PREDICTIVE FACTORS FOR FAILED PROSEAL™ LARYNGEAL MASK AIRWAY (PLMA) INSERTION

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Abstract

Background: The ProSeal™ laryngeal mask airway (PLMA) is a second generation laryngeal mask airway which is more difficult to insert than conventional laryngeal mask airway. This study aimed to identify the factors to predict failed PLMA insertion.

Methods: This prospective, observational study included 181 patients, aged between 18 to 65 years, who had PLMA insertion during general anesthesia. Patients with body mass index ≥35 kg/m², had cervical spine pathology and risk of aspiration were excluded. It was conducted by multiple operators with minimum of 3 years' experience of PLMA insertion. Factors studied were modified Mallampati classification, thyromental distance, interincisor gap, Wilson sum score, neck circumference, range of head and neck movement, retrognathia, buck teeth and jaw movement. The ease of insertion was graded as easy or difficult.

Results: Our study demonstrated 4.97% failure rates. Patients with flexible jaw movement had significant risk for failed PLMA insertion (OR: 7.25, 95% CI: 1.46-36.04, p = 0.015). It was demonstrated as an independent predictive factor for PLMA insertion failure (OR: 15.11, 95% CI: 1.83-124.67, p = 0.012). It also demonstrated 77.78% sensitivity, 67.44% specificity with 11.11% positive predictive value and 98.31% negative predictive value. Study also showed that difficult insertion was associated with higher risk of failure (OR: 16.11, 95% CI: 3.72-69.74, p = 0.000) and was demonstrated as a significant independent factor to detect failed insertion (OR: 45.95, 95% CI: 5.98-352.88, p = 0.000).

Conclusion: The flexible jaw movement was found to be as an independent predictive factor, with moderate sensitivity and specificity and difficult insertion was a strong indicator for PLMA insertion failure.

Keywords*:* ProSeal Laryngeal mask airway, difficult insertion.

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Introduction

The laryngeal mask airway (LMA) is a type of supraglottic airway (SGA) device that was introduced into clinical practice in 1988[1]. It is widely used in hospitals for patients undergoing general anesthesia as well as out of hospital by paramedics to secure airway. SGA are also used for difficult airway management as an airway rescue. The immediately life threatening ''cannot intubate, cannot ventilate'' situation occurs in approximately 1:10,000 anesthesia cases[2] and the use of SGA has been part of the difficult airway algorithm. According to practice guidelines for management of the difficult airway by American Society of Anesthesiologists (ASA), they recommended that assessment for the possibility of difficult SGA placement is important as part of the strategy for difficult airway intubation[3].

The ProSeal™ laryngeal mask airway (PLMA) is a second generation SGA device. It contains dedicated gastric channel for gastric drainage to prevent aspiration and gastric insufflation. Suboptimal positioning of the PLMA was reported in 30%-66% of cases[4]. Brimacombe et al. demonstrated that PLMA was more difficult and slower to insert at the first attempt than the LMA[5] with success rates varying between 81%-87%[6]. He indicated that the increased difficulty with PLMA insertion probably reflects the larger cuff (impeding digital intraoral positioning and propulsion into the pharynx), the lack of a back-plate (making the cuff more likely to fold over at the back of the mouth), and the need for precise tip positioning (to prevent air leaks up the drainage tube)[5].

Malposition of PLMA may increase the risk of regurgitation, cause injuries to the lingual and hypoglossal nerves, and minor trauma to the airway[7,8]. Given the potentially severe consequences of PLMA insertions failure with current limited data on predictive factors on failed PLMA insertion, identifying the potential risk factors for failed PLMA insertion may provide valuable information to anesthesiologists when assessing the feasibility of PLMA for general anesthesia.

Jun et al. used airway score that included modified Mallampati class, inter-incisor distance, head and neck movement, buck teeth, upper lip bite test (ULBT) and history of difficult intubation to predict PLMA insertion. They found that only ULBT showed significant correlation with failure of the PLMA insertion[6]. Ramachandran et al. demonstrated that male gender, poor dentition and reduced thyromental distance of <6 cm to be independent risk factors for failed LMA insertion[1].

Our study aimed to identify the clinical parameters and bedside assessments that will be useful as predictive factors in predicting failed PLMA insertion.

Materials and Methods

Study approval was obtained from the Research Committee of Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre (UKMMC), Medical Research & Ethics Committee from UKMMC and Medical Research & Ethics Committee (MREC) under National Medical Research Register (NMRR), Ministry of Health Malaysia.

This was a prospective, observational study which included patients between 18-65 years of age, ASA physical status I or II and undergoing surgery under general anesthesia using the PLMA for airway management. Patients with body mass index (BMI) more than 35 kg/m², presence of cervical spine pathology and risk of aspiration were excluded. Written informed consents were obtained from patients recruited into the study. PLMA insertion was conducted by multiple operators, who had a minimum of 3 years' experience in PLMA insertion.

Preoperatively, age, gender, weight, height, and BMI were recorded. Bedside airway assessments which included modified Mallampati classification[9,10], thyromental distance (TMD), inter-incisor gap (IIG), neck circumference (NC), Wilson sum score, range of head and neck movement (HNM), retrognathia, buck teeth and jaw movement were performed and recorded (Appendix A). We defined TMD <6 cm as short TMD[11], IIG ≤3cm as small gap[1], NC >42 cm as thick neck[12], Wilson sum score ≥2 as higher risk of difficult insertion[10,13] and HNM ≤90 degree as limited movement[10,13]. Jaw movement was graded as flexible if the inter-incisor opening (IO) >5 cm or lower incisors can be protruded beyond the upper incisors level and

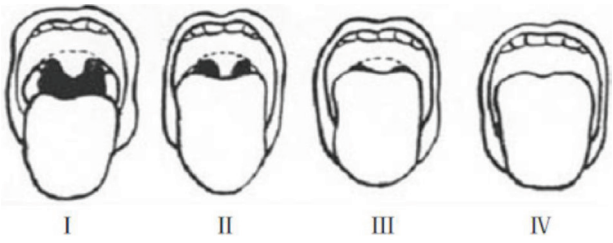
limited jaw movement was defined as IO ≤5 cm or lower incisors cannot be protruded beyond the upper incisors level or just at the upper incisors level.

Appendix A

1. Modified Mallampati classcification

Modified Mallampati classcification by Samsoon and Young is performed by asking the patient to open his or her mouth maximally and to protrude the tongue without phonation, while seated.

Class	Visible structures (Patient upright, maximal opening of mouth and protrusion of tongue)
I	Uvula, fauces, soft palate, hard palate
II	Fauces, soft palate, hard palate
III	Soft palate, hard palate
IV	Hard palate alone



Modified Mallampati Classification

2. Thyromental Distance (TMD)

Thyromental Distance (TMD) is measured from the thyroid cartilage to the bony point of the mentum while the head was fully extended and the mouth closed in centimeter (cm).

3. Inter-incisor gap (IIG)

Inter-incisor gap (IIG) is assessed by asking each patient to open the mouth as wide as possible. The distance between upper and lower incisor at the midline is measured in cm.

4. Neck circumference

Neck circumference is measured at the level of thyroid cartilage in cm using a flexible measuring tape. Neck circumference was >42cm in obese patients.

5. Wilson sum score

RISK FACTOR	SCORE POINTS
WEIGHT	
<90kg	0
90-110kg	1
>110kg	2
HEAD AND NECK MOVEMENT *(Angle formed between the positions of greatest extension and greatest flexion of the neck)*	
>90°	0
~90°	1
<90°	2
JAW MOVEMENT *IO: maximum interincisal opening* *SLux: Jaw subluxation and maximum forward protrusion of the lower incisors beyond the upper incisors.*	
IO >5 cm or SLux >0	0
IO <5 cm or SLux = 0	1
IO <5 cm or SLux <0	2
RETROGNATHIA	
Absent	0
Moderate	1
Severe	2
BUCK TEETH	
Absent	0
Moderate	1
Severe	2

Minimum point = 0, maximum points = 10.

Scores ≥ 2 and ≤4 = a possibly difficult intubation;

>4 = often difficult intubation.

6. Upper lip bite test (ULBT)

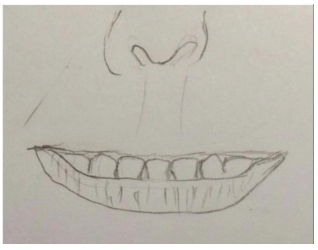
Upper lip bite test (ULBT) is done by asking each patient to bite their upper lip with lower incisor and categorized as

Class I - lower incisor can bite the upper lip above the vermillion line (picture A);

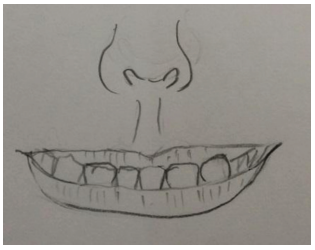
Class II - lower incisor can bite the upper lip below the vermillion line (picture B);

Class III - lower incisor cannot bite the upper lip (picture C).

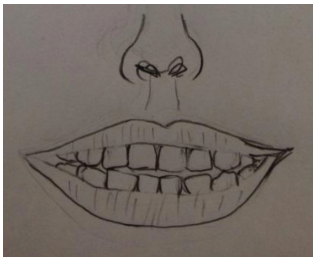
Picture A



Picture B



Picture C



7. PLMA patient selection and inflation volume

PLMA size	Patient selection information	Maximum inflation volume
1	Neonates up to 5 kg	4ml
1½	5-10 kg	7ml
2	10-20 kg	10ml
2½	20-30 kg	14ml
3	30-50 kg	20ml
4	50-70 kg	30ml
5	70-100 kg	40ml

Appendix B

Standard formula for different test for data analysis

Term	Actual	Predicted
True-positive (TP)	Failed	Failed
False-positive (FP)	Successful	Failed
True-negative (TN)	Successful	Successful
False-negative (FN)	Failed	Successful

Sensitivity:

Percentage of correctly predicted failed PLMA insertion as a proportion of all insertions that were truly failed. TP/(TP + FN)

Specificity:

Percentage of correctly predicted successful PLMA insertion as a proportion of all insertions that were truly successful. TN/(TN + FP)

Positive Predictive Value (PPV):

Percentage of correctly predicted failed PLMA insertion as a proportion of all predicted failed insertions. TP/(TP + FP)

Negative Predictive Value (NPV):

Percentage of correctly predicted successful PLMA insertion as a proportion of all predicted successful insertions. TN/(TN + FN)

Patients were fasted for at least 6 hours prior to general anesthesia and no sedative premedication was given. In the operating theatre, routine monitoring was applied, including pulse oximetry, noninvasive blood pressure and electrocardiography. Anesthesia was conducted in the supine position with the head in an optimal intubating position. The size selection of the PLMA was based on the manufacturer's recommendation. A size 3 PLMA was used for patients less than 50 kg; a size 4 PLMA was used in patients 50-70 kg; and a size 5 PLMA was used in patients more than 70 kg[14]. Minor variations to the sizing of the PLMA was allowed at the discretion of the attending anesthetist. The back surface of the PLMA was lubricated with water-soluble lubricant. The PLMA was mounted on the dedicated metal introducer and the cuff was completely deflated before insertion.

Prior to induction of anesthesia, patients were pre-oxygenated with 100% oxygen at 6 L/min. Intraveneous (IV) fentanyl 2 mcg/kg and IV propofol 2.5 mg/kg were administered, followed by IV atracurium 0.5 mg/kg to facilitate PLMA insertion. Patients were manually ventilated with sevoflurane in 100% oxygen at the flow of 6 L/min for 3 minutes to achieve minimum alveolar concentration (MAC) of 1.0-1.2. The optimum insertion condition of PLMA achieved when the patient was apneic with relaxed jaw and no response to jaw thrust[15]. PLMA was inserted by using the dedicated metal introducer and advanced into the hypopharynx until resistance was felt[14]. The cuff was inflated with air according to the recommended inflation volume from the manufacturer until an effective airway was established[14].

Only two attempts of insertions were allowed. Number of attempts was recorded and the ease of insertion for the attempt was graded by the operator as easy for smooth insertion or difficult if there was any resistance felt. Failed insertion was defined by the presence of any of the following criteria: failure to advance the PLMA into the pharynx; or PLMA malposition (air leaks despite cuff inflation); or ineffective ventilation (maximum expired tidal volume <6 ml/kg)[6]; or the need of conversion into endotracheal intubation for any reasons during any period of the attempt and attempts of more than 2 times. A successful PLMA insertion was defined as absence of oropharyngeal air leak at an airway pressure of 20 cmH_2O (detected by listening over mouth)[16], bilateral equal breath sound on chest auscultation, the absence of air influx in the gastrointestinal tract (detected by listening with a stethoscope over the epigastrium)[16], presence of a normal rectangular shaped capnogram, able to ventilate with an expired tidal volume of >6 ml/min. The choice of airway management following failed PLMA insertion was at the discretion of the attending anesthetist.

The predictive factors studied included modified

Mallampati classification, TMD, IIG gap, NC, Wilson Sum score, range of HNM, retrognathia, buck teeth and jaw movement. Two outcomes were studied, successful and failed attempts. According to Peduzzi et al. for number of events per variable (EPV) of 10 or greater, no major problems or bias occur[17]. Thus, with 9 predictive factors and 2 outcomes studied, sample size estimated was 180 samples.

The data was analyzed with SPSS version 20. Demographic data was presented as mean (standard deviation, range) and evaluated using the Student t tests. The p-values of the preoperative data for the categorical variables were calculated using Pearson chi-square or Fisher exact test, while Student t tests for continuous variables. A value of $p < 0.05$ was considered statistically significant. The predictive factors were further analyzed using multivariate analysis and expressed as odds ratio as well as further test to evaluate the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of each factors according to standard formulas.

Table 1:
Demographic data of the patients.

	PLMA insertions (n=181)		
	Successful	Failed	
	(n=172)	(n=9)	*p value
Age	35.8±12.7	35.9±18.7	0.991
Weight	65.1±12.3	58.7 ±7.4	0.054
Height	161.4±8.0	157.3±9.9	0.134
BMI<30	149(86.6)	9(100)	0.606
BMI≥30	23(13.4)	0(0.0)	
Gender			0.490
Male	71(41.3)	5(55.6)	
Female	101(58.7)	4(44.4)	
Race			0.174
Malay	112(65.1)	4(44.4)	
Chinese	22(12.8)	1(11.1)	
Indian	28(16.3)	2(22.2)	
Others	10(5.8)	2(22.2)	
ASA			1.000
I	129(75)	7(77.8)	
II	43(25)	2(22.2)	

*p values calculated using Pearson chi-square or Fisher exact test for categorical variables and Student *t* test for continuous variables. Values for continuous variables were expressed in mean ± standard deviation and for categorical variables were expressed in n (%).

Table 2

Predictive factors for successful/failed PLMA insertion

Predictive	**Sucessful**	**Failed**			**95% CI**		
Factors	**(n = 172)**	**(n = 9)**	***p value**	**OR**	**lower**	**upper**	**^ p value**
TMD			0.210				
<6 cm	35(20.3)	0(0.0)					
≥6 cm	137(79.7)	9(100)					
IIG			0.733				
≤3 cm	6(3.5)	0(0.0)					
>3 cm	166(96.5)	9(100)					
NC			0.625				
≤42 cm	163(94.8)	9(100)					
>42 cm	9(5.2)	0(0)					
Wilson Sum Score			0.493				
<2	109(63.4)	7(77.8)					
≥2	63(36.6)	2(22.2)					
HNM			0.695				
>90degree	165(95.9)	9(100)					
≤90degree	7(4.1)	0(0.0)					
Buck teeth			0.066				
absent	165(95.9)	7(77.8)					
present	7(4.1)	2(22.2)					
Retrognathia			0.733				
absent	166(96.5)	9(100)					
present	6(3.5)	0(0.0)					
Jaw movement			0.009				
flexible	56(32.6)	7(77.8)		7.250	1.459	36.036	0.015
limited	116(67.4)	2(22.2)					
Mallampati			0.076				
I	108(62.8)	9(100)					
II	63(36.6)	0(0.0)					
III	1(0.6)	0(0.0)					
Ease of insertion			0.000				
Easy	135(89)	3(33.3)					
Difficult	19(11.0)	6(66.7)		16.105	3.719	69.739	0.000

Values for categorical variables were expressed in n (%)

* p values calculated using Pearson chi-square or Fisher exact test for categorical variables and Student *t* test for continuous variables

OR: odds ratio

CI: confidence interval

^ p values calculated with logistic regression analysis

The flexible jaw movement assessment showed 77.78% sensitivity and 67.44% specificity in predicting failed Results

There were 181 patients enrolled into this study. The demographic data included age, weight, height, BMI, gender and race and were normally distributed and statistically comparable (Table 1). On the first attempt of PLMA insertion, 35(19.34%) patients failed PLMA insertion and 146(80.66%) patients had successful PLMA insertions. There were 9(4.97%) failure of PLMA insertions after two attempts while, 172(94.03%) PLMA insertions were successful.

Our study showed that patients with flexible jaw movement had 7 folds more risk to have failure of PLMA insertion (OR: 7.250, 95% CI: 1.459-36.036, p = 0.015). No other predictive factors showed statistically significant association to failure of PLMA insertion (Table 2). It also showed that patients who had difficult insertion had 16 folds more risk of insertion failure (OR: 16.105, 95% CI: 3.719-69.739, p = 0.000).

PLMA insertion. It had a positive predictive value (PPV) of 11.11% while the negative predictive value (NPV) was 98.31%. Difficult insertions showed a sensitivity of 66.67% and high specificity of 88.95% for failed PLMA insertion. Its PPV was 24% and NPV was 98.08% (Table 3).

Further analysis on multiple logistic regressions adjusted these two factors to age, gender, BMI, TMD and NC showed that flexible jaw movement and difficult PLMA were significant independent risk factors for failed PLMA insertion. Patients with flexible jaw movement had 15 folds more likely to failed PLMA insertion (OR: 15.107, 95% CI: 1.831-124.674, p = 0.012) and risk of failed PLMA insertion increased to 45 folds with patients who had difficult PLMA insertion (OR: 45.946, 95% CI: 5.982-352.887, p = 0.000).

Discussions

We evaluated the modified Mallampati classification, TMD, IIG, NC, range of HNM, retrognathia, buck teeth, jaw movement as well as ease of insertion as predictive factors for failed PLMA insertion. The failure rate for first attempt of PLMA insertion in this study was 19.34% and were comparable to previous studies by Hwang et al and Brimacombe et al[5,18]. Only 2 attempts of insertions were allowed in our study and the overall failure rate of PLMA insertion was 4.97% while Jun et al and Brimacombe et al reported failure rate of 3.90% and 2% respectively after 3 attempts of insertion[4,5].

Our study demonstrated that flexible jaw movement was an independent predictor for failed PLMA insertion. It has been reported that it is possible to insert a supraglottic airway device through an inter-incisor gap of <3 cm and a successful insertion has been reported in patients with <2 cm mouth opening[19]. Thus, we postulated that the degree of jaw protrusion was the main component that affected the PLMA insertion in our study.

Both the assessments of lower jaw protrusion and upper lip bite tests (ULBT) are clinically used to assess temporo-mandibular joint function and prognathic ability[18]. ULBT is a clinical assessment used to assess the range of free movement of the mandibular and the architecture of the teeth concurrently[20]. It is categorized as Class I, Class II and Class III, describing less flexible lower jaw movement as the grading increases. Jun et al demonstrated that ULBT Class I was an

Table 3

Sensitivity, specificity, positive predicted value and negative predictive value for PLMA risk factors

Predictive/risk factors	Sensitivity	Specificity	PPV	NPV
Flexible Jaw Movement	77.78	67.44	11.11	98.31
Difficult insertion	66.67	88.95	24.00	98.08

All values were express in percentage (%)
PPV: positive predicted value
NPV: negative predictive value

indication of difficult PLMA insertion[4]. Similarly, our study demonstrated that failure of PLMA insertion was significantly higher in patients with flexible jaw movement. It also demonstrated moderate sensitivity and specificity in predicting failed PLMA insertions. However, there are no available data to date to compare these findings.

The PLMA insertion in this study was graded by the operators as easy or difficult. Although it was a subjective evaluation and varies between different operators, a difficult PLMA insertion was shown to be a good indicator for failed insertion. The risk of PLMA insertion failure was higher when the insertion was graded as difficult.

Brain et al. suggested that the more 'anterior' the larynx, the easier it is to insert the laryngeal mask which will be placed behind it[21]. If the larynx is more posterior, it will be easier to intubate but proper placement of the laryngeal mask may be more difficult[19]. This may suggest that, when intubation is difficult the use of the laryngeal mask may be easy and vice versa[21]. In our study, all patients who failed PLMA insertion were intubated. Intubation in all these patients were not difficult with 5 out of 9 patients had Cormack Lehane score of I while another 4 had Cormack Lehane score of II. Among the 9 patients who failed PLMA insertion in our study, 7 had flexible jaw movement (77.78%) and 6 was graded as difficult insertion (66.67%).

Other bedside airway assessments evaluated in our study were modified Mallampati classification, TMD, IIG, NC, range of HNM, retrognathia, buck teeth and Wilson Sum score. None of these factors demonstrated significant association with failed PLMA insertion. This was consistent with the result from Jun et al[4]. Their study reported that BMI, modified Mallampati classification, TMD and HNM were unable to predict difficult PLMA insertion. Similarly, Ramachandran et al. reported that modified Mallampati classification, reduced mouth opening, reduced neck movement did not predict failed LMA insertion[1].

There were few limitations in this study. First, most of the patients included in our study were young adult patients with mean age of 35 and morbidly obese patients (BMI >35 kg/m²) were excluded as they are at risk of aspiration. Thus, the result of this study should not be extrapolated to the pediatric, elderly or obese patients. Second, we did not assess or confirm the PLMA position with a fiber-optic scope as our successful PLMA insertions were assessed clinically. Fibre-optic assessment of successful PLMA positioning is not routinely performed in our clinical setting. Chen et al. reported, that there was no difference between fibre-optic bronchoscope guided and introducer tool assisted PLMA insertions, in achieving correct positioning, with the latter technique was significantly quicker[6]. Jun et al. demonstrated that 52% of patients had suboptimal PLMA position despite successful PLMA insertion[4] and perfect positioning is not necessary for maintaining satisfactory airway function[17]. Third, the PLMA attempts were conducted by multiple operators. The grading of easy and difficult was subjective and may vary between different operators despite all of them have more than 3 years of experience in PLMA insertions. Lastly, we did not perform an alternative method of PLMA insertion such as digital assisted, rotational or bougie-assisted, when the PLMA insertion failed the second attempt. All of the patients were intubated.

Conclusion

We concluded that flexible jaw movement was an independent predictive factor for failed PLMA insertion with moderate sensitivity and specificity, while difficult PLMA insertion was a strong indicator of PLMA insertion failure.

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