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Original Research Article

PRESSURE-GUIDED VERSUS VOLUME-GUIDED CUFF INFLATION IN SINGLE USE LARYNGEAL MASK AIRWAYS TO ACHIEVE RECOMMENDED CUFF PRESSURE OF 60 CMH_20

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ABSTRACT

Background: The Single use laryngeal mask airway (LMA) is a widely used single-use supraglottic airway device with manufacturer recommendations for cuff inflation volumes. However, optimal cuff inflation practices remain unclear, with concerns that standard volume-guided inflation may result in excessive intracuff pressures leading to pharyngeal mucosal ischemia and increased postoperative complications. The present study aims to assess the volume of air required for cuff inflation to achieve a cuff pressure of 60 cmH_2O for Ambu® Auraonce ™ laryngeal mask airways size 3 and 4. **Materials and Methods:** Prospective quasi-experimental study of 60 female patients (American Society of Anaesthesiologists (ASA) I-II, 18-60 years) undergoing general anesthesia with with Ambu® Auraonce ™ LMA sizes 3 and 4. **Aims:** Primary outcomes: cuff volume to achieve 60 cmH_2 O intracuff pressure and oropharyngeal leak pressure. Secondary outcome: postoperative sore throat at 0, 6, 12, and 24 hours using standardized assessment. **Results:** The mean volume of air inflated, which could achieve a desirable intra-cuff pressure of 60 cmH_2O was much lower than the recommended volume of air. Oropharyngeal leak pressure achieved was 24.4±3.6 and 24.53±3.26 cmH2O, respectively in women with LMA size 3 and LMA size 4 insertion. The incidence and severity of a sore throat were lower than that of the reported incidence when standard cuff inflating volumes were used. **Conclusion:** Single use LMAs require significantly lower cuff volumes than manufacturer recommendations to achieve safe intracuff pressures while maintaining an adequate seal. This approach may reduce postoperative complications. Clinical protocols should emphasize pressure-guided rather than volume-guided cuff inflation.

INTRODUCTION

The most important and widely used supraglottic device today is the laryngeal mask airway (LMA). The inventor of the LMA is Dr. Archie Brain, an anesthesiologist from the United Kingdom. Development started on the LMA in 1981 and was available for commercial use, in the United States, by 1992. Since its introduction, several modifications, additions, and variations have been developed, and are currently in use.[1]

Supraglottic airway devices (SAD) are being used in the majority of cases under general anesthesia. Insertion of these devices is easy and involves minimal manipulation of the airway as compared to the endotracheal tube (ETT). Also, the ventilatory functions and prevention of gastric aspiration are almost similar with the added advantage of relatively fewer postoperative complications (ETT 14.4% to 50% and SAD 5.8% to 34%). Considering the extensive use of SADs these days, the incidence of sore throat associated with its use is still bothersome. The cuff pressure is one of the risk factors with the use of SADs and studies done with various types of SADs have shown decreased incidence when the cuff pressure is kept low.[2,5]

Depending on the type of surgery and individual patient characteristics, either an endotracheal tube or SAD can be used. Naturally, these airway devices suppress and irritate anatomical structures and can,

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therefore, lead to trouble swallowing, hoarseness, and sore throat postoperatively.[6] The incidence of postoperative sore throat (POST) and hoarseness following general anaesthesia via laryngeal masks (LM) ranges between 12% and 49%. Following Click or tap here to enter text. tracheal intubation 7-10, the incidence of POST is slightly higher in about 62% of cases.[10]

Oropharyngeal leak pressure (OLP), measured by closing the expiratory valve of the anesthetic circle system at a fixed gas flow rate and noting the equilibrium airway pressure, is used to quantify the efficacy of airway sealing in SGA devices. Importantly, OLP indicates airway protection, successful SGA placement, and positive pressure ventilation. Several methods are used to quantify OLP, including audible noise detection, oral capnography, stethoscopic noise, and manometric stability.[11]

The Single use Laryngeal Mask (Ambu A ⁄ S, Ballerup, Denmark) is claimed to have advantages over its competitors. It features an in-built curve in the airway tube designed to allow the head to remain in a more natural position and to reduce stress on the upper jaw and lacks epiglottic bars. The risk of breakage is claimed to be limited as it has a one-piece construction. It also has a soft cuff made of 0.4-mm-thick polyvinyl chloride. The manufacturer claims that this allows improved conformation to the shape of the airway.[12] Optimal cuff volume for LMA in adult patients is unknown, specifically regarding the minimum effective cuff inflating volume that ensures a satisfactory airway seal during positive pressure ventilation while keeping intracuff pressure below the safety upper limit to prevent oropharyngeal mucosal ischemia. Studies regarding optimal cuff volume for LMA are lacking particularly in adult patients.[13,14] Hence, we conducted the current study to assess the volume of air required for cuff inflation to achieve a cuff pressure of 60 cmH2O for Ambu® Auraonce TM laryngeal mask airways size 3 and 4.

MATERIALS AND METHODS

This was a prospective quasi-experimental study in which patients were allocated into two non-randomized groups (LMA size 3 and size 4) based on clinical weight-based criteria. All LMAs were inflated using a pressure-guided technique to achieve a target intracuff pressure of 60 cmH_2 O. This study was conducted in the Department of Anaesthesiology, Trichy SRM Medical College Hospital and Research Centre. All the patients who were posted for various surgical procedures, requiring general anesthesia were considered as the study population. The data collection for the study was done between September 2025 to November 2025 for 3 months.

The study population included patients from the American Society of Anesthesiologists (ASA) grade I-II, aged 18 to 60 years, and any cases requiring general anesthesia with Ambu® AuraonceTM LMA size 3 and 4. Patients with active respiratory tract infections or undergoing surgeries lasting >2 hours were excluded. After obtaining informed written consent all participants were evaluated by thorough clinical history and clinical examination. All the selected patients underwent standard pre-anesthetic assessment. Written informed consent was obtained from all the patients after explaining the procedure in detail. Patients were Premedicated with Tab. Ranitidine 150 mg, 2 hours before surgery.

Size 3 Single use LMA was used in patients weighing between 30 to 49 kgs and size 4 Ambu® Single use LMA was used in patients weighing 50 to 70 kgs.

Once the appropriate size LMA was selected, the device was inspected for any visible damage. Size 3 and 4 Single use LMA were deflated completely, then inflated with 20 ml and 30 ml of air respectively to check for a bulge or any sign of leakage in the cuff. The cuff was then pressed against a flat sterile surface and deflated completely in such a way that the cuff was flat and wrinkle-free. Once the LMA was prepared, it was kept in a sterile towel.

Patients were made to lie supine on the operating table, with the head resting on a pillow. An intravenous line was started and routine monitors i.e. non-invasive blood pressure, ECG, and pulse oximeter were attached. Patients were pre-oxygenated with 6 liters of 100% O2 for 3 minutes. Induction of anesthesia was accomplished with in intravenous injection of fentanyl 2 mcg/kg and an injection of propofol 1.5-2.5 mg/kg, titrated to induction. Once patients were induced, ventilation was continued with 6 liters of oxygen and 1% isoflurane. Lack of response to jaw thrust was considered as an adequate depth of insertion of the LMA. The completely deflated Single use LMA was lubricated with 2% lignocaine jelly just before insertion. Anaesthesia was maintained with an O2:air mixture and isoflurane at 1 minimum alveolar concentration. Ventilation was assisted to maintain an end-tidal (Et) CO2 of 35 to 45 mmHg.

Sample Size: The sample size was estimated, assuming the mean volume of air to be injected to be 2ml less than the reference value (20 ml for LMA size 3 and 30 ml for LMA size 4), with an alpha error of 0.05 and 90% power of the study. The required sample size was 24 Participants for each of the two different LMA sizes. To account for non-participation and loss to follow-up, it was decided to include 30 subjects in each of the LMA sizes.

Sampling Method: All the eligible participants were recruited into the study consecutively by convenient sampling till the sample size was reached.

The study was approved by the institutional human ethics committee. Voluntary informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and the voluntary nature of participation were explained to the participants before obtaining consent. The

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confidentiality of the study participants was maintained.

Ethical and Informed Consent: Ethical approval was obtained from the institutional review board [Ref: 949/TSRMMCH&RC/ME-1/2025-IEC No:315] of the center and study was carried out with informed consent from the participants.

Statistical Methods

Descriptive analysis was carried out by mean and standard deviation for quantitative measures such as final volume (ml), oro-pharyngeal leak pressure (cmH2O), duration of surgery (mins), pulse (beats/min), systolic blood pressure (mmHg), and diastolic blood pressure (mmHg). All quantitative variables were assessed for normal distribution or not by using histograms, Q-Q plots, and Shapiro- Wilk test (P value > 0.05). For normally distributed final volume (ml) and initial pressure (cmH2O) the mean values were compared against the recommended volume using a one-sample t-test. MMP, ST 0, and ST 6 were compared between LMA sizes using the Chi-square test. P value <0.05 was considered statistically significant. Data were analyzed by using SPSS software.[15]

RESULTS

A total of 60 participants were included in the final analysis, 30 (50.00%) participants were managed with LMA size 3 and other 30 (50.00%) participants were managed with LMA size4

The mean age was 27±8.35 years, the youngest person was aged 18 years and the eldest was aged 48 years with size 3 LMA. The mean age was 34.77±10.39 years, the youngest person was aged 20 years and the eldest was aged 60 years with size 4 LMA. The mean weight was 45.87±4.75 kg, the minimum weight was 35 kg and the maximum weight was 50 kg, with size 3 LMA. The mean weight was 58. 97±4.14 kg, the minimum weight was 50 kg and the maximum weight was 70 kg with size 4 LMA.The mean volume of air inflated (ml) was 11.31±1.962 the minimum volume was 7.50 and the maximum volume was 15 with size 3 LMA. The mean volume of air inflated (ml) was 13.66±1.94 the minimum volume was 10ml and the maximum volume was 19 ml with size 4 LMA. In the current study, in the LMA size 3 group, the mean volume of air inflated was 11.31±1.96 ml, which was statistically significantly lower than the recommended volume of 20 ml (P value < 0.001). And in the LMA size 4 group, the mean volume of air inflated was 13.66±1.94 ml, which was also statistically significantly lower than the recommended volume of 30 ml (P value < 0.001). The mean Oro-pharyngeal leak pressure (cmH2O) was 24.4±3.66 the minimum was 18 cmH2O and the maximum was 30 cmH2O in the study population LMA size 3. The mean Oro-pharyngeal leak pressure was 24.53±3.26 cmH2O the minimum was 23 cmH2O and the maximum was 30 cmH2O in the study population LMA size 4.

The mean SpO2 was constantly maintained at 100%, and at no point in the postoperative period there was any reduction in oxygen saturation. The mean EtCO2 values ranged from a minimum value of 31 to a maximum value of 43.47, indicating no major fluctuations in the LMA size 3 group. The mean EtCO2 values ranged from a minimum value of 32.97 to a maximum value of 34.57, indicating no major fluctuations in the LMA size 4 group.

Among the study participants in LMA size 3, Dilatation & Curettage was 1 (3.33%), Excision Biopsy was 24 (80.00%), Incision & Drainage was1 (3.33%), Interval sterilization was 1 (3.33%), and Puerperal sterilization was 3 (10%). Among the study participants in LMA size 4, Dilatation & Curettage was 2 (6.67%), Excision Biopsy was 18 (60.00%), Incision & Drainage was 4 (13.33%), Lt. URSL & DJ stenting was 1 (3.33%), Mirena Insertion was 1 (3.33%), ORIF+PO was 1 (3.33%), Puerperal Sterilization was 2 (67.67%) and secondary suturing was 1 (3.33%). Among the 30 participants, in 29 (96.67%) participants, the LMA size 3 was inserted in a single attempt, and in 1 (3.33%) participants, it took 2 attempts to insert LMA size 3.

In all 100% of participants, LMA size 4 was inserted in the first attempt in the study. Among the study participants with LMA size 3, 2 (6.67%) of the participants had a sore throat 6 hours after surgery. Out of the two cases of sore throat, both were minimal. Among the study participants with LMA size 4, 5 (16.67%) of the participants presented with sore throats at 6 hours in the study participants. Out of the 5 subjects with a sore throat, 4 (13.33%) had minimal and 1 (3.34%) had a moderate sore throat, none of the participants had grade 3 severe sore throat.

Table 1: Descriptive analysis of Parameters between LMA size in the study population (N=60)

Parameters	LMA size			
	LMA size 3 (n=30)		LMA size 4 (n=30)	
	Mean±SD	95% CI	Mean±SD	95% CI
Age (years)	27.00±8.35 (18 to 48)	24.01 to 29.99	34.77±10.39 (20 to 60)	31.05 to 38.49
Weight (kgs)	46.00±4.93 (35 to 54)	44.24 to 54.00	63.03±4.57 (55 to 70)	61.40 to 64.67
Final volume (ml)	11.32±1.96 (7.50 to 15)	10.61 to 12.02	13.67±1.94 (10 to 19)	12.97 to 14.36
Oro-pharyngeal leak pressure (cmH2O)	24.40±3.66 (18 to 30)	23.09 to 25.71	24.53±3.26 (20 to 30)	23.37 to 25.70
Duration of surgery (mins)	46.00±30.94 (10 to 120)	34.93 to 57.07	53.50±31.13 (15 to 120)	42.36 to 64.64

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Table 2: Descriptive analysis of Baseline Parameters between LMA size in the study population (N=60)

Baseline Parameters	LMA size (Mean±SD)	
	LMA size 3 (n=30)	LMA size 4 (n=30)
$ETCO_2$ (mmHg)		
0 min	33.70±3.71	32.97±4.94
5 min	43.47±4.82	33.57±3.56
10 min	32.80±3.49	34.07±3.33
15 min	33.24±3.73	33.53±3.04
20 min	32.76±3.80	33.48 ±2.38
25 min	33.21±3.79	33.57±2.10
30 min	33.04±3.93	33.67±2.39
45 min	33.18±3.28	33.59±2.45
60 min	34.13±2.85	33.33±2.57
90 min	33.00±3.00	34.57±2.57
120 min	31.00±3.00	33.33±3.21

Is it necessary because all the time periods SpO2 (%) values are static (constant) as 100.00.

Table 3: Comparison of Parameters between LMA size in the study population (N=60)

Parameters	LMA size		P value
	LMA size 3 (N=30)	LMA size 4 (N=30)	
Procedure			
Excision Biopsy	24 (80.00%)	18 (60.00%)	*
Secondary Suturing	0 (0.00%)	1 (3.33%)	
Dilatation & Curettage	1 (3.33%)	2 (6.67%)	
Mirena Insertion	0 (0.00%)	1 (3.33%)	
Puerperal Sterilisation	3 (10.00%)	2 (6.67%)	
Incision & Drainage	1 (3.33%)	4 (13.33%)	
Interval sterilisation	1 (3.33%)	0 (0.00%)	
ORIF+PO	0 (0.00%)	1 (3.33%)	
Lt. URSL & DJ Stenting	0 (0.00%)	1 (3.33%)	
MMP			
I	8 (26.67%)	4 (13.33%)	0.1967 †
II	22 (73.33%)	26 (86.67%)	
Initial volume (ml)	20 ±0.0	30.0 ±0.0	‡
Final volume (ml)	11.32±1.96	13.67±1.94	<0.001§
Initial pressure (cmH2O)	113.33±9.59	113.67±10.66	0.899§
Final pressure (cmH2O)	60 ±0.0	60 ±0.0	‡
ST 0			
Yes	3 (10.00%)	8 (26.67%)	0.0953 †
No	27 (90.00%)	22 (73.33%)	
ST 6			
Yes	2 (6.67%)	5 (16.67%)	0.4238 †
No	28 (93.33%)	25 (83.33%)	
ST 12			
Yes	0 (0.00%)	2 (6.67%)	*
No	30 (100.00%)	28 (93.33%)	
Number of attempts			
1	29 (96.67%)	30 (100.00%)	*
2	1 (3.33%)	0 (0.00%)	

*=No Test is Applicable due to zero cell value; †=Chisq P value; ‡=t could not be computed because the standard deviations of both groups were 0; §=IST test P value.

DISCUSSION

The instruction manual of the laryngeal mask indicates that size 4 should be used in adults of average or large size, and size 3 in children or small adults of more than 25 kg in weight. After the introduction of a larger size (size 5), the inventor recommended using as large size a mask as possible. Despite these instructions, the size 3 laryngeal mask seems to be used frequently in females and the size 4 in males, although larger masks have been used increasingly in controlled studies.[16]

The major findings of the current study suggested that, in women where LMA size 3 was used, the mean volume of air inflated was statistically significantly lower than the recommended volume of 20 ml (P value < 0.001), and in the LMA size 4 group, the mean volume of air inflated was statistically significantly lower than the recommended volume of 30 ml (P value < 0.001). The study conducted found that the mean (SD) volume of air required to achieve the intracuff pressure of 60 cmH2O in Soft Seal®, AuraOnce™, LMA-Classic™, LMA-ProSeal™ laryngeal mask size 3 was 11.80 (1.88), 9.20 (1.88), 8.95 (1.50) and 13.50 (2.48) ml, respectively. The volumes required for the same type laryngeal mask size 4 were 14.45 (4.12), 12.55 (1.85), 11.30 (1.95) and 18.20 (3.47) ml, respectively.17 Our results are in line with previous studies showing hyperinflation of the laryngeal mask cuff when applying the

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maximum recommended volume.[13,18,22] In agreement with early studies,[19] half of the maximum cuff volume produced a high intracuff pressure of 120 to 133 cmH2O in either size of LMA Well Lead™. Also, our data demonstrated that less cuff inflating volume was required for LMA Well Lead™ to produce the intracuff pressure of 60 cmH2O in contrast with the results from Asai et al,[14] Several factors may be responsible for this difference in cuff inflating volume. First, the made-up material and figuration varied from one to another brand of LMA, therefore, distinct brand of LMA exhibits unique compliance characteristic of their own. Second, the initial residual cuff volume for LMA is a key determinant while considering the volume difference among these trials. In the study by Asai et al,[14] they withdrew air from the cuff to obtain the arbitrarily defined intracuff pressure of 20 mmHg below atmospheric pressure before insertion of the LMA. A study by Kang J E et al (2014), have also demonstrated significantly lower cuff volume and pressure and OLP in low (limiting 25 cmH2O,) cuff pressure group, as compared to high at 60 cmH2O) cuff pressure groups.[4]

In LMA size 3, the mean OLP achieved was 24.4±3.6 cmH2O, with a range of 18 to 30 cmH2O. In the LMA size 4 group, the mean oro-pharyngeal leak pressure achieved was 24.53±3.26 cmH2O with a range of 23 to 30 cmH2O. In a meta-analysis it was found that OLP was significantly higher with LMA ProSeal™ than with i-gel® (mean difference −2.95 cmH2O; 95% confidence interval −4.30, −1.60).[23] Meta-analyses comparing LMA Proseal™ and i-gel® have reported similar OLP for both devices.[24,25] This is in contrast to our findings, which showed that LMA ProSeal™ provided higher OLP than i-gel®. This disparity may be due to differences in data collection. OLP is also referred to as airway sealing pressure and airway leak pressure.[11,26] Success rate for the first attempt was 95% for the i-gel group and 90% for the two laryngeal mask airway groups. Insertion was found to be easy in most cases in all groups, and there was no change in blood pressure, heart rate, or oxygen saturation on insertion. The OSP was 26±2.6, 23±1.2, and 22± 2.3 cm H2O for i-gel, PLMA, and cLMA, respectively. The difference between the i-gel and both LMA groups was statistically significant (P <0.01). There were no clinically important complications in the postoperative period.[27] The LMA Protector™ enabled a higher OLP compared to the LMA Supreme™. This finding may be important for patients requiring a higher peak pressure for sufficient supraglottic airway device ventilation.28

In our study at 24 hours, we could not find any sore throat participants. Pharyngolaryngeal complications consisting of sore throat, dysphonia, and dysphagia were assessed at 1, 2, and 24 h postoperatively. The incidence of pharyngolaryngeal complications at any time point was 42% in the routine care group and 32% in the pressure-monitored group (95% CI for difference +28 to −7%, p = 0.26). There was no difference between groups for any of the secondary outcomes.[29] In prospective randomized controlled trials, high intracuff pressure was associated with high pharyngeal adverse events owing to pharyngeal mucous ischemia.[30,31] However several studies also have conflicting results. The results from Rieger et al. indicated that there was no difference in the occurrence of pharyngeal complications for patients using LMA under high or low intracuff pressure.[32] The relationship between cuff pressure and pharyngeal morbidities has not been yet clearly elucidated. The cuff pressure does not represent the pressure directly exerted on the pharyngeal mucosa.[33] In a study by Wong et al, the use of a new supraglottic airway with a built-in pressure indicator, resulted in significantly lower pharyngolaryngeal symptoms in the intervention group than in the LMA group (26% vs 49%; P = 0.002), with an absolute risk reduction of 24%, and the number-needed-to-treat was 4.3

Limitations

This was a prospective quasi-experimental study. Hence the effect of the intervention in reducing post-operative sore throat and hemodynamic stability could not be compared. Only the volume of air inflated and intra-cuff pressure was compared against that of recommended volume and the pressure achieved with it. The inclusion of a separate control group would have facilitated more scientific documentation of the efficacy of the intervention, but could not be done due to ethical considerations. Since the measurement of postoperative sore throat was by subjective methods, the possible role of bias could not be eliminated. The role of confounding by potential confounding variables could not be evaluated, considering the small sample size. The study participants included only female patients, hence the results may not be able to be extrapolated to male patients.

CONCLUSION

Single use LMAs require significantly lower cuff volumes than manufacturer recommendations to achieve safe intracuff pressures while maintaining adequate seal. For size 3 LMAs, a mean volume of 11.32±1.96 ml (vs. recommended 20 ml) and for size 4 LMAs, a mean volume of 13.67±1.94 ml (vs. recommended 30 ml) achieved optimal 60 cmH_2O intracuff pressure with adequate OLPs of 24.4±3.6 and 24.53±3.26 cmH_2O respectively. This pressure-guided approach reduced postoperative sore throat incidence compared to standard volume-guided protocols. Clinical protocols should emphasize pressure-guided rather than volume-guided cuff inflation for improved patient safety and comfort.

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