

Insertion of LMA Classic™ with and without digital intraoral manipulation in anesthetized unparalyzed patients

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Abstract

Background: The standard recommended insertion technique for LMA Classic™ requires the insertion of index finger into the oral cavity. Several anesthesiologists are reluctant to do this. We conducted this study to evaluate the modified technique of insertion of LMA Classic™ (not requiring insertion of fingers into the patient's mouth) against the standard index finger insertion technique.

Materials and Methods: This prospective, randomized, comparative study was conducted on 200 consenting patients. Patients suitable for anesthesia with LMA Classic™ were randomized to standard technique group (standard insertion technique) and modified technique group (technique not requiring digital intraoral manipulation). Laryngeal mask airway (LMA) was inserted by five designated anesthesiologists. Anesthetic protocol was standardized. Time taken to achieve an effective airway, ease of insertion, glottic view obtained through LMA, and incidence of sore throat were assessed.

Results: Patient characteristics and duration of surgery were comparable between the groups. Time to achieve an effective airway was comparable [18.5 (8) s with standard technique and 19.7 (10) s with modified technique; data are mean (standard deviation)]. Ease of insertion (92 easy with standard technique and 91 easy with modified technique), success rate (99% in both the groups), glottic view with fiberoptic bronchoscope, and sore throat incidence (six patients with standard technique and eight patients with modified technique) were comparable. The first attempt success rate was significantly higher with the standard technique (98 patients in the standard technique group and 91 patients in the modified technique group).

Conclusions: LMA Classic™ can be inserted successfully without the need to insert index finger into patient's mouth, though the first attempt success rate is higher with the standard technique.

Key words: Insertion technique, LMA Classic™ Supraglottic device

Introduction

Experience with newer supraglottic devices like i-gel and laryngeal tube has shown that these devices can be appropriately positioned even without introducing the index finger into the oral cavity during insertion. Studies with recent prototypes of laryngeal mask airway (LMA) like LMA Unique™ and LMA Soft Seal™ have shown that these LMAs can be satisfactorily positioned without digital intraoral manipulation.^[1,2] However, the standard

recommended insertion technique for LMA Classic™ still requires the insertion of index finger into the oral cavity. Several anesthesiologists are reluctant to do this. We conducted this study to evaluate the modified technique of insertion of LMA Classic™, which does not require the insertion of fingers into the patient's mouth, as against the standard technique.

Materials and Methods

This prospective, randomized, comparative study was conducted at a tertiary care hospital after obtaining approval from Institutional Ethics Committee. This study was registered in the Clinical Trials Registry India (CTRI/2010/091/000355). Two hundred patients scheduled for elective surgery were enrolled. The inclusion criteria were: a) patients of either gender, aged between 18 and 65 years, scheduled for surgery with anticipated duration <2 h and (b) American Society of Anesthesiologists physical status 1 and 2. The exclusion criteria were: (a) patients at risk of regurgitation and aspiration; (b) surgeries where use of LMA would be inappropriate; (c) body mass index > 35 kg/m²;

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(d) predicted airway difficulty; and (e) emergency surgery. Written informed consent was obtained from all the patients included. Preoperative nil per oral instructions were 6 h for solids and 2 h for clear fluids. Patients were premedicated with oral diazepam, 5 mg (if body weight \leq 50 kg) or 10 mg (if body weight $>$ 50 kg), on the night prior to surgery.

Patients were randomized to two groups: standard technique group (standard insertion technique with digital intraoral manipulation) or modified technique group (modified insertion technique without digital intraoral manipulation) using computer generated random number table and the allocation was concealed in a sealed envelope. The sealed envelope was opened before shifting the patient to the operating room. Stratified randomization into five strata was done for LMA Classic™ to be inserted by five designated anesthesiologists (two consultant and three resident anesthesiologists). The consultant/resident anesthesiologist who inserted the LMA had an experience of at least 100 insertions with the standard technique. They were briefed about the modified technique of insertion before the start of the study and were given the opportunity to practice this technique on a manikin.

In the operating room, standard monitoring included ECG, pulse oximetry, non-invasive blood pressure, and end-tidal carbon dioxide. Intravenous (IV) access was secured. Glycopyrrolate 10 mcg/kg and fentanyl 2 mcg/kg were administered IV. After 3 min of preoxygenation, anesthesia was induced with propofol 3 mg/kg IV. Loss of verbal contact was considered as the end point of induction. If required, additional boluses of 10 mg propofol were administered. Ventilation was then assisted with 2% isoflurane in 100% oxygen for 1 min. After ensuring adequate jaw relaxation, LMA Classic™ was inserted either by the standard technique or by the modified technique, depending on the randomization. If the jaw was not adequately relaxed or the patient moved during insertion, further boluses of 10 mg propofol were injected. The total dose of propofol injected was recorded. In either group, LMA Classic™ of appropriate size was used based on the patient's weight. Pre-use test was performed before LMA Classic™ insertion.^[3] Number of repetitive use of LMA Classic™ was restricted to 40 as recommended by the manufacturer, in both the groups.^[3] The LMA Classic™ was deflated completely and the posterior aspect lubricated with water-soluble jelly prior to insertion. In the standard technique group, LMA Classic™ was inserted as recommended by the manufacturer. (The patient was positioned supine with head and neck in sniffing position. LMA Classic™ was held like a pen, with the index finger placed at the junction of the cuff and the airway tube. Under direct vision, the tip of the cuff was pressed upward against the hard palate and the cuff was flattened against it. Using the index finger, the cuff was pressed backward toward the occiput and the device

was advanced into the hypopharynx. The index finger was inserted to its fullest extent into oral cavity before resistance was encountered. Before removing the index finger, the non-dominant hand was used to stabilize the shaft of the LMA, to prevent the LMA from being displaced, when the index finger of the dominant hand was removed.) In the modified technique group, the patient was positioned supine with head and neck in sniffing position. After opening the mouth, LMA Classic™ was held at the junction of the proximal one-third and distal two-thirds of the shaft, between the index finger and the thumb of the dominant hand. LMA Classic™ was introduced into the mouth, flattening the cuff against the hard palate and pushing it down into the pharynx until resistance was encountered. When the index finger and the thumb reached the mouth of the patient as the LMA was introduced, these fingers were readjusted to the proximal end of the LMA. No undue force was exerted on the LMA during these steps.

If the anesthesiologist felt that the tongue was hampering the advancement of LMA, then the assistant was asked to provide jaw thrust externally, by lifting the angle of the mandible. Such maneuvers were recorded, if used.

After insertion of LMA Classic™, the cuff was inflated with maximum recommended volume of air for that particular size. Ventilation was assisted to check whether an effective airway was secured (as defined by square wave capnogram trace, without audible leak at peak inspiratory pressure 20 cm H₂O and normal chest movements). Subsequently, the intracuff pressure was measured with an aneroid cuff pressure manometer. The cuff was inflated or deflated to achieve an intracuff pressure of 60 cm H₂O.

A maximum of 90 s was allowed for successful insertion. A maximum of two attempts within this 90 s duration was allowed. An attempt was defined as inserting the LMA into patient's mouth and removing it from the patient's mouth. If both the attempts failed with one technique, then crossover to the other technique was tried with only one attempt. If this too failed, then the concerned anesthesiologist was free to decide on further airway management. If there was desaturation to 95% or below during an attempt to insert, the attempt was aborted and mask ventilation with 100% oxygen was resumed.

The time taken to achieve an effective airway was defined as the time from picking up of LMA Classic™ till achievement of square wave capnogram trace without audible leak at 20 cm H₂O and normal chest movements.

Ease of insertion was graded as follows: grade 1 – easy, no resistance; grade 2 – some difficulty, some resistance; and grade 3 – impossible to insert.

Number of attempts taken to insert LMA Classic™ successfully was recorded. If the LMA could not be inserted in two attempts, it was considered as failed insertion.

A blinded observer (blinded to insertion technique) assessed the final position of LMA Classic™ after successful insertion and its fixation. The glottic view obtained by fiberoptic scope through LMA Classic™ was recorded, keeping the tip of the fiberoptic scope at the aperture bar in neutral position. Glottic view was graded as follows: grade 1 – vocal cords entirely visible, grade 2 – vocal cords or arytenoids partially visible, grade 3 – epiglottis only visible, and grade 4 – no laryngeal structure visible. The patient was blinded to the technique of insertion.

Any blood stain on LMA Classic™ at the end of the procedure was noted. Patients were interviewed for the presence of sore throat after 1 h and then 24 h after the procedure. The modified Mallampati class of every patient was recorded preoperatively to analyze whether the relative size of the tongue in the oral cavity influenced the success rate of insertion.

Assuming $\alpha = 0.05$ and $\beta = 0.20$, with success rate at first attempt for standard technique and modified technique of insertion at 97%, the hypothesized difference of ≤ 0.1 considered as equivalence, it was calculated that this study would require a total of 192 patients. To account for any dropouts, we included 200 patients in this study. Data were analyzed using SPSS 13.0 for Windows. Duration of surgery, dose of propofol injected, and time to achieve an effective airway were compared with independent samples *t*-test. Modified Mallampati class of patients, number of attempts taken to achieve an effective airway, success rate of LMA insertion, ease of LMA insertion, and the glottis view through the fiberoptic bronchoscope were compared with Chi-square test. *P* value < 0.05 was considered significant.

Results

Patient characteristics, duration of surgery, and the dose of propofol injected are given in Table 1. There were no losses and exclusions after randomization in both the groups. The modified Mallampati class of the patients was comparable between the two groups [Table 1]. Time taken to achieve an effective airway was comparable between the two groups [Table 2]. The number of attempts taken to achieve an effective airway is given in Table 3. The first attempt success rate was significantly higher with the standard technique group. However, the overall success rate was equal in both the groups [Table 3]. Ease of insertion was comparable between the two groups [Table 3]. There was no significant difference

Table 1: Patient characteristics, duration of surgery, propofol dose injected, and modified Mallampati class of patients

	Standard technique group (n = 100)	Modified technique group (n = 100)	P value
Age (years)	40 (12)	40 (13)	
Gender			
Male	80	77	
Female	20	23	
Weight (kg)	61 (11)	62 (11)	
Duration of surgery (minutes)	28 (17)	28 (19)	1.00
Dose of propofol injected (mg)	197 (42)	199 (41)	0.734
MMP class 1	29	27	0.531
MMP class 2	48	50	
MMP class 3	21	23	
MMP class 4	2	0	

Data are mean (standard deviation) for age, weight, duration of surgery, and dose of propofol injected; absolute numbers for gender distribution and modified Mallampati (MMP) classification

Table 2: Time taken to achieve an effective airway

	Standard technique group (n = 100)	Modified technique group (n = 100)	P value
Time taken to achieve an effective airway (seconds)	18.5 (8)	19.7 (10)	0.349

Data are mean (standard deviation)

Table 3: Number of attempts taken to achieve an effective airway, success rate, ease of insertion, and glottic view with fiberoptic bronchoscope through the LMA

Insertion success	Standard technique group (n = 100)	Modified technique group (n = 100)	P value
Successful insertion			
First attempt	98	91	0.017
Second attempt	1	8	
Failed insertion	1	1	
Ease of insertion			
Grade 1: Easy, no resistance	92	91	0.965
Grade 2: Some difficulty, some resistance	7	8	
Grade 3: Impossible to insert LMA Classic™	1	1	
Glottic view through the LMA			
Grade 1 (vocal cords are entirely visible)	58	68	0.378
Grade 2 (vocal cords or arytenoids partially visible)	29	25	
Grade 3 (epiglottis only visible)	10	6	
Grade 4 (no laryngeal structures seen)	3	1	

in the final position of the LMA as assessed by the glottic view with fiberoptic bronchoscope [Table 3]. Seven patients in each group had blood stain on the LMA at the end of the procedure. After 1 h of surgery, three patients in the standard technique group and eight patients in the modified technique group had sore throat, but the difference was statistically not significant ($P = 0.187$). After 24 h, the incidence of sore throat was comparable between the two groups (six patients in the standard technique group and eight patients in the modified technique group, $P = 0.579$).

Discussion

A significant number of anesthesiologists are still reluctant to insert their index finger into patient's mouth for LMA Classic™ insertion, fearing the potential risk of trauma and infection. The reverse or the rotational technique of insertion and direct laryngoscopy aided insertion technique do not require finger insertion into the patient's mouth. But they have several disadvantages like dislocation of the arytenoid cartilages, unsatisfactory positioning, and need for laryngoscopy.^[3-5] Experience with newer supraglottic devices has shown that these can be just "pushed in" to their correct final position when steered along the palate, without the need for digital intraoral manipulation.

Techniques which do not require the insertion of index finger into the oral cavity for LMA insertion have been described, which triggered us to conduct this study.^[1,2] These techniques have been described with LMA Unique™ and Soft Seal™ LMA, which cannot be directly extrapolated to the use of LMA Classic™.^[1,2] The material of LMA Classic™, LMA Unique™, and Soft Seal™ LMA is different. Hence, we felt that the technique of LMA Classic™ insertion without digital intraoral manipulation, as described by Brimacombe and Keller, with minor modifications (holding the LMA Classic™ in the proximal one third rather than middle one third to obviate the need for finger repositioning as mouth is reached during insertion), needs to be evaluated against the "gold standard" standard technique of insertion.

While designing the study, several precautions were taken to minimize confounding factors. LMA Classic™ was inserted by anesthesiologists with an experience of >100 insertions by standard insertion technique. This ensured that the operator inserting the LMA Classic™ was at the plateau of the learning curve. Contradicting this, most of the operators had no or very limited experience with the modified technique. This did place the standard technique group at advantage over the modified technique group. We preferred to involve five anesthesiologists for LMA insertion rather than a single

anesthesiologist to insert the LMA in all the cases to avoid single-operator bias.

To ensure patient safety, only 90 s were allowed for successful insertion. Within these 90 s, only two attempts were allowed for obvious ethical reasons. Crossover from one technique to another was not done on each patient. We were concerned about subjecting the patient to unnecessary repeated airway manipulations. Crossover from one technique to another in a patient was done only if the primary technique failed despite two attempts. Only one attempt with the alternate technique was permitted to evaluate if it was effective in case of failure with the primary technique.

The time taken to achieve an effective airway was comparable between both the techniques. The time taken to obtain an effective airway in the study by Brimacombe *et al.* was longer for both the standard and modified technique groups, as compared to our study.^[1] This was possibly because they defined the time to achieve effective airway as the time from picking up the device to two consecutive breaths with an expired tidal volume ≥ 8 mL/kg.^[1]

Majority of the insertions were described to be easy by the operators in both the groups. The exact causes for difficulty in insertion in the remaining cases, when questioned, were as follows – first time insertion with the modified technique, mouth opening inadequate despite deepening the plane of anesthesia, and bucked tooth.

The success rate for insertion was equal with both the techniques (99%). The success rate in our study was higher for both the techniques when compared to the study by Brimacombe *et al.* (94% for with digital intraoral manipulation and 93% for without digital intraoral manipulation).^[1] While in our study experienced anesthesiologists inserted the LMA Classic™, it was inserted by inexperienced personnel after manikin training only in their study. The difference in the type of the LMA used could also account for this.^[1] The success rate with the direct insertion technique without digital intraoral manipulation for Soft Seal™ LMA was 100%.^[2] Although the overall success rate in our study was comparable between the two groups, the first attempt success rate was significantly higher with the standard technique. In our study, the anesthesiologists inserting the LMA Classic™ had considerable experience with the standard technique, but nil to minimal experience with the modified technique. This could have accounted for the difference in the first attempt success rate.

The cause for failure to achieve an effective airway in the standard group (modified Mallampati class 4) and the

modified technique group (modified Mallampati class 3) was similar and it was the failure to advance the LMA beyond the oral cavity. After crossover to the alternate technique, LMA Classic™ was inserted successfully in the first attempt.

The glottic view obtained with fiberoptic bronchoscope was comparable with both the techniques. More number of patients in the modified technique group had grade 1 view, though it was not statistically significant. Also, while only one patient in the modified group had grade 4 view (no laryngeal structures visualized), three patients in the standard group had grade 4 view. The clinical relevance of these is not clear because it has been recognized that lung ventilation is often adequate and clinical signs of improper placement are rarely observed even when the LMA Classic™ is not in the optimal position.^[2] Kuvaki *et al.* found that in 67% of patients in the direct insertion group, only vocal cords were visible.^[2] We assessed the glottic view by the method described by Verghese *et al.*^[6]

The incidence of blood stain on the LMA at the time of removal and postoperative sore throat were assessed as surrogate markers of airway trauma secondary to LMA insertion. The incidence of blood on LMA and postoperative sore throat were comparable between the two groups.

We conclude that LMA Classic™ can be inserted successfully without the need to insert fingers into patient's mouth, though the first attempt success rate is higher with the standard technique of insertion.

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