



Original Article

Clinical Effects of Reduced ProSeal Laryngeal Mask Airway Cuff Pressure During General Anaesthesia

Sudharani¹, Sukha Prada K², Sailaja K³, Vasanth Kumar J⁴

¹Assistant Professor, Department of Anaesthesiology, Mahavir Institute of Medical Sciences, Shivareddypet, Vikarabad, Telangana, India

²Assistant Professor, Department of Anaesthesiology, Mahavir Institute of Medical Sciences, Shivareddypet, Vikarabad, Telangana, India

³Associate Professor, Department of Anaesthesiology, Mahavir Institute of Medical Sciences, Shivareddypet, Vikarabad, Telangana, India

⁴Professor & HOD, Department of Anaesthesia and Emergency Medicine, Akash Institute of Medical Sciences and Research Institute, Devanahalli, Bangalore rural district, Karnataka, India

OPEN ACCESS

Corresponding Author:

Dr. Sudharani

(M.D) Assistant Professor,
Department of Anaesthesiology,
Mahavir Institute of Medical
Sciences, Shivareddypet, Vikarabad,
Telangana, India

Received: 12-04-2026

Accepted: 28-05-2026

Available online: 30-06-2026

ABSTRACT

Background: Inflatable supraglottic airway cuffs must provide an effective seal without exerting avoidable pressure on the pharyngeal mucosa. The ProSeal laryngeal mask airway (PLMA) offers a high-pressure seal, but the cuff pressure that best balances ventilation and postoperative airway comfort remains clinically relevant. The current study is designed to compare a low PLMA cuff pressure of 45 cmH₂O with a normal cuff pressure of 60 cmH₂O in relation to peri-insertion hemodynamic response, oropharyngeal leak pressure, and postoperative pharyngolaryngeal adverse events.

Methods: This randomized, open-label comparative study enrolled 60 adults aged 18 to 60 years with American Society of Anesthesiologists physical status I or II who underwent elective surgery under general anesthesia at hospitals attached to Bangalore Medical College and Research Institute between February 2021 and August 2022. Participants were allocated in equal numbers to cuff pressures of 45 cmH₂O (Group L) or 60 cmH₂O (Group N). Anesthetic management and PLMA insertion were standardized. Heart rate and arterial pressures were recorded serially. Oropharyngeal leak pressure was measured at 10, 30, and 50 minutes. Device blood staining, cough, and sore throat were assessed postoperatively. Analyses were specified in IBM SPSS Statistics for Windows, version 28.0.

Results: All 60 randomized participants completed the study. Age-category distribution and sex were comparable between groups. Mean oropharyngeal leak pressure remained approximately 2 cmH₂O lower with 45 cmH₂O cuff pressure at 10 minutes (28.01±0.26 vs 30.03±0.18 cmH₂O), 30 minutes (28.10±0.26 vs 30.02±0.18 cmH₂O), and 50 minutes (28.00±0.26 vs 30.01±0.18 cmH₂O; all reported p<0.001), while remaining above commonly accepted pressures for controlled ventilation. Heart rate and arterial pressures were lower in Group L at several intraoperative measurements, although baseline imbalance and internal inconsistencies in the source summary tables restrict causal interpretation. Blood staining occurred in 0/30 versus 5/30 participants (Pearson $\chi^2=5.455$, p=0.020), while cough and sore throat each occurred in 0/30 versus 4/30 participants (Pearson $\chi^2=4.286$, p=0.038). Exact-test sensitivity analyses were not statistically significant because event counts were small.

Conclusion: A PLMA cuff pressure of 45 cmH₂O produced a modest reduction in leak pressure but retained a clinically satisfactory seal and was associated with fewer observed airway complaints. The hemodynamic findings should be interpreted cautiously and verified against participant-level records before publication. Routine cuff manometry and avoidance of unnecessarily high pressure

Keywords: ProSeal laryngeal mask airway; cuff pressure; oropharyngeal leak pressure; hemodynamic response; postoperative sore throat; supraglottic airway device; airway morbidity.

INTRODUCTION

Supraglottic airway devices occupy an established position between facemask ventilation and tracheal intubation. Their routine use has reduced the need for direct laryngoscopy in suitable operations and can limit the pressor response, airway irritation, and postoperative discomfort associated with passage of a tracheal tube. The ProSeal laryngeal mask airway is a second-generation device that incorporates a larger, dual-component cuff and a drain tube. These features improve separation of the respiratory and alimentary tracts and usually generate a higher oropharyngeal leak pressure than first-generation laryngeal masks [1,2].

The clinical performance of an inflatable laryngeal mask depends not only on device design and position but also on the pressure within its cuff. Insufficient pressure may result in an inadequate seal, gas leakage, gastric insufflation, and ineffective positive-pressure ventilation. Excessive pressure can increase the force transmitted to the pharyngeal mucosa, impair local perfusion, and contribute to sore throat, dysphagia, hoarseness, cough, mucosal injury, or visible blood on the device [3-5]. Cuff inflation by volume or tactile estimation alone is unreliable because the pressure-volume relation varies between individuals and devices. Manometry therefore provides a direct means of maintaining a predefined pressure throughout anesthesia [5,6].

Several randomized studies have shown that limiting cuff pressure reduces postoperative pharyngolaryngeal morbidity without compromising ventilation [4-11]. The magnitude of benefit, however, depends on device type, cuff material, anesthetic gas mixture, surgical duration, and the pressure chosen for comparison. A lower pressure may also reduce the mechanical stimulus produced by cuff expansion after insertion and could attenuate transient changes in heart rate and arterial pressure. Evidence on this hemodynamic effect is less consistent than evidence on postoperative throat symptoms [7].

The PLMA generally provides a robust seal and is suitable for controlled ventilation in appropriately selected fasted patients [1,2,12,13]. Because its design already favors a high seal pressure, a cuff pressure below the conventional upper limit of 60 cmH₂O may preserve airway security while reducing mucosal compression. The present study compared 45 cmH₂O and 60 cmH₂O during standardized general anesthesia, with serial hemodynamic measurements, repeated assessment of oropharyngeal leak pressure, and documentation of short-term airway adverse events. The primary aim was to determine whether a PLMA cuff pressure of 45 cmH₂O altered the hemodynamic response compared with a cuff pressure of 60 cmH₂O. The measured hemodynamic variables were heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure. Secondary objectives were to compare oropharyngeal leak pressure and the occurrence of device blood staining, postoperative cough, and sore throat.

MATERIALS AND METHODS

Study design and setting

A prospective, randomized, open-label, parallel-group comparative study was conducted in hospitals attached to Bangalore Medical College and Research Institute, Bengaluru, India, from February 2021 through August 2022. The study evaluated two predefined PLMA intracuff pressures during elective operations performed under general anesthesia. The source dissertation described the work as a randomized comparative trial and reported complete follow-up for all enrolled participants.

Ethical considerations

Approval was obtained from the institutional ethics committee of Bangalore Medical College and Research Institute before recruitment, and written informed consent was obtained from every participant. The ethics approval number was not stated in the source document and should be inserted from the institutional record before submission. The study was conducted in accordance with accepted ethical principles for research involving human participants. Prospective trial registration was not reported in the dissertation.

Participants

Adults of either sex, aged 18 to 60 years, with American Society of Anesthesiologists physical status I or II and scheduled for elective surgery using a PLMA under general anesthesia were eligible. Exclusion criteria were refusal of consent, known allergy or hypersensitivity to a laryngeal mask airway, recent upper respiratory tract infection or pre-existing pharyngolaryngeal symptoms, body mass index above 40 kg/m², treatment with antihypertensive medication, laparoscopic surgery, head and neck surgery, or an expected surgical duration exceeding 120 minutes. These restrictions

were intended to reduce confounding from difficult ventilation, altered airway pressures, pre-existing throat complaints, and prolonged device exposure.

Randomization and allocation

Sixty participants were allocated in a 1:1 ratio using computer-generated numbers obtained from randomization.org. Group L received a target PLMA cuff pressure of 45 cmH₂O, and Group N received a target pressure of 60 cmH₂O. Each group contained 30 participants. The trial was open label because the anesthesiologist managing the airway had to view and adjust the manometer. The source document did not describe allocation concealment or blinded postoperative outcome assessment.

Preoperative preparation and anesthetic technique

A detailed preanesthetic assessment was completed on the day before surgery. In the operating theatre, electrocardiography, noninvasive arterial pressure, pulse oximetry, and capnography were applied, and intravenous access was established. Premedication comprised glycopyrrolate 0.01 mg/kg, fentanyl 2 µg/kg, and midazolam 0.05 mg/kg intravenously. Participants were preoxygenated with 100% oxygen at 6 L/min for three minutes. Anesthesia was induced with propofol 2 mg/kg, and vecuronium 0.1 mg/kg was administered after confirming adequate facemask ventilation.

PLMA insertion and cuff-pressure intervention

After three minutes of assisted ventilation, an appropriately sized PLMA was inserted by one experienced anesthesiologist. The cuff was inflated and connected to a Portex cuff inflator pressure gauge. Intracuff pressure was adjusted to 45 cmH₂O in Group L or 60 cmH₂O in Group N and was monitored during the operation so that the assigned target was maintained. Correct placement was defined by bilateral chest expansion, a square capnographic waveform, and absence of an audible oral leak at a peak airway pressure of 25 cmH₂O. When ventilation was unsatisfactory, the device was manipulated or reinserted. Failure after three attempts required tracheal intubation and exclusion, although no such exclusion was reported.

Ventilation and maintenance of anesthesia

Mechanical ventilation was delivered using a tidal volume of 7 mL/kg ideal body weight, a respiratory rate of 12 to 14 breaths/min, and 5 cmH₂O of positive end-expiratory pressure. Ventilation was considered adequate when chest movement was symmetrical, oxygen saturation remained above 95%, and end-tidal carbon dioxide was within the clinically accepted range. Anesthesia was maintained with an oxygen-air mixture at an inspired oxygen fraction of approximately 0.50, sevoflurane at 1.5% to 2.4%, and intermittent vecuronium 0.02 mg/kg as required.

Outcome measurements

Heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were recorded before induction, immediately after PLMA insertion, and at serial intraoperative time points. The protocol listed measurements at 2, 4, 6, 8, 10, 20, 30, 40, 50, and 60 minutes. The summary tables did not contain a complete 6-minute series, and the 40-minute heart-rate row was blank. These unavailable observations were not reconstructed.

Oropharyngeal leak pressure was measured at 10, 30, and 50 minutes after insertion. With a fresh-gas flow of 3 L/min, the adjustable pressure-limiting valve was closed and airway pressure was allowed to rise to equilibrium, subject to a safety ceiling of 40 cmH₂O. Leakage was assessed by listening over the mouth and by epigastric auscultation. At the end of surgery, sevoflurane was discontinued, neuromuscular block was antagonized with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg, and the PLMA was removed after adequate recovery. The lips, teeth, and tongue were inspected, the removed device was examined for blood, and participants were questioned about cough and sore throat immediately and at 4 and 12 hours. The source results presented a single cumulative count for each adverse event rather than time-specific severity scores.

Sample-size determination

The sample size was based on an earlier comparison in which mean seal pressures were 24.1±3.1 and 26.2±3.9 cmH₂O. Using a two-sided 5% significance level, 80% power, and an allowance for attrition, the dissertation specified a final sample of 30 participants per group, giving a total sample size of 60.

Statistical analysis

Statistical analysis was specified using IBM SPSS Statistics for Windows, version 28.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as mean±standard deviation and compared between groups using the independent-samples Student t test. Categorical variables were reported as number and percentage and compared using Pearson's chi-square test. Because the adverse-event tables contained expected cell counts below five, Fisher's exact test was additionally considered as a sensitivity analysis. A two-sided p value below 0.05 was regarded as statistically significant. The source file contained group-level summary tables but not participant-level data; consequently, repeated-

measures modeling, baseline-adjusted analysis, and verification of distributional assumptions could not be performed during manuscript reconstruction.

RESULTS

Participant flow

Sixty eligible patients were approached, consented, randomized, and included in the analysis. Thirty participants received a cuff pressure of 45 cmH₂O and 30 received 60 cmH₂O. The source report did not record failed insertion, conversion to tracheal intubation, withdrawal, or loss to postoperative assessment. The analyzed population therefore comprised all 60 randomized participants.

Baseline characteristics

The age-category distribution was similar between groups (Pearson $\chi^2=0.269$, df=3, p=0.966). In Group L, eight participants were aged 21 to 30 years, eight were 31 to 40 years, six were 41 to 50 years, and eight were 51 to 60 years. The corresponding counts in Group N were nine, seven, seven, and seven. Each group contained 15 women and 15 men (Pearson $\chi^2=0.000$, df=1, p=1.000). Baseline demographic balance is summarized in Table 1.

Table 1: Baseline demographic distribution

Characteristic	Group L, n=30	Group N, n=30	χ^2	df	p value
Age 21–30 years	8 (26.7)	9 (30.0)	0.269	3	0.966
Age 31–40 years	8 (26.7)	7 (23.3)			
Age 41–50 years	6 (20.0)	7 (23.3)			
Age 51–60 years	8 (26.7)	7 (23.3)			
Female sex	15 (50.0)	15 (50.0)	0.000	1	1.000
Male sex	15 (50.0)	15 (50.0)			

Values are n (%). Group L: cuff pressure 45 cmH₂O; Group N: cuff pressure 60 cmH₂O. Pearson chi-square tests were transcribed from the source analysis. The dissertation's narrative mean-age values were inconsistent with the stated age range and were therefore not reproduced

Hemodynamic response

The source summary tables showed lower heart rate and arterial pressure in Group L at several time points after insertion. Heart rate did not differ immediately after PLMA insertion (83.17±6.60 vs 85.10±6.18 beats/min, p=0.246), but lower values were reported in Group L at 2, 4, 8, 20, and 60 minutes (all p<0.001). Mean arterial pressure was lower in Group L at 2 minutes (81.03±10.95 vs 89.07±4.95 mmHg, p=0.001), 4 minutes (79.83±5.80 vs 83.17±5.74 mmHg, p=0.029), and from 8 through 50 minutes at the available measurements (all p<0.001). Selected values are presented in Table 2, and the descriptive profiles are shown in Figures 1 and 2.

Interpretation of the heart-rate findings requires caution. Baseline heart rate was markedly higher in Group L (99.03±0.72 vs 81.13±7.21 beats/min, p<0.001), while several values were duplicated across time and the 40-minute observation was absent. These features suggest possible transcription, coding, or table-generation errors. Accordingly, the displayed profile is descriptive and should not be treated as a definitive baseline-adjusted treatment effect.

Table 2: Selected heart-rate and mean arterial-pressure measurements

Measurement	Group L mean±SD	Group N mean±SD	t value	p value
Baseline HR	99.03±0.72	81.13±7.21	13.531	<0.001
Immediately after insertion HR	83.17±6.60	85.10±6.18	−1.171	0.246
2-min HR	74.67±5.50	95.83±7.09	−12.921	<0.001
4-min HR	77.37±7.21	99.50±13.18	−8.069	<0.001
8-min HR	81.43±7.15	94.40±10.16	−5.718	<0.001
20-min HR	77.37±7.21	97.80±11.35	−8.320	<0.001
60-min HR	81.07±6.05	125.23±5.33	−30.003	<0.001
Baseline MAP	71.27±5.12	72.80±5.75	−1.091	0.280
Immediately after insertion MAP	76.73±8.44	80.63±6.87	−1.963	0.054
2-min MAP	81.03±10.95	89.07±4.95	−3.662	0.001
4-min MAP	79.83±5.80	83.17±5.74	−2.238	0.029
8-min MAP	72.63±4.16	88.60±5.77	−12.291	<0.001
20-min MAP	79.83±5.80	92.27±6.36	−7.909	<0.001
30-min MAP	71.27±5.12	89.07±4.95	−13.695	<0.001
40-min MAP	79.83±5.80	88.60±5.77	−6.757	<0.001
50-min MAP	71.27±5.12	92.83±5.34	−16.064	<0.001
60-min MAP	72.20±4.14	74.57±8.45	−1.377	0.174

HR: heart rate in beats/min; MAP: mean arterial pressure in mmHg. Values are transcribed from the dissertation's group summary tables. The protocol listed a 6-min measurement, but no complete 6-min row was available. The 40-min HR row was blank. The 10-min MAP value for Group N had an implausibly large SD and was omitted from the main table and figure pending source-data verification. Reported $p=.000$ values are expressed as $p<0.001$.

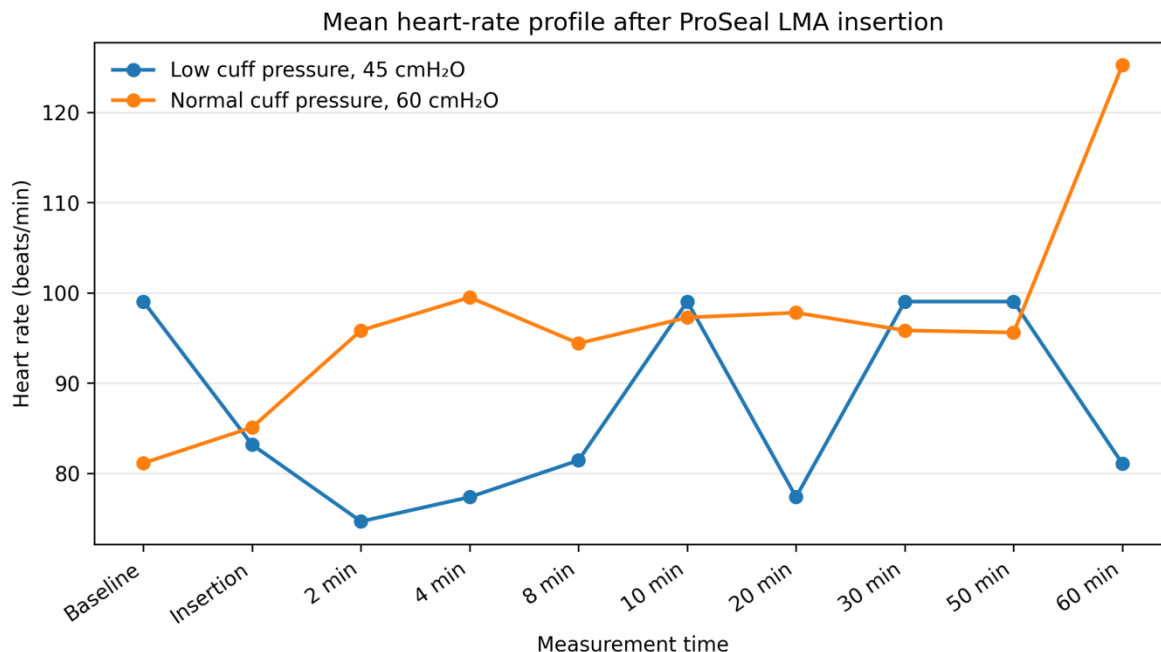


Figure 1: Mean heart-rate profile in the two cuff-pressure groups. The plotted values are unadjusted means transcribed from the source summary table. The 40-minute value was unavailable. Baseline imbalance and repeated values across time limit interpretation.

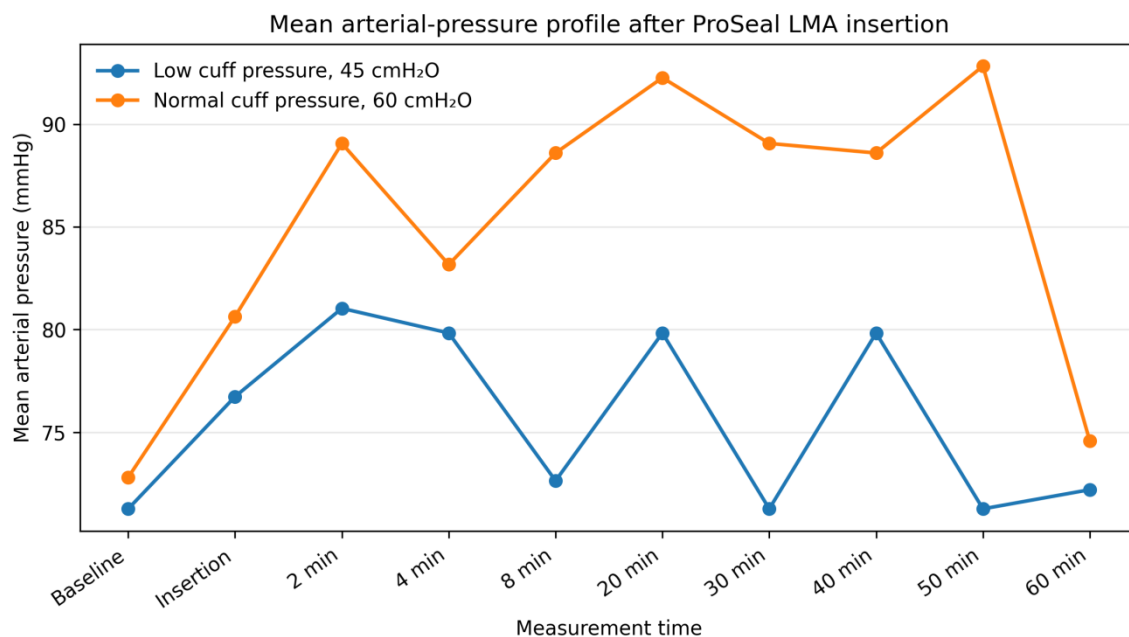


Figure 2: Mean arterial-pressure profile in the two cuff-pressure groups. The source-table 10-minute value for Group N was excluded from the figure because its standard deviation and mean were internally implausible and require checking against the original case records.

Systolic pressure was comparable immediately after insertion (120.70 ± 7.10 vs 121.20 ± 6.21 mmHg, $p=0.773$) and at 2 minutes (122.00 ± 6.23 vs 125.10 ± 8.48 mmHg, $p=0.112$), but lower values were reported in Group L at 4, 8, 20, 30, 40, and 60 minutes. Diastolic pressure was similar immediately after insertion (70.53 ± 6.06 vs 71.57 ± 5.06 mmHg, $p=0.476$), followed by lower Group L values at all available intraoperative measurements from 2 to 60 minutes. Table 3 gives the principal comparisons, and Figures 3 and 4 show the reported mean profiles.

Table 3: Selected systolic and diastolic blood-pressure measurements

Measurement	Group L mean±SD	Group N mean±SD	t value	p value
Baseline SBP	118.63±7.90	122.70±5.48	-2.331	0.024
Immediately after insertion SBP	120.70±7.10	121.20±6.21	-0.290	0.773
2-min SBP	122.00±6.23	125.10±8.48	-1.613	0.112
4-min SBP	121.20±6.79	125.23±5.33	-2.560	0.013
8-min SBP	118.63±7.90	126.20±10.87	-3.083	0.003
20-min SBP	118.63±7.90	128.37±7.42	-4.918	<0.001
30-min SBP	120.70±7.10	125.10±8.48	-2.183	0.033
40-min SBP	118.63±7.90	127.07±10.37	-3.544	0.001
60-min SBP	121.07±6.07	125.10±8.48	-2.118	0.039
Baseline DBP	69.60±5.22	73.20±7.75	-2.112	0.039
Immediately after insertion DBP	70.53±6.06	71.57±5.06	-0.718	0.476
2-min DBP	72.47±5.00	80.87±7.63	-5.039	<0.001
4-min DBP	70.47±6.27	74.57±8.45	-2.135	0.037
8-min DBP	69.60±5.22	87.67±5.38	-13.203	<0.001
10-min DBP	70.53±6.06	90.77±5.60	-13.436	<0.001
20-min DBP	69.60±5.22	87.03±5.99	-12.021	<0.001
30-min DBP	70.53±6.06	80.87±7.63	-5.799	<0.001
40-min DBP	69.60±5.22	81.53±6.65	-7.738	<0.001
50-min DBP	70.53±6.06	90.77±5.60	-13.436	<0.001
60-min DBP	70.10±5.96	80.87±7.63	-6.085	<0.001

SBP: systolic blood pressure; DBP: diastolic blood pressure; units: mmHg. The 10- and 50-min Group N SBP values in the source table were 167.10±227.75 mmHg and appeared to be duplicated or miscoded; they were omitted pending verification. Baseline SBP and DBP were statistically different, so unadjusted post-insertion comparisons may be confounded by baseline imbalance

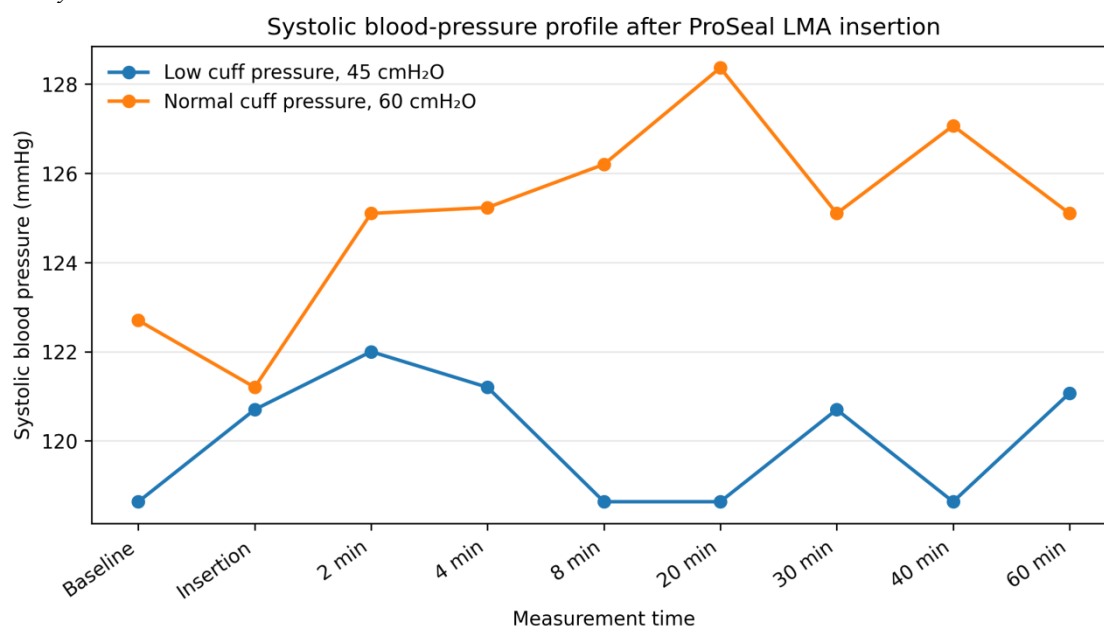


Figure 3: Systolic blood-pressure profile. The 10- and 50-minute source values were omitted because they were internally implausible. Lines represent unadjusted group means.

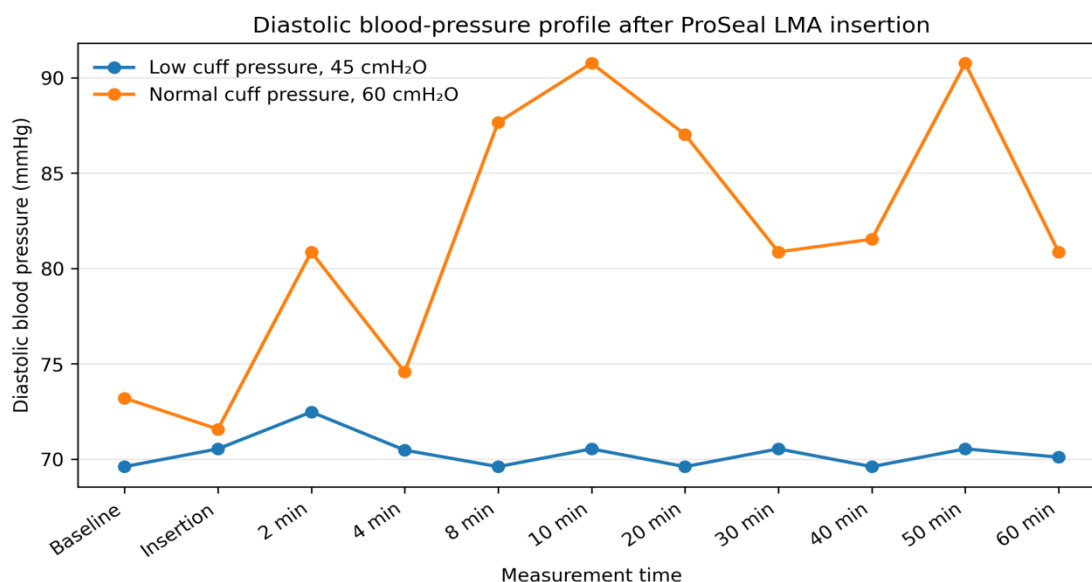


Figure 4: Diastolic blood-pressure profile. Values are unadjusted means from the source summary table and should be verified using participant-level records before inferential repeated-measures analysis.

Oropharyngeal leak pressure

Oropharyngeal leak pressure was consistently higher in Group N. At 10 minutes, mean pressure was 28.01 ± 0.26 cmH₂O in Group L and 30.03 ± 0.18 cmH₂O in Group N. The corresponding values were 28.10 ± 0.26 and 30.02 ± 0.18 cmH₂O at 30 minutes, and 28.00 ± 0.26 and 30.01 ± 0.18 cmH₂O at 50 minutes. Each reported comparison had $p < 0.001$ (Table 4). Thus, reducing cuff pressure from 60 to 45 cmH₂O lowered the measured seal by approximately 2 cmH₂O, but the mean seal in Group L remained near 28 cmH₂O throughout the observation period. The stable separation between groups is illustrated in Figure 5.

Table 4. Oropharyngeal leak pressure after PLMA insertion

Time	Group L, cmH ₂ O	Group N, cmH ₂ O	Reported t	p value
10 min	28.013 ± 0.263	30.033 ± 0.183	51.945	<0.001
30 min	28.103 ± 0.263	30.023 ± 0.183	51.945	<0.001
50 min	28.003 ± 0.263	30.013 ± 0.183	51.945	<0.001

Values are mean $\pm$ SD. Group L: cuff pressure 45 cmH₂O; Group N: cuff pressure 60 cmH₂O. The same t value was printed for all three measurements in the source table. Because participant-level data were unavailable, this value could not be independently verified

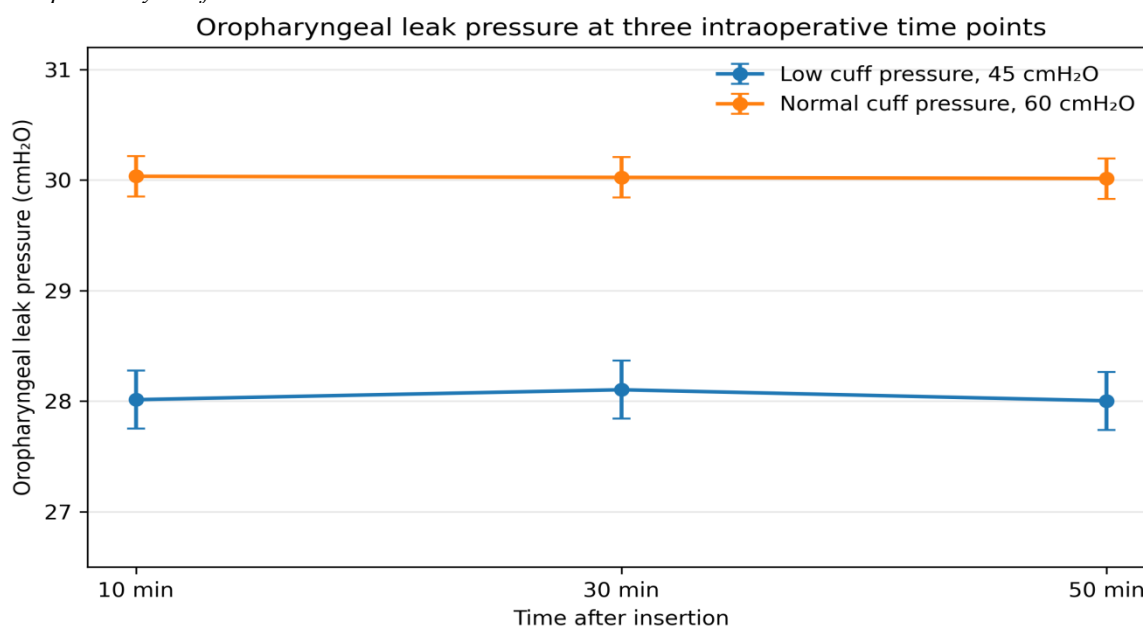


Figure 5: Oropharyngeal leak pressure at 10, 30, and 50 minutes. Points show mean values and error bars show the reported standard deviation.

Postoperative airway adverse events

No participant in Group L had visible blood staining of the PLMA, postoperative cough, or sore throat. In Group N, blood staining occurred in five participants (16.7%), cough in four (13.3%), and sore throat in four (13.3%). Pearson chi-square analysis gave $p=0.020$ for blood staining and $p=0.038$ for both cough and sore throat (Table 5 and Figure 6). Because one cell contained zero events and expected counts were small, Fisher's exact tests were examined as a sensitivity analysis. The two-sided exact p values were 0.052 for blood staining and 0.112 for cough and sore throat. These exact results support a clear numerical reduction but not a definitive inferential conclusion at the conventional 0.05 threshold.

Table 5.:Postoperative pharyngolaryngeal adverse events

Outcome	Group L, n (%)	Group N, n (%)	Pearson χ^2	Pearson p	Fisher p
Blood staining	0 (0.0)	5 (16.7)	5.455	0.020	0.052
Cough	0 (0.0)	4 (13.3)	4.286	0.038	0.112
Sore throat	0 (0.0)	4 (13.3)	4.286	0.038	0.112

Group L: cuff pressure 45 cmH₂O; Group N: cuff pressure 60 cmH₂O. Pearson values were reported in the dissertation. Two-sided Fisher exact p values were calculated from the displayed 2×2 counts because expected frequencies were below five. No correction for multiple secondary outcomes was applied

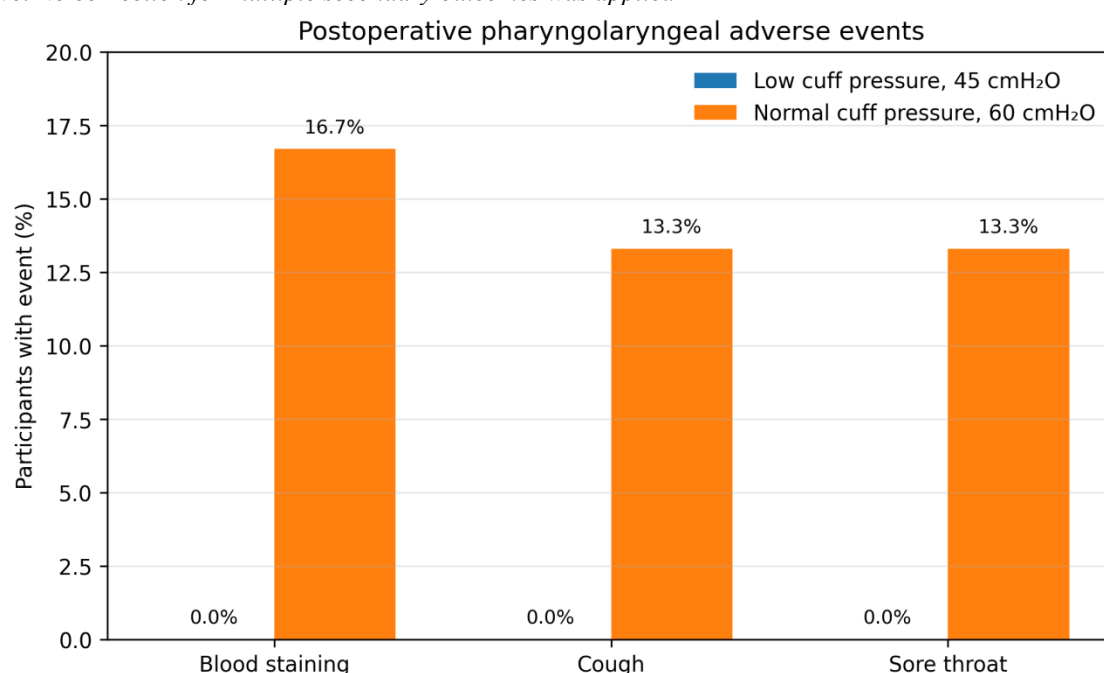


Figure 6: Incidence of postoperative device blood staining, cough, and sore throat. Event counts were small; exact-test results are provided in Table 5

DISCUSSION

Principal findings

This randomized comparison found that reducing PLMA cuff pressure from 60 to 45 cmH₂O decreased oropharyngeal leak pressure by about 2 cmH₂O without reducing the mean seal below 28 cmH₂O. The lower-pressure group also had no recorded device blood staining, cough, or sore throat, whereas each event occurred in 13% to 17% of participants managed at 60 cmH₂O. The source tables reported lower heart rate and arterial pressure at numerous intraoperative measurements in the low-pressure group. That hemodynamic pattern is directionally consistent with less pharyngeal stimulation, but baseline imbalances and several implausible or duplicated entries prevent an unqualified causal interpretation.

Cuff pressure and hemodynamic response

Insertion of any airway device can activate sympathetic responses through contact with pharyngeal and laryngeal structures. A supraglottic device generally produces less stimulation than laryngoscopy and tracheal intubation, yet expansion of an inflatable cuff may still produce a transient pressor response. Ali and colleagues compared 45 and 60 cmH₂O using the Supreme laryngeal mask airway and reported lower heart rate and mean arterial pressure with the lower cuff pressure [7]. The present study was designed around a similar physiological premise and likewise recorded lower values at several time points.

The internal structure of the current hemodynamic dataset, however, raises important analytical concerns. Baseline heart rate differed by nearly 18 beats/min, and baseline systolic and diastolic pressures also differed significantly. Some mean and standard-deviation combinations were duplicated at nonadjacent time points, the 40-minute heart-rate row was blank, and selected Group N pressure values were not physiologically credible. A series of independent t tests does not account for within-participant correlation and increases the probability of false-positive findings when many time points are examined. The preferred analysis would use a linear mixed model or repeated-measures analysis with treatment, time, treatment-by-time interaction, and baseline adjustment. Such analysis requires the original participant-level dataset. Therefore, the hemodynamic findings in this manuscript are best considered provisional.

Oropharyngeal leak pressure and ventilation

The PLMA was developed to improve the seal obtainable with the classic laryngeal mask and to provide a drain channel for gastric access [1,2]. Its larger ventral cuff, dorsal component, and deeper bowl explain why it commonly achieves leak pressures suitable for controlled ventilation [12-18]. In the present study, raising cuff pressure from 45 to 60 cmH₂O increased the mean leak pressure from approximately 28 to 30 cmH₂O. The difference was statistically large because variability in the summary table was very small, but the absolute change was modest.

Comparable pressure-dependent effects have been reported with other second-generation devices. Zhang and colleagues demonstrated that intracuff pressure influences oropharyngeal leak pressure with the LMA Supreme [9]. Ali et al. reported a reduction of roughly 2 cmH₂O at 45 cmH₂O compared with 60 cmH₂O, without loss of airway security [7]. Studies comparing PLMA with i-gel, Supreme, and classic devices consistently show that device design and cuff behavior materially influence the achieved seal [14-25]. A mean leak pressure near 28 cmH₂O is generally adequate for the ventilation strategy used in this study, in which peak airway pressure at placement testing was 25 cmH₂O and participants undergoing laparoscopic or prolonged surgery were excluded.

Postoperative pharyngolaryngeal morbidity

The lower event counts at 45 cmH₂O are biologically plausible. Pressure exerted by an inflated cuff can reduce pharyngeal mucosal perfusion and cause localized compression or abrasion. Continuous pressure limitation has reduced sore throat and other pharyngolaryngeal complaints in randomized trials [3-6,8,10,11]. Seet et al. found that cuff manometry substantially reduced composite postoperative pharyngolaryngeal adverse events compared with routine inflation [5]. Karthik et al. similarly reported fewer complications when PLMA cuff pressure was monitored and maintained below 60 cmH₂O [6]. Waruingi et al. showed benefit from reducing pressure to approximately 30 to 32 cmH₂O in spontaneously breathing adults [11]. These findings support routine manometry rather than inflation to a fixed volume or subjective pilot-balloon tension.

The current adverse-event results should nevertheless be interpreted by effect size and event count rather than by Pearson p values alone. With only four or five events in the normal-pressure group and none in the low-pressure group, expected frequencies were below the usual chi-square threshold. Fisher's exact sensitivity analysis did not reach p<0.05. A larger trial with blinded assessment, predefined severity grading, and time-specific follow-up would provide more stable estimates. Even so, the complete absence of recorded events in Group L, combined with an adequate seal, favors avoiding unnecessary cuff pressure when clinical conditions do not demand the maximum available seal.

Clinical implications

The practical message is not that every PLMA should be fixed at one pressure, but that cuff pressure should be measured and titrated. A target near 45 cmH₂O may be appropriate for many nonlaparoscopic elective procedures when airway pressure is modest and the device is correctly positioned. Clinicians should confirm effective ventilation, observe the capnogram, check for oral and gastric leakage, and reassess pressure after changes in head position, anesthetic gas composition, or surgical conditions. When higher inspiratory pressures are anticipated, the pressure should be individualized to the minimum that maintains an effective seal. The upper recommended limit should not become an automatic inflation target.

Strengths and limitations

The study used randomized allocation, equal group sizes, a standardized anesthetic technique, insertion by one experienced operator, manometric confirmation of cuff pressure, and repeated leak-pressure assessment. These features reduce variability related to operator skill and anesthetic management. The comparison also addressed both functional performance and patient-centered airway morbidity.

Several limitations are important. The study was conducted at one institution and included only 60 relatively healthy adults. Participants with severe obesity, antihypertensive treatment, laparoscopic procedures, head and neck surgery, or operations longer than two hours were excluded, limiting external validity. The trial was open label, and blinding of postoperative assessment was not reported. The adverse events were not graded for severity or presented separately at the immediate, 4-hour, and 12-hour assessments. No participant-level dataset was available for manuscript reconstruction.

Consequently, baseline adjustment, repeated-measures analysis, confidence intervals, missing-data review, and independent verification of the tables were not possible. The source tables contain internal inconsistencies that must be reconciled with case-record forms and the original SPSS file before submission. Finally, trial registration and the ethics approval number were not documented in the source manuscript.

CONCLUSION

In adults undergoing selected elective procedures under general anesthesia, a PLMA cuff pressure of 45 cmH₂O produced an oropharyngeal leak pressure approximately 2 cmH₂O lower than that obtained at 60 cmH₂O, while maintaining a mean seal near 28 cmH₂O. Postoperative blood staining, cough, and sore throat were observed only in the 60 cmH₂O group, although exact-test analyses were limited by the small number of events. The reported hemodynamic differences favoring lower cuff pressure are hypothesis-supporting rather than definitive because of baseline imbalance and inconsistencies in the source tables. Cuff manometry and titration to the lowest pressure that provides effective ventilation are supported by the functional and airway-morbidity findings. Verification against the original participant-level dataset is essential before journal submission.

Funding

No external funding was reported in the source document.

Conflict of interest

The authors should provide their current conflict-of-interest declarations before submission. No conflict was reported in the source document.

REFERENCES

1. Brain AIJ, Verghese C, Strube PJ. The LMA 'ProSeal': a laryngeal mask with an oesophageal vent. *Br J Anaesth.* 2000;84(5):650-654. doi:10.1093/bja/84.5.650.
2. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: a randomized, crossover study with the standard laryngeal mask airway in paralysed, anesthetized patients. *Anesthesiology.* 2000;93(1):104-109. doi:10.1097/00000542-200007000-00019.
3. Brimacombe J, Holyoake L, Keller C, Brimacombe N, Scully M, Barry J, et al. Pharyngolaryngeal, neck, and jaw discomfort after anesthesia with the face mask and laryngeal mask airway at high and low cuff volumes in males and females. *Anesthesiology.* 2000;93(1):26-31. doi:10.1097/00000542-200007000-00009.
4. Burgard G, Möllhoff T, Prien T. The effect of laryngeal mask cuff pressure on postoperative sore throat incidence. *J Clin Anesth.* 1996;8(3):198-201. doi:10.1016/0952-8180(95)00229-4.
5. Seet E, Yousaf F, Gupta S, Subramanyam R, Wong DT, Chung F. Use of manometry for optimizing laryngeal mask airway cuff pressure and reducing pharyngolaryngeal adverse events. *Anesthesiology.* 2010;112(3):652-657. doi:10.1097/ALN.0b013e3181cf4346.
6. Vasanth Karthik R, Ranganathan P, Kulkarni AP, Sharma KS. Does cuff pressure monitoring reduce postoperative pharyngolaryngeal adverse events after LMA-ProSeal insertion? A parallel group randomised trial. *J Anesth.* 2014;28(5):662-667. doi:10.1007/s00540-014-1811-0.
7. Ali A, Altun D, Sivriköz N, Yornuk M, Turgut N, Akinci IO. Comparison of different cuff pressure use with the Supreme laryngeal mask airway on haemodynamic response, seal pressure and postoperative adverse events: a prospective randomized study. *Turk J Anaesthesiol Reanim.* 2018;46(2):151-157. doi:10.5152/TJAR.2017.89587.
8. Kang JE, Oh CS, Choi JW, Son IS, Kim SH. Postoperative pharyngolaryngeal adverse events with laryngeal mask airway in laparoscopic surgical procedures with cuff pressure limiting 25 cmH₂O: a prospective, randomized study. *ScientificWorldJournal.* 2014;2014:709801. doi:10.1155/2014/709801.
9. Zhang L, Seet E, Mehta V, Subramanyam R, Ankichetty SP, Wong DT, et al. Oropharyngeal leak pressure with the laryngeal mask airway Supreme at different intracuff pressures: a randomized controlled trial. *Can J Anaesth.* 2011;58(7):624-629. doi:10.1007/s12630-011-9514-6.
10. Jeon YS, Choi JW, Jung HS, Kim YS, Kim DW, Kim JH, et al. Effect of continuous cuff pressure regulator in general anaesthesia with laryngeal mask airway. *J Int Med Res.* 2011;39(5):1900-1907. doi:10.1177/147323001103900534.
11. Waruingi D, Mung'ayi V, Gisore E, Wanyonyi S. A randomised controlled trial of the effect of laryngeal mask airway manometry on postoperative sore throat in spontaneously breathing adult patients presenting for surgery at a university teaching hospital. *Afr Health Sci.* 2019;19(1):1705-1715. doi:10.4314/ahs.v19i1.47.
12. Keller C, Brimacombe J, Bittersohl J, Lirk P, von Goedecke A. Aspiration and the laryngeal mask airway: three cases and a review of the literature. *Br J Anaesth.* 2004;93(4):579-582. doi:10.1093/bja/aeh213.
13. Schmidbauer W, Bercker S, Volk T, Bogusch G, Mager G, Kerner T. Oesophageal seal of the novel supralaryngeal airway device i-gel in comparison with the laryngeal mask airways Classic and ProSeal using a cadaver model. *Br J Anaesth.* 2009;102(1):135-139. doi:10.1093/bja/aen319.

14. Park SK, Choi GJ, Choi YS, Ahn EJ, Kang H. Comparison of the i-gel and the laryngeal mask airway ProSeal during general anesthesia: a systematic review and meta-analysis. *PLoS One*. 2015;10(3):e0119469. doi:10.1371/journal.pone.0119469.
15. Gasteiger L, Brimacombe J, Perkhofer D, Kaufmann M, Keller C. Comparison of guided insertion of the LMA ProSeal versus the i-gel. *Anaesthesia*. 2010;65(9):913-916. doi:10.1111/j.1365-2044.2010.06422.x.
16. Beleña JM, Núñez M, Anta D, Carnero M, Gracia JL, Ayala JL, et al. Comparison of Laryngeal Mask Airway Supreme and Laryngeal Mask Airway ProSeal with respect to oropharyngeal leak pressure during laparoscopic cholecystectomy: a randomised controlled trial. *Eur J Anaesthesiol*. 2013;30(3):119-123. doi:10.1097/EJA.0b013e32835aba6a.
17. Maltby JR, Beriault MT, Watson NC, Liepert D, Fick GH. The LMA-ProSeal is an effective alternative to tracheal intubation for laparoscopic cholecystectomy. *Can J Anaesth*. 2002;49(8):857-862. doi:10.1007/BF03017420.
18. Natalini G, Franceschetti ME, Pantelidi MT, Rosano A, Lanza G, Bernardini A. Comparison of the standard laryngeal mask airway and the ProSeal laryngeal mask airway in obese patients. *Br J Anaesth*. 2003;90(3):323-326. doi:10.1093/bja/aeg060.
19. Uppal V, Gangaiah S, Fletcher G, Kinsella J. Randomized crossover comparison between the i-gel and the LMA-Unique in anaesthetized, paralysed adults. *Br J Anaesth*. 2009;103(6):882-885. doi:10.1093/bja/aep292.
20. Ragazzi R, Finessi L, Farinelli I, Alvisi R, Volta CA. LMA Supreme versus i-gel: a comparison of insertion success in novices. *Anaesthesia*. 2012;67(4):384-388. doi:10.1111/j.1365-2044.2011.07002.x.
21. Verghese C, Ramaswamy B. LMA-Supreme, a new single-use LMA with gastric access: a report on its clinical efficacy. *Br J Anaesth*. 2008;101(3):405-410. doi:10.1093/bja/aen174.
22. Cook TM, Lee G, Nolan JP. The ProSeal laryngeal mask airway: a review of the literature. *Can J Anaesth*. 2005;52(7):739-760. doi:10.1007/BF03016565.
23. Chen X, Jiao J, Cong X, Liu L, Wu X. A comparison of the performance of the i-gel versus the LMA-S during anesthesia: a meta-analysis of randomized controlled trials. *PLoS One*. 2013;8(8):e71910. doi:10.1371/journal.pone.0071910.
24. Chew EEF, Hashim NHM, Wang CY. Randomised comparison of the LMA Supreme with the i-gel in spontaneously breathing anaesthetised adult patients. *Anaesth Intensive Care*. 2010;38(6):1018-1022. doi:10.1177/0310057X1003800609.
25. Verghese C, Berlet J, Kapila A, Pollard R. Clinical assessment of the single use laryngeal mask airway, the LMA-Unique. *Br J Anaesth*. 1998;80(5):677-679. doi:10.1093/bja/80.5.677.