

ORIGINAL RESEARCH

GENERAL ANESTHESIA

Laryngeal mask airway cuff pressure and its influence on the incidence of pharyngolaryngeal adverse effects: need for regular monitoring

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Abstract

Background: During general anesthesia with laryngeal mask airway (LMA), cuff pressure needs to be maintained at an optimal level in order to prevent endothelial lesions and postoperative pharyngolaryngeal side effects, like cough, sore throat, hoarseness and even mucosal bleeding. This study evaluated the changes in the LMA cuff pressure after insertion with the passage of time and the effect of the increased pressure on the incidence of pharyngolaryngeal adverse effects.

Methodology: Sixty patients (18-60 y) belonging to American Society of Anesthesiologists (ASA) I or II, meeting the inclusion and exclusion criteria were included in the study and were randomly grouped into Groups A and B (n=30 each). They were evaluated and educated about LMA insertion, its advantages and side effects, following which written informed consent was obtained. Pre-anesthetic evaluation was carried out. For Group A, the cuff pressure was monitored every 10 min intra-operatively from the start of surgery and maintained at 60 cmH₂O throughout the surgery. In Group B the cuff was inflated to 60 cmH₂O initially and the cuff pressure was recorded at the end of surgery. The volume of air removed from the cuffs was measured and any postoperative complications immediately after removal of LMA and after 24 h were recorded and tabulated.

Result: The mean cuff pressure in Group A was 61.07 cmH₂O. The mean cuff pressure in Group B was 108.42 cmH₂O and was significantly higher than Group A (p < 0.001). The volume of air removed was also significantly higher in Group B than Group A (p < 0.001). No association of age, gender and ASA classification on the cuff pressures was observed. There were also significantly more postoperative complications in Group B than in Group A, both immediately after and 24 h after removal of LMA.

Conclusion: The results of our study show that while using a laryngeal mask airway during anesthesia, continual monitoring of cuff pressure and its maintenance within the allowable limits is essential in preventing postoperative complications and reducing pharyngolaryngeal morbidity.

Key words: Anesthesia, General; Insufflation; Laryngeal mask airway; Morbidity

Abbreviations: LMA – laryngeal mask airway; LMA-S – Laryngeal mask airway supreme; SAD – supraglottic airway devices; ETT – endotracheal tube; PVC – polyvinylchloride

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1. Introduction

A major role of anesthesiologists during surgeries is to secure patients airway and ensure adequate ventilation during surgery, especially in patients under general anesthesia.¹ Until recently, the endotracheal tube (ETT) was the most common airway device used. However, endotracheal intubation has been shown to be associated with many adverse effects ranging from sore throat to more serious complications such as difficult or failed intubation and autonomic stimulation.² The supraglottic airway devices (SADs) have been introduced to bridge the gap between tracheal intubation and face mask. These can be used with minimal invasion as opposed to ETTs, which is attributed to their positioning outside of the larynx. The original prototype of SAD have undergone many improvements, and the latest SADs come with better features to secure a patent airway.³ The new SADs offer advantages such as fast and efficient placement, better maintenance of hemodynamic stability during induction, better oxygenation during emergence and fewer postoperative side effects like sore throat and voice alteration.⁴

The disposable versions of SADs are made of polyvinylchloride (PVC) and are latex free. One of these is the laryngeal mask airway (LMA). The drainage tube in some of these devices is separated from ventilation tube and these have a modified cuff designed to provide better seal around the laryngeal opening.⁵ The device is easy to insert without the need of an introducer. The ventilation tubes have patented 'fins' which prevent airway obstruction by the epiglottis.⁶

The LMA-Supreme (LMA-S) belongs to the second generation of SADs. Meta analyses have shown very low incidence of complications with these devices and these have been recommended for emergency situations.⁷ In order to maintain the optimal pharyngeal seal with minimum side effects, a cuff pressure equal to 60 cmH₂O has been recommended.⁸ However, elevated LMA cuff pressure in development of pharyngo-laryngeal symptoms have been demonstrated earlier and thus been a subject of investigation ever since. Major complications thus produced are rare but minor complaints such as sore

throat and hoarseness have been reported.⁹ This study evaluated the pharyngolaryngeal complications in surgeries under general anesthesia and their relationship with a cuff pressure maintained by regular monitoring or an unregulated cuff pressure.

2. Methodology

Following approval by the Institutional Ethics committee, a randomized prospective single blind study was conducted at the Department of Anesthesiology of our tertiary care hospital, from December 2017 to July 2019. The lowest sample size was calculated (n=28) considering 80% power with 95% level of significance in R studio (v 1.2.5001) software using appropriate R code (pwr.t.test (d = 0.76, sig. level = 0.05, power = 0.08, type = "two sample")), where d is effect size.¹⁰ The sample size chosen for this study was 60.

Sixty patients with ages ranging from 18 to 60 y, scheduled to undergo elective surgery under general anesthesia were included in the study after obtaining written, informed consent. Pre-anesthetic evaluation was carried out and they were educated about LMA-S and anesthesia, its advantages, side effects and potential complications.

Patients belonging to either American Society of Anesthesiologists (ASA) PS I or II, patients with Mallampati score I or II, those posted for elective laparoscopic or open surgeries under general anesthesia, requiring LMA-S insertion were included in the study. Pregnant women, morbidly obese patients, patients with a restricted mobility of neck and mouth opening, patients with emergent conditions, those with gastro-esophageal reflux, hiatus hernia and with oropharyngeal and neck pathology were excluded. Patients in whom LMA insertion failed in the first attempt were also excluded.

All the patients were premedicated with tablet alprazolam 0.5 mg at night. On arrival in the operating room, an 18 G or 20 G IV cannula was inserted and infusion of Ringer's lactate was started. The patient was connected to a multipara monitor, which recorded heart rate (HR), systolic (SBP), diastolic blood pressure (DBP), and continuous ECG monitoring and oxygen saturation. Premedication was provided by inj.

midazolam 0.05 mg, inj. ranitidine 0.1 mg/kg, inj. ondansetron 0.8 – 0.1 mg/kg, inj. glycopyrrolate 0.004 mg/kg, and inj. pentazocine 0.6 mg/kg IV. Pre-oxygenation was followed by induction of anesthesia with propofol 2 mg/kg and confirmed by eyelash reflex. LMA-S was inserted as per the manufacturer's instructions. Before insertion LMA-S was fully deflated. The cuff was inflated with air to achieve a pressure of 60 cmH₂O. After securing airway, intermittent positive pressure ventilation was maintained using traces of sevoflurane in oxygen and N₂O. Inj. vecuronium 0.08 mg/kg was used as a loading dose and then intermittent doses were used. Air entry in both of lungs was checked by auscultation. SpO₂ was maintained at more than 95%.

Patients were randomly divided into two Groups of 30 each. In Group A, the cuff pressure was checked every 10 min and was maintained at 60 cmH₂O, whereas in Group B, the cuff pressure was checked at the beginning and after end of the surgery. The volume of air extracted from LMA cuff was also recorded in all cases.

When surgery was completed, anesthesia was reversed. Suctioning was done. The LMA was removed when patient started breathing spontaneously and followed verbal commands. The oropharynx was examined for any visible injury and the device for bloodstains. Patient was asked for the presence of sore throat, dysphonia, throat pain, or hoarseness etc.

The examination and the interview was repeated after 24 h.

Statistical Analysis: Descriptive data are presented on MS-Excel 365 package and analysis performed on R studio v 1.2.5001. Independent sample t-test and Mann Whitney are used to find the significance between variables. Chi square test is used to find the association between the variables. A $p < 0.05$ is considered to be significant.

3. Results

The important demographic characteristic like age, weight and gender were equivalent among both the study groups, and no significant difference was observed ($p > 0.05$) (Table 1).

There were 19 and 18 ASA grade I patients in Group A and B respectively. Similarly, there were 11 and 12

ASA grade II patients in Group A and B respectively ($p = 1$).

The mean cuff pressure of Group B was found to be significantly higher than in Group A (108.43 ± 9.183 vs. 61.07 ± 1.143 cmH₂O; $p < 0.001$). Similarly, the total volume of air removed at the end of the surgery was significantly higher in Group B (43.07 ± 5.91 vs. 33.47 ± 5.75 mL; $p < 0.001$) as compared to Group A (Figure 1).

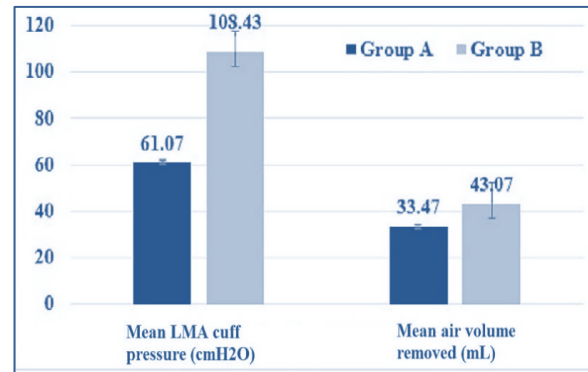


Figure 1: Distribution of mean cuff pressure and volume of air removed (mL), SD represented as error bars

Regarding post-operative complications, immediate and 24 h postoperative complications were significantly higher in Group B compared to Group A. While only 4 individuals showed mild cough and hoarseness in immediate postoperative period in Group A, all 30 subjects in Group B presented with complications (Table 2).

Similarly, 24-hour post-operation, none in Group A showed any complications while 28 of 30 in Group B presented with complications (Table 3).

No significant association was noted between the occurrence of complications with the gender, duration of surgery or ASA classification.

4. Discussion

During general anesthesia, the LMA cuff pressure needs to be frequently monitored and maintained at an optimum level to prevent endothelium from ischemic changes, yet high enough to ensure the air seal. Maintaining the recommended cuff pressure gains much importance during long durations.¹⁰ Sandhu et al. studied cuff pressures in ETTs and LMAs and concluded that approximately 52% of the ETT and

Table 1: Demographic data of the study groups

Variable	Group A	Group B	p-value
Mean Age (years)	35.93 ± 14.49	33.87 ± 16.01	0.6624
Gender			
Female	16	15	0.8551
Male	14	15	
Mean Weight (kg)	48.63 ± 11.25	46.63 ± 11.32	0.4995

Table 2: Distribution of immediate postoperative pharyngo-laryngeal side effects in Group B

Pharyngo-laryngeal side effect					Group-B n (%)
Bleeding	Cough	Throat pain	Sore throat	Hoarse-ness	
+	+				2 (6.66)
+	+				2 (6.66)
+	+	+			5 (16.66)
+		+			2 (6.66)
+		+	+		2 (6.66)
	+			+	4 (13.33)
	+		+		3 (10.00)
	+	+			3 (10.00)
		+		+	1 (3.33)
		+	+	+	2 (6.66)
		+		+	2 (6.66)
		+	+		2 (6.66)

Table 3: Distribution of 24 h postoperative pharyngo-laryngeal side effects in Group B

Pharyngo-laryngeal side effect					Group-B n (%)
Bleeding	Cough	Throat pain	Sore throat	Hoarse-ness	
	+	+	+		1 (6.66)
				+	3 (6.66)
			+	+	2 (6.66)
		+		+	5 (6.66)
		+			4 (6.66)
		+	+		4 (13.33)
	+	+	+		3 (10.00)
		+			5 (10.00)
		+	+	+	1 (3.33)

97% of the LMA cuff pressures measured in the studied cohort were greater than the recommendations. It was proposed that frequent use of manometers throughout the course of operation would provide better maintenance of cuff pressures.¹¹ In our study, Group A constituted the intervention group, where the cuff pressure was monitored every 10 min throughout the surgery; whereas in Group B the cuff pressure was recorded at zero time and at the end of the surgery. In the end, Group A showed significantly lower cuff pressures as compared to Group B. No association of the cuff pressure with age, type of surgery, time of induction of anesthesia was observed by Rokamp et al. in their study, which is in agreement to the results of our study.¹¹ According to Hensel M, et al. the measurement of cuff pressure should be compulsory during LMA anesthesia.¹²

Nitrous oxide (N₂O) is an inhalational anesthetic which is routinely used during induction of general anesthesia. However, it has also been reported to increase the intracuff pressure as it diffuses into the cuff during anesthesia. A study reported that despite this, 50:50 mixture of O₂:N₂O provided a stable cuff pressure than O₂ – air mixture in contrast to earlier studies.¹³

There have been some contrasting opinions on the adverse effects of the recommended LMA cuff pressure on pharyngolaryngeal structures.¹⁴ A few of the studies have reported that there is a decrease in the postoperative adverse effects if LMA cuff pressure is maintained below 60

cmH₂O.^{15,16} Patients with low cuff pressures were less prone to the adverse effects.¹⁶ Many other studies have also suggested that maintaining cuff pressures well below 60 cmH₂O can reduce the side effects. A particular study by Ali et al. showed that a lowered cuff pressure of 45 cmH₂O, has better hemodynamic responses and lesser side effects as compared to the recommended cuff-pressure of 60 cmH₂O.¹⁷

In addition to the recent LMA-S device, other second-generation SADs used are Unique (LMA-U), ProSeal LMA (LMA-P) and I-gel.⁴ A comparative study by Joel et al. demonstrated that there were no significant differences in the post-operative sore throat. They also reported that patients were at greater risk of developing severe sore throat in the LMA-S group as compared to the LMA-U and I-gel groups.¹⁸ Other side effects like neck and/or jaw pain, dysphonia, nausea and/or vomiting, and dysphagia were shown to vary insignificantly among groups.¹⁸ Likewise, some other studies have also reported that LMA-S performs equally good in different procedures as other devices providing a good seal, easier insertion and less side effects when cuff pressure is maintained.^{19,20} It has been recommended that cuff pressure be monitored and reduced to < 60 cmH₂O in order to reduce sore throat.^{18,21} In a particular study by Chantzara et al., an intervention of maintaining and monitoring the overall cuff pressure led to a significant decrease of adverse effects as compared to the non-intervention approach, regardless of the ventilation mode.¹⁴ Joen et al. have reported that maintaining cuff pressure below 60 cmH₂O significantly reduced incidences of post-operative sore-throats.²² On the contrary, some studies showed no significant association between the cuff pressure and postoperative sore throat.^{13,23} Our study demonstrated that none of the patients in Group A presented any complications.

The presence of blood on LMA on its removal post-surgery has also been previously reported.²⁴ Another common side effect of increased LMA cuff pressure is hoarseness, which occurs in about 0-12% of the people, and lasts not more than 2 days.²⁵ Maintaining cuff pressures has been shown to reduce the postoperative incidence of hoarseness (dysphonia), which was a common side effect in patients of Group B in our study, where cuff pressure was not regularly monitored.²⁶ Dysphagia or difficulty in swallowing has also been reported.^{24,15} Some rare side effects like

neck and/or jaw pain, dysphonia, nausea and/or vomiting.¹⁸

5. Limitations

A small sample size of the groups prevented exact assessment of all side effects that have been documented so far, e.g., dysphagia, dysphonia, nausea, and vomiting could be included in the future studies to estimate proper outcomes of the LMA cuff related undesirable side effects.

6. Conclusion

The results of our study conclude that the continual cuff pressure monitoring in LMA Supreme to maintain it at sealing pressure (below 60 cmH₂O) reduces the incidence of pharyngolaryngeal adverse effects like sore throat, hoarseness, throat pain, cough and bleeding.

7. Conflict of interest

None declared by the authors.

8. Author Contributions

HM: Literature search, clinical studies, experimental studies, data acquisition, data analysis, statistical analysis, manuscript preparation.

SK: Concept, design, definition of intellectual content, manuscript editing, manuscript review, guarantor.

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