

Are there predictive tests that determine the difficulty in Laryngeal Mask Airway Insertion?

Gamze Kucukosman, Bengu Gulhan Aydin

Abstract

Objective: To determine the predictive tests for difficulty in laryngeal mask airway insertion, and to observe the success rate of insertion in the first attempt.

Methods: The prospective, observational study was conducted at Bülent Ecevit University Hospital, Turkey, from September 2013 to 2014, and comprised patients of American Society of Anaesthesiologists grade I to IV adult patients who underwent elective surgery under general anaesthesia. The supraglottic airway device was randomly selected for each patient, and the laryngeal mask airway was used as per the decision of an anaesthesiologist who was not part of the study. Patients were divided into three groups according to laryngeal mask airway types as classic group A, i-gel group B and suprema group C. These were inserted by anaesthesia residents with the same seniority when bispectral index value reached 40-60. Data was noted and analysed using SPSS 24.

Results: Of the 120 patients, 40(33.33%) were in cLMA, 38(31.66%) in i-gel, and 42(35%) in sLMA. There was no significant difference among the groups in terms of demographics ($p>0.05$). Apart from the height/thyromental distance ratio ($p=0.046$), no predictive test was statistically significant in identifying the difficulty in laryngeal mask airway insertion ($p>0.05$). There was no significant difference involving number of attempts, difficulty in insertion, and patient response ($p>0.05$). Placement success rate at first attempt was similar among the groups ($p>0.05$).

Conclusion: Higher height/thyromental distance ratio values were associated with difficulty in laryngeal mask airway insertion, and first-attempt success rate was similar in all the three laryngeal mask airway types.

Keywords: Laryngeal masks, Predictive tests, Prospective study. (JPMA 71: 434; 2021)

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Introduction

Supraglottic airway devices (SADs) play an important role in modern anaesthesia practice.¹ Since the first use of the classic laryngeal mask (cLMA), a number of devices have been produced to increase anaesthesia safety and efficacy, such as i-gel, ProSeal, and suprema LMA (sLMA). The cLMA is the most commonly used SAD, and has an inflatable cuff that is invasive, anatomically placed between the facemask and the endotracheal tube and is generally inserted at the larynx level to preserve spontaneous respiration. The sLMA is a polyvinyl chloride, anatomically shaped, single-use SAD that incorporates a gastric access port^{2,3} and i-gel is a new LMA type that does not have an inflatable cuff.⁴

Unexpected difficulties in endotracheal intubation are one of the aetiological factors in patient morbidity and mortality. The current American Society of Anaesthesiologists (ASA) practice guidelines suggest that the LMA has a role in managing difficult airways.⁵ However, there have been reports of difficulty in maintaining the airway with LMAs in a significant percentage of patients, and the device's suboptimal seating suggests that its role

may be limited.^{5,6} Therefore, pre-operative assessment of not only difficult mask ventilation and tracheal intubation, but also difficult ventilation through an SAD may decrease the risk of major airway complication during difficult airway management.^{6,7} Failure to insert an SAD, or to ventilate through it, occurs in 0.1-4.7% cases.^{8,9} However, there is paucity of data on independent risk factors for SAD failure, reflecting a gap in current knowledge.

The information obtained by physical examination has proven its role in predicting the presence of difficult airway. Performing bedside testing for identifying a potential difficult airway before general anaesthesia is part of routine clinical practice. The most commonly used tests for predicting difficult airway are mouth opening (MO), sternomental distance (SMD), thyromental distance (TMD), the Modified Mallampati Test (MMT) and the height/thyromental distance ratio (RHTMD).^{7,10-23} However, no single test or combination of tests has been validated as the best predictor of difficult airway, and there has been no reliable method of predicting difficult supraglottic airway ventilation.²⁴ Recently, RHTMD has variably been shown to be a better predictor of difficult airway compared to MMT, TMD and SMD.^{14,16-21} The tests' ability to predict successful LMA insertion or adequate LMA sealing is also unknown. SADs are of particular importance due to their

Department of Anaesthesiology and Reanimation, Bulent Ecevit University, Zonguldak, Turkey.

Correspondence: Gamze Kucukosman e-mail: gamzebeu@gmail.com

high success regarding placement in difficult airway management and cardiopulmonary resuscitation even by inexperienced users.²⁵⁻²⁹

The current study was planned to determine the predictive tests for difficulty in LMA insertion, and to observe the success rate of insertion in the first attempt.

Patients and Methods

The prospective, observational study was conducted at Bülent Ecevit University Hospital, Turkey, from September 2013 to 2014. After approval from the institutional ethics committee, the sample size was calculated using G-Power with type I error (α) = 0.05, power (1- β) = 0.95 and effect size (d) = 0.810.³⁰

The sample was raised from among patients aged ≥ 18 years of either gender in ASA I to IV risk group who underwent elective surgery under general anaesthesia. Patients with difficult airway, laparoscopic surgical interventions, obesity, pregnancy, gastric reflux history, or high aspiration risk were excluded.

After written informed consent from each patient, the sample was divided into cLMA, i-gel and sLMA groups. The patients' age, height, weight, gender, and body mass index (BMI) were recorded. Anthropometric measurements for predictive tests used to evaluate difficult airway were performed and recorded by anaesthesia residents with similar seniority to avoid inter-observer variability. The residents were blind to the study. The process was done in a comfortable and well-lit environment where patients could communicate freely during the pre-operative period. Airway assessment included maximum MO, measured as the inter-incisor gap (mm). Each patient was asked to open his or her mouth as wide as possible, and the distance between the upper and lower incisors at the midline was measured. MMT was checked in the sitting position with full extension of the craniocervical junction with phonation. It was defined as Class I = entire uvula clearly visible, Class II = upper half of the uvula visible, Class III = soft and hard palate clearly visible, and Class IV = only the hard palate visible. TMD was measured in cm as the distance from the thyroid notch to the inner margin of the mental prominence when the head was fully extended. SMD was measured in cm as the straight distance between the upper border of the manubrium sterni and the bony point of the mentum with the head in full extension and the mouth closed. RHTMD was calculated as height in cm divided by TMD in cm.^{7,10-23}

The SAD was randomly selected for each patient, and LMA which was already present in the operating room was used, according to the decision of an anaesthesiologist who was

not part of the study. Patients without premedication had heart rate (HR), non-invasive blood pressure (BP), peripheral oxygen saturation (SpO_2), and bispectral index (BIS) monitoring applied in the operating room, and then intravenous (IV) access was established. Before anaesthesia induction, all patients had a 7cm high pillow placed under their heads. After patients were pre-oxygenated with 100% oxygen for 3 min, 1.5mcg kg⁻¹ fentanyl, 1.5mg kg⁻¹ lidocaine, and 2-2.5mg kg⁻¹ propofol were administered intravenously. Neuromuscular agent was not administered. Until the appropriate anaesthesia level for device insertion was reached, additional propofol bolus (0.5 mg kg⁻¹) was planned. Patients were ventilated through a facial mask, and when the BIS values reached between 40 and 60, an LMA of adequate size for the patient's weight was inserted according to the manufacturers' recommendations by anaesthesia residents with same seniority in using LMAs. All patients were treated by anaesthetists who had an experience of LMA insertion for over 3 years. Size 4 LMA was used for those with a weight of 50-70 kg and size 5 LMA for 70-100kg. The SADs were completely deflated before insertion. Before insertion, a water-soluble lubricant was applied to the rear of the cuff. The patient's head was placed in the sniffing position. The cuff was inflated with the recommended volume of air for LMA's size. After LMA insertion, observation of capnography fluctuation, bilateral chest movements and stridor absence were taken as successful insertion. LMA insertion was graded by the attending anaesthesiologist as 'easy' or 'difficult'. An easy insertion was defined as insertion without resistance in a single manoeuvre. A difficult insertion was one where more than one manoeuvre was required to insert the device. In case it was not possible to insert the device in two attempts, it was labelled as failure, indicating inability to place the device. If insertion failed after two attempts, the airway was properly secured in accordance with the attending anaesthesiologist's preference, and these patients were excluded from the study. The number of insertion attempts (1 or 2), difficulty in insertion (easy and difficult), and patient responses (excellent = no resistance to insertion, good = slight resistance to insertion, poor = moderate resistance to insertion) were recorded according to LMA type. For anaesthesia maintenance, respiratory volume was set at 6-8ml kg⁻¹ and respiration rate was 12/min, with controlled mechanical ventilation in 50/50% : nitrous oxide (N_2O/O_2) mixture with 1-2% sevoflurane. Any episode of hypoxaemia ($SpO_2 < 90\%$), aspiration or regurgitation, bronchospasm and airway obstruction were recorded.

Data was analysed using SPSS 24. Kolmogorov-Smirnov test was used to test the numerical variables for normal distribution. Categorical variables were expressed as

frequency and percentage, while numerical variables are expressed as mean and standard deviation (SD), or median and inter-quartile range (IQR). The correlation between categorical variables was investigated with chi-square test.

Table-1: Demographic characteristics.

	cLMA (n=40)	i-gel (n=38)	sLMA (n=42)	p-value
Age (years)	45±13.9	51.7±11.5	48.2±15.2	0.103
Height (cm)	163.7±7.9	165.2±8.4	165.9±8.3	0.491
Body weight (kg)	69.6±12.9	76.3±11.5	74.3±12	0.051
BMI (kg/m ²)	26.2±6	27.9±4.9	27.2±5.5	0.424
Sex (F/M)	22/18	18/20	21/21	0.790

Data is presented as mean±SD; LMA: Laryngeal mask airway

Table-2: Laryngeal mask airway (LMA) insertion attempt number, insertion, and patient response.

	cLMA (n=40, %)	i-gel (n=38, %)	sLMA (n=42, %)	p-value
LMA insertion attempt number				
1	35(87.5)	35(92.1)	38 (90.5)	0.788
2	5 (12.5)	3 (7.9)	4 (9.5)	
LMA insertion				
Easy	28(70)	31(81.6)	34(81)	0.379
Difficult	12(30)	7 (18.4)	8(19)	
Patient Response				
Excellent	30(75)	28(73.7)	35(83.3)	0.751
Good	9(22.5)	9 (23.7)	7(16)	
Poor	1(2.5)	1 (2.6)	0(0)	

Data are presented as number (n), and percent (%).

Table-3: Distribution of predictive tests according to laryngeal mask airway (LMA) type.

	cLMA (n=40, %)	i-gel (n=38, %)	sLMA (n=42, %)	p-value
MO (cm)	4.70±0.85	4.74±0.97	4.86±0.78	0.695
MMT				
1	8 (20)	10 (26.3)	13 (31)	0.691
2	27 (67.5)	21 (55.3)	24 (57.1)	
3	5 (12.5)	7 (18.4)	5 (11.9)	
TMD (cm)	8.95±1.46	8.58±1.32	8.71±1.23	0.468
SMD (cm)	15.40±2.08	15.08±2.00	15.29±2.30	0.800
RHTMD (cm)	19.02±3.88	20.06±4.01	19.56±3.23	0.465

Data is presented as mean±SD, number (n), and percent (%). MO: Mouth opening, MMT: Modified mallampati test, TMD: Thyromental distance, SMD: Sternomental distance, RHTMD: Height/thyromental distance ratio.

Table-5: Logistic regression analysis of predictive tests.

	cLMA (n=40)		i-gel (n=38)		sLMA (n=42)	
	OR (%95 CI)	p-value	OR (%95 CI)	p-value	OR (%95 CI)	p-value
MO	2.465 (0.883-6.878)	0.085	1.087 (0.388-3.046)	0.875	0.74 (0.239-2.295)	0.602
MMT	1.608 (0.417-6.208)	0.490	0.849 (0.126-5.708)	0.866	1.802 (0.494-6.58)	0.373
TMD	3.412 (0.409-28.427)	0.257	0.407 (0.034-4.848)	0.477	0.765 (0.105-5.601)	0.792
SMD	0.74 (0.433-1.267)	0.273	0.926 (0.468-1.832)	0.824	1.006 (0.645-1.569)	0.979
RHTMD	1.6 (0.741-3.455)	0.232	0.988 (0.471-2.071)	0.974	0.929 (0.461-1.872)	0.836

LMA: Laryngeal mask airway MO: Mouth opening, MMT: Modified mallampati test, TMD: Thyromental distance, SMD: Sternomental distance, RHTMD: Height/thyromental distance ratio.

One-way analysis of variance (ANOVA) test was used to compare normally distributed data. The impact of variables on the prediction on difficulty in LMA insertion was investigated with univariate analysis and binary logistic

Table-4: Association of predictive tests and difficulty in laryngeal mask airway insertion.

	Easy (n=93)	Difficult (n=27)	p-value
MO (cm)	4.8±0.8	4.8±0.9	0.940
MMT	1.84±0.63	2.04±0.58	0.147
TMD (cm)	8.86±1.32	8.37±1.36	0.095
SMD (cm)	15.39±2.13	14.81±2.09	0.220
RHTMD (cm)	19.18±3.44	20.79±4.32	0.046

Data is presented as mean±SD, number (n), and percent (%). MO: Mouth opening, MMT: Modified mallampati test, TMD: Thyromental distance, SMD: Sternomental distance, RHTMD: Height/thyromental distance ratio.

regression (BLR), run on variables with p<0.15 in univariate analysis. BLR results were expressed as odds ratio (OR) with 95 % confidence interval (CI). P<0.05 indicated statistical significance.

Results

Of the 120 patients, 40(33.33%) were in cLMA, 38(31.66%) in i-gel, and 42(35%) in sLMA. Age, height, weight, BMI and gender were similar among the groups (Table 1). There were no significant differences between number of LMA attempts, difficulty in insertion, and patient response among the groups (p>0.05). Placement success rate at first attempt was similar among groups (Table 2). There was no patient requiring >2 LMA attempts. For intubation difficulty prediction tests, no significant differences were observed among the groups (Table 3). There was no patient with MMT Class 4. Apart from the RHTMD (p=0.046), no predictive test was significant in identifying the difficulty in LMA insertion (Table 4). Logistic regression analysis identified five risk factors affecting the difficulty in LMA insertion, and MO, MMT, TMD, SMD and RHTMD were not independent risk factors for difficulty in LMA insertion (Table 5).

Discussion

The current study found that MO, MMT, TMD, SMD, RHTMD tests that predict difficult airway had no effect on the difficulty in LMA insertion. All three LMA types were placed at a similar success rate. Insertion success in the first attempt for LMAs inserted by anaesthesia residents with the same seniority was nearly 90%.

An important responsibility of an anaesthesiologist is to maintain a patent airway in anaesthetised patients. Failure to secure the airway and

interruption of gas exchange for even a few minutes can result in catastrophic outcomes, such as brain damage or even death.³¹ In adults, SADs can be used as an alternative to tracheal intubation in difficult airways, both electively and for rescue of failed airways.²⁵ However, there has been controversy about predicting difficulty with LMA insertion and suboptimal position of LMA. Some reports have described the risk factors for LMA insertion failure.^{6,8,9,32} Ramachandran et al. examined the entire anaesthesia process, including providing and maintaining ventilation in 15,795 adult surgeries performed with LMA under general anaesthesia, and reported that changes in intra-operative position, high BMI, male gender and depth of anaesthesia were four independent risk factors for LMA insertion failure.⁹ Saito et al. suggested that the incidence of difficult ventilation through SAD was 0.42% and that four risk scores could be assessed using male gender, age >45 years, short TMD, and limited neck movement.^{6,8} Wang et al. showed that patient age >61 years, high body weight, BMI <20kg/m², and non-use of lidocaine gel as a lubricant could increase the risk of first-attempt LMA insertion failure.³² Some authors reported that higher MMT scores with increased LMA failure rates, whereas others reported that insertion and placement of LMA were independent of the MMT classification.³³⁻³⁵ Tan et al. reported poor correlation between MMT score and LMA results in pregnant women.³⁶ In the current study, MMT Class 3, MO <3cm, SMD <12.5 cm, TMD <6cm values, which are known as difficult intubation indicators, were normal in all the cases that affected the results. A variety of anatomic features, tests and parameters are used to predict difficult airways. To complete the necessary preparations and correct interventions before anaesthesia, the use of more than one of these tests together increases the predictive value.^{5,10-23} Literature has reported that RHTMD may be used as a simple airway assessment test for predicting difficult intubation, but it should often be used with other airway assessment tests. Honarmond et al. reported that RHTMD and upper lip biting test were a simple pre-operative airway assessment test and had a higher accuracy rate than TMD or MMT.¹⁶ Schmitt et al. showed that RHTMD ≥ 25 could be used to predict difficult laryngoscopies for white men and women. In the same study, the RHTMD was reported to have a better predictive value than TMD in predicting difficult laryngoscopy.²⁰ For Krobbuaban et al., the cut-off limit of RHTMD ≥ 23.5 was a risk factor for predicting difficult laryngoscopy, and observed variable results, while for Safavi et al., RHTMD >21.06 was a determining factor for predicting a poor laryngeal view in patients. Studies suggest that there may be ethnic differences, so the cut-off point for each population is calculated separately.^{14,21} The current study

found that RHTMD was the highest in the resistant LMA; therefore, RHTMD may be important in determining the difficulty in LMA insertion. The fact that a certain cut-off value for RHTMD ratio was not determined in difficult intubation cases makes this finding questionable. The study did not attempt to quote new cut-off levels for RHTMD, as the number of subjects in the study was too small for the purpose. For this reason, the practical applicability of RHTMD measurement is not clear. These minor differences in RHTMD in the literature may be due to ethnic origin, but further research is needed to determine such an effect. Alternatively, this finding may be coincidental, and its clinical significance should be evaluated separately. The predictive tests used in the current study were not successful enough to determine the difficulty in LMA insertion when performed alone.

There are simulation studies commonly done in education and research with the aim of defining the optimal supraglottic airway for airway management by health service providers.²⁵⁻²⁹ The success rate on first attempt is important in the selection of SAD in emergencies and has been reported high in many studies.^{27-29,31-39} Chen et al. compared i-gel's performance with sLMA and reported similar initial insertion success rates, while Kuş et al. reported higher success rates for sLMA use (100%) compared to i-gel (90%) in paediatric surgical patients.^{37,38} Ari et al. compared i-gel and cLMA's ease of use, reporting that the first-attempt success was 88% in both groups while the number of attempts was fewer in the i-gel group.³⁹ It also reported the success incidence to secure the airway of non-hospital cardiac arrest cases was 90% for i-gel, which was higher than the cLMA (85%).²⁷ After a short theoretical training of emergency medicine technicians, higher success rates were reported for i-gel insertion compared to the cLMA.²⁸ In the current study, the first-insertion success was 87.5% in the cLMA group, 92.1% in the i-gel group, and 90.5% in the sLMA group. All LMAs with unsuccessful initial attempts were successfully inserted on the second attempt. The success rate of nearly 90% in the current study for the initial insertion is similar to the studies cited above, and we postulate that the reason for the lower detection is due to the fact that neuromuscular agent was used in some studies.

The major limitation of the current study is exclusion of patients in whom LMAs were placed after the second trial. They were considered unsuccessful placement, and, as such, limited the assessment of the impact of these tests on failing LMA states. Second, evaluating predictive tests on patients with difficult intubation on LMA insertion is recommended for further studies. Third, the number of patients was relatively small. Fourth, because data from this

study were drawn from a single centre, attention should be paid when applying the results to patients nationally or internationally because anaesthesia care delivery processes are variable among geographical regions. Nevertheless, this validation score may have clinical utility worldwide, and future studies using this scoring system on a more heterogeneous group of patients are needed. Finally, we did not directly correlate failed intubation with LMA failure, and, therefore, cannot comment on the use of SADs as a rescue airway. The data is at least six years old, and even though the delay was due to health problems, it might be considered a limiting factor.

Conclusion

Higher RHTMD values were associated with difficulty in LMA insertion. More studies are required to evaluate the accuracy of other bedside tests on predicting SADs airway outcomes in patients.

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