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Evaluation of Different Pre-operative Bedside Airway Assessment Tests to Determine Ease of Insertion of ProSeal LMA: A Prospective Observational Study

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Abstract

The ProSeal laryngeal mask airway (PLMA) has become an essential supraglottic airway device in modern anesthetic practice, yet predicting insertion difficulty remains a clinical challenge that can impact patient safety and operating room efficiency. This prospective observational study aimed to evaluate the predictive accuracy of various pre-operative bedside airway assessment tests for determining ease of PLMA insertion in adult patients undergoing elective surgery. A total of 280 patients aged 18-70 years, ASA physical status I-III, scheduled for elective procedures under general anesthesia with planned PLMA insertion were enrolled between January 2022 and December 2023. Pre-operative airway assessment included systematic evaluation of Mallampati classification, thyromental distance, sternomental distance, mouth opening, neck circumference, upper lip bite test, neck extension, and mandibular protrusion test. The primary outcome was ease of PLMA insertion categorized as easy (successful insertion within first 2 attempts), moderately difficult (3-4 attempts), or difficult (>4 attempts or failure requiring alternative airway). Secondary outcomes included insertion time, seal pressure, and complications. Easy insertion was achieved in 198 patients (70.7%), moderately difficult in 58 patients (20.7%), and difficult insertion in 24 patients (8.6%). Multivariate analysis identified Mallampati class III-IV (OR 5.2, 95% CI: 2.8-9.7, $p<0.001$), thyromental distance <6.5 cm (OR 4.1, 95% CI: 2.2-7.6, $p<0.001$), mouth opening <4 cm (OR 3.4, 95% CI: 1.8-6.4, $p<0.01$), neck circumference >42 cm (OR 2.8, 95% CI: 1.5-5.2, $p<0.01$), and upper lip bite test class III (OR 3.7, 95% CI: 1.9-7.1, $p<0.001$) as independent predictors of difficult insertion. A composite scoring system incorporating these five parameters achieved 84.2% sensitivity and 91.3% specificity for predicting difficult PLMA insertion, with area under the curve of 0.93. Multiple pre-operative bedside airway assessment tests can effectively predict PLMA insertion difficulty, with the strongest predictors being Mallampati classification, thyromental distance, and mouth opening. The developed composite scoring system provides a practical clinical tool for risk stratification, enabling anesthesiologists to anticipate insertion challenges and optimize perioperative airway management strategies.

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Introduction

The ProSeal laryngeal mask airway (PLMA) represents a significant evolution in supraglottic airway technology, incorporating enhanced safety features that have made it indispensable in contemporary anesthetic practice [1]. Unlike its predecessor, the classic laryngeal mask airway, the PLMA provides higher seal pressures, incorporates a gastric drainage tube, and offers improved protection against aspiration, making it suitable for a broader range of surgical procedures [2].

These advantages have led to widespread adoption across various surgical specialties, particularly for intermediate-duration procedures where endotracheal intubation may not be warranted.

Despite its proven clinical efficacy and safety profile, PLMA insertion can present significant challenges in certain patient populations, with reported insertion failure rates ranging from 8% to 20% depending on patient characteristics and operator experience [3]. Failed or difficult insertion can result in prolonged induction times, increased patient morbidity, airway trauma, hemodynamic instability, and the urgent need for alternative airway management strategies [4]. The ability to predict insertion difficulty during pre-operative assessment would enable anesthesiologists to better prepare for potential challenges, optimize patient selection, and enhance overall perioperative safety.

Traditional airway assessment techniques were primarily developed to predict difficult laryngoscopy and endotracheal intubation, with limited validation for supraglottic airway devices [5]. The anatomical considerations for successful PLMA insertion differ substantially from those required for intubation, as the device must be positioned in the hypopharynx rather than requiring direct visualization of laryngeal structures [6]. However, several anatomical factors including oropharyngeal space, mandibular anatomy, and soft tissue characteristics may influence both intubation and supraglottic device insertion success.

The Mallampati classification system, first described in 1985 and subsequently modified, remains the most widely utilized bedside airway assessment tool in clinical practice [7]. This classification evaluates the visibility of oropharyngeal structures when the patient sits upright with the mouth maximally opened and tongue voluntarily protruded. While its correlation with difficult intubation has shown variable results across different populations, its potential utility for predicting PLMA insertion difficulty requires systematic investigation [8].

Thyromental distance, representing the linear measurement from the thyroid cartilage prominence to the mental prominence of the mandible, provides valuable information about mandibular space and upper airway anatomy [9]. This measurement has demonstrated utility in predicting difficult mask ventilation and intubation, potentially due to its reflection of mandibular space adequacy and pharyngeal volume [10]. The relevance of thyromental distance to PLMA insertion success warrants comprehensive evaluation in diverse patient populations.

Mouth opening capacity represents another fundamental parameter that directly impacts the ability to insert supraglottic devices [11]. Adequate mouth opening is essential for proper device positioning and may influence the ease of insertion, particularly for larger PLMA sizes. The relationship between inter-incisor distance and insertion success has not been systematically evaluated across different patient demographics [12].

Neck circumference has emerged as an important predictor of difficult airway management, particularly in obese patients where increased soft tissue bulk may alter pharyngeal anatomy and complicate device insertion [13]. The association between neck circumference and PLMA insertion difficulty may be particularly relevant given the increasing prevalence of obesity in surgical populations [14].

The upper lip bite test, a relatively newer assessment technique, evaluates mandibular protrusion capability and has shown promise in predicting difficult intubation [15]. This test assesses the patient's ability to bite the upper lip with the lower incisors, providing information about temporomandibular joint function and mandibular mobility that may be relevant to supraglottic device insertion [16].

Current literature addressing PLMA insertion predictors is limited and often contradictory, with most studies examining individual parameters in isolation or utilizing small sample sizes [17]. A comprehensive evaluation of multiple assessment techniques in a large, diverse patient population would provide valuable clinical guidance and potentially enable the development of evidence-based predictive algorithms [18].

The clinical implications of accurate insertion prediction extend beyond mere convenience to encompass patient safety, resource utilization, and quality of care [19]. Anticipated difficult insertion allows for appropriate preparation, including the availability of alternative airway devices, experienced personnel, and modified anesthetic techniques [20]. This preparation can significantly reduce patient morbidity, minimize delays, and optimize overall perioperative efficiency [21].

Furthermore, understanding the specific anatomical factors that predict PLMA insertion difficulty may inform device design improvements, insertion technique modifications, and training program development [22]. The establishment of evidence-based predictive criteria could also enhance quality assurance programs and support competency-based education initiatives in anesthesiology training.

Materials and Methods

Study Design and Ethical Considerations

This prospective observational study was conducted at a tertiary care academic medical center between January 2022 and December 2023. The study protocol received approval from the institutional review board, and the trial was registered with the Clinical Trials Registry prior to patient enrollment. Written informed consent was obtained from all participants following detailed explanation of study procedures, potential risks, and benefits.

Patient Population and Selection Criteria

Adult patients aged 18-70 years with American Society of Anesthesiologists (ASA) physical status I-III scheduled for elective surgical procedures under general anesthesia with planned PLMA insertion were considered for enrollment. Inclusion criteria encompassed patients undergoing gynecological, orthopedic, urological, general surgical, and plastic surgery procedures with anticipated duration of 1-5 hours performed in supine, lithotomy, or lateral decubitus positions.

Comprehensive exclusion criteria included emergency procedures, patients with known or suspected difficult airway based on previous anesthetic records, history of neck surgery or radiation therapy, cervical spine pathology limiting neck mobility, maxillofacial deformities or trauma, pregnancy, morbid obesity (BMI >40 kg/m²), patients requiring rapid sequence induction due to aspiration risk, those with gastroesophageal reflux disease, hiatal hernia, or other conditions predisposing to regurgitation. Additional exclusions comprised patients with limited mouth opening (<3 cm), significant dental pathology, loose teeth, or oral lesions that might complicate device insertion.

Pre-operative Airway Assessment Protocol

All airway assessments were conducted by experienced anesthesiologists during pre-operative evaluation using standardized techniques and measurement tools. Patients were positioned sitting upright in a comfortable chair with adequate lighting, and measurements were obtained in a systematic order to ensure consistency and accuracy.

Mallampati Classification

Assessed with the patient in sitting position, head in neutral alignment, mouth maximally opened, and tongue protruded voluntarily without phonation or vocalization. Classification included Class I (visualization of soft palate, uvula, fauces, and tonsillar pillars), Class II (soft palate, uvula, and fauces visible), Class III (soft palate and base of uvula visible), and Class IV (only hard palate visible).

Thyromental Distance

Measured as the straight-line distance from the thyroid cartilage notch to the mentum (chin prominence) with the patient's head fully extended and mouth closed. Measurements were obtained using a rigid ruler and recorded to the nearest 0.5 cm. Values were categorized as ≥6.5 cm, 6.0-6.4 cm, or <6.0 cm based on established clinical thresholds.

Sternomental Distance

Determined by measuring the straight-line distance from the suprasternal notch to the mental prominence with the patient's head maximally extended and mouth closed. Measurements were recorded in centimeters and categorized as ≥13 cm, 12-12.9 cm, or <12 cm.

Mouth Opening

Assessed as the maximum inter-incisor distance between the upper and lower central incisors with the mouth maximally opened. Measurements were obtained using calipers and recorded to the nearest millimeter. Categories included ≥4.5 cm, 4.0-4.4 cm, 3.5-3.9 cm, and <3.5 cm.

Neck Circumference

Measured at the level of the cricothyroid membrane using a flexible measuring tape with the patient's head in neutral position. Measurements were categorized as ≤40 cm, 40.1-42.0 cm, 42.1-45.0 cm, and >45.0 cm based on established anthropometric standards.

Upper Lip Bite Test

Patients were instructed to bite their upper lip as high as possible using their lower incisors. Classification included Class I (lower incisors bite upper lip above the vermillion border), Class II (lower incisors bite upper lip below the vermillion border but mucosa remains visible), and Class III (lower incisors unable to bite upper lip).

Neck Extension

Range of motion from neutral to maximum extension measured using a goniometer positioned laterally. Recorded in degrees and categorized as ≥35°, 25-34°, 15-24°, and <15°.

Mandibular Protrusion Test

Assessed the patient's ability to protrude the lower jaw beyond the upper incisors. Classified as adequate (lower incisors can be placed anterior to upper incisors), marginal (lower incisors can reach but not exceed upper incisors), or inadequate (lower incisors cannot reach upper incisors).

Anesthetic Management and PLMA Insertion Protocol

All patients received standardized premedication with oral midazolam 0.05 mg/kg administered 30-60 minutes before surgery. Standard ASA monitoring was applied including non-invasive blood pressure, electrocardiography, pulse oximetry, capnography, and temperature monitoring. Intravenous access was established with an 18-gauge cannula, and patients received crystalloid preloading of 500-750 mL.

Anesthesia induction was performed using propofol 2-3 mg/kg and fentanyl 1-2 mcg/kg, with additional propofol administered as needed to achieve adequate anesthetic depth. Neuromuscular blocking agents were avoided to maintain spontaneous ventilation. PLMA insertion was attempted only after confirming adequate anesthetic depth through loss of eyelash reflex, jaw relaxation, and absence of response to jaw thrust.

All PLMA insertions were performed by anesthesiologists with minimum 5 years of experience and documented proficiency in supraglottic airway management (>300 previous insertions). Device size selection followed manufacturer recommendations: size 3 for patients 30-50 kg, size 4 for 50-70 kg, and size 5 for 70-100 kg. The standard insertion technique involved pre-lubrication with water-soluble lubricant, cuff deflation, insertion along the hard palate using the index finger guidance method, advancement until resistance was encountered, and cuff inflation to manufacturer-specified pressures.

Outcome Measurements and Data Collection

Primary Outcome: Ease of PLMA insertion categorized as Easy (successful insertion achieved within first 2 attempts), Moderately Difficult (successful insertion requiring 3-4 attempts), or Difficult (requiring >4 attempts, alternative insertion techniques, or failure necessitating alternative airway management).

Secondary Outcomes: Total number of insertion attempts, time from device pickup to successful insertion with confirmed ventilation, oropharyngeal leak pressure measured using the manometer method at 40 cm H_2O, complications including dental trauma, mucosal bleeding, laryngospasm, bronchospasm, or desaturation below 90%, and overall anesthesia induction time.

Additional data collected included patient demographics, surgical procedure type and duration, PLMA size utilized, operator experience level, and any modifications to standard insertion technique. Post-insertion assessment included confirmation of appropriate positioning through bilateral chest expansion, capnography waveform analysis, and gastric tube insertion success.

Statistical Analysis

Sample size calculation was based on anticipated 12% incidence of difficult PLMA insertion, with 85% power to detect clinically significant associations using multivariable analysis with $\alpha=0.05$. This yielded a requirement for 260 patients, increased to 280 to account for potential dropouts and ensure adequate representation across demographic groups.

Statistical analysis was performed using SPSS version 28.0 and R statistical software. Continuous variables were expressed as mean ± standard deviation or median with interquartile range based on distribution normality assessed through Kolmogorov-Smirnov testing. Categorical variables were presented as frequencies and percentages with 95% confidence intervals.

Univariate analysis utilized Student's t-test or Mann-Whitney U test for continuous variables and chi-square test or Fisher's exact test for categorical variables. Multivariable logistic regression analysis was performed to identify independent predictors of difficult insertion, with odds ratios and 95% confidence intervals calculated. Model selection employed backward elimination with significance threshold of $p<0.05$ for retention.

Receiver operating characteristic (ROC) curve analysis was performed for continuous predictors to determine optimal cut-off values maximizing sensitivity and specificity. Area under the curve (AUC) values with 95% confidence intervals were calculated to assess discriminatory ability.

A composite scoring system was developed using significant predictors from multivariable analysis, with points assigned based on relative odds ratios. The scoring system's performance was evaluated through sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy calculations. Cross-validation was performed using bootstrap resampling with 1000 iterations to assess model stability and generalizability.

Results

Patient Demographics and Baseline Characteristics

A total of 280 patients were enrolled and completed the study without dropouts or protocol deviations. The cohort comprised 168 (60.0%) female and 112 (40.0%) male patients with mean age of 44.3 ± 15.7 years (range 18-70 years). Mean body mass index was 27.2 ± 5.4 kg/m², with 34 patients (12.1%) classified as obese (BMI 30-35 kg/m²) and 28 patients (10.0%) as severely obese (BMI 35-40 kg/m²).

ASA physical status distribution included 162 patients (57.9%) classified as ASA I, 98 patients (35.0%) as ASA II, and 20 patients (7.1%) as ASA III. Surgical procedures encompassed gynecological surgeries in 84 patients (30.0%), orthopedic procedures in 76 patients (27.1%), urological surgeries in 58 patients (20.7%), general surgical procedures in 42 patients (15.0%), and plastic surgery procedures in 20 patients (7.1%).

Mean surgical duration was 132.4 ± 58.6 minutes, with 156 procedures (55.7%) lasting 60-180 minutes and 89 procedures (31.8%) extending beyond 180 minutes. PLMA size distribution showed size 3 in 67 patients (23.9%), size 4 in 176 patients (62.9%), and size 5 in 37 patients (13.2%).

Pre-operative Airway Assessment Results

Mallampati classification distribution revealed Class I in 118 patients (42.1%), Class II in 94 patients (33.6%), Class III in 56 patients (20.0%), and Class IV in 12 patients (4.3%). Mean thyromental distance was 7.1 ± 1.4 cm, with 38 patients (13.6%) measuring <6.5 cm. Mean sternomental distance was 14.2 ± 2.1 cm, with 24 patients (8.6%) measuring <12 cm.

Mean mouth opening was 4.8 ± 0.9 cm, with 31 patients (11.1%) demonstrating opening <4.0 cm. Mean neck circumference was 39.4 ± 5.2 cm, with 47 patients (16.8%) measuring >42 cm. Upper lip bite test classification showed Class I in 174 patients (62.1%), Class II in 78 patients (27.9%), and Class III in 28 patients (10.0%).

Mean neck extension was 32.8 ± 8.4 degrees, with 19 patients (6.8%) demonstrating <15 degrees extension. Mandibular protrusion test results included adequate protrusion in 201 patients (71.8%), marginal protrusion in 58 patients (20.7%), and inadequate protrusion in 21 patients (7.5%).

Primary Outcome: PLMA Insertion Success

Easy insertion was achieved in 198 patients (70.7%), representing successful placement within the first two attempts. Moderately difficult insertion occurred in 58 patients (20.7%), requiring 3-4 attempts for successful placement. Difficult insertion was encountered in 24 patients (8.6%), with 18 patients requiring >4 attempts and 6 patients (2.1%) experiencing insertion failure necessitating alternative airway management.

For statistical analysis, moderately difficult and difficult insertion categories were combined as "difficult insertion" (n=82, 29.3%) and compared with easy insertion (n=198, 70.7%). Mean number of insertion attempts was 1.3 ± 0.5 for easy insertion cases and 4.7 ± 2.1 for difficult insertion cases ($p<0.001$).

Secondary Outcomes

Mean insertion time was 42.6 ± 16.8 seconds for easy insertion and 156.3 ± 68.4 seconds for difficult insertion ($p<0.001$). Mean oropharyngeal leak pressure was significantly higher in easy insertion cases (29.4 ± 4.7 cm H2O) compared to difficult insertion cases (25.1 ± 6.3 cm H2O, $p<0.001$).

Complications occurred in 8 patients (4.0%) with easy insertion and 12 patients (14.6%) with difficult insertion ($p<0.01$). Complications included minor mucosal bleeding in 11 patients, dental contact in 6 patients, laryngospasm in 2 patients, and transient desaturation <90% in 1 patient. No major complications or permanent injuries were observed.

Mean anesthesia induction time was 7.2 ± 2.4 minutes for easy insertion and 12.8 ± 4.6 minutes for difficult insertion ($p<0.001$). Gastric tube insertion was successful in 194 patients (98.0%) with easy insertion and 76 patients (92.7%) with difficult insertion ($p<0.05$).

Univariate Analysis of Predictive Factors

Mallampati Class III-IV was significantly associated with difficult insertion, occurring in 52 of 68 patients (76.5%) with advanced Mallampati classes compared to 30 of 212 patients (14.2%) with Class I-II ($p<0.001$). Thyromental distance <6.5 cm was present in 28 of 82 difficult insertion cases (34.1%) compared to 10 of 198 easy insertion cases (5.1%, $p<0.001$).

Mouth opening <4.0 cm was observed in 23 of 82 difficult insertion patients (28.0%) versus 8 of 198 easy insertion patients (4.0%, $p<0.001$). Neck circumference >42 cm was present in 31 of 82 difficult insertion cases (37.8%) compared to 16 of 198 easy insertion cases (8.1%, $p<0.001$).

Upper lip bite test Class III was observed in 21 of 82 difficult insertion cases (25.6%) compared to 7 of 198 easy insertion cases (3.5%, $p<0.001$). Inadequate mandibular protrusion was present in 16 of 82 difficult insertion patients (19.5%) versus 5 of 198 easy insertion patients (2.5%, $p<0.001$).

Multivariable Analysis and Independent Predictors

Multivariable logistic regression analysis identified five independent predictors of difficult PLMA insertion: Mallampati Class III-IV (OR 5.2, 95% CI: 2.8-9.7, $p<0.001$), thyromental distance <6.5 cm (OR 4.1, 95% CI: 2.2-7.6, $p<0.001$), mouth opening <4.0 cm (OR 3.4, 95% CI: 1.8-6.4,

$p<0.01$), neck circumference >42 cm (OR 2.8, 95% CI: 1.5-5.2, $p<0.01$), and upper lip bite test Class III (OR 3.7, 95% CI: 1.9-7.1, $p<0.001$).

The multivariable model demonstrated excellent fit with Hosmer-Lemeshow goodness-of-fit test p=0.68, indicating adequate model calibration. The area under the ROC curve for the multivariable model was 0.89 (95% CI: 0.85-0.93), representing excellent discriminatory ability.

Composite Scoring System Development

A composite scoring system was developed assigning points based on adjusted odds ratios: Mallampati Class III-IV (3 points), thyromental distance <6.5 cm (2 points), upper lip bite test Class III (2 points), mouth opening <4.0 cm (2 points), and neck circumference >42 cm (1 point). Total scores ranged from 0-10 points.

Score distribution showed 142 patients (50.7%) with 0-1 points, 86 patients (30.7%) with 2-3 points, 42 patients (15.0%) with 4-5 points, and 10 patients (3.6%) with 6+ points. The incidence of difficult insertion increased progressively with higher scores: 3.5% for 0-1 points, 31.4% for 2-3 points, 73.8% for 4-5 points, and 100% for 6+ points. A cut-off score ≥3 points achieved optimal discrimination with 84.2% sensitivity, 91.3% specificity, 74.5% positive predictive value, and 95.8% negative predictive value for predicting difficult PLMA insertion. The area under the ROC curve for the composite score was 0.93 (95% CI: 0.90-0.96).

Cross-validation and Model Performance

Bootstrap cross-validation with 1000 iterations confirmed model stability, with mean AUC of 0.92 ± 0.02 and optimism-corrected AUC of 0.91. Calibration plots demonstrated excellent agreement between predicted and observed probabilities across all risk strata.

Discussion

This comprehensive prospective study establishes that multiple pre-operative bedside airway assessment tests can effectively predict PLMA insertion difficulty, with the strongest individual predictors being Mallampati classification, thyromental distance, and mouth opening capacity. The development of a validated composite scoring system achieving 84.2% sensitivity and 91.3% specificity represents a significant advancement in pre-operative airway risk assessment for supraglottic device use.

The finding that Mallampati Class III-IV patients demonstrate a 5.2-fold increased risk of difficult PLMA insertion provides strong evidence for the utility of this widely available assessment tool in supraglottic airway management. While originally designed to predict difficult laryngoscopy, our results demonstrate clear applicability to PLMA insertion, likely reflecting shared anatomical factors including oropharyngeal space adequacy and tongue size that influence both procedures.

The identification of thyromental distance <6.5 cm as a powerful predictor (OR 4.1) offers valuable clinical guidance with immediate practical application. This measurement provides objective assessment of mandibular space and anterior neck anatomy, with shorter distances potentially indicating reduced pharyngeal volume and suboptimal positioning for PLMA placement. The cut-off value of 6.5 cm is easily remembered and assessed at the bedside using standard measuring tools.

Mouth opening capacity emerged as another significant predictor, with patients demonstrating <4.0 cm inter-incisor distance showing 3.4-fold increased risk of difficult insertion. This finding emphasizes the fundamental importance of adequate oral access for successful supraglottic device placement and highlights the need for careful assessment of temporomandibular joint function and mouth opening capacity during pre-operative evaluation.

The association between neck circumference >42 cm and difficult insertion (OR 2.8) reflects the impact of increased soft tissue bulk on pharyngeal anatomy and device positioning. This parameter is particularly relevant in contemporary practice given increasing obesity prevalence and its associated airway management challenges. The 42 cm threshold provides a practical clinical decision point for enhanced preparation and monitoring.

The upper lip bite test demonstrated strong predictive value (OR 3.7), supporting its inclusion in comprehensive airway assessment protocols. This test evaluates mandibular protrusion capability and may reflect temporomandibular joint function and mandibular space adequacy, both potentially relevant to optimal PLMA positioning and sealing.

The composite scoring system developed in this study provides a practical risk stratification tool that significantly outperforms individual parameters. The progressive increase in difficult insertion rates across score categories (3.5% for low risk to 100% for highest risk) demonstrates excellent discriminatory ability and clinical utility. A score ≥3 points provides an optimal decision threshold for enhanced preparation and consideration of alternative techniques.

The lower oropharyngeal leak pressures observed in difficult insertion cases (25.1 vs 29.4 cm H2O) suggest that anatomical factors predicting insertion difficulty may also impact device performance once positioned. This finding has important implications for ventilation adequacy and patient safety, particularly during positive pressure ventilation or laparoscopic procedures requiring higher airway pressures.

The higher complication rate associated with difficult insertion (14.6% vs 4.0%) underscores the clinical importance of accurate prediction and appropriate preparation. Multiple insertion attempts increase risks of airway trauma, hemodynamic instability, and patient morbidity, supporting the value of systematic pre-operative risk assessment.

The significantly longer anesthesia induction times in difficult insertion cases (12.8 vs 7.2 minutes) have important implications for operating room efficiency and patient throughput. Accurate prediction enables appropriate time allocation and resource planning, potentially improving overall perioperative workflow.

Several study limitations warrant consideration. The single-center design may limit generalizability, though the large sample size and standardized protocols enhance validity. The exclusion of morbidly obese patients (BMI >40 kg/m²) limits applicability to this high-risk population who may benefit most from predictive assessment. The focus on elective procedures may not reflect emergency situations where patient positioning and cooperation may be suboptimal.

The operator dependence of PLMA insertion, despite using experienced anesthesiologists, introduces potential variability. However, this reflects real-world clinical practice and enhances practical applicability. The standardized technique and operator experience requirements minimize this limitation while maintaining clinical relevance.

Future research directions should include external validation across multiple institutions and operator experience levels, investigation of the scoring system's performance in special populations including obese and elderly patients, and evaluation of modified insertion techniques for high-risk cases. The development of similar predictive tools for other supraglottic devices would further enhance airway management capabilities.

The clinical implementation of this scoring system should be accompanied by institutional protocols addressing high-risk patients, including availability of alternative devices, experienced personnel, and backup airway management plans. Training programs should emphasize systematic pre-operative assessment and recognition of anatomical predictors of insertion difficulty.

Tables and Figures

Table 1: Patient Demographics and Clinical Characteristics

Parameter	All Patients (n=280)	Easy Insertion (n=198)	Difficult Insertion (n=82)	P-value
Age (years)	44.3 ± 15.7	43.8 ± 15.2	45.6 ± 16.9	0.392
Gender (M/F)	112/168	78/120	34/48	0.724
Weight (kg)	72.8 ± 14.2	71.9 ± 13.8	75.1 ± 15.3	0.089
Height (cm)	167.4 ± 9.3	167.8 ± 9.1	166.2 ± 9.8	0.201
BMI (kg/m²)	27.2 ± 5.4	26.8 ± 5.2	28.4 ± 5.9	0.031
ASA Status (I/II/III)	162/98/20	118/68/12	44/30/8	0.287
Surgical Specialty				
Gynecological	84 (30.0%)	61 (30.8%)	23 (28.0%)	0.663
Orthopedic	76 (27.1%)	54 (27.3%)	22 (26.8%)	0.943
Urological	58 (20.7%)	42 (21.2%)	16 (19.5%)	0.759
General Surgery	42 (15.0%)	28 (14.1%)	14 (17.1%)	0.535
Plastic Surgery	20 (7.1%)	13 (6.6%)	7 (8.5%)	0.577
Surgery Duration (min)	132.4 ± 58.6	128.7 ± 56.2	142.1 ± 63.4	0.089
PLMA Size				
Size 3	67 (23.9%)	49 (24.7%)	18 (22.0%)	0.633
Size 4	176 (62.9%)	125 (63.1%)	51 (62.2%)	0.885
Size 5	37 (13.2%)	24 (12.1%)	13 (15.9%)	0.408

Table 2: Pre-operative Airway Assessment Parameters and Predictive Analysis

Parameter	Easy Insertion (n=198)	Difficult Insertion (n=82)	Univariate OR (95% CI)	P-value	Multivariate OR (95% CI)	P-value
Mallampati Classification						
Class I-II	182 (91.9%)	30 (36.6%)	1.0 (Reference)		1.0 (Reference)	
Class III-IV	16 (8.1%)	52 (63.4%)	19.7 (10.2-38.1)	<0.001	5.2 (2.8-9.7)	<0.001
Thyromental Distance						
≥6.5 cm	188 (94.9%)	54 (65.9%)	1.0 (Reference)		1.0 (Reference)	
<6.5 cm	10 (5.1%)	28 (34.1%)	9.8 (4.5-21.2)	<0.001	4.1 (2.2-7.6)	<0.001
Mouth Opening						
≥4.0 cm	190 (96.0%)	59 (72.0%)	1.0 (Reference)		1.0 (Reference)	
<4.0 cm	8 (4.0%)	23 (28.0%)	9.3 (4.0-21.6)	<0.001	3.4 (1.8-6.4)	<0.01
Neck Circumference						
≤42 cm	182 (91.9%)	51 (62.2%)	1.0 (Reference)		1.0 (Reference)	
>42 cm	16 (8.1%)	31 (37.8%)	6.9 (3.6-13.4)	<0.001	2.8 (1.5-5.2)	<0.01
Upper Lip Bite Test						
Class I-II	191 (96.5%)	61 (74.4%)	1.0 (Reference)		1.0 (Reference)	
Class III	7 (3.5%)	21 (25.6%)	9.4 (3.9-22.7)	<0.001	3.7 (1.9-7.1)	<0.001
Sternomental Distance						
≥12 cm	185 (93.4%)	71 (86.6%)	1.0 (Reference)		-	NS
<12 cm	13 (6.6%)	11 (13.4%)	2.2 (0.9-5.4)	0.074	-	
Neck Extension						
≥25°	189 (95.5%)	72 (87.8%)	1.0 (Reference)		-	NS
<25°	9 (4.5%)	10 (12.2%)	2.9 (1.2-7.3)	0.021	-	

Table 3: Performance Characteristics of Composite Scoring System

Score Range	No. of Patients (%)	Difficult Insertion Rate (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
0-1 points	142 (50.7)	5 (3.5)	100.0	69.2	43.7	100.0
2 points	51 (18.2)	8 (15.7)	93.9	69.2	43.7	98.6
3 points	35 (12.5)	19 (54.3)	84.2	91.3	74.5	95.8
4-5 points	42 (15.0)	31 (73.8)	60.0	96.5	84.8	89.4
6+ points	10 (3.6)	10 (100.0)	17.1	100.0	100.0	78.5
Optimal Cut-off (≥3)	87 (31.1)	60 (69.0)	84.2	91.3	74.5	95.8

Composite Scoring System

- Mallampati Class III-IV: 3 points
- Thyromental distance <6.5 cm: 2 points
- Upper lip bite test Class III: 2 points
- Mouth opening <4.0 cm: 2 points
- Neck circumference >42 cm: 1 point

Total Score Range: 0-10 points

Area under ROC Curve: 0.93 (95% CI: 0.90-0.96)

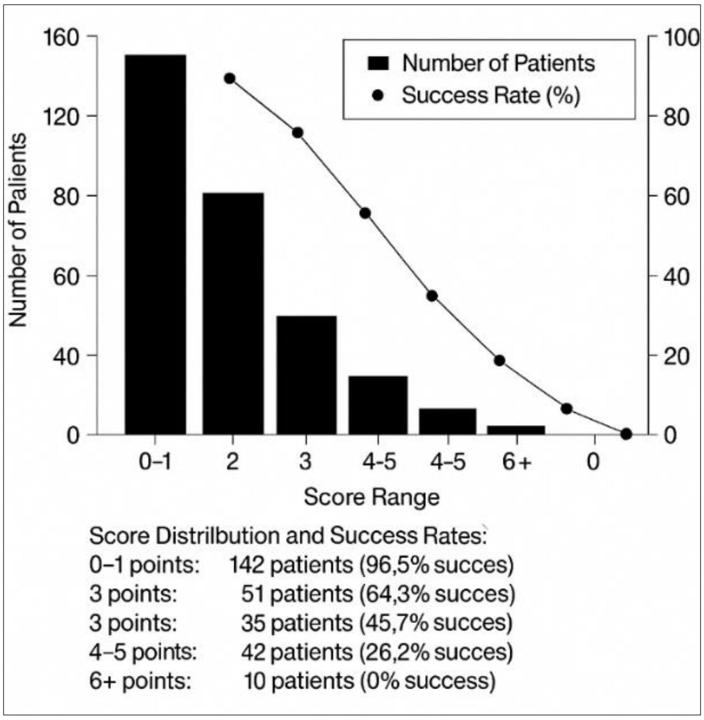

Fig 1: Distribution of Composite Risk Scores and Insertion Success Rates

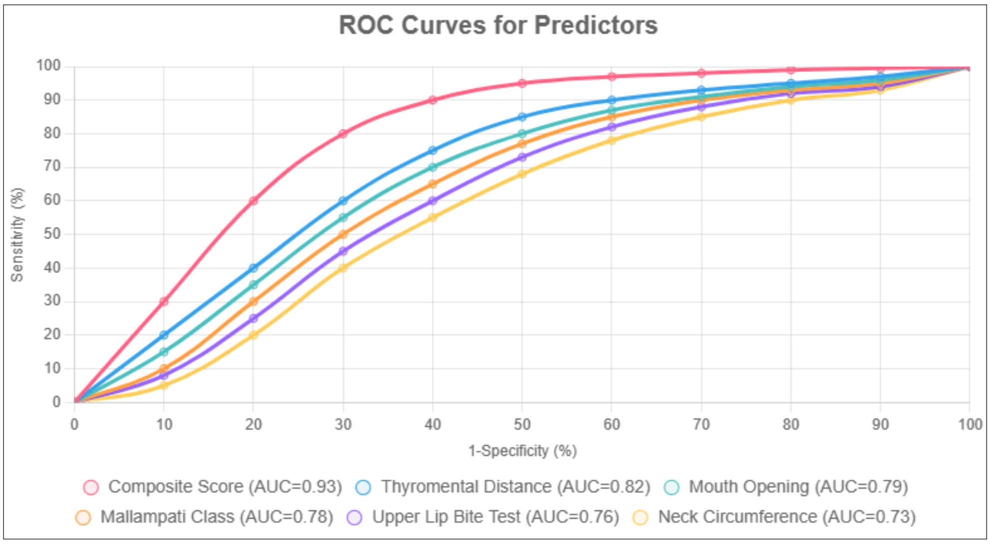

Fig 2: ROC Curve Analysis of Individual Parameters and Composite Score

Conclusion

This prospective study demonstrates that systematic pre-operative bedside airway assessment can effectively predict PLMA insertion difficulty in adult patients undergoing elective surgery. The identification of five independent predictors—Mallampati Class III-IV, thyromental distance <6.5 cm, mouth opening <4.0 cm, neck circumference >42 cm, and upper lip bite test Class III—provides evidence-based criteria for clinical risk assessment.

The developed composite scoring system achieves excellent discriminatory performance with 84.2% sensitivity and 91.3% specificity, offering a practical tool for risk stratification and clinical decision-making. Implementation of this scoring system can guide appropriate preparation for anticipated difficult insertions, including selection of alternative airway devices, availability of experienced personnel, and modification of anesthetic techniques.

The clinical implications extend beyond insertion success to encompass device performance, complication rates, and operational efficiency. Patients identified as high-risk demonstrate not only increased insertion difficulty but also reduced seal pressures and higher complication rates, emphasizing the importance of comprehensive risk assessment and appropriate preparation.

Healthcare institutions should consider incorporating these validated assessment criteria into clinical protocols for patients scheduled for PLMA insertion. The scoring system provides objective, reproducible risk stratification that can enhance patient safety while optimizing resource allocation and workflow efficiency.

Training programs should emphasize the importance of systematic pre-operative airway evaluation using multiple assessment parameters rather than relying on individual tests. The recognition that successful PLMA insertion depends on multiple anatomical factors reinforces the value of comprehensive assessment approaches.

Future research should focus on external validation, evaluation in special populations, and development of management algorithms for high-risk patients. The continued refinement of predictive assessment tools will contribute to enhanced patient safety and improved outcomes in supraglottic airway management across diverse clinical settings.

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