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Study of Correlation between Airway Assessment Parameters and Intubating Success with Intubating Laryngeal Mask Airway using PVC Endotracheal Tube – A Prospective Open Label Observational Study

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Abstract

Background and Aims: Evidence is limited regarding the correlation of airway assessment parameters with success rate of intubation with Intubating laryngeal mask airway (ILMA). Aim was to assess the correlation between airway parameters and success rate of blind intubation with conventional polyvinyl chloride (PVC) tube using ILMA. **Methods**: After ethical clearance and informed consent, 200 patients undergoing elective surgical procedures under general anaesthesia were enrolled. Mallapatti class, upper lip bite test (ULBT) grade, thyromental distance (cm), mouth opening (cm), neck circumference were noted. Anaesthesia regimen was standardized, Cormack Lehane grade noted by laryngoscopy. Appropriate sized ILMA inserted as per standard technique and proper placement confirmed. Appropriate sized PVC tube was passed through the ILMA and its position in trachea confirmed. If intubation failed, two more attempts were allowed by rotating the tube 1800 before passing through ILMA. Number of attempts required for ILMA placement, intubation, success rate of intubation were noted. Complications such as desaturation, laryngospasm, sore throat, hoarseness were recorded if any. **Results**: Proper ILMA placement was successful in all patients. Blind intubation with PVC endotracheal tubes through ILMA was successful in 194 (97%) patients. There was no correlation between mouth opening, Mallampatti grade, thyromental distance, Cormack Lehane grade, neck circumference, ULBT class and success rates of ILMA insertion and intubation. Mean thyromental distance was 7.5 ± 0.8 cm in those intubated successfully and 5.5 ± 0.3 cm in failed intubations ($p < 0.001$, Mann Whitney U test). Twenty two patients had sore throat and 29 patients had hoarseness of voice. **Conclusion**: Thyromental distance less than 5 cm is associated with increased number of attempts for intubation and failed intubation and no other airway assessment parameters influence the success rate of ILMA insertion and intubation.

Keywords: Airway, Correlation, Intubating, Laryngeal Mask Airway

1. Introduction

Laryngeal mask airways have evolved as a major innovation in airway management. Intubating laryngeal mask airway has been used in clinical practice for over ten years and is designed to facilitate blind or fiberoptic guided intubation without need to move the cervical spine during intubation[1,2]. It has been used with success

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in difficult intubation cases. Intubation with ILMA has achieved high success rates in patients with difficult intubation or where traditional techniques have failed. The hemodynamic response with ILMA is similar to that of classic LMA and hence safer in patients with compromised cardiovascular function, compared to rigid laryngoscopy[3]. ILMA has a better learning curve as compared to rigid laryngoscopy[4]. These features render the ILMA a valuable device in operating room as well as in emergency medical care.

The reusable, relatively expensive Fastrach silicone wire reinforced tube was designed for tracheal intubation with ILMA[5]. However studies have shown that conventional polyvinyl chloride (PVC) endotracheal tube which is disposable, less expensive and readily available can be used successfully for tracheal intubation through ILMA. The success rates of intubation with PVC endotracheal tubes and Fastrach silicone wire-reinforced tube varies due to their angle of emergence from the aperture of ILMA. Hence airway assessment parameters might play a role in success of intubation with PVC endotracheal tubes.

Nevertheless very few studies have evaluated a possible association between airway assessment parameters and ease of ILMA insertion and blind tracheal intubation using PVC tracheal tubes in general population. In this study we investigate the possible correlation between airway assessment parameters (Mallampatti classification, mouth opening, upper lip bite test class, thyromental distance, neck circumference and Cormack-Lehane grade) and intubating LMA insertion and blind intubation when PVC tubes are used for intubation through ILMA.

The purpose of this study was to evaluate the possible association between following airway parameters and success rates for proper placement of the intubating LMA and blind intubation using polyvinyl chloride tubes in patients undergoing surgeries under general anaesthesia.

2. Methodology

After obtaining institutional ethical committee clearence and informed written consent from the patients, 200 adults, American Society of Anaesthesiologists grade I & II scheduled for surgical procedures in supine position under general anaesthesia in hospitals attached to a tertiary medical college were enrolled between Nov 2015-May 2017.

Patients were preoperatively assessed by an anaesthesiologist for Mallampatti classification, mouth opening, upper lip bite test class, thyromental distance and neck circumference. Mouth opening was measured as the difference between the upper and lower incisor at the midline in cm measured using a scale. Mallampatti classification was assessed, while the patient was sitting with the mouth wide open and the tongue protruding without phonation. Thyromental distance was defined as the distance in cm, measured from upper border of thyroid cartilage to inside of the mentum with neck extended using a tape. Neck circumference measured immediately above the thyroid cartilage.

Patients were kept fasting overnight and aspiration prophylaxis with oral Ranitidine 150 mg night before surgery, Ondensetron 4mg intravenous ½ hour before surgery was administered. In operating room, standard monitoring consisted of ECG, non-invasive blood pressure measurement, pulse oximetry. Baseline heart rate, systolic, diastolic and mean blood pressures and peripheral oxygen saturation were recorded. All patients were premedicated with Glycopyrrolate 0.004mg/kg, Midazolam 0.03 mg/kg and Fentanyl 2 mcg/kg intravenously and preoxygenated with 100% O_2 for 3 min. Anaesthesia was induced with Propofol 2 mg/kg, Vecuronium 0.1 mg/kg was administered for muscle relaxation, after confirming mask ventilation. After 3 min, by direct laryngoscopy using a macintosh blade without external maneuver, Cormack-Lehane grade was evaluated by an independent anaesthesiologist not involved in the study and not aware of the airway assessment parameters. At completion of laryngoscopy, face mask was applied again and 3-5 inflations provided with 100% oxygen. Then with the patient's head in neutral position, by standing behind patient's head, an appropriate size intubating LMA depending on weight of the patient as per manufacturer's recommendations was inserted by an anaesthesiologist with experience of more than 50 insertions of ILMA and not aware of airway assessment parameters. Insertion of ILMA was considered to be successful if there was easy bag ventilation, absence of air leak around the cuff at peak airway pressures at 20cm of H_2O airway pressure and a normal capnogram. Manipulations such as up and down manoeuvre, side tilt and Chandy's manoeuvre[6] were done to achieve adequate seal. If insertion was not successful at first attempt inspite of manipulations, ILMA was removed and re inserted, manipulations as mentioned

above were repeated to achieve good seal. A maximum of 3 attempts was allowed and the number of attempts recorded. Manual ventilation by face mask with 100% O_2 and additional boluses of Propofol (20-40mg) was given to maintain oxygenation and adequate level of anaesthesia between insertion attempts. Inability to successfully place the ILMA even after 3 attempts was considered as failure and alternative methods for intubation was followed as per institutional protocol. Following successful insertion of ILMA, blind intubation of the trachea was attempted with polyvinyl chloride tracheal tubes (6.5 mm internal diameter tube for ILMA size 3, and 7.5 mm internal diameter tube for ILMA size 4) normal direction at first 2 attempts and by reversing the curve direction during 3rd attempt. Manipulations of ILMA using manoeuvers mentioned above were repeated after first attempt at intubation. Between the intubation attempts patients were ventilated via the ILMA with 100% oxygen and additional boluses of Propofol (20-40 mg) as necessary, was given to ensure adequate anesthetic depth. If blind intubation was not possible after three attempts, it was considered failure and subsequent management of the patient was left to discretion of attending anaesthesiologist, whether to continue with ILMA or to follow alternate methods at intubation. Subsequent anaesthetic management was done as per the standard institutional protocol. At the end of surgery muscle relaxant was reversed using inj. Neostigmine 0.05 mg/kg and inj.Glycopyrrolate 0.008 mg/kg. Extubation was done after stable hemodynamics, normothermia, adequate respiratory efforts, muscle tone and TOF ratio >0.9. Patients were followed up post operatively for 24hrs and observed for complications of intubation such as hoarseness of voice and sore throat.

Time required for insertion of ILMA (Time from removal of facemask to the time where adequate ventilation was established through ILMA with capnographic confirmation), number of attempts required for insertion of ILMA, time required to achieve intubation (Time from disconnection of the breathing circuit of the ILMA to confirmation of tracheal placement of the tracheal tube by auscultation and display of square wave capnograph trace), number of attempts required for blind endotracheal intubation, additional manoeuvers required for proper placement of ILMA and ET tube were recorded. Haemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were recorded: before insertion of ILMA, after insertion of ILMA and after tracheal intubation at zero, one, two, five and ten minutes. Occurrence of dysrhythmias if any, were monitored through electrocardiogram. Oxygen saturation was monitored throughout the procedure.

Complications such as desaturation (SpO_2<90%), regurgitation or aspiration, bronchospasm and Oropharyngeal or dental trauma, occurring at insertion of the ILMA or at blind intubation and post-operative complications such as sore throat, hoarseness of voice was recorded.

Sample size estimation was done on basis of a pilot study involving 50 patients, where significant correlation was noted between thyromental distance and attempts at intubation. Assuming a correlation co efficient for thyromental distance and attempts for intubation to be 0.2 (obtained from results of pilot study) and alpha error at 5%, a sample of 194 patients would be required to attain a power of 80%. We included 200 patients to compensate for drop outs. 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. Mann Whitney U test was used for comparison of continuous variables between successful and failed intubation groups. Paired t test or Wilcoxon Signed rank test is the test of significance for paired data such as before and after anaesthesia for quantitative and qualitative data respectively. Spearman's correlation was done to find the correlation between two qualitative variables. Linear regression was done to find the regression equation and to estimate the unknown quantitative variables when one quantitative variable is known. p value of <0.05 was considered as statistically significant after assuming all the rules of statistical tests. SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data and MS Excel and MS word was used to obtain various types of graphs such as bar diagram, line diagram, Pie diagram and Scatter plots.

3. Results

A total of 210 patients were assessed, 10 patients were excluded as they had pre existing airway abnormality.

200 patients were enrolled into the study and all completed the study and were included in statistical analysis.

The mean age of patients was 38.9 ± 11.9 years. There were 108 (54%) females and 92 (46%) males in the study, 142 (71%) belonged to ASA grade I and 58 (29%) belonged to ASA grade II. Mean height of subjects in the study was 157. 4 ± 7.1 cm and mean weight was 56.5 ± 10.6 Kg.

Insertion of ILMA was successful in all the patients. In 197 patients insertion was successful in first attempt whereas 3 patients required second attempt for proper insertion of ILMA. Chandy manoeuver was required in all 3 patients in 2nd attempt. No other manipulations were used during ILMA insertion. There was no significant correlation between mouth opening, thyromental distance, neck circumference with manipulations of ILMA required for proper seal and intubation.

Blind intubation with PVC endotracheal tubes through ILMA was successful in 194 patients out of 200. Blind intubation was unsuccessful in 6 (3%) patients who were intubated using direct laryngoscopy (Table 1). Mean time taken for insertion of ILMA was 33.47±6.27s and mean time for intubation was 21.74±6.9s.

There was no correlation between mouth opening, Mallampatti grade, thyromental distance, Cormack Lehane grade, neck circumference, ULBT class and ILMA insertion attempts.

Mean thyromental distance among those who had successful intubation was 7.5 ± 0.8 cm and among unsuccessful intubation was 5.5 ± 0.3 cm (p <0.001). This difference in mean Thyromental distance was statistically significant. There was no significant correlation between neck circumference and mouth opening with intubation success (Table 2).

Successful intubation was noted in all grades of mallampatti classification. Of the 6 patients having failed intubation, mallampatti grade was 2 and 3. There was no significant correlation between mallampatti grade and intubation success. Successful intubation was noted in Cormack Lehane class 1,2 and 3 patients. Out of 6 failed intubation, 3 patients had Cormack lehane grade 1 and 1 patient had Cormack Lehane grade 3. Out of 6 failed intubation 4 patients had ULBT class 2 and 2 patients had ULBT class 1. There was no significant correlation between ULBT class and intubation success (Table 3).

Table 1. Number of attempts for successful intubation

No of attempts for successful intubation	No of cases	%
1st attempt	162	81%
2nd attempt	27	13.5%
3rd attempt	5	2.5%

Table 2. Correlation between mouth opening, thyromental distance and neck circumference with intubation success

	Intubation success				P value
	Yes		No		
	Mean	SD	Mean	SD	
Mouth opening (cm)	4.3	0.5	4.2	0.2	0.629
Thyromental distance (cm)	7.5	0.8	5.5	0.3	<0.001*
Neck Circumference (cm)	36.6	2.9	37.2	1.7	0.633

Table 3. Correlation between Mallampatti grade, Cormack – Lehane grade, upper lip bite test and intubation success

Mallampatti Grade	No of patients	Intubation success		Pvalue
		Yes	No	
Grade 1	81	81	0	0.56
Grade 2	84	79	5	
Grade 3	34	33	1	
Grade 4	1	1	0	
Cormack-Lehane grade				
Grade 1	139	136	3	0.62
Grade 2	53	51	2	
Grade 3	8	7	1	
ULBT				
Class 1	94	92	2	0.39
Class 2	105	101	4	
Class 3	1	1	0	

Table 4. Spearman's rho correlation between Number of attempts to intubate and airway parameters.

	Correlation Coefficient	P value
Mouth opening (cm)	-0.065	0.361
Mallampatti Score	0.109	0.123
Thyromental distance	-0.222**	0.002*
Upper Lip Bite Test	0.071	0.316
Neck Circumference (cm)	0.060	0.396
Cormack-Lehane Grade	0.130	0.066

There was weak negative correlation between number of attempts to intubate with Mouth opening (Cm) and Thyromental distance (r = -0.222, p – 0.002). i.e. with decrease in Mouth opening and Thyromental distance there was increase in number of attempts to intubate. However significant negative correlation was observed with Thyromental distance. There was positive correlation between number of attempts to intubate with Mallampatti

Table 5. Correlation between mouth opening, thyromental distance, neck circumference with ETT manipulation

	Manipulation				P value
	180 degree		No		
	Mean	SD	Mean	SD	
Mouth opening (cm)	4.2	0.4	4.3	0.5	0.374
Thyromental Distance (cm)	6.7	1.3	7.5	0.7	<0.001*
Neck Circumference (cm)	37.5	3.1	36.5	2.8	0.170

Table 6. Linear regression with No of attempts to intubate and various measurements

Model B		Unstandardized Coefficients		Standardized Coefficients	P value Lower Bound	95.0% Confidence Interval for B	
		SE	Beta			Upper Bound	
1	(Constant)	1.081	1.360		0.428	-1.601	3.764
	Mallampatti	0.039	0.057	0.053	0.492	-0.073	0.152
	Mouth opening (cm)	0.000	0.077	0.000	0.999	-0.153	0.153
	Thyromental distance (cm)	-0.129	0.097	-0.195	0.183	-0.319	0.062
	Upper lip bite test	0.027	0.080	0.025	0.737	-0.132	0.186
	Neck circumference (cm)	0.012	0.014	0.063	0.388	-0.015	0.040
	Cormack Lehane grade	0.052	0.073	0.053	0.475	-0.091	0.195

Grade, Upper Lip Bite Test class, Neck Circumference (cm) and Cormack-Lehane Grade. I.e. with increase in the above said measurements there was increase in no of attempts to intubate. But the correlation was weak and not statistically significant (Table 4). In the study there was significant difference in mean TM distance with respect to degree of manipulation. I.e. lower mean TM distance were observed among those who required 180 degree manipulation. There was no clinical or statistically significant correlation between Mallampatti class, ULBT, Cormack Lehane grade and ETT manipulations (Table 5). However, regression models did not reveal a statistically significant correlation between any of the airway assessment parameters and attempts at intubation (Table 6).

In our study 12 (6%) patients had blood staining of ILMA/ETT, 29 (14.5%) patients had sore throat, 22 (11%) patients had hoarseness of voice and 7 (3.5%) patients had nausea and vomiting. With increase in No of attempts there was statistically significant increase in Hoarseness of voice and Sore throat (Table 7).

Table 7. Correlation between side effects and No. of attempts to intubate

		No of attempts to intubate						P value
	One attempt		Two attempts		Three attempts			
	Count	%	Count	%	Count	%		
Blood stain	No	152	93.8%	26	96.3%	10	90.9%	0.800
	Yes	10	6.2%	1	3.7%	1	9.1%	
Hoarseness	No	149	92.0%	21	77.8%	8	72.7%	0.019*
	Yes	13	8.0%	6	22.2%	3	27.3%	
Sore throat	No	144	88.9%	21	77.8%	6	54.5%	0.004*
	Yes	18	11.1%	6	22.2%	5	45.5%	
N&V	No	156	96.3%	26	96.3%	11	100.0%	0.810
	Yes	6	3.7%	1	3.7%	0	0.0%	

4. Discussion

The present study aimed at evaluating the possible association between airway parameters and success rates of proper placement of the intubating LMA and blind intubation using polyvinyl chloride tubes in patients undergoing surgeries under general anaesthesia. It was noted that there was no correlation between the airway assessment parameters and success of ILMA insertion. However, there was weak negative correlation between thyromental distance and number of attempts required for intubation. Also there was correlation between thyromental distance and tube orientation, with shorter thyromental distance requiring rotation of tube by 180 degrees while placing it through ILMA. There was no correlation between Mallampatti grading, Cormack Lehane grading, upper lip bite test and attempts at intubation, tube orientation.

ILMA has been successfully used in clinical practice for over ten years in patients with normal and difficult airways. The polyvinyl chloride conventional endotracheal tube has been used as suitable alternative to silicone wire reinforced tube is designed for tracheal intubation with ILMA[7]. Many factors can influence the success rate of intubation, the technique of insertion being one of them. Previous studies have tried both spontaneous and controlled ventilation for placement of ILMA and intubation[8,11]. To ensure uniformity, we adopted uniform anaesthetic technique with use of muscle relaxant to negate the effect of inadequate relaxation on success rate. The success rates on ILMA insertion and intubation was similar to that noticed by other authors[10,12-16]. It is well known that an important factor that determines the success of tracheal intubation is the angle at which the tracheal tube emerges from the distal aperture of the ILMA, different angle of emergence of the tracheal tube with conventional orientation may produces a different success rate of tracheal intubation[13,17]. Studies evaluating the orientation of tube on success rate of blind intubation through ILMA noticed no difference in the overall success rates of tracheal intubation between the normal and reverse orientation groups; but the first attempt success rate in the reverse group was higher than that in normal orientation group[14,18]. In our study, tracheal intubation was attempted with normal orientation of the ETT during first attempt and reverse orientation for second and third attempt.

Few studies have been conducted where intubation success was compared with airway assessment parameters. Ferson *et al*[9]. in a retrospective study found that in 111 patients with a Cormack-Lehane Grade IV, intubation with the ILMA was achieved in 92% of patients and in 63.6% intubation was successful at first attempt. Staikou[16] *et al.* investigated the possible impact of mouth opening, Mallampati classification, thyromental distance and Cormack-Lehane grade, on ILMA insertion and blind

intubation. No relationship was found between factors predicting or assessing difficult airway and easiness of the ILMA use. Ye *et al*[20]. in their study to assess whether the patients' Mallampati class can affect the success rate of intubation through an ILMA concluded that tracheal intubation was equally successful in patients with high and low Mallampati class.

Incidence of failure to intubate has varied from 0.7% - 10% in various studies[12-14,16,19]. Some of the reasons cited include inexperience in earlier studies, where as poor ILMA-larynx alignment, elongated and downfolded epiglottis, or tip of tracheal tube impinging on larynx or trachea in few other studies[14,20]. The exact reason for failure to intubate in the present study was not clear and there was no correlation between any of the airway assessment parameters and failure of intubation. In all the 6 cases where intubation through ILMA failed, ventilation could easily be performed and the mean thyromental distance in them was 5.5±0.3 cm.

The incidence of side effects can be more with use of conventional PVC tubes compared to that of reinforced silicon tubes, and were similar to that reported in earlier studies using conventional PVC tubes[14,15]. Sore throat and mucosal trauma was mild in all cases and subsided within 48 hours without any treatment.

There are few limitations in the present study. Patients involved were of normal BMI and belonged to ASA grade I & II, and the inferences drawn from this study population cannot be extrapolated for those with cervical spine injury and for obese patients. We did not assess the proper placement of ILMA and the glottic view using fiberoptic bronchoscope. Use of fibreoptic bronchoscope to ascertain the position of epigolttis and alignment of glottic opening with that ILMA would help in finding the cause of failed intubations.

5. Conclusion

There is no correlation between airway assessment parameters like mouth opening, Mallampatti grade, neck circumference, ULBT class, thyromental distance and Cormack-Lehane grade and ease of intubation using ILMA. Thyromental distance less than 5 cm may be associated with increased number of attempts for intubation and failed intubation.

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