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Determine Difficulty in Intubation By Using CL Grade and to Determine Validity of Inter Incisor Gap, Modified Mallampati Test

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ABSTRACT
The reported incidence of difficult laryngoscope and tracheal intubation occurs in 1.5-8% of patients in general anaesthesia. Predicting a difficult intubation employing a myriad of measurements and observations has not demonstrated itself to be practicable or even reliable. To determine difficulty in intubation by using CL grade and to determine validity of Inter incisor gap, Modified Mallampati Test. This Prospective observational study was conducted among patients undergoing elective surgery under general anaesthesia in Department of Anaesthesiology, Bangalore Medical College and research institute. Duration of study was November 2018 to March 2020. In the study majority of subjects were in the age group 31-40 years (35.75%), Majority of subjects were males and had ASA grade 1. Based on Cormack Lehane scoring, 59% had Score 1, 23% had Score 2, 16% had Score 3 and 2% had Score 4. 72 subjects with difficult grade in CL, 97.2% were difficult in MMT, 58.3% were difficult in IIG, MMT grading was close to CL grade compared to other scores. From the study we observed that Modified Mallampati Test (MMT) had highest sensitivity, Negative predictive value, Accuracy and almost perfect Kappa agreement. Hence, we conclude that MMT was the best airway predictor is for predicting difficult intubation when taken as a single clinical parameter over other measurements.

INTRODUCTION

Although prediction and forecasting are tenacious, in light of the complications, considerable attention has been given to predict difficult intubation in patients. Many preoperative airway assessment tests such as inter-incisor gap (IIG), Modified Mallampati test (MMT), Sternomental distance (SMD), Thyromental distance (TMD) and Ratio of Height to Thyromental distance (RHTMD) may be used as anatomical parameters to predict difficult Intubation but sensitivity and positive predictive value for these individual tests are low while false positive results are high4. So, predicting a difficult intubation employing a myriad of measurements and observations has not demonstrated itself to be practical approach or even reliable in clinical practice. Several studies have evaluated the predictive criteria individually or in arbitrary combinations, there has been no sufficiently powered systematic multi variate analysis of the clinical variables like upper lip bite test (ULBT), ratio of height to thyromental distance (RHTMD), Inter incisor gap (IIG), Modified Mallampati test (MMT), Horizontal length of the mandible (HLM) Head and neck movements (HNM), Sternomental distance (SMD) and Thyromental distance (TMD) studied simultaneously. Hence this study was undertaken to compare the various airway assessment predictors for difficult endotracheal intubation.

MATERIALS AND METHODS

This Prospective observational study was conducted among patients undergoing elective surgery under general anaesthesia in Department of Anaesthesiology, Bangalore Medical College and research institute. Duration of study was November 2018 to March 2020

Inclusion Criteria:

- Patients who gave informed written consent
- Male and female patients aged 18-65 years
- Patients scheduled for elective surgeries under general anesthesia
- Patients under ASA grade 1 and 2

Exclusion Criteria:

- Uncooperative and unwilling patients
- History of burns/trauma involving head and neck
- History of airway surgeries
- Tumor/mass in the neck or airway
- Restricted mobility at neck and mandible
- Patients with inability to sit
- Edentulous
- Patients in the need of awake intubation
- Pregnant females
- BMI >35

Sampling Technique: Patients were recruited by convenience sampling method.

Sample Size: was estimated by using the sensitivity of modified Mallampati test in difficult intubation in comparison with CL grade from the study by Shobha *et al.*[1]. Using the formula = [2×(100-](2×). By considering above values: n = 382 subjects undergoing general anaesthesia were included in the study. Considering a non-response rate of 5%, 382+19 ˜ 400 subjects were included in the study.

Data Collection: The oropharyngeal view was assessed using Modified Mallampati Test[2]: Sampson and Young's modification of Mallampati test recorded oropharyngeal structures visible upon maximal mouth opening. Each patient when seated is asked to open mouth maximally and to protrude the tongue without phonation. The view is classified as:

Grade 1: Good visualization of palate, fauces, uvula and tonsillar pillars.

Grade 2: Pillars obscured by the base of the tongue but the soft palate, fauces and uvula visible.

Grade 3: Soft palate and base of the uvula visible.

Grade 4: Soft palate not visible.

Inter Incisor Gap[3]: It was assessed by asking each patient to open the mouth to maximum extent. The distance between upper and lower incisor at the midline is measured, which is usually >3.5cm.

Statistical Analysis: Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. Independent t test was used as test of significance to identify the mean difference between two quantitative variables.

RESULTS AND DISCUSSIONS

In the study majority, 143 subjects (35.75%) belonged to the age group 31-40 years followed by 90 subjects (22.5%) in the age group of 21-30 years. 73 subjects (18.25%) belonged to the age group of 41-50 years, 56 subjects (14%) belonged to the age group of 51-60 years, 28 subjects (7%) belonged to the age group of 10-20 years and 10 subjects (2.5%) belonged to >60 years of age. In this study, 217 subjects (54.25%) were males and 183 subjects (45.75%) were females. In the study, 210 subjects

Table 1: Investigations distribution of patients studied

		Subjects	Percentage
MMT	Grade I	15	3.75
	Grade II	301	75.25
	Grade III	64	16.00
	Grade IV	20	5.00
	Total	400	100.00
IIG	Grade I	347	86.75
	Grade II	53	13.25
	Total	400	100.00

Table 2: Cormack Lehane Score

		Subjects	Percentage
Cormack Lehane	Score 1	236	59.00
	Score 2	92	23.00
	Score 3	64	16.00
	Score 4	8	2.00
	Total	400	100.00

Table 3: MMT/IIG/ of patients studied in relation to CL score

		Cormack Lehane										
		Score 1		Score 2		Score 3		Score 4		Total		Chi Square
grade		Subject	%	Subject	%	Subject	%	Subject	%	Subject	%	
MMT	I	11	4.66%	4	4.35%	0	0.00%	0	0.00%	15	3.75	χ^2 = 375.249,df = 9, p<0.001*
	II	225	95.34 %	74	80.43 %	2	3.13 %	0	0.00 %	301	75.2 5%	
	III	0	0.00%	14	15.22%	48	75.00%	2	25.00%	64	16.00%	
	IV	0	0.00%	0	0.00%	14	21.88%	6	75.00%	20	5.00%	
IIG	I	236	100.00%	81	88.04%	28	43.75%	2	25.00%	347	86.75%	χ^2 = 165.67,df = 3,p<0.001
	I	0	0.00%	11	11.96%	36	56.25%	6	75.00%	53	13.25%	
	II	2	0.85%	17	18.48%	57	89.06%	8	100.00%	84	21.00%	

Table 4: Validity of Measurements in predicting difficult intubation (CL grade gold standard)

		CL Grade				
		Difficult		Easy		
		Subjects	Percentage	Subjects	Percentage	p-value
MMT Grading	Difficult	70	97.2	14	4.3	<0.001*
	Easy	2	2.8	314	95.7	
IIG	Difficult	42	58.3	11	3.4	<0.001*
	Easy	30	41.7	317	96.6	
	Easy	45	62.5	328	100.0	

Table 5: Validity of MMT grade in predicting difficult intubation compared to CL Grading

Parameter	Estimate	Lower - Upper 95% Cis
Sensitivity	97.22%	(90.43, 99.23[1])
Specificity	95.73%	(92.96, 97.44[1])
Positive Predictive Value	83.33%	(73.95, 89.8[1])
Negative Predictive Value	99.37%	(97.72, 99.83[1])
Diagnostic Accuracy	96%	(93.6, 97.52[1])
Cohen's kappa (Un weighted)	0.8728	(0.7752 - 0.9703)

Table 6: Validity of IIG grade in predicting difficult intubation compared to CL Grading

Parameter	Estimate	Lower - Upper 95% CIs
Sensitivity	58.33%	(46.81, 69.01[1])
Specificity	96.65%	(94.1, 98.12[1])
Positive Predictive Value	79.25%	(66.54, 88[1])
Negative Predictive Value	91.35%	(87.93, 93.88[1])
Diagnostic Accuracy	89.75%	(86.39, 92.35[1])
Cohen's kappa (Un weighted)	0.6129	(0.5165-0.7093)

(52.5%) belong to ASA grade 1 and 190 subjects (47.5%) belong to ASA grade 2.

In this Study, majority of subjects:

- 239 (59.75%) belong to weight range of 61 to 70 kilograms
- 95 subjects (23.75%) belong to weight range of 51-60 kilograms 47 subjects (11.75%) belong to weight range of 71-80 kilograms 19 subjects (4.75%) belong to the weight range of <50 kilograms
- Based on Modified Mallampati Test(MMT), 15 subjects (3.75%) belong to Grade I,
- 301 subjects (75.25%) belong to Grade II,
- 64 subjects (16%) belong to Grade III and 20 subjects (5%) belong to Grade IV
- Based on Inter Incisor Gap (IIG),
- 347 subjects (86.75%) belong to Grade I 53 subjects (13.25%) belong to Grade II
- Based on Cormack Lehane scoring, 236 subjects (59%) belong to Score 1, 92 subjects (23%)
- belong to Score 2, 64 subjects (16%) belong to Score 3 and 8 subjects (2%) belong to Score 4

- In the study there was significant association between CL score and Age distribution. With increase in age, there was increase in CL score. i.e. higher age made intubation difficult
- In the study there was no significant association between Gender and CL score
- In the study there was no significant association between ASA grade and CL score
- In the study there was no significant association between BMI and CL score

In the study there was significant association between MMT and CL grade. i.e. with increase in MMT grade there was increase in CL score. Similarly, there was significant association between IIG and CL grade.

In the study out of 72 subjects with difficult grade in CL:

- 70 subjects (97.2%) had difficult MMT grading 42 subjects (58.3%) had difficult IIG grading

There was significant association between CL grade and MMT, IIG, scoring MMT had sensitivity of 97.22%, Specificity of 95.73%, PPV of 83.33%, NPV of 99.37%, Diagnostic accuracy of 96% and Kappa agreement was 0.872 (Almost perfect agreement) in comparison with CL grade. IIG had sensitivity of 58.33%, Specificity of 96.65%, PPV of 79.25%, NPV of 91.35%, Diagnostic accuracy of 89.75% and Kappa agreement was 0.6129 (Substantial agreement) in comparison with CL grade.

Predicting difficult intubation can reduce anaesthesia associated morbidity and mortality[4]. In order to be clinically useful, a test predicting difficult intubation must be easily applicable at the bedside and must give reliable results. No test has 100% sensitivity and there will always be some patients with unpredicted difficult intubation. A test to predict difficult intubation should have high sensitivity so that it will identify most patients in whom intubation will truly be difficult. It should also have a high positive predictive value so that only a few patients who can be actually incubated easily are subjected to the protocol for management of a difficult intubation.

The demographic characteristics in the present study was comparable to studies done by Srinivas *et al.*[5], Shobha *et al.*[1], that is , majority of subjects were middle aged, males constituting higher percentage and majority with ASA grade I. In this study, the incidence of difficult intubation based on CL grade was found to be 18% which was within the 0.5-18% stated by Zahid *et al.*[6] reported incidence of 1-4%. It was also comparable to other studies that stated the incidence to be between 1% and 15%[7,8]. One of the major reasons for these variations could be traced to the type and size of laryngoscope blade used, the degree of muscle relaxation, different definitions for difficult intubations and the different reference standards used for the different studies. The reference standards in majority of studies were based on Cormack and Lehane intubation grades[9].

The Sensitivity and specificity of Modified Mallampati test (MMT) was 97.2% and 95.73% in our study. This is in contrary to the results obtained by Khan *et al.*[10], Eberhart *et al.*[9]. and Hester *et al.*[11]. wherein they reported specificity of MMT as 66.8%, 61.0%, and 75% respectively. From the studies in the above table suggests that Diagnostic Accuracy was lower compared to the present. The nearest Diagnostic Accuracy to our study was found in the study by D. Shobha *et al.*[1]. MMT grading depends on the experience of the person grading it. Hence inter observer variations can be an important factor in determining the true validity of MMT. The IIG has been demonstrated to be one of the most sensitive single predictors of a difficult airway. In the present study the sensitivity of the IIG was not high enough (58.33%), suggesting that it was not reliable as a single predictor. Our findings were comparable with studies by Srinivasa *et al.*[5], Jigisha Prahladrai Badheka[12] *et al*. Tadese but Shobha *et al.*[1] showed lower sensitivity of IIG.

MMT has been used regularly over the years clinically, but it does have a few limitations as pointed out by many previous studies. The definitive demarcation between Class 2 and 3 and between Class 3 and 4, the effect of phonation and patient's cooperation leads to high inter observer variability and decreased variability. In our evaluation, MMT had acceptable sensitivity, good specificity and NPV. Other studies had reported different reports of sensitivity, specificity and PPV of IIG, This difference in the results obtained may be explained due to different ethnicity of study population, low sample size and inter observer variations and experience of the observer.

CONCLUSION

From the study we observed that Modified mallampati test (MMT) has highest sensitivity, Negative predictive value (NPV), accuracy and almost perfect Kappa agreement. Modified Mallampati test was the closest to Cormack Lehane grading . Hence, we conclude that Modified Mallampati Test was the best airway parameter for predicting difficult intubation when taken as a single clinical parameter over other measurements.

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