A STUDY OF INSERTION OF LMA CLASSIC™ WITH AND WITHOUT DIGITAL INTRAORAL MANIPULATION IN ANAESTHETISED PATIENTS

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ABSTRACT

BACKGROUND

Airway management is the most essential skill in anaesthesiology and inability to secure the airway is one of the most common reasons for major anaesthesia-related morbidities and mortalities. Laryngeal Mask Airway (LMA) has established role in modern anaesthetic practice. It is used for airway maintenance of spontaneously breathing patients who are undergoing elective short surgical procedures.

The aim of the study is 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

Patients were randomly allocated to one of two equal-sized groups (n=100).Patients were randomised to 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 sealed envelope technique.

RESULTS

Both the groups were comparable with respect to distribution of age (0.935), weight (0.733) and sex (0.606) and the p values were nonsignificance. As indicated in Table 2, the groups were comparable with respect to American Society of Anaesthesiologists Physical Status of the patients. The duration of the entire surgical procedure was similar in both the groups. This implies that the duration for which the LMA Classic™ was in situ in the patient was comparable between the two groups. The incidence of postoperative sore throat was comparable in both the groups. Five patients who had blood on the LMA Classic™ at the end of the procedure had sore throat, 4 had sore throat after 1 hour and 1 after 24 hours. The glottic view obtained with the fiberoptic bronchoscope passed through the LMA Classic™ was comparable in both the groups. Though more number of patients (68 patients) had grade 1 view in the modified group compared to standard group (58 patients), it was not significant statistically.

CONCLUSION

We conclude that LMA Classic™ can be inserted successfully without the need to insert finger into patient's mouth with results comparable to that obtained by the standard index finger insertion technique.

KEYWORDS

Laryngeal Mask Airway, Standard Insertion Technique, Modified Insertion Technique.

BACKGROUND

Airway management is the most essential skill in anaesthesiology and inability to secure the airway is one of the most common reasons for major anaesthesia-related morbidities and mortalities.[1] Laryngeal Mask Airway (LMA) has established role in modern anaesthetic practice. It is used for airway maintenance of spontaneously breathing patients who are undergoing elective short surgical procedures.[2] Controlled ventilation via LMA has been successfully used at modest level of airway pressures.[3] Insertion of LMA by using the standard technique is not always successful. In addition, a degree of skill is required to place LMA correctly and suboptimal positioning of the device can give rise to such problems as air leakage or airway obstruction.[4]

Experience with newer supraglottic device like i-gel, LMA Unique and LMA Soft seal has shown that these devices can be appropriately positioned even without introducing the index finger into the oral cavity during

insertion. However, the standard recommended insertion technique for LMA Classic™ still requires the insertion of index finger into the oral cavity. Several anaesthesiologists are reluctant to do this.

Aims of the Study
To compare the insertion of LMA Classic™ with and without digital intraoral manipulation with respect to-
- Time taken to achieve an effective airway.
- Ease of insertion.
- Number of attempts taken for successful insertion of LMA.
- Fiberoptic evaluation of LMA position.
- Blood stain on LMA after the procedure.
- Postoperative sore throat.

MATERIALS AND METHODS
The study was a prospective, randomised, comparative study. It was started after obtaining approval from department dissertation committee and Institutional Ethics Committee. 200 patients who were scheduled for elective surgery were enrolled for the study based on the following criteria.

Inclusion Criteria- Patients of age between 18-80 years, ASA I and II, MPC I and II scheduled for elective short surgical procedures requiring general anaesthesia with spontaneous breathing were included in the study.

Exclusion Criteria- Patients refused for the procedure, with BMI >30 kg/m2, known or predicted difficult airway (MPC 3 and 4), recent sore throat, difficulty in mouth opening <2.5cm, anticipated risk of aspiration (nonfasted or history of GERD) and bleeding disorders were excluded from the study.

Preoperative Evaluation- A written informed consent for participation in the study was obtained from patients enrolled for the study. Patients were kept nil per oral at least 6 hours for solids and 3 hours for clear fluids.

Premedication- Tablet. Alprazolam 0.5 mg and Tablet. Ranitidine 150 mg was given as premedication on preoperative day.

Depending on the randomisation, LMA Classic™ was inserted either with standard technique or modified technique.In either group, LMA Classic™ of appropriate size was used based on patient's weight.

The LMA Classic™ was deflated completely and the posterior aspect lubricated with water soluble jelly prior to insertion.

Standard Technique Group- LMA Classic™ inserted as recommended by the manufacturer.[3]

The patient was positioned supine with head and neck in sniffing position. The 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 against it. Using the index finger, the cuff was pressed backward toward the occiput. 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 stabilise the shaft of the LMA Classic™ to prevent the LMA Classic™ from being displaced, when the index finger of the dominant hand was removed.

Modified Technique Group- The modified technique without digital intraoral manipulation involved the following steps.

The patient was positioned supine with head and neck in sniffing position. Neck was flexed and head extended, cupping the occiput with the non-dominant hand. 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 Classic™ was introduced, these fingers were readjusted to the proximal end of the LMA Classic.™

No undue force was exerted on the LMA Classic™ during these steps.

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 H_2O 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 cmH_2O.

A maximum of 90 seconds was allowed for successful insertion. A maximum of two attempts within this 90 seconds duration was allowed.

If both the attempts failed, crossover to the other technique was tried with only one attempt. If this too failed, concerned anaesthesiologist posted was free to do further management.

If there was desaturation to 95% or below during an attempt to insert LMA Classic™, 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 H_2O and normal chest movements.

Number of attempts taken to insert LMA Classic™ successfully was recorded. If the LMA Classic™ could not be inserted in 2 attempts, it was considered as failed insertion.

The glottic view obtained by fiberoptic scope through LMA Classic™ was recorded, keeping the tip of the fiberoptic scope at the aperture bar.

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 hour and then after 24hrs.after the procedure.

RESULTS

A total of 200 patients were enrolled in the study and were randomly allocated to one of the two groups. Each group consisted of 100 patients.

1. Standard technique group (with digital intraoral manipulation).
2. Modified technique group (without digital intraoral manipulation).

Demographic Data

Parameter	Standard Technique Group n=100	Modified Technique Group n=100	p Value
Age (years) Mean ± SD	40 ± 12	40 ±13	0.935*(NS)
Gender Male Female	80 20	77 23	0.606**(NS)
Weight (kg) Mean ± SD	61 ± 11	62 ± 11	0.733*(NS)
Table 1. Both the Groups were Comparable with Respect to Distribution of Age, Weight and Sex			

*Independent Sample T test; **Chi-square test; SD- Standard Deviation; NS- Not statistically significant.

Patient characteristics are given in Table 1.

Parameter	Standard Technique Group n=100	Modified Technique Group n=100	P Value
ASA PS 1	81	74	0.236*(NS)
ASA PS 2	19	26	
Table 2. ASA Physical Status Classification			

*Chi-square test.

ASA PS- American Society of Anaesthesiologists Physical Status. As indicated in Table 2, the groups were comparable with respect to American Society of Anaesthesiologists Physical Status of the patients.

Parameter	Standard Technique Group n=100	Modified Technique Group n=100	P Value
Duration (minutes) Mean ± SD	28 ± 17	28 ± 19	0.784 *(NS)
Table 3. Duration of the Surgical Procedure			

*Mann-Whitney test; SD- Standard deviation; NS- Not statistically significant.

Modified Mallampati Class	Standard Technique Group n=100	Modified Technique Group n=100	P Value
Class 1	29	17	
Class 2	48	50	0.531*(NS)
Class 3	21	23	
Class 4	2	0	
Table 4. Modified Mallampati Classification			

*Chi-square test; NS- Not significant statistically.

As shown in table 4, the distribution of patients in the four classes of modified Mallampati classification was comparable between the two groups. Though 44 patients belonged to modified Mallampati class 3 and 2 patients belonged to modified Mallampati class 4, the other parameters of airway assessment in these patients were normal and difficult airway was not anticipated in these patients by the concerned anaesthesiologist posted for the case.

Parameter	Standard Technique Group n=100	Modified Technique Group n=100	P Value
Propofol (mg) Mean ± SD	197 ± 42	199 ± 41	0.789*(NS)
Table 5. Dose of Propofol Injected			

*Independent sample t-test; NS- Not significant statistically.

The total dose of propofol injected in patients in either group was comparable. It was ensured that all patients in either group had adequate jaw relaxation before LMA Classic™ insertion. To achieve this, bolus increments of propofol were injected if required over and above the precalculated 3 mg/kg dose of propofol.

Parameter	Standard Technique Group n=100	Modified Technique Group n=100	P Value
Time taken (seconds) Mean ± SD	18.5 ± 8	19.7 ± 10	0.962*(NS)
Table 6. Time Taken to Achieve an Effective Airway			

*Mann-Whitney test; NS- Not significant statistically.

The time taken for achieving an effective airway was comparable in both the groups.

Ease of Insertion	Standard Technique Group n=100	Modified Technique Group n=100	P Value
Grade 1-easy, no resistance	92	91	
Grade 2-some difficulty, some resistance	7	8	0.965 *(NS)
Grade 3-impossible to insert LMA Classic™	1	1	
Table 7. Ease of Insertion			

*Chi-square test; NS- Not significant statistically.

From the table above, the ease of insertion was grade 1 (easy, no resistance) in 92% of patients in standard technique group patients and 91% in modified technique group patients. In 2 cases, 1 each in both groups, it was impossible to insert the LMA Classic™ beyond the oral cavity in 2 attempts, therefore crossover was done and LMA Classic™ was successfully inserted.

Attempt	Standard Technique Group n=100	Modified Technique Group n=100	P Value
1st attempt	98	91	0.035*(S)
2nd attempt	1	8	
Table 8. Number of Attempts Taken to Achieve an Effective Airway			

*Exact Chi-square test; S- Statistically significant.

As per table 8 in standard technique group, first attempt success rate was 98%, while in modified technique group, it was 91%. The first attempt success rate was significantly higher with standard technique of insertion compared to modified technique.

	Standard Technique Group n=100	Modified Technique Group n=100
Successful insertion of LMA Classic™	99	99
Failed insertion of LMA Classic™	1	1
Table 9.Success of LMA Classic™ Insertion		

According to Table 9, the successful insertion of LMA Classic™ was 99% in both the groups. The overall success rate was equal with both the techniques of insertion.

	Standard Technique Group n=100	Modified Technique Group n=100	P Value
Grade 1	58	68	
Grade 2	29	25	0.378*(NS)
Grade 3	10	6	
Grade 4	3	1	
Table 10. Glottic View Grading			

*Chi-square test; NS- Not significant statistically.

Grade 1- Vocal cords are entirely visible.
Grade 2- Vocal cords or arytenoids partially visible.
Grade 3- Epiglottis only visible.
Grade 4- No laryngeal structures seen.

	Standard Technique Group n=100	Modified Technique Group n=100	P Value
Blood stain present on LMA Classic™	7	7	1*(NS)
Blood stain absent on LMA Classic™	93	93	
Table 11. Presence of Blood Stain on the LMA Classic™ at the End of the Procedure			

*Chi-square test; NS- Not significant statistically.

Blood stain on the LMA Classic™ at the end of the procedure was comparable in both the groups. There was no correlation with the number of attempts and presence of blood stain. Only one patient in standard group with failed insertion had blood stain on LMA Classic™.

Sore Throat	Standard Technique Group n=100	Modified Technique Group n=100	P Value
After 1 Hour			
Yes	3	8	0.187*(NS)
No	97	92	
After 24 Hours			
Yes	6	8	0.579*(NS)
No	94	92	
Table 12. Number of Patients with Postoperative Sore Throat			

* Chi-square test; NS- Not significant statistically.

DISCUSSION

Before we start this study, several precautions were taken to nullify the effects of possible confounding factors. Meticulous attention was given to the randomisation and blinding of the observers. LMA Classic™ was inserted by anaesthesiologists with an experience of >100 LMA Classic™ 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 (without digital intraoral manipulation). They were explained in detail the modified technique of insertion before LMA Classic™ insertion. This did place the standard technique group at advantage over the modified technique group.

Though a pre-calculated dose of propofol (3 mg/kg) was used for induction of anaesthesia in both the groups, the endpoint before LMA Classic™ insertion, i.e. jaw relaxation was ensured in both the groups by additional doses of propofol, if required. On completion of the study, it was observed that both the groups had received comparable doses of propofol.

Pre-use test was performed before LMA Classic™ insertion.[3] Number of repetitive use was restricted to 40 as recommended by the manufacturer in both the groups.[3] This eliminated the possibility of defective or worn out LMA Classic™ confounding the results. To avoid intracuff pressure acting as a confounding factor on the incidence of postoperative sore throat, intracuff pressure was monitored and kept below 60 mmHg.

To ensure patient safety, only 90 seconds were allowed for successful insertion. Within these 90 seconds, only 2 attempts were allowed for obvious ethical reasons. Contrary to the study design of Brimacombe J et al crossover from one technique to another was not done on each patient.[5]This was due to our ethical concerns 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.

Time taken to achieve an effective airway was comparable between both the techniques of LMA Classic™ insertion. Our results correlate with the results quoted in the literature for both the standard technique and the modified technique. The time taken to obtain effective airway in the study by Brimacombe J et al was longer for both the standard and modified technique groups as compared to our study.[5]This is because they defined the time to achieve effective airway as time from picking up the device to two consecutive breaths with an expired tidal volume ≥8 mL/kg.[5]

Majority of insertions were described to be easy by the operators in both the groups (92% in standard technique group and 91% in modified technique group). The exact cause for difficulty in insertion in the remaining cases when questioned were as follows-First time insertion with the modified technique, mouth opening inadequate despite of deepening the plane of anaesthesia, bucked tooth, nonspecific. This subjective estimation of ease of insertion was not done in the studies by Brimacombe J et al and Kuvaki B et al.[5,6]

The success rate for LMA Classic™ 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 J et al (94% for with digital intraoral manipulation and 93% for without digital intraoral manipulation).[5] While in our study experienced anaesthesiologists inserted the LMA Classic™, it was inserted by inexperienced personnel after manikin only training in their study. The difference in the type of the LMA Classic™ used (LMA Classic™ in our study versus LMA Unique™ in the study by Brimacombe J et al) could also account for this.[5] The success rate with the direct insertion technique without digital intraoral manipulation described by Kuvaki B et al was 100%.[6] Though 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 (98% with standard technique versus 91% with modified technique, P=0.035). The first attempt success rate reported by Brimacombe J et al was 84% for with digital intraoral manipulation technique and 87% for without digital intraoral manipulation technique (statistically not significant).[5] The first attempt success rate in the study by Kuvaki B et al was 98% for direct insertion technique and was significantly higher than that for the rotational insertion technique.[6] In our study, the anaesthesiologists inserting the LMA Classic™ had considerable experience (>100 LMA Classic™ insertions) with the standard technique, but nil to minimal experience with the modified technique. This could have accounted for the statistical difference in the first attempt success rate. Kuvaki B et al only state that Soft Seal™ LMA was inserted by those with at least 10 years of anaesthetic experience (not clear about the experience with particular techniques evaluated in their study).[6]

The glottic view obtained with fiberoptic bronchoscope with its tip placed at the level of aperture bar of LMA Classic™ was comparable with both the techniques of insertion. We standardised the location of the tip of the bronchoscope for assessment to eliminate the observer bias to get the best view. Though blinding of the observer assessing the glottic view would have added strength to the study, we could not do so due to practical problems. More number of patients in the modified group had grade 1 view, i.e. vocal cords were entirely visible (68 patients) than in the standard group (58 patients), though it was not statistically significant. Also, while only 1 patient in modified group had grade 4 view (no laryngeal structures visualised), 3 patients in the standard group had grade 4 view. The clinical relevance of these is not clear because it has been recognised 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.[6] Assessment of glottic view was not done in the study by Brimacombe J et al.[5]Kuvaki B et al found that in 67% of patients in the direct insertion group only vocal cords were visible.[6] We assessed the glottic view by the method described by Varghese C et al[7] and which is slightly different from the scoring system of Brimacombe and Berry[8]used by Kuvaki B et al in their study.[6] Blood stain on the LMA Classic™ was assessed at the time of removal of the LMA Classic™ as a surrogate marker of soft tissue trauma during insertion. A 7% of patients in each group had blood on LMA Classic™ in our study. Kuvaki B et al found a higher incidence of blood on Soft Seal™ LMA compared to our study with the direct insertion technique (31% had trace amount of blood and 8% had significant amount of blood).[6] They commented that these side effects were not just due to the insertion technique, but also to use or omission of lubricant or other patient factors.[6] Unlike their study, we had standardised the lubrication of LMA before insertion for all the patients.

The incidence of sore throat was assessed as another index of airway morbidity caused by the technique. It was comparable between the two groups in our study, though slightly more number of patients in the modified group had sore throat at the end of both 1 hour and 24 hours. The overall incidence was lower than that found in the study by Kuvaki B et al.[6] The difference in the type of the LMA used and protocol for lubrication could have accounted for this difference. Brimacombe Jet al did not compare postoperative airway morbidity (incidence of blood stain on LMA Unique™ or postoperative sore throat) between the two techniques that they evaluated.[5]

CONCLUSION
The time taken to achieve an effective airway, rate of successful insertion, final position of the LMA Classic™ and oropharyngeal morbidity are comparable between the standard technique of insertion and modified technique in anaesthetised and unparalysed patients.

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