ORIGINAL ARTICLE ASIAN JOURNAL OF MEDICAL SCIENCES

Safety and efficacy of laryngeal mask airway placement in term of oropharyngeal leak pressure: A comparison between conventional insertion and laryngoscope guided insertion

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Submission: 08-12-2024 Revision: 02-01-2025 Publication: 01-02-2025

ABSTRACT

Background: The effectiveness of laryngeal mask airway (LMA) through conventional insertion technique versus laryngoscope-guided insertion is a debatable issue. Use of only fiberoptic scoring for assessment has shown conflicting results. A newly presented clinical sign – oropharyngeal leak oropharyngeal leak pressure (OLP) – is showing promise for assessing airway sealing in LMA placement. **Aims and Objectives:** The present study was undertaken to compare the conventional blind insertion versus laryngoscope-guided insertion of LMA using OLP as the main indicator. **Materials and Methods:** A prospective randomized comparison was done between two groups (Group C-Conventional LMA insertion and Group L-Laryngoscope guided LMA insertion) numbering 100 patients in total. OLP, first attempt success rate, time taken for insertion, hemodynamic variation, and adverse effects were recorded and compared between the groups. **Results:** OLP was significantly high in laryngoscope-guided LMA insertion than conventional insertion (22.6 ± 3.59 vs. 17.4 ± 3.53 cm H_2O [Mean ± Standard deviation]). Time taken for LMA insertion (28.3 ± 5.92 vs. 23.3 ± 5.03 s) and hemodynamic stress response was higher in laryngoscope-guided insertion than conventional insertion. The two methods showed a similar profile of complications. **Conclusions:** Laryngoscope-guided LMA insertion improves the airway seal pressure over conventional blind LMA insertion with some limitations. We suggest laryngoscope guidance may be a better technique for LMA insertion.

Key words: Laryngeal mask airway; Oropharyngeal leak pressure; Laryngoscopy

Access this article online

Website: https://ajmsjournal.info/index.php/AJMS/index

DOI: 10.71152/ajms.v16i2.4393

E-ISSN: 2091-0576

P-ISSN: 2467-9100

INTRODUCTION

The laryngeal mask airway (LMA) has been designed as a tool for elective ventilation for use in the operating room. It is a good alternative to bag-mask ventilation, freeing the hand of the anesthesia provider and acting as bridge between face mask ventilation and endotracheal intubation.[1]

LMA is conventionally inserted blindly by the index finger insertion technique as described by Dr. Archie Brain.[2] However, this conventional technique is sometimes difficult and anesthetic gas leakage and gastric insufflation may happen.[3] In some recent studies, it has been shown that LMA insertion under laryngoscope guidance can achieve better placement over tongue at a level below the epiglottis, with minimal resistance from oral soft tissue.[4,5]

However, an effective assessment tool for the LMA, in terms of airway sealing, is still unclear.[6] Other than fiberoptic assessment, which is based on the anatomical

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position of epiglottis and vocal cord, no other test for the efficacy of technique and position of LMA is established till now. This fiberoptic scoring is not always reliable and conflicting results are there.[7]

In recent times, it has been suggested that the accuracy of LMA placement can be determined effectively by oropharyngeal leak pressure (OLP), which assesses airway sealing of LMA around vocal cord. High OLP indicates better airway sealing, that is, less O_2/anesthetic gas leak during anesthesia and facilitates delivery of positive pressure ventilation and thereby indicates successful LMA placement.

We hypothesized that laryngoscope-guided LMA insertion would provide better LMA placement experience than conventional blind insertion, in terms of OLP as the primary outcome measure. Such head-to-head comparisons are very limited. Hence, to fill up the knowledge gaps, the present study was conducted. The rate of success of the first attempt at insertion, the time taken for insertion of the LMA, and the occurrence of any adverse events were secondary outcome measures.

Aims and objectives

Primary objective

To conduct a comparative evaluation between laryngoscope guided LMA insertion and conventional LMA insertion, in term of safety, efficacy & better seal in terms of oropharyngeal leak pressure(OLP)

Secondary objective

To estimate the time taken for LMA insertion , To note whether first attempt of LMA insertion is successful , adverse events after removal of LMA

MATERIALS AND METHODS

This prospective, randomized study was conducted at a tertiary care center from March 2021 to August 2022 in elective General Surgery, Urology, Gynecology and Obstetrics, and Orthopedic operation theatres. The trial was registered with Clinical Trials Registry of India (CTRI/2022/06/043121 dated June 09, 2022). The principles of the Declaration of Helsinki were followed, Institutional Ethics Committee approval (BSMC/ACA/170 dated January 19, 2021) was obtained and written informed consent was sought from all study participants after explaining the scope and nature of the study.

Inclusion criteria

Participants were enrolled with the following inclusion criteria age between 19 and 70 years, either gender, American Society of Anesthesiologists (ASA) physical Status I or II, scheduled to receive general anesthesia with LMA insertion for elective surgery in the supine position.

Exclusion criteria

Subjects not giving consent, trauma cases, those with a history of recent respiratory tract infection, body mass index >40 kg/m^2, on full stomach, at increased risk of aspiration, unable to open mouth, or with any infection or pathogenic abnormality in the oral cavity or pharynx were excluded from the study.

Enrolled patients were randomized equally to two groups: Group C (conventional insertion) and Group L (laryngoscope guided insertion) using computer-generated random number table followed by allocation concealment using the sequentially numbered opaque sealed envelope technique. This study was a double-blind one in terms of both participants (patients were not aware of the technique to which they were subjected) and assessors (outcome parameters were recorded by an observer also unaware of the technique).

After the patient arrived in the operating room, proper explanation of the study procedure and expected outcome were given in their own vernacular language before seeking informed consent. Demographic data, physical examination findings, and laboratory investigation results were captured on predesigned case report form.

An IV line was inserted with proper size cannula (usually 18G size) and IV fluid started with Ringer's lactate. Hemodynamic monitors were attached according to ASA standard, that is, ECG, pulse oximetry, non-invasive blood pressure, and end-tidal CO_2 ($ETCO_2$). Bispectral index (BIS) monitoring was also attached. Patients were pre-oxygenated with 100% O_2 at 6 L/min for 5 min, and premedicated with Inj Ondansetron (0.1 mg/kg), Inj Glycopyrrolate (4 mcg/kg), Inj Midazolam (0.05 mg/kg), and Inj Fentanyl (2 mcg/kg). Induction was done with IV Propofol (2 mg/kg). Mask ventilation was continued with 2% sevoflurane to achieve adequate jaw relaxation and BIS <60. No muscle relaxant was used. LMA Classic™ (size 3 or 4 according to patient weight) was inserted blindly (conventional method) or laryngoscope guided as per the randomized allocation. Macintosh curved blade size 3 or 4 was used. OLP, time taken for LMA insertion, number of attempts, ease of insertion, hemodynamic parameters were noted. To ensure double-blinding, these parameters were recorded by the anesthesiologist undertaking LMA insertion and reported to the investigator, who was not privy to the actual procedure. Anesthesia was maintained with 66% N_2O and 33% O_2 and isoflurane inhalation at titrated dose. Patients were

kept on closed circuit breathing system with soda lime CO_2 absorbent.

Method to measure OLP: After successful LMA placement (confirmed by bilateral chest auscultation, absence of audible leak on positive pressure ventilation, square wave capnograph trace) and ventilation, OLP was measured by adjusting the adjustable pressure-limiting (APL) valve at fixed gas flow @ 6 L/min. N_2O was not used in this period, only O_2 and sevoflurane were used. APL valve was gradually reduced from 40 cm H_2O to a minimum 10 cm H_2O. Head and neck were kept in sniffing position during this measurement. A stethoscope was placed from the side of neck (side from thyroid cartilage) and the APL valve pressure at which gas leaked into the mouth (i.e. audible sound auscultated) was noted.

Time taken for LMA insertion was defined as the duration from picking up the LMA till the capnography tracing was detected. A failed attempt was defined as failed passage of the LMA into the pharynx or ineffective ventilation (expiratory tidal volume <5 mg/kg or absence of a capnography tracing). The second attempt would be performed without sniffing position and if the second attempt failed endotracheal intubation was to be done. An easy insertion was defined as one in which there was no resistance to insertion into pharynx in a single maneuver. In a difficult insertion, there was resistance to insertion or more than one maneuver was required for the correct placement of the device.

Hemodynamic parameters, namely, heart rate (HR) and mean arterial blood pressure (MBP), were measured at pre-induction, 1 min post-induction, and 1 min post-insertion of LMA. Oxygen saturation was also measured. At the end of the surgery, an independent observer who was also blind to the group allocation removed the LMA and inspected it for any blood stains. Any sore throat or dysphonia was also noted 1 h postoperatively.

For statistical analysis, all raw data were entered in Microsoft Excel spreadsheet and subsequently analyzed by SPSS version 26 software. Descriptive data have been summarized as mean (μ) ±standard deviation (SD) or as category count and percentage. The numerical variables were normally distributed by Kolmogorov–Smirnov goodness-of-fit test and were compared between groups by Student's t-test. Categorical variables were compared by Chi-square test or Fisher's exact test as appropriate. All comparisons were two-tailed and $P<0.05$ was considered as statistically significant.

Sample size was calculated referring to a previous study[6] to compare μ and SD of OLP between conventional insertion and laryngoscope-guided LMA insertion groups. Values used were $\mu1=18.1$, $\mu2=22.4$, $SD1=6.1$, and $SD2=8.6$. Calculated n (for each arm)$=[(Z\alpha+Z\beta)^2 X (SD1^2+SD2^2)]/d2$, where $Z\alpha=1.96$ (two-tailed) at 95% confidence level, $Z\beta=0.84$ at 80% power and d=Effect Size, that is, the minimum difference between groups to suggest a discernible clinical benefit. By putting the above-mentioned values, the sample size in each arm was calculated to be 45; the recruitment target was set at 50 per group considering a margin of 10% for possible dropouts.

RESULTS

A total of 100 patients were enrolled in this study. The CONSORT style diagram showing patient flow is given in Figure 1.

Evidently, as seen in Table 1, there was no significant difference between the two groups with respect to demographic data, ASA physical status, Mallampati score, and duration of operation.

OLP was significantly high in laryngoscope-guided insertion group than convention blind insertion group (Table 2 and Figure 2). However, laryngoscope-guided insertion took about 5 s more time on average than conventional insertion. LMA was inserted in 45 out of 50 (90%) participants at 1st attempt in the conventional insertion group. In the laryngoscope-guided insertion group in 42 out of 50 participants (84%) LMA was inserted at 1st attempt. This difference was not significant (P=0.554) statistically.

In both groups, there was no significant difference in adverse events (Table 3). However, post-LMA insertion HR and mean blood pressure were relatively more in

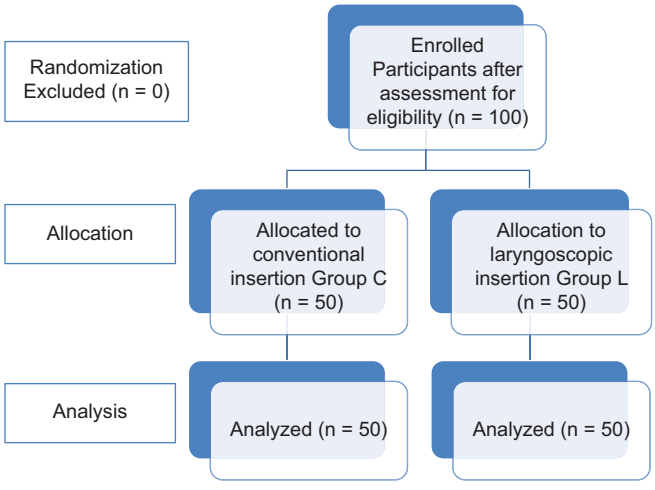

Figure 1: Patient flow in the study

Table 1: Comparison of demographic profile, American Society of Anesthesiologists physical status (ASA-PS), and duration of surgery between the two study groups

Parameter	Group C (Conventional insertion)	Group L (laryngoscope guided)	P-value
Age (y)	39.6±14.09	37.9±12.85	0.525
Sex ratio (M : F)	25:25	24:26	1.000
Weight (kg)	53.2±6.69	51.2±7.81	0.185
Height (m)	1.57±0.11	1.55±0.08	0.448
BMI (kg/m^2)	21.7±1.93	21.2±2.70	0.369
ASA-PS status (I/II)	37/13	40/10	0.645
Mallampati score (I/II/III/IV)	25/20/5/0	25/21/4/0	0.136
Duration of surgery (min)	60.7±14.72	62.3±15.70	0.600

BMI: Body mass index

Table 2: Safety and efficacy comparison between the study groups

Parameter	Group C (Conventional insertion)	Group L (laryngoscope guided)	P-value
Oropharyngeal leak pressure (cm H_2O)	17.4±3.53	22.6±3.59	**0.001**
No of insertion attempts (1st/2nd)	45/5	42/8	0.554
Time taken for insertion	23.3±5.03	28.3±5.92	0.010
Ease of insertion (easy/fair/difficult)	42/5/3	38/8/4	**0.410**

Table 3: Adverse event data

Parameter	Group C (Conventional insertion)	Group L (laryngoscope guided)	P-value
Bloodstain on LMA	48/2/0	44/4/2	0.242
Adverse events (Nil/Sore throat/ Dysphonia)	45/5/0	41/9/0	0.388

LMA: Laryngeal mask airway

Table 4: Hemodynamic parameters compared between the study groups

Parameter	Group C (Conventional insertion)	Group L (laryngoscope guided)	P-value
Baseline heart rate	77.1±8.74	75.6±9.85	0.448
Post-induction heart rate	72.6±8.27	70.3±9.47	0.215
Pre-insertion heart rate	68.8±8.31	65.8±8.34	0.061
Post-insertion heart rate	69.9±8.33	66.1±8.07	**0.025**
Baseline mean blood pressure	86.8±12.76	85.2±12.73	0.542
Post-induction mean blood pressure	73.2±8.91	71.7±10.71	0.442
Pre-insertion mean blood pressure	63.8±7.51	61.9±9.31	0.259
Post-insertion mean blood pressure	68.5±9.76	73.3±11.67	**0.029**

Heart rate recorded in bpm and blood pressure in mmHg, Bold implies statistically significant

laryngoscope-guided insertion technique than in the conventional method (Table 4) which may be attributable to the laryngoscopic stress response.

DISCUSSION

The main finding in this study was that OLP was significantly high in laryngoscope-guided insertion group than blind insertion group. The plausible explanation for this is that due to direct visualization at laryngoscopy, LMA cuff may plug firmly to periglottic tissue. Furthermore, leftward displacement of tongue by laryngoscope helps the LMA to be introduced straight forward and minimizes lateral deviation. Laryngoscopy may also help to maintain alignment of LMA to laryngeal skeleton. Kim et al.,[6] in their study, reported higher OLP when LMA (LarySeal™) was inserted under laryngoscope guidance (21±8.6 cm H_2O)

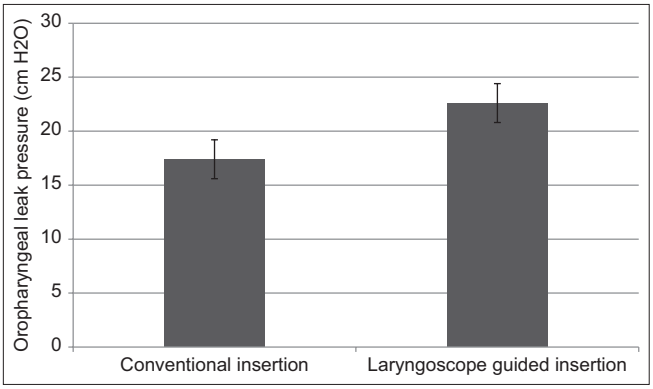

Figure 2: Graphical representation of mean oropharyngeal leak pressure achieved in the two study arms

when compared to blind insertion technique (18.1±6.1 cm of H_2O). Similar study was conducted by Ozgul et al.,[7] who was also achieved higher OLP values of ProSeal™ LMA in video laryngoscope-guided insertion group in comparison to the blind insertion technique. Vyas et al.,[8] in

their Macintosh laryngoscope-guided insertion group also found higher OLP values (26.9±3.37 cm H_2O) which was comparable with the previous studies. Hence, our study also found that higher OLP denotes better sealing of LMA cuff to periglottic area, helps to deliver better positive pressure ventilation, reduces O_2/anesthetic gas leak, and causes less gastric insufflation.

In this study, we also found that time taken for insertion of LMA was higher in laryngoscope-guided insertion than the conventional LMA insertion. Possible reason for this is the need to handle two instruments and the time required for laryngoscopic manipulation. However, the extent of prolongation (5 s only) was modest and unlikely to affect outcome. The LMA was easily inserted in 84% of participants in the conventional group and 76% of participants in laryngoscope-guided group. The insertion was difficult in 6% and 8% of participants in the two groups, respectively. However, this comparison was not significant statistically. Again, the possible reason is the need for handling two instruments in confined space simultaneously.

Incidence of airway trauma (blood staining on LMA) and adverse events (sore throat and dysphonia) postoperatively were not statistically significant. Regarding hemodynamic parameters, baseline and 1 min post-induction HR and MBP variations were not statistically different between the two groups. However, after insertion of LMA, there was a significant rise in HR and MBP in laryngoscope-guided insertion compared to conventional insertion. These post-insertion hemodynamic changes are short-lived and not a concern to healthy individuals. Nevertheless, the laryngoscopic technique should be avoided in patients with pre-existing myocardial or cerebral disease.[9] Potentially, these hemodynamic changes may be avoided by only gentle lift of epiglottis at laryngoscopy and adequate depth of anesthesia before laryngoscopy.

Limitations of the study

Our study had limitations. First, the assessment of ease of insertion was subjective; therefore, there is a potential chance of bias. Second, in the present study, LMA insertion was done by an experienced anesthesiologist familiar with both techniques. Therefore, the results do not necessarily apply to novice users. Third, our data cannot be applied to all kinds of supraglottic airway. Results may vary with cuff properties and shape of supraglottic airway. Fourth, we did not use muscle relaxants before insertion of the LMA, because the LMA can be inserted easily without muscle relaxants when adequate depth of anesthesia has been established.[10,11] There is some evidence that the use of neuromuscular blocker can alter the OLP[12], this fact needs be considered in future studies.

CONCLUSION

Despite these limitations, we can conclude that laryngoscope-guided LMA insertion improves the airway seal pressure better than conventional technique with some limitations. These results need confirmation in the hands of a wider spectrum of users and a wider variety of patients than those we have included in this study.

ACKNOWLEDGMENT

We are grateful to all the patient who have given their consent and time for participants. We would also like to thank our faculty members who spare their valuable time for these study.

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Authors Contribution:
AG- Definition of intellectual content, literature survey, prepared the first draft of manuscript, implementation of the study protocol, data collection, data analysis, manuscript preparation; **BL**- Concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision; **SRB**- Concept, design of study, statistical analysis, manuscript preparation, editing, and manuscript revision; **DS**- Coordination and manuscript revision.

Work attributed to:
Not applicable.

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Source of Support: Nil, **Conflicts of Interest:** None declared.