ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

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Is Awake Videolaryngoscopic Assessment of the Airway a New Tool to Predict the Unpredictable?: A Randomised Crossover Clinical Trial

Havayolunun Uyanık Video Laringoskopik Değerlendirmesi Öngörülmeyeni Öngörmekte Yeni Araç Olabilir mi?: Randomize Çapraz Geçişli Çalışma

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This trial was presented as a poster in WAMM (World Airway Management Meeting) 13-16 November 2019, Amsterdam, Holland.

ABSTRACT Objective: Even with worldwide acceptance and obedience to airway evaluation tests, there have not been enough tests performed to predict a difficult intubation with 100% accuracy. The Cochrane database published a review about the insufficiency of airway examination tests. For decades, anesthesiologists have tried to identify these issues. **Material and Methods:** After ethics committee approval and written informed consent had been obtained, 20 patients were enrolled to this prospective randomised study. All patients were oxygenated before and during the procedure. Standard anesthesia monitoring and 0.05 $mg.kg^{-1}$ midazolam was administered intravenously. The nasopharynx was prepared with a topical 10% lidocaine spray then a continuous remifentanil infusion was given at a rate of 0.07 $\mu.kg.min^{-1}$ at least for 3 minutes. Awake videolaryngoscopy with Storz C-MAC, Storz D-Blade, McGrath MAC X-Blade and Airtraq was performed in random order to the same patient. **Results:** Two women denied participation and we analysed 18 patients. One patient did not allow the Airtraq to be inserted deeper and so we had 17 analyses for awake assessment for the Airtraq. Demographic and airway variables of patients were similar. The duration to obtain the optimal view was similar among the videolaryngoscopes. The comfort rating of patient and the observer were lower in the C-MAC ($p<0.001$). The Cormack-Lehane grades were worse in the C-MAC when compared to the others ($p=0.006$). Gag reflex occurred more in the Airtraq and the C-MAC videolaryngoscopes ($p=0.007$). **Conclusion:** Airtraq, McGrath MAC X-Blade, Storz D-Blade was superior to Storz C-MAC for awake videolaryngoscopic assessment of the airway as a new tool to predict a difficult laryngoscopy.

Keywords: Laryngoscopes; intubation; airway management

ÖZET Amaç: Havayolu değerlendirme testleri tüm dünyaca kabul edilmiş ve itaat edilmiş olunmasına rağmen zor havayolunu %100 öngörebilecek yeterli test bulunmamaktadır. Cochrane veri tabanı, havayolu değerlendirme testlerinin yetersizliği ile ilgili derleme yayımlamıştır. Dekatlardan beri anestezistler, bu konuları tanımlamaya çalışmıştır. **Gereç ve Yöntemler:** Yazılı bilgilendirilmiş hasta onamı ve etik kurul onamı alındıktan sonra bu prospektif randomize çalışmaya 20 hasta dâhil edildi. Tüm hastalar işlem öncesi ve sonrasında oksijene edildi. Standart anestezi monitörizasyonu ve 0,05 $mg.kg^{-1}$ midazolam intravenöz olarak uygulandı. Nazofarinks, %10 topikal lidokain sprey ile hazırlandıktan sonra en az 3 dk boyunca 0,07 $\mu gr.kg.dk^{-1}$ hızda sürekli remifentanil infüzyonu verildi. Storz C-MAC, Storz D-Blade, McGrath MAC X-Blade ve Airtraq ile uyanık video laringoskopi rastgele aynı hastaya uygulandı. **Bulgular:** İki kadın hasta katılmayı reddetti ve 18 hasta analiz edildi. Bir hasta Airtraq'in derine yerleştirilmesine izin vermedi, böylece uyanık değerlendirmede Airtraq için 17 hasta analizimiz oldu. Hastaların demografik ve havayolu verileri benzerdi. Optimal görüntüyü elde etme zamanı gruplar arasında benzerdi. Hastanın ve gözlemcinin konfor derecelendirmesi C-MAC'de düşüktü ($p<0,001$). Cormack-Lehane evreleri C-MAC'de diğerlerine kıyasla kötüydü ($p=0,006$). Krikoid bası ile Cormack-Lehane evreleri video laringoskoplar arasında benzerdi. Airtraq ve C-MAC video laringoskoplarında daha fazla öğürme refleksi gelişti ($p=0,007$). **Sonuç:** Zor laringoskopinin öngörülmesinde yeni araç olarak, Airtraq, McGrath MAC X-Blade ve Storz D-Blade, uyanık video laringoskopik değerlendirmede Storz C-MAC'den üstündür.

Anahtar Kelimeler: Laringoskoplar; entübasyon; havayolu yönetimi

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The American Society of Anesthesiologists (ASA) has defined many difficult situations during mask ventilation, direct laryngoscopy or videolaryngoscopy, intubation, supraglottic airway placement and front of neck axes. The ASA has defined difficult laryngoscopy as "impossible to visualise any portion of the vocal cords after multiple attempts at laryngoscopy".[1] In adults, difficult laryngoscopy occurs in 4.9% of the patients.[2] An increased intubation attempt increases the risk of airway related problems such as aspiration, esophageal intubation, dental injury, pneumothorax, brain injury or it can also lead to death.[3] The National Audit Project 4, ASA and Difficult Airway Society (DAS) guidelines insist that the most important factor leading to the inability to ventilate or intubate with these various factors is not having predicted a difficult airway.[1,4,5]

The Cochrane database published a review about the insufficiency of airway examination tests.[6] The Cochrane review included 133 studies and 844,206 participants and they conclude that future research is needed to develop highly sensitive tests or methods.[6] A systematic review showed reliable criteria to predict difficult laryngoscopy which remains the subject of debate.[7] Prof. Yentis said that difficult airway is a frightening situation for all anesthetists. The existing tests are worthwhile but are very complicated. However, they must continue to be used until a new method is discovered that accurately predicts difficult airways will be discovered.[8]

The C-MAC videolaryngoscope is similar to the Macintosh laryngoscope. The Airtraq is a channeled typed videolaryngoscope. The McGarth MAC X-Blade and the D-Blade are hyperangulated blade typed videolaryngoscopes.[9] The main difference between the McGrath MAC X-Blade and the D-Blade is their thickness.

We hypothesised that patient and the observer satisfaction rate could be higher in the hyperangulated typed videolaryngoscopes. According to our knowledge, this is the first study conducted to compare awake airway assessment using the Airtraq, McGrath MAC X-Blade, Storz D-Blade and C-MAC videolaryngoscopes to predict difficult laryngoscopy in terms of patient and observer comfort, Cormack-Lehane grades and the occurrence of the gag reflex.

MATERIAL AND METHODS

After Kocaeli University Clinical Research Ethics Committee approval (KIA 2019/18, 22.01.2019) and written informed patient consent was obtained from all patients at the anaesthesia polyclinic or at the preoperative care unit of our department, we decided to enrol 20 patients with an ASA physical status of 1-2 undergoing elective surgery starting from 1 July 2019 to 1 September 2019. This prospective randomised crossover trial was also registered at www.ClinicalTrials.com (NCT03999866) before commencement. Two participants denied participation, then we analysed 18 patients. This trial was conducted according to the principals of Helsinki Declaration.

Exclusion criteria included factors such as age being younger than 18 or older than 60, pregnancy, heart disease, epilepsy, asthma, a history of upper respiratory tract infection in the past ten days, an allergy to drugs used in this trial, and a body mass index (BMI)>30.

All patients were pre-oxygenated with 5-7 $l.min^{-1}$ 100% O_2 using a nasal cannula at the operating theatre and continued to be given during the whole procedure. Standard anesthesia monitoring including electrocardiogram, non-invasive blood pressure measurement every 5 minutes, SpO_2, heart rate, ET-CO_2 was applied. Bolus 0.05 $mg.kg^{-1}$ intravenous (iv) midazolam was administered. Demographic characteristics of patients (age, sex, ASA, weight, height, BMI) and airway variables [thyromental distance, sternomental distance, neck circumference, Mallampati, mandibular protrusion, head extension and flexion, interincisor distance, teeth morphology (full/lack/absent)] were recorded.

Oropharynx and nasopharynx were topicalised with 10% lidocaine spray then a continuous remifentanil infusion was given at a rate of 0.07 $m.kg.min^{-1}$ for at least 3 minutes. We inserted the Airtraq (Prodol Meditec, Vizcaya, Spain), McGrath MAC X-Blade (Medtronic Medical; Minneapolis, USA), C-MAC and D-Blade (Karl Storz, Tuttlingen, Germany) into the patients' mouth in a random manner. The procedure was conducted by an experienced operator (having at least 15 years of anesthesia experience and 10 years of videolaryngoscope experience). We deter-

mined which videolaryngoscope was to be used first by conducting the sealed envelope technique. All of the patients were assessed orally in the supine position with a jelly pillow under their head. We ask the patient to give a number from zero=bad to ten=excellent (visual analog scale) about their comfort after each videolaryngoscopy was performed. Our primary aim was to compare the observer and the patient satisfaction rate. We asked each patient if he/she had the sense of asphyxia or occlusion during the videolaryngoscopy. We asked a surgeon that was watching to observe and to give a number based on their opinion on the patients face grimace, gaging, or reactions to the videolaryngoscope used zero=worse to ten=excellent. Our secondary aim was to record and compare the duration needed to obtain an optimal view: which elapsed from the time the device entered the oral cavity until the best visualisation had occurred. We recorded the Cormack-Lehane grade on the view and the Cormack-Lehane grade under cricoid pressure and the position of the vocal cords (open or closed). The occurrence of the gag reflex, nausea and vomiting, sore throat, hypoxia (SpO_2<92%), mucosal or pharyngeal injury, aspiration, laryngospasm, arrhythmia and cardiac arrest were also recorded. All patients were anaesthetized using propofol 3 $mg.kg^{-1}$ and fentanyl 1 $mg.kg^{-1}$. After this, 0.6 $mg.kg^{-1}$ rocuronium was used for muscle relaxation. After 3 minutes of facemask ventilation, patients were easily intubated with the Storz C-MAC D-Blade videolaryngoscope.

According to our preliminary study assuming an observer comfort rate for the McGrath MAC X-Blade to be 8.(6-10) and for the Storz C-MAC 4 (3-6) and an a error rate 0.05, we estimated our sample size as 16 crossover subjects with 80% power. We enrolled 20 patients for possible exclusions. Statistical analyses were completed by utilising IBM Statistical Package of Social Sciences (SPSS) 20.0 (IBM Corp, Armonk, NY, USA). The Kolmogrov-Smirnov test was used to test the normality. Numerical data were expressed as mean±standard deviation (SD) or as median (25-75 percentiles). Calculating the statistical difference between non-normally distributed data, we used the Kruskal-Wallis One-way variance analysis and Dunn's multiple comparing tests. Categorical data were given as numbers. The Monte Carlo Chi-squared test was used for comparing categorical data. $p<0.05$ was considered as statistically significant.

RESULTS

We enrolled 20 patients for this trial. However, two patients denied participation, so we analysed 18 patients. One patient did not allow insertion deeper than we had for the analyses for awake assessment of the Airtraq in the 17 other patients. Descriptive variables and airway variables of the patients are given in Table 1. Only 1 patient's teeth were absent and other patients' dental profiles were full. 1 patient had long upper teeth. All patient's mandibular protrusions were A and head extension and flexion were normal. No patient had a difficult airway history. No patient had hypertension, 2 patients had diabetes mellitus and 10 patients were current cigarette smokers. The duration of optimal view was similar among the groups. Position of the vocal cords were similar among the patients. The rate of patient and observer comfort was statistically different from each other ($p<0.001$) (Table 2). The C-MAC had the worst Cormack-Lehane grade between the groups ($p=0.006$). The Cormack-Lehane grade with cricoid pressure was similar among the groups. Gag reflex occurred more in the C-MAC and the Airtraq groups (0.007). Sore throat and vocal cord positions were similar between the groups (Table 3). One patient experienced nausea. No vomit, aspiration, hypoxia (SpO_2<92%), car-

TABLE 1: Demographic variables of 18 patients; values are given as mean±SD or median (25-75 percentiles) or as numbers.

Age; years	38.22±13.93
Sex; M/F	4/14
ASA; 1/2	16/2
Weight; kg	73.83±11.32
Height; cm	172.61±8.79
BMI; $kg.m^{-2}$	24.61±2.52
TMD; cm	8 (7-8)
SMD; cm	16.17±1.65
Neck circumference; cm	39.27±3.59
Interincisor distance; cm	4.05±0.42
Mallampati; 1/2	10/8

SD: Standard deviation; ASA: The American Society of Anesthesiologists; BMI: Body mass index; TMD: Thyromental distance; SMD: Sternomental distance.

TABLE 2: Duration of time for optimal view, patient comfort and observer comfort scales are given as numbers. VAS scale 0-10 was used for assessing the comfort level.

			p value
Duration of optimal view (seconds)	Airtraq	4.00 (3.50-7.00)	0.118
	McGrath MAC X-Blade	4.00 (3.00-5.00)	
	Storz D-Blade	4.00 (3.00-5.00)	
	Storz C-MAC	3.00 (2.75-4.25)	
Rate of patient comfort	Airtraq	7.00 (3.50-7.50)	<0.001[Ψ,$]
	McGrath MAC X-Blade	8.00 (5.75-10.00)	
	Storz D-Blade	7.00 (5.00-8.00)	
	Storz C-MAC	4.00 (3.00-6.00)	
Rate of observer comfort	Airtraq	6.00 (5.00-8.50)	<0.001[Ψ,$]
	McGrath MAC X-Blade	8.00 (5.75-9.00)	
	Storz D-Blade	7.50 (5.75-9.00)	
	Storz C-MAC	3.50 (2.00-5.25)	

VAS: Visual Analog Scale; [Ψ]p<0.05 between the D-blade and the C-MAC; [$]p<0.05 between the McGrath MAC X-Blade and the C-MAC.

TABLE 3: Cormack-Lehane grades with or without cricoid pressure, position of the vocal cords, occurrence of the gag reflex and sore throat variables are given as numbers.

		Videolaryngoscopes				
		Airtraq	McGrath MAC X-Blade	Storz D-Balde	Storz C-MAC	p value
Cormack-Lehane grade without cricoid pressure,	1	1	0	2	1	0.006
	2	13	16	14	6	
	3	0	1	1	6	
	4	3	1	1	5	
Cormack-Lehane grade with cricoid pressure	1	2	3	3	1	0.260
	2	12	13	13	8	
	3	1	1	1	4	
	4	2	1	1	5	
	Closed	1	1	1	1	
Gag reflex	Occurred	11	4	5	12	0.007
	None	6	14	13	6	
	None	17	17	17	16	
Sore throat	Occurred	0	1	3	2	0.499
	None	17	17	15	16	

diac arrest, arrhythmia, mucosal or pharyngeal injury was detected in any of the patients. None of the patients suffered from a sense of occlusion or asphyxia. All patients were easily intubated at the first attempt with Storz C-MAC D-Blade videolaryngoscope.

DISCUSSION

The main result of this study was that we were able to predict a difficult videolaryngoscopy preoperatively with awake videolaryngoscopic assessment. Hyperangulated blade typed videolaryngoscopes are superior in this field. We could avoid unnecessary awake fiberoptic intubation which is expensive and requires skilled operators with an overall ongoing practice. Awake videolaryngoscopy is a valuable option to awake fibreoptic with respect to patient comfort, first intubation success rates and duration of intubation times.[10]

As we mentioned, multicenter studies have shown that independent predictors of difficult mask ventilation and intubation included age older than 46, BMI>30, male gender, Mallampati 3-4 score, short thyromental distance and sternomental distance, limited cervical spine movement, thick neck, neck mass

or radiation to the neck, dentition, limited jaw protrusion, limited mouth opening, presence of obstructive sleep apnea, and the presence of a beard were listed as predictors of difficult mask ventilation and difficult direct laryngoscopy.[11,12] The World Health Organization arranged a surgical and anesthesiology safety check lists for preoperatively including the Mallampati test, and a history of difficult intubation.[13] Even with worldwide acceptance and obedience to these airway evaluation tests, these tests are not specific enough for 100% accuracy in predicting a difficult intubation.

Unfortunately, a meta-analysis containing 35 studies evaluating the Mallampati, thyromental distance, mouth opening and Wilson risk index (a simple summation of weight, interincisor distance, head and neck movement, jaw protrusion, receding mandible and buck teeth tests) result in a final conclusion that the clinical value of preoperative airway tests for predicting difficult intubation were still unclear. The superlative from well is a combination of decreased thyromental distance and Mallamapti 3-4.[14]

A Danish database which included 188,064 patients showed that the predictive accuracy of anesthesiologists of difficult intubation or difficult mask ventilation is poor. They concluded that prediction remains a challenging task. Twenty nine airway assessment tools were included in this trial; Mallampati, cervical spine movement, jaw protrusion, thyromental distance, history of previous difficult intubation and so on. In this trial, the median number of risk factors needed was shown to be at least 4 (range 1-6).[15] An Italian survey of 1,956 patients found a correlation with oropharyngeal volume and difficult intubation. However, they concluded that Mallampati score by itself is not sufficient for predicting difficult intubation.[16] The role of airway evaluation tests used worldwide in predicting a difficult laryngoscopy is limited. As such, we still are faced with unpredictable difficult airway guidelines. Nowakowski et al., reported findings regarding predictors of difficulty when using Bonfils rigid fiberscope in 400 patients.[17] Limited mouth opening, increased BMI, high Cormack-Lehane grades were shown to be associated with longer intubation times.

We published a case in which we used the McGrath MAC X-Blade in a patient with a limited mouth opening that had to be intubated awake, fibreoptically during her previous operations. We determined that we could ventilate the patient and we assessed the Cormack-Lehane grade after administration of a low dose bolus propofol and midazolam and a continuous remifentanil infusion. We had a Cormack-Lehane grade 2 and then we anesthetized the patient, performed videolaryngoscopic nasotracheal intubation. We avoided an unnecessary awake fibreoptic approach and made a plan using this awake videolaryngoscopic assessment technique.[18]

Awake upright laryngoscopy was evaluated by a crossover trial with the Glidescope in the upright position and was compared with C-MAC intubation performed with instructors who had various levels of anesthesia experience. They enrolled 26 healthy subjects with a mean age of 31.9 years. In concordance with our results, they demonstrated that under local anesthesia, similar to our results, the hyperangulated blade typed Glidescope provides superior Cormack-Lehane views (1.5 versus 2) than the C-MAC and a shorter time to best views [7 sec (6.5-18) versus 9 sec (8-13)] and the number of intubation attempts.[19] As recommended, in the event of an expected difficult intubation, hyperangulated typed blades or channeled videolaryngoscopes are the ones to be selected.[11] The Glidescope videolaryngoscope and fiberoptic bronchoscopy were compared for awake upright videolaryngoscopy in 23 healthy patients. Glidescope had a better view in 96% of the patients and a shorter duration when compared to the fibreoptic bronchoscope.[20] Indirect laryngoscopic assessment performed by an otolaryngologist on patients undergoing microlaryngeal surgery demonstrated that this was a simple and valuable technique that can be used for detecting difficult intubations.[21] A recently published study determined that preoperative fibreoptic airway evaluation supplies superior airway information and may prevent the use of unnecessary awake intubation.[22] At our hospital, we routinely conduct preoperative nasopharyngoscopic evaluation which is performed by ear, nose, throat surgeons at their clinic in patients who have thyroid tumors or multinodular goiters, oral, tongue, nasopharyngeal, neck or tra-

cheal tumors as recommended by the new DAS unexpected difficult airway management guidelines. This however, will lead to a delay in their operation and costs, but this is not as important as costs related to difficult airway and health threatening complications.[5] Why not use the awake videolaryngoscopic assessment as a highly effective predictor of difficult laryngoscopy for every patient? Our trial gave us a point shot of difficult videolaryngoscopy which is where we face difficulties in our daily practice. It is promising hopefully to see that over the past decade, many studies have been published investigating the predictors of difficult bag mask ventilation, difficult direct laryngoscopy or difficult cricothyrotomy.[23,24] For a long time, anesthesiologists have tried to identify these issues. Being able to anticipate a difficult intubation and being sure to select the most appropriate tools in advance is critical. This trial could be generalized to all expected difficult intubation patients to make a brief plan and strategy suitable and comfortable for the patient. Some experts in the field of airway management wanted to draw attention to the need of new methods or strategies for predicting difficult intubation, because the scoring systems we are using now is a waste of time.[9,25] If we could clearly anticipate the difficulty before starting the anesthesia induction, then we would avoid needless awake intubations and the narrated complications that unavoidably occur and manage a safer anesthesia process overall.[26] The other important issue is that we could take the opportunity to make a detailed airway plan of action based on fundamental factors.[1,5]

The limitations of our study are as follows; our population had normal airways not expected to be difficult airway patients, otherwise the results would have changed. Another limitation of this study was that no endotracheal intubation was done during the study. The consequences of not predicting a difficult intubation and its complications such as prolonged morbidity, emergency cricothyrotomy, intensive care stay, hypoxic brain injury and death are critically important and should be addressed.

CONCLUSION

As a result, Airtraq, McGrath MAC X-Blade, Storz D-Blade was superior to Storz C-MAC Blade for awake videolaryngoscopic assessment of the airway as a new tool to predict a difficult laryngoscopy. In addition, we recommend combining all airway evaluation tests and awake videolaryngoscopic assessment together to better predict the seemingly unpredictable.

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During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Zehra İpek Arslan;* ***Design:*** *Zehra İpek Arslan, Funda Seyhan, Huri Yeşildal;* ***Control/Supervision:*** *Zehra İpek Arslan, Funda Seyhan, Huri Yeşildal;* ***Data Collection and/or Processing:*** *Zehra İpek Arslan, Funda Seyhan, Huri Yeşildal;* ***Analysis and/or Interpretation:*** *Zehra İpek Arslan;* ***Literature Review:*** *Zehra İpek Arslan;* ***Writing the Article:*** *Zehra İpek Arslan;* ***Critical Review:*** *Zehra İpek Arslan;* ***References and Fundings:*** *Zehra İpek Arslan, Funda Seyhan, Huri Yeşildal;* ***Materials:*** *Zehra İpek Arslan, Funda Seyhan, Huri Yeşildal.*

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