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Research Article

Comparative Evaluation of I-Gel and ProSeal Laryngeal Mask Airway in Patients Undergoing Elective Surgery Under General Anaesthesia: A Randomized Controlled Study

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ABSTRACT
Background: I-Gel and ProSeal laryngeal mask airway (PLMA) are widely used supraglottic airway devices during general anaesthesia. This study aimed to compare their insertion characteristics, airway sealing efficacy, haemodynamic responses, and complications.
Materials and Methods: This randomized controlled study included 150 patients undergoing elective surgery under general anaesthesia, divided equally into I-Gel (n = 75) and ProSeal LMA (n = 75) groups. Insertion characteristics, oropharyngeal leak pressure, ventilation parameters, haemodynamic responses, and complications were compared.
Results: Mean insertion time was significantly shorter with I-Gel (14.82 ± 3.64 versus 21.36 ± 5.18 seconds; $p<0.001$), with higher first-attempt success (93.33% versus 82.67%; $p = 0.044$). ProSeal LMA demonstrated higher oropharyngeal leak pressure (28.46 ± 4.18 versus 25.84 ± 3.62 cmH_2O; $p<0.001$). Postoperative sore throat (8.00% versus 22.67%; $p = 0.013$) and blood staining (4.00% versus 16.00%; $p = 0.027$) were less frequent with I-Gel.
Conclusion: I-Gel demonstrated easier insertion and fewer postoperative complications, whereas ProSeal LMA provided superior airway sealing. Both devices maintained satisfactory ventilation during elective surgery.

Keywords: I-Gel, ProSeal LMA, General anaesthesia, Supraglottic airway, Oropharyngeal leak pressure.

INTRODUCTION

Airway management is a fundamental component of general anaesthesia, ensuring adequate oxygenation and ventilation throughout surgical procedures[1]. Endotracheal intubation has traditionally been considered a reliable method of securing the airway; however, it may be associated with haemodynamic disturbances, airway trauma, coughing, and postoperative sore throat. Supraglottic airway devices (SGADs) have emerged as effective alternatives in appropriately selected patients undergoing elective surgery, offering easier insertion, reduced airway manipulation, and satisfactory ventilation without direct laryngoscopy.[1,2]Advancements in airway management have led to the development of second-generation SGADs with improved airway sealing and gastric drainage facilities. Among these, the I-Gel and ProSeal laryngeal mask airway (PLMA) are widely used because of their effectiveness and favourable safety profiles. Both devices facilitate ventilation during general anaesthesia, although differences in their design may influence insertion characteristics, airway sealing pressure, haemodynamic responses, and postoperative complications.[3,4]The ProSeal LMA incorporates an inflatable cuff that provides an effective seal around the laryngeal inlet and a separate drainage channel for gastric tube insertion. Its improved airway sealing characteristics facilitate positive-pressure ventilation; however, cuff inflation and manipulation during insertion may contribute to mucosal trauma and postoperative pharyngolaryngeal discomfort.[5,6] In contrast, the I-Gel is manufactured from a soft

thermoplastic elastomer and possesses a non-inflatable, anatomically shaped cuff that conforms to perilaryngeal structures. Its integrated gastric drainage channel and simplified insertion technique may facilitate rapid airway establishment while minimizing cuff-related complications.[7,8]Several randomized studies have compared the clinical performance of these devices. Jadhav et al. evaluated I-Gel and ProSeal LMA during short surgical procedures and demonstrated their effectiveness in maintaining ventilation, with differences in insertion characteristics and airway sealing performance.[9] Das et al. compared ProSeal LMA, I-Gel, and laryngeal tube suction-D in elective surgical patients and reported differences in insertion outcomes and oropharyngeal sealing pressures.[10] Similarly, Singh et al. assessed ProSeal LMA, I-Gel, and Supreme LMA and observed variations in insertion characteristics and airway sealing efficacy among the devices.[11]Recent investigations have further explored their comparative effectiveness under different surgical and ventilation conditions. Sule et al. evaluated I-Gel and ProSeal LMA during laparoscopic procedures, while Tan et al., in a meta-analysis, examined differences in oropharyngeal leak pressure and clinical performance.[12,13] Hemlata et al. compared both devices during spontaneous ventilation in daycare procedures, demonstrating their clinical utility.[14] Furthermore, a network meta-analysis by Kanakaraj et al. highlighted differences in the performance of various supraglottic airway devices, emphasizing the importance of appropriate device selection.[15]An ideal supraglottic airway device should permit rapid, atraumatic insertion, provide an adequate airway seal, maintain effective ventilation, and minimize haemodynamic disturbances and postoperative complications. Despite existing evidence, variations in patient characteristics, anaesthetic techniques, operator experience, and surgical procedures warrant further comparative evaluation. Therefore, the present randomized controlled study was designedto compare I-Gel and ProSeal LMA in patients undergoing elective surgery under general anaesthesia, focusing on insertion characteristics, ease of placement, insertion attempts, airway sealing efficacy, haemodynamic responses, and perioperative airway-related complications.

MATERIALS AND METHODS

Study Design and Setting

The present prospective, randomized controlled comparative study was conducted in the Department of Anaesthesiology at a tertiary care teaching hospital to compare the clinical performance of I-Gel and ProSeal laryngeal mask airway (PLMA) in patients undergoing elective surgical procedures under general anaesthesia. A total of 150 patients scheduled for elective surgical procedures under general anaesthesia were enrolled in the study. Patients fulfilling the eligibility criteria were randomly allocated into two equal groups of 75 patients each.

Study Groups

- **Group I (n = 75):** Patients in whom the I-Gel supraglottic airway device was used.
- **Group II (n = 75):** Patients in whom the ProSeal laryngeal mask airway was used.

Inclusion Criteria

Patients aged 18–60 years, belonging to American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective surgery under general anaesthesia, with an anticipated surgical duration of 30–120 minutes and suitable for supraglottic airway placement, were included.

Exclusion Criteria

Patients with anticipated difficult airway, restricted mouth opening, significant airway abnormalities, increased aspiration risk, symptomatic gastroesophageal reflux disease, morbid obesity (BMI ≥35 kg/m²), upper respiratory tract infection, pregnancy, or contraindications to supraglottic airway insertion were excluded.

Randomization and Group Allocation

Patients were randomly allocated into two groups in a 1:1 ratio using a computer-generated randomization sequence. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes opened before induction of anaesthesia. Blinding of the inserting anaesthesiologist was not feasible because of differences in device design.

Preoperative Assessment

All patients underwent detailed preanaesthetic evaluation, including medical history, physical examination, airway assessment, and relevant investigations. Airway evaluation included modified

Mallampati classification, mouth opening, thyromental distance, and neck mobility. Preoperative fasting was ensured, and baseline haemodynamic parameters were recorded.

Anaesthetic Technique

Standard monitoring, including electrocardiography, non-invasive blood pressure, pulse oximetry, and capnography, was established. After securing intravenous access, patients were preoxygenated with 100% oxygen for three minutes. General anaesthesia was induced using intravenous fentanyl (2 µg/kg) and propofol (2 mg/kg), with doses adjusted according to clinical requirements.

Following adequate anaesthetic depth, the allocated airway device was inserted by an experienced anaesthesiologist. Anaesthesia was maintained using oxygen, air, and an inhalational anaesthetic agent. Ventilation was adjusted to maintain appropriate end-tidal carbon dioxide levels.

Airway Device Insertion

Group I (I-Gel): An appropriately sized I-Gel was lubricated and inserted along the hard palate until resistance was encountered.

Group II (ProSeal LMA): An appropriately sized ProSeal LMA was inserted using the recommended technique, and the cuff was inflated according to the manufacturer's guidelines.

Correct placement in both groups was confirmed by bilateral chest expansion, adequate air entry, satisfactory capnography, and effective ventilation.

Assessment of Insertion Characteristics

Insertion time was measured from introduction of the device into the oral cavity until the appearance of the first satisfactory capnographic waveform. Ease of insertion was categorized as easy, moderate, or difficult. The number of insertion attempts and first-attempt success rate were recorded. A maximum of three attempts was permitted, after which an alternative airway management technique was used if insertion remained unsuccessful.

Assessment of Oropharyngeal Leak Pressure

Oropharyngeal leak pressure was measured after successful device placement by closing the adjustable pressure-limiting valve at a fresh gas flow of 3 L/min. The airway pressure at which an audible leak occurred was recorded, with a maximum pressure limit of 40 cmH_2O.

Haemodynamic Monitoring

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and peripheral oxygen saturation (SpO_2) were recorded at baseline, immediately before insertion, immediately after insertion, and at 1, 3, 5, and 10 minutes following device placement.

Assessment of Complications

Intraoperative complications, including air leakage, inadequate ventilation, oxygen desaturation, laryngospasm, bronchospasm, and device displacement, were recorded. Postoperative complications, including blood staining of the device, sore throat, dysphagia, hoarseness, and coughing, were assessed after device removal and during the first 24 postoperative hours.

Outcome Measures

Primary outcomes included insertion time, ease of insertion, first-attempt success rate, and oropharyngeal leak pressure.

Secondary outcomes included overall insertion success, haemodynamic changes, adequacy of ventilation, and perioperative airway-related complications.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using SPSS software.26 Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Independent Student's t-test or Mann–Whitney U test was used for continuous variables, while Chi-square or Fisher's exact test was applied for categorical variables. Repeated haemodynamic measurements were analysed using repeated-measures ANOVA or an appropriate mixed-effects model. A p-value less than 0.05 was considered statistically significant.

RESULTS

A total of 150 patients undergoing elective surgeries under general anaesthesia were included and equally divided into two groups: I-Gel (n = 75) and ProSeal LMA (n = 75).

The baseline characteristics were comparable between the two groups. The mean age was 38.64 ± 11.25 years in the I-Gel group and 39.12 ± 10.86 years in the

ProSeal LMA group (p = 0.791). Mean weight, BMI, gender distribution, ASA grade, and duration of surgery were also comparable, with no statistically significant differences (p > 0.05) (Table 1).

The mean insertion time was significantly shorter in the I-Gel group (14.82 ± 3.64 seconds) compared with the ProSeal LMA group (21.36 ± 5.18 seconds; p < 0.001). Easy insertion was more frequent with I-Gel (86.67% versus 68.00%; p = 0.006), while first-attempt success was significantly higher (93.33% versus 82.67%; p = 0.044). Overall insertion success was 100% with I-Gel and 98.67% with ProSeal LMA (p = 1.000) (Table 2).

Oropharyngeal leak pressure was significantly higher with ProSeal LMA (28.46 ± 4.18 cmH_2O) compared with I-Gel (25.84 ± 3.62 cmH_2O; p < 0.001). However, peak airway pressure, SpO_2, $EtCO_2$, adequate ventilation, air leakage, and successful gastric tube insertion were comparable between the groups (p > 0.05). Adequate ventilation was achieved in 98.67% of I-Gel patients and 97.33% of ProSeal LMA patients (Table 3).

Immediately after insertion, heart rate was significantly higher in the ProSeal LMA group (91.68 ± 11.24 beats/min) than in the I-Gel group (86.24 ± 10.16 beats/min; p = 0.002). This difference persisted at 1 minute (p = 0.004). Mean arterial pressure was also significantly higher with ProSeal LMA immediately after insertion (101.68 ± 10.42 versus 95.24 ± 9.16 mmHg; p < 0.001), at 1 minute (p < 0.001), and at 3 minutes (p = 0.039). Differences became nonsignificant at subsequent intervals (Table 4).

Intraoperative complications were infrequent and comparable between the groups. Air leakage occurred in 4.00% of I-Gel patients and 2.67% of ProSeal LMA patients. Inadequate ventilation, oxygen desaturation, laryngospasm, and device displacement showed no significant differences. Coughing during removal was more frequent with ProSeal LMA (9.33% versus 4.00%; p = 0.326), although statistically nonsignificant (Table 5 and Figure 1).

Postoperative sore throat was significantly more frequent in the ProSeal LMA group (22.67%) compared with the I-Gel group (8.00%; p = 0.013). Blood staining of the device was also significantly higher with ProSeal LMA (16.00% versus 4.00%; p = 0.027). Dysphagia (13.33% versus 4.00%), hoarseness (9.33% versus 2.67%), and postoperative coughing (12.00% versus 5.33%) were more frequent with ProSeal LMA, although these differences were not statistically significant (Table 6 and Figure 2).

BMI showed a significant positive correlation with insertion time in the ProSeal LMA group (r = 0.29; p = 0.012) but not in the I-Gel group (r = 0.18; p = 0.122). Significant negative correlations were observed between BMI and oropharyngeal leak pressure (r = −0.26; p = 0.024) and between insertion time and oropharyngeal leak pressure (r = −0.24; p = 0.038) in the ProSeal LMA group. Age showed no significant correlation with insertion time in either group (Table 7 and Figure 3).

Table 1. Comparison of Baseline Demographic and Clinical Characteristics (N = 150)

Parameter	I-Gel (n = 75)	ProSeal LMA (n = 75)	p-value	Statistical test
Age (years), Mean ± SD	38.64 ± 11.25	39.12 ± 10.86	0.791	Independent t-test
Weight (kg), Mean ± SD	62.45 ± 8.36	63.12 ± 8.74	0.632	Independent t-test
BMI (kg/m²), Mean ± SD	23.84 ± 2.91	24.12 ± 3.06	0.567	Independent t-test
Male, n (%)	42 (56.00)	40 (53.33)	0.743	Chi-square
Female, n (%)	33 (44.00)	35 (46.67)	0.743	Chi-square
ASA Grade I, n (%)	48 (64.00)	46 (61.33)	0.736	Chi-square
ASA Grade II, n (%)	27 (36.00)	29 (38.67)	0.736	Chi-square
Duration of surgery (min), Mean ± SD	72.46 ± 18.52	74.18 ± 19.36	0.579	Independent t-test

Table 2. Comparison of Airway Device Insertion Characteristics (N = 150)

Parameter	I-Gel (n = 75)	ProSeal LMA (n = 75)	p-value	Statistical test
Insertion time (seconds), Mean ± SD	14.82 ± 3.64	21.36 ± 5.18	**<0.001**	Independent t-test
Easy insertion, n (%)	65 (86.67)	51 (68.00)	**0.006**	Chi-square
Moderate insertion, n (%)	8 (10.67)	19 (25.33)	**0.019**	Chi-square
Difficult insertion, n (%)	2 (2.67)	5 (6.67)	0.442	Fisher's exact
First-attempt success, n (%)	70 (93.33)	62 (82.67)	**0.044**	Chi-square
Second-attempt success, n (%)	4 (5.33)	10 (13.33)	0.164	Fisher's exact
Third-attempt success, n (%)	1 (1.33)	2 (2.67)	1.000	Fisher's exact
Overall insertion success, n (%)	75 (100.00)	74 (98.67)	1.000	Fisher's exact

Table 3. Comparison of Oropharyngeal Leak Pressure and Ventilation Parameters (N = 150)

Parameter	I-Gel (n = 75)	ProSeal LMA (n = 75)	p-value	Statistical test
Oropharyngeal leak pressure (cmH_2O), Mean ± SD	25.84 ± 3.62	28.46 ± 4.18	**<0.001**	Independent t-test
Peak airway pressure (cmH_2O), Mean ± SD	16.42 ± 2.86	16.78 ± 3.12	0.463	Independent t-test
SpO_2 (%), Mean ± SD	99.12 ± 0.74	99.06 ± 0.82	0.639	Independent t-test
$EtCO_2$ (mmHg), Mean ± SD	35.84 ± 2.46	36.12 ± 2.68	0.506	Independent t-test
Adequate ventilation, n (%)	74 (98.67)	73 (97.33)	1.000	Fisher's exact
Audible air leakage, n (%)	3 (4.00)	2 (2.67)	1.000	Fisher's exact
Successful gastric tube insertion, n (%)	73 (97.33)	70 (93.33)	0.442	Fisher's exact

Table 4. Comparison of Haemodynamic Parameters at Different Time Intervals (N = 150)

Parameter / Time interval	I-Gel (n = 75)	ProSeal LMA (n = 75)	p-value	Statistical test
Heart rate (beats/min)				
Baseline	82.46 ± 9.24	83.12 ± 9.68	0.670	Independent t-test
Immediately after insertion	86.24 ± 10.16	91.68 ± 11.24	**0.002**	Independent t-test
1 minute	84.36 ± 9.72	89.24 ± 10.62	**0.004**	Independent t-test
3 minutes	82.84 ± 9.18	85.46 ± 9.86	0.094	Independent t-test
5 minutes	81.72 ± 8.94	83.18 ± 9.26	0.327	Independent t-test
10 minutes	80.94 ± 8.62	81.76 ± 8.84	0.566	Independent t-test
Mean arterial pressure (mmHg)				
Baseline	92.46 ± 8.62	93.12 ± 8.94	0.646	Independent t-test
Immediately after insertion	95.24 ± 9.16	101.68 ± 10.42	**<0.001**	Independent t-test
1 minute	93.84 ± 8.72	99.26 ± 9.64	**<0.001**	Independent t-test

Parameter / Time interval	I-Gel (n = 75)	ProSeal LMA (n = 75)	p-value	Statistical test
3 minutes	92.18 ± 8.46	95.12 ± 8.82	**0.039**	Independent t-test
5 minutes	91.24 ± 8.18	92.86 ± 8.42	0.234	Independent t-test
10 minutes	90.68 ± 7.96	91.42 ± 8.14	0.574	Independent t-test

Table 5. Comparison of Intraoperative Airway-Related Complications (N = 150)

Complication	I-Gel (n = 75)	ProSeal LMA (n = 75)	p-value	Statistical test
Air leakage, n (%)	3 (4.00)	2 (2.67)	1.000	Fisher's exact
Inadequate ventilation, n (%)	1 (1.33)	2 (2.67)	1.000	Fisher's exact
Oxygen desaturation, n (%)	1 (1.33)	2 (2.67)	1.000	Fisher's exact
Laryngospasm, n (%)	0 (0.00)	1 (1.33)	1.000	Fisher's exact
Bronchospasm, n (%)	0 (0.00)	0 (0.00)	—	Not applicable
Device displacement, n (%)	1 (1.33)	2 (2.67)	1.000	Fisher's exact
Coughing during removal, n (%)	3 (4.00)	7 (9.33)	0.326	Fisher's exact

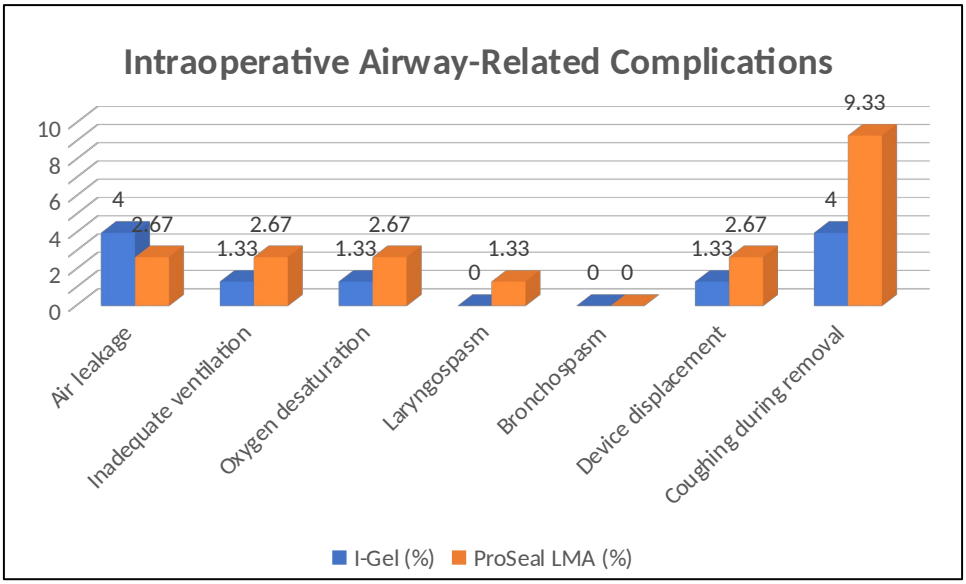

Figure 1. Comparison of Intraoperative Airway-Related Complications (N = 150)

Table 6. Comparison of Postoperative Airway-Related Complications (N = 150)

Complication	I-Gel (n = 75)	ProSeal LMA (n = 75)	p-value	Statistical test
Sore throat, n (%)	6 (8.00)	17 (22.67)	0.013	Chi-square
Dysphagia, n (%)	3 (4.00)	10 (13.33)	0.078	Fisher's exact
Hoarseness of voice, n (%)	2 (2.67)	7 (9.33)	0.166	Fisher's exact
Blood staining of device, n (%)	3 (4.00)	12 (16.00)	0.027	Fisher's exact
Postoperative coughing, n (%)	4 (5.33)	9 (12.00)	0.147	Chi-square
Nausea and vomiting, n (%)	5 (6.67)	7 (9.33)	0.765	Fisher's exact

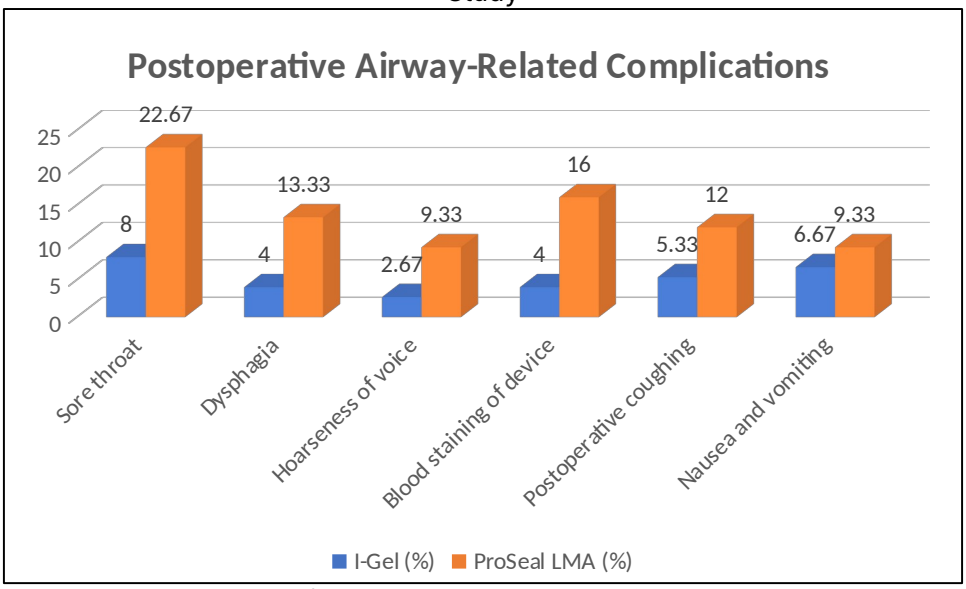

Figure 2. Comparison of Postoperative Airway-Related Complications (N = 150)

Table 7. Correlation of Insertion Time and Oropharyngeal Leak Pressure with Selected Patient Characteristics (N = 150)

Variables correlated	Group	Pearson's r	p-value	Statistical test
BMI vs insertion time	I-Gel	0.18	0.122	Pearson correlation
BMI vs insertion time	ProSeal LMA	0.29	0.012	
BMI vs oropharyngeal leak pressure	I-Gel	−0.21	0.070	
BMI vs oropharyngeal leak pressure	ProSeal LMA	−0.26	0.024	
Insertion time vs oropharyngeal leak pressure	I-Gel	−0.16	0.170	
Insertion time vs oropharyngeal leak pressure	ProSeal LMA	−0.24	0.038	
Age vs insertion time	I-Gel	0.12	0.305	
Age vs insertion time	ProSeal LMA	0.19	0.102	

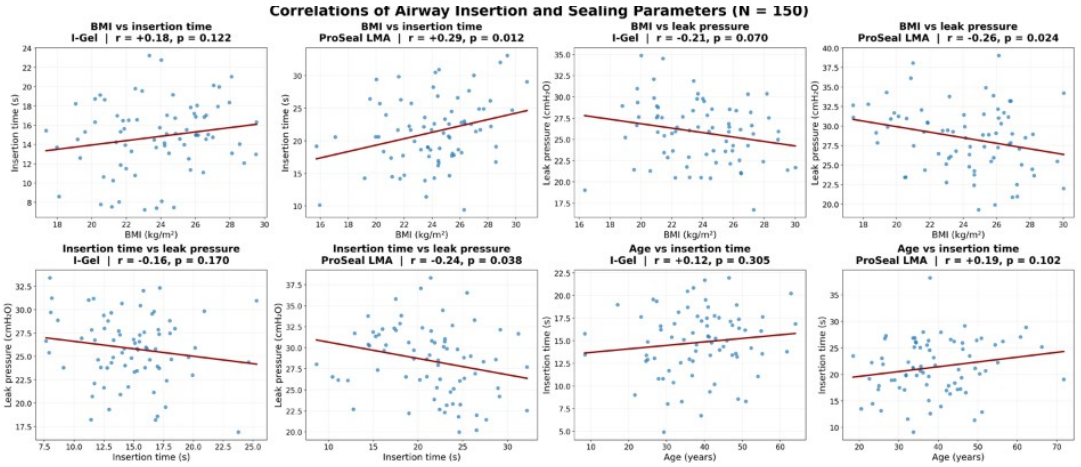

Figure 3. Correlation of Insertion Time and Oropharyngeal Leak Pressure with Selected Patient Characteristics (N = 150)

DISCUSSION

In the present study, mean age was 38.64 ± 11.25 years in the I-Gel group and 39.12 ± 10.86 years in the ProSeal LMA group (p = 0.791). Mean BMI was also comparable (23.84 ± 2.91 versus 24.12 ± 3.06 kg/m²; p = 0.567). Similarly, Singh et al.[11] (n = 84), Jadhav et al.[16] (n = 60), and Chauhan et al.[17] (n = 80) reported comparable baseline characteristics, supporting appropriate between-group comparisons.

In the present study, I-Gel demonstrated significantly shorter insertion time than ProSeal LMA (14.82 ± 3.64 versus 21.36 ±

5.18 seconds; p<0.001), with higher first-attempt success (93.33% versus 82.67%; p = 0.044). Similarly, Jadhav et al.[16] reported insertion times of 29.53 ± 8.23 versus 41.00 ± 9.41 seconds, while Chauhan et al.[17] observed 11.12 ± 1.81 versus 15.13 ± 2.91 seconds (p = 0.001), favouring I-Gel. Singh et al.[11] also reported significantly longer insertion time with ProSeal LMA (p = 0.001). These findings suggest that I-Gel facilitates faster airway placement.

In the present study, ProSeal LMA demonstrated significantly higher leak pressure than I-Gel (28.46 ± 4.18 versus 25.84 ± 3.62 cmH_2O; p<0.001). Similarly, Singh et al.[11] reported 32.64 ± 4.14 versus 26.71 ± 3.45 cmH_2O, Jadhav et al.[16] observed 25.73 ± 2.21 versus 20.07 ± 2.94 cmH_2O, and Chauhan et al.[17] reported 29.55 ± 3.53 versus 26.73 ± 2.52 cmH_2O, respectively. All three studies supported superior airway sealing with ProSeal LMA.

In the present study, peak airway pressure (16.42 ± 2.86 versus 16.78 ± 3.12 cmH_2O; p = 0.463) and SpO_2 (99.12% versus 99.06%; p = 0.639) were comparable. Gastric tube insertion was successful in 97.33% of I-Gel and 93.33% of ProSeal LMA patients. Jadhav et al.[16] also reported satisfactory ventilation with both devices. Chauhan et al.[17] observed easier gastric tube insertion with I-Gel (p = 0.001), whereas Singh et al.[11] reported longer gastric tube insertion time with I-Gel (p = 0.001).

In the present study, heart rate immediately after insertion was lower with I-Gel than ProSeal LMA (86.24 ± 10.16 versus 91.68 ± 11.24 beats/min; p = 0.002). Mean arterial pressure was also lower (95.24 ± 9.16 versus 101.68 ± 10.42 mmHg; p<0.001). However, Singh et al.[11] and Jadhav et al.[16] reported comparable haemodynamic responses between devices, suggesting that both generally provide satisfactory haemodynamic stability.

In the present study, air leakage occurred in 4.00% of I-Gel patients and 2.67% of ProSeal LMA patients, while oxygen desaturation occurred in 1.33% and 2.67%, respectively (both p = 1.000). Jadhav et al.[16] reported no significant difference in overall adverse events, while Singh et al.[11] found acceptable clinical performance with all three devices. Chauhan et al.[17] also reported satisfactory airway management without major complications. These findings indicated comparable intraoperative safety in the studied populations.

In the present study, postoperative sore throat was less frequent with I-Gel than ProSeal LMA (8.00% versus 22.67%; p = 0.013), as was blood staining (4.00% versus 16.00%; p = 0.027). Similarly, Jadhav et al.[16] reported greater postoperative throat discomfort with ProSeal LMA, while Chauhan et al.[17] observed more sore throat, dysphagia, and blood staining with ProSeal LMA. However, Singh et al.[11] reported comparable pharyngolaryngeal morbidity among the devices. The non-inflatable cuff of I-Gel may contribute to reduced mucosal trauma.

CONCLUSION

The present study suggested that I-Gel provided shorter insertion time, higher first-attempt success, and fewer postoperative airway-related complications compared with ProSeal LMA. However, ProSeal LMA demonstrated superior oropharyngeal sealing pressure. Both devices provided satisfactory ventilation, with I-Gel offering potential advantages in ease of insertion and postoperative patient comfort.

LIMITATIONS

The study was limited by its single-centre design, relatively small sample size, and inability to blind the anaesthesiologist performing device insertion. Additionally, inclusion of only ASA I–II patients undergoing elective surgery limited the generalizability of findings to high-risk patients and difficult airway situations.

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