: Head and Neck Mobility, BT: Buck Teeth, IIG: Inter Incisors Gap, BMI: Body Mass Index, ULBT: Upper Lip Bite Test, SMD: Sternomental Distance

During the examination, the patient's speech, stimulation of the gag reflex and patients position affect the test result (3). In addition, companionship examinations in children and patients with syndrome may prevent an efficient evaluation. The study results show a heterogeneous structure since non-standardized material method errors, lack of objective examination findings, and personal evaluations contribute to the outcome (4). A metaanalysis of 133 studies published in Anesthesia was the most commonly used mallampati among predictive tests. 111 studies (6 MP, 105 modified MP) were performed. In general, MP, IIG and TMM were more reliable than these studies (4). This is one of the parameters that elevated TAS in our study, but it was not a sensitive test for DI alone.

Thyromental distance (TMD) is the distance between the thyroid cartilage and the mandible measured by the full extension of the neck. Short TMD has been defined as less than 6 cm (14,15) Being an anatomical marker, supporting the measurement with objective data and expressing it with numerical values provides an advantage in terms of providing a standard.

In our study, we obtained significant results consistent with the literature (16) and TMD was both a parameter that increases TAS. It was also a test that was a marker for difficult intubation alone.

The sternomental distance is measured by full neck extension between the stern notch and the mandible. According to the literature, it should not be less than 12 cm for an easy laryngoscopy (17,18). In our study, we performed SMD evaluation in the range of 12-13.5 cm. In addition to the tests used by Seo et al. (3), the aim of this test was to evaluate the predictive tests in a wider range and combination in number, and to look for compliance with TMD as an anatomical marker. However, we did not reach the expected result. According to our results, SMD measurement was neither a sensory test for TAS nor for DI. Although there is a specific test for difficult laryngoscopy according to the literature (17), this was not the case for difficult intubation. It can be thought that these results may be due to the limitation in the number of bias samples and difficult laryngoscopy and difficult intubation.

Neck movements may be limited in patients with arthritis of the neck, cervical spine disease, or previous spine surgery. Some studies has shown that neck mobility decreases with age and is associated with difficulty in airway management (19). An optimal position for intubation may be more difficult in these patients. The risk of difficult intubation increases from 5% to 58% when neck mobilization is not fully achieved in patients without muscle relaxants (20). In our study, HNM did not significantly affect the outcome. This test did not raise the TAS score, nor was it a marker for DI. We attributed this result to the low average age in our sample and to the effect of the muscle relaxant used for intubation.

Among the predictive tests, patients with dental problems during IIG, ULBT, and BT examinations have more features than those without (3). In patients receiving dental treatment, oral examination should be performed with particular attention to the presence of missing teeth, post-shaped repairs, crowns, implants, veneers, dentures, braces, or loose teeth. If the patient

has braces, there is a risk of soft tissue damage to the lips during airway management (4).

The limited IIG is an obstacle to performing laryngoscopy and limits our field of view. Especially in patients with mandibular joint, mouth opening may be extremely limited. Contrary to expectations, muscle relaxants used in the induction of anesthesia may cause trismus. In our study, although the test affected the TAS score as a parameter predicting difficult intubation in patients with IIG 3 cm, it did not change the result alone. We attribute this result to the exclusion of patients with mouth openings of less than 3 cm, and the experience of the anesthesia team working specifically on dental surgeries (21).

The upper lip bite test, which is similar to the IIG but more objective measurement, is the most popular bedside test, which is the most accurate and confirmed by itself. In the literature, both in the operating room studies and difficult airway evaluation studies performed in emergency departments, it is said to have predictive value even by itself. In our study, this test gave meaningful results in TAS, and it was one of the DI markers as well as TMD (22,23).

Another airway difficulty prediction test is the Buck teeth test. In our study, Buck's teeth was one of the tests that elevated TAS but did not have a positive predictive value alone. In the literature, dental anomalies are frequently encountered in patients with difficult airway. Buck teeth may prevent us from forming a right angle of view during laryngoscopy, but this did not lead to difficult intubation according to our data (3).

Obesity is a known risk factor for difficulty in airway management (24). A study reported twice the incidence of complications, especially in morbidly obese patients (25). In this patient group, intubation difficulty, airway obstruction during extubation, and aspiration risk increase. Besides, the use of supraglottic airway equipment has resulted in more unsuccessful results in providing a safe airway (26).

In difficult intubation, intubation time is prolonged and SPO<sub>2</sub> level decreases. There are many studies supporting this (27). Oxygenation will naturally decrease as the hypoxia duration increases. There is a risk of difficult intubation from systemic diseases, especially in diabetes. Joint problems may occur in chronic diabetic patients (28). Hypertension itself cannot be considered as an indicator of difficult airway. However, inappropriate induction of anesthesia and prolonged inability to intubate may cause hypertensive crisis and increase complications. These patients are more susceptible to myocardial damage, thus increasing the risk of preoperative MI (29). Maxillofacial anomalies, especially in patients with syndrome, are associated with difficult intubation. Due to the existing systemic diseases of these patients, tolerance to apnea duration is limited. Rapid desaturation may occur in induction (30). However, in our study, we did not find any data about difficult intubation in diabetic, hypertensive, or syndrome patients.

In conclusion; a good preoperative evaluation and preparation of the airway should be performed in patients receiving dental treatment under general anesthesia. Contrary to our expectation, we encountered difficulty in intubation, which is no different from other

surgical branches. However, more attention should be paid to those with high TAS scores and preliminary preparation for difficult intubation. Predictive tests, especially ULBT and TMD, should be evaluated. Surgical risk is low in dental treatments. Severe complications related to anesthesia should not be increased by insufficient airway evaluation. Anesthesiologists and dentists working in this field should be familiar with the complicated airway algorithm. Many studies agree that the combined use of bedside tests increases predictability. However, we believe that more valuable data can be reached through multicentre studies, with a large number of patients whose standards are defined with sharp limits.

#### Conflict of Interests

None.

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