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Research Article

A comparative study of overall efficacy and hemodynamic effects following blind oro-tracheal intubation with ILMA vs. conventional direct laryngoscopy guided intubation with Macintosh laryngoscope

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ABSTRACT

Background: Intubating Laryngeal Mask Airway (ILMA) is a new device to guide blind oro-tracheal intubation thus offering a new approach for endotracheal intubation and is expected to produce less sympathetically driven haemodynamic stress response. The purpose of this study was to assess overall efficacy, haemodynamic advantage and complication rate with use of ILMA compared to conventional method of endotracheal intubation with use of Macintosh Laryngoscope (ML).
Methods: This randomized controlled study was conducted on 60 adult patients comparable in age, sex, weight, MPC and ASA status scheduled for elective surgeries. Patients were randomly allocated into two groups of 30 each. Both the groups received similar balanced anaesthesia technique (Inj. fentanyl 2 µg/kg, propofol 2-2.5 mg/kg, rocuronium 1 mg/kg). Tracheal intubation was done using either ILMA or Macintosh laryngoscope. The intubation time, number of attempts required for successful intubation, haemodynamic changes and oro-pharyngo-laryngeal complications encountered during both the methods were recorded.
Results: Time to intubation was comparatively longer in the ILMA group than laryngoscopy group ($P < 0.05$). The success rate of intubation was 100% in both the groups. Overall haemodynamic changes in both the groups were statistically comparable ($P > 0.05$) and ILMA appears to be offering no haemodynamic advantage over ML. The incidence of complications was rare and comparable amongst both the groups ($P > 0.05$).
Conclusions: Therefore in patients with normal airway blind intubation with ILMA is a successful and equally efficacious method without significant oro-pharyngo-laryngeal morbidity but offers no added haemodynamic advantage compared to conventional direct laryngoscopy with ML. Thus ILMA may act as a suitable alternative to ML for patients with normal airway.

Keywords: Overall efficacy, Haemodynamic effects, Intubating laryngeal mask airway (ILMA), Macintosh Laryngoscope

INTRODUCTION

The Intubating Laryngeal Mask Airway (ILMA) is a new device specially designed to guide blind intubation.[1] Various reports have shown that ILMA has advantage over laryngoscope guided tracheal intubation in patients of cervical trauma and difficult airways. It does not require head and neck manipulation for insertion and facilitate better alignment of tracheal tube. It is an effective means of maintaining ventilation and oxygenation.[2] In addition it has been reported to be effective in facial trauma and neck immobilization as well as intubating or maintaining airway in lateral position.[3-5] However it is yet to be determined whether ILMA is feasible to use as a primary intubating device in patients with normal airways. Investigators have certainly

reported a lesser stress response with ILMA. But even this has been debated and challenged. Neeraja Bharti et al. reported use of ILMA with equal success and better haemodynamic advantage over Macintosh Laryngoscope (ML) guided conventional intubation. Joo and Rose observed that Mean Arterial Pressure (MAP) was higher in patients of direct laryngoscopy compared to ILMA.[6] However Kihara et al., and Zhang Guo-Huo et al. found no haemodynamic advantage of ILMA over laryngoscopic intubation. In this randomized study, we studied and compared the overall efficacy in terms of successful intubation rates, intubation attempts, time required for intubation, haemodynamic effects and oro-pharyngeal complications with the two methods of intubation.

METHODS

After seeking approval from institutional ethical committee and patient's informed written consent in their vernacular language, 60 healthy adult patients of either sex ranging from 18-55 years, belonging to ASA status I and II, Mallampatti score ≤II, and BMI <40 scheduled to undergo elective surgical procedure under general anaesthesia requiring endotracheal intubation were randomly allocated to be assigned into two groups "L" and "I". In group-L (Laryngoscopy group) patients were intubated with the help of conventional direct laryngoscopy with ML whereas in the other group-I (ILMA group) the patients were intubated with the help of ILMA. This study was single blinded since the person carrying out intubation knew the kind of intubation method used hence couldn't be blinded however the independent observer noting down readings was kept unaware about details and nature of the study to limit the bias. The patients were blinded from the method of intubation. Patients with age <18 and >55 years, ASA status III and above, Mallampatti grading ≥III, those with anticipated difficult intubation, gastro-oesophageal reflux, cardio respiratory or cerebrovascular disease, H/o of sore throat within last 10 days and those unwilling to participate in the trial were excluded. All patients received oral sedation and antacid prophylaxis on previous night of the operation day with tablet diazepam 5 mg and tablet ranitidine 150 mg respectively. Standard fasting guidelines (6 hours for solids, 2 hours for liquids) were followed. In the morning of the scheduled surgery eligible patients were randomized in the pre op room by self-hand picking one of the 60 preformed envelopes equally divided into either of the two study groups I and L. Inside the operation room ECG, Pulse oximetry plythesmography, capnography and invasive blood pressure monitoring was applied to the patient and baseline values of Heart Rate (HR), Systolic BP (SBP), Diastolic BP (DBP), MAP were noted. As premedicants patient received inj. ondansetron 0.08 mg/kg, inj. rantac 1 mg/kg, inj. glycopyrolate 5 µg/kg, inj. midazolam 0.03 mg/kg, inj. fentanyl 2 µg/kg. After preoxygenation for 3 min with 100% oxygen, anaesthesia was induced with propofol (2-2.5 mg/kg) and inj. rocuronium (1 mg/kg) was given to facilitate tracheal intubation. The patient's lungs were manually ventilated by face mask with 100% oxygen and 1% Inspired isoflurane for 120 seconds. Patients in the group L were intubated with size 7.5 or 8 mm ID, cuffed PVC (polyvinylchloride tube), using size 3 or 4 Macintosh blade. In group I, a size 3 or 4 intubating laryngeal mask (3 for female, 4 for male) was inserted with the head in a neutral position, and the cuff inflated with 20-30 ml of air (size 3:20 ml, size 4:30 ml) both finally maintaining ILMA cuff pressure close to and not exceeding 60 cm of H_2O as checked by portex cuff pressure manometer. The ILMA was then attached to the anaesthesia breathing system and adequate ventilation was judged by chest wall movement, capnography and oro-pharyngeal leak. When ventilation with the ILMA was found to be unobstructed 2 effective breaths with 100% oxygen plus 1% isoflurane was given. A size 7.5 or 8.0mm ID well lubricated reinforced, straight, cuffed, silicone tracheal tube was passed through the metal tube of ILMA into the trachea without applying undue forces, the cuff inflated and the circuit was reconnected. The correct tube placement was confirmed clinically by the presence of bilateral breath sound and simultaneously by capnography. If resistance was encountered or oesophageal intubation occurred, following adjusting maneuvers were tried: Optimizing the airway, up-down maneuver of ILMA, raising the mask upwards, adding the air to the cuff, partial withdrawal and rotating the tube bevel. Tracheal intubation attempt was considered to have failed if it could not be accomplished after all adjusting maneuvers had failed. In these patients, the next attempt was planned to be made with either similar or different size ILMA according to the cause of failed intubation and the depth of the tube at which resistance occurred. When tracheal intubation was not be successful after two attempts, the patients were planned to be intubated through ML. When tracheal intubation was successful, the ILMA device was removed using a 25 cm stabilising rod. Anaesthesia was maintained with isoflurane 1% and 50% nitrous oxide in oxygen using closed circuit and controlled ventilation. Success rate of intubation, no. of attempts required, time required for intubation (measured from removal of pre oxygenation mask till ETT correct placement into trachea was confirmed) was noted for both methods .Maximum rise or fall in values of HR, SBP, DBP, MAP were noted by an independent observer at baseline values, pre-induction, post-induction, after laryngoscopy or ILMA insertion, ILMA removal, and at every min till 5 min post intubation. Any complications during the intubation procedure in form of fall in oxygen saturation (SpO_2 <95%), dental or mucosal trauma, oesophageal intubation or laryngospasm were also noted for both the techniques

A structured data entry form was utilized to record the values at various points of observation during the study. EXCEL spreadsheet (Microsoft Corp) was used for electronic data entry. All Analysis was done with the help of software STATA (version 10, Stata Corporation, Texas, USA). The Continuous variables between the two

groups were compared by applying student's t-test whereas the binary variables were compared by Chi-square test. Data is presented as (Mean ± standard deviation) wherever applicable. P value of (<0.05) is presumed to be statistically significant.

RESULTS

The mean age, weight, ASA physical status, Mallampatti score and sex ratio were comparable in both the groups (refer Table 1).

The time required for successful intubation was significantly longer in the group I as compared to group L (152.46 ± 26.06 and 34.9 ± 7.59 respectively). 93.3% cases were intubated successfully in the group L with single attempt and no adjusting maneuver while only 76.6% of cases in the group I could be successfully intubated in 1st attempt without any adjusting maneuver. 6.6% patients of the group L required application of some adjusting maneuver but intubation could be finished within the same i.e. 1st attempt, whereas 20% of patients in the group I required one attempt with some adjustment maneuver to complete intubation. Second attempt to intubation was required only for one patient in the group I. Overall success rate of our intubation in both the groups was 100%. None of the patients in either of the groups had any dental injury. However 3 patients (10%) in group L had evidence of mucosal injury judged by visualization of blood on laryngoscope blade after the procedure and 2 patients (6.6%) in group I had mucosal injuries judged by blood spots over the ILMA cuff after its removal. The procedure of intubation using ILMA being a blind one, oesophageal intubations are possible. We encountered two such incidences (6.6%) where oesophageal intubation resulted on first attempt with ILMA but second attempt with adjustment maneuver of the ILMA resulted in successful intubation. No oesophageal intubation occurred in group L. None of the patients in either of the study groups developed laryngospasm peri-operatively.

Table 1: Demographic data (Mean ± SD).

Variables	Group-laryngoscope (L) (n=30)	Group-ILMA (I) (n=30)
Age (years)	37.96 ± 9.99	37.36 ± 11.24
BMI	22.79 ± 1.68	22.37 ± 1.45
Sex ratio (M:F)	19:1	17:13
ASA Physical status ≤II (No. of patients)	30	30
Mallampatti score ≤II (No. of patients)	30	30

Maximum average HR in group L achieved over the whole process on intubation was 97.6 ± 4.06 (baseline: 81.63 ± 7.83) and that in the group I was 95.9 ± 6.96 (baseline: 82.86 ± 7.84). Maximum average MAP in group L achieved over the whole process on intubation was 102.15 ± 4.16 (baseline: 92.64 ± 2.99) and that with the ILMA was 104.43 ± 5.90 (baseline: 91.42 ± 2.89) (P <0.05). All The changes in HR and MAP remained within acceptable 20% from the baseline values in both the groups and hence were clinically insignificant.

Table 2: Intubation data (Mean ± SD).

Variables	Group-laryngoscope (L) (n=30)	Group-ILMA (I) (n=30)
Total intubation time (seconds)	34.9 ± 7.59	152.46 ± 26.06
Intubation attempts		
IA1 = one (without manoeuvre)	28 (93.3%)	23 (76.6%)
IA2 = one (with adjusting manoeuvre)	2 (6.6%)	6 (20.0%)
IA3 = two	0	1 (3.3%)
Overall intubation success	30 (100%)	30 (100%)

Table 3: Complications in the two study groups.

Variable	Control group-L (n=30)	Study group-I (n=30)	P value
No. of patients whose SpO_2 fell below 95%	0	0	-
No. of patients who had dental injury	0	0	-
No. of patients who had mucosal injury	3	2	0.64
No. of patients who got oesophageal intubation	0	2	0.15
No. of patients who had laryngospasm	0	0	-

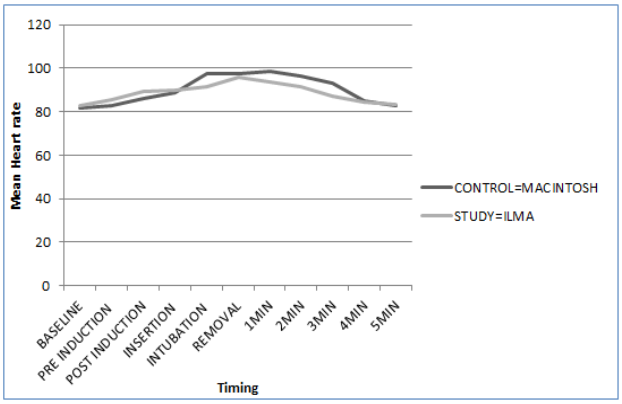

Figure 1: Showing comparison of mean heart rates in the two study groups.

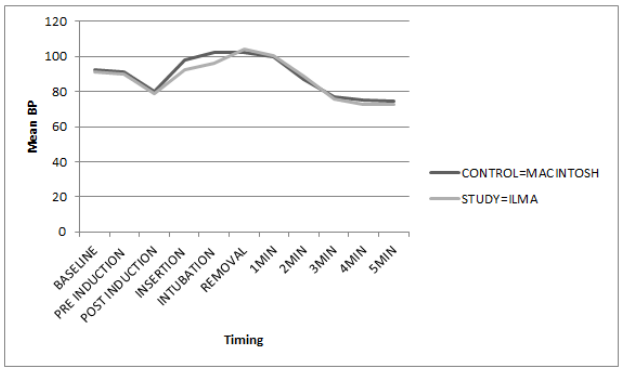

Figure 2: showing comparison of mean systolic BP in the two study groups.

DISCUSSION

Laryngoscopy and tracheal intubation can cause significant pressor responses by sympathetic stimulation.[7] Although these are only transient but may pose life threatening dangers to patients already compromised by underlying cardio-cerebral or respiratory disease states.[8] Stimulation of mechanoreceptors spread over the pharyngeal wall, epiglottis, arytenoid cartilages, vocal cords etc. are believed to be the cause for initiation of haemodynamic response to laryngoscopy and intubation. It is hence natural to expect that during the conduct of anaesthesia maximum and personal care is deputed during the stage of laryngoscopy and intubation. The search for literature therefore reveals plethora of studies during this period. The results of our study have shown that both the techniques of intubation are equally successful in intubating trachea with similar oro-pharyngeal morbidity. However time needed for intubation was longer with ILMA. Also both the methods have similar haemodynamic effects and ILMA offers no added haemodynamic advantage over Macintosh laryngoscope. But when looked at individual steps of intubation it was seen that insertion of ILMA and passing of Endo-Tracheal Tube (ETT) through ILMA generates lesser pressor response compared to laryngoscopy and intubation with Macintosh laryngoscope ($P < 0.05$).This haemodynamic advantage of ILMA however is lost at the time of its removal over ILMA-ETT where MAP of ILMA rises to become comparable with that of ML. All the changes in HR and MAP remained within acceptable 20% from the baseline values in both the groups. In previous studies Zhang Guo-Hua studied 53 adult patients and found out that intubation with direct laryngoscopy and ILMA produce similar haemodynamic responses and maximum increase in heart rate was less than 20% of baseline values. Our results match with this study. However Joo and Rose observed that MAP was higher in patients of direct laryngoscopy compared to ILMA. This interstudy difference might be due to various factors such as pressure exerted through laryngoscope, choice and dose of analgesics, depth of anaesthesia, and the fact that contrary to routine clinical practice Joo and rose passed ETT 5 min after ILMA insertion. Kihara et al. demonstrated that impact of ILMA removal on haemodynamic response depends on its timing. If ILMA removal is accomplished 2 min after insertion, MAP and HR are raised but if same is done after 3min the effect is less prominent. This could be summation effect of the two stimuli viz. ILMA insertion and removal or change in depth of anaesthesia over time.[9] D. K. Singh found no significant increase in HR on insertion and intubation with ILMA as compared to baseline but reported significant increase in MAP during insertion and intubation with ILMA.[10] The results are in contrast to our study and could be due to superior effect of fentanyl - 2 µg/kg (used in our study) in attenuating pressor response as compared to morphine (0.1 mg/kg) used by D. K. Singh et al. Zhang Guo-Hua[11] reported that the ILMA guided oro-tracheal intubation which includes three basic steps viz; (insertion and confirmation of ILMA, insertion and confirmation of ILMA-ETT and removal of ILMA over the ILMA-ETT) is a time consuming procedure compared to the intubation using Direct laryngoscopy. They concluded that longer Apnea and repeated airway manipulations may enhance the haemodynamic response with use of ILMA.As compared to laryngoscopic intubation, ILMA guided oro-tracheal intubation may impart a greater pressure on the oro-pharyngeal structure and cervical vertebrae which even exceeds capillary perfusion pressure of the pharyngeal structures resulting in backward shifting of the vertebrae thus producing more stimuli to the local structures.[12,13] In order to obtain an optimal position of ILMA to facilitate insertion of ILMA-ETT, it is often required to move the ILMA back and further, grasp and lift the jaw, adjust the patients head neck portion and increase the volume of ILMA cuff inflation or change the size of ILMA. These Auxiliary maneuvers may cause additional stimuli to the oro-pharyngeal structures. A study has found that grasping and lifting the jaw upwards can cause haemodynamic response similar to those observed in conventional laryngoscopic intubation.[14] Also before inserting the tracheal tube into the trachea via ILMA, the epiglottis elevating bar of ILMA is lifted to elevate the epiglottis and approach the glottis which results in stimuli to the epiglottis and periglottic structures. There is a study which suggests that mechanical stimuli to the supralaryngeal area rich in nociceptive receptors can cause strong haemodynamic responses.[15] The ILMA guided oro-tracheal intubation is a blind technique and the tracheal tube is likely to be blocked off by the down folding epiglottis, anterior commissure, vocal cords and anterior tracheal wall. When this occurs it is necessary to move the ILMA up and down which results in further stimulation. Removal of the ILMA after successful intubation is a more severe stimulus than insertion of ILMA and tracheal tube which can produce more significant haemodynamic responses because of stronger frictions.[16] Finally in order to avoid accidental extubation, anaesthesiologists often use stabilizing rod to further advance the tracheal tube that may result in more frictions against the tracheal wall and even stimulating the carina when the tracheal tube is inserted too deeply. It

is demonstrated in one of the studies that tracheal stimulus is another main cause of haemodynamic responses to tracheal intubation.[14,17] A similar study by Neeraja Bharti and Asit Kumar Naik reported intubation attempts as follows 1st attempt LS (85%) vs. ILMA (65%), 1st attempt with adjusting maneuver LS (10%) vs. ILMA (22.5%) and 2 attempts LS (5%) vs. ILMA (10%). Overall success rate of intubation in LS and ILMA group was 100% vs. 97.5%.[18] Compared to these results our percentage of intubation on first attempt in both the groups is higher and at the same time we required lesser adjusting maneuvers and less second attempt to intubation in both the groups. Our overall success rate in laryngoscope group is similar with that laryngoscopy group in the above study but success rate of ILMA in our study exceeds that in the above study. Our incidence of oro-pharyngeal morbidity was better as compared to some of the previous studies Incidences of complications in our study were slightly lesser in comparison to similar study by Neeraja Bharti and Asit Kumar Naik on 40 patients in each group. Our results are similar to Joo and rose[6] and Kihara et al. (2000)[9] who found no difference in airway injury occurring with use of ILMA vs. laryngoscopy. Our complications encountered with use of ILMA are lesser than that of Komatsu and coworkers[5] who reported greater percentage of mucosal injury (36%) and oesophageal intubation (14%). It is to be noted that the Komatsu and coworkers had more percentage of 2 and more intubation attempts with ILMA than our study which might be the cause. Kihara et al. (2003)[19] reported that airway injury is more common with ILMA than laryngoscopy. It may reflect genuine increase in injury because of high mucosal pressures of ILMA[13] or because of easier detection of bleeding with ILMA due to cuff collecting supraglottic material. The complications were thus rare and comparable between the two study groups.

In our study this intubation time was found to be significantly longer i.e. 152.46 ± 26.06 seconds. It is notable that different investigators have used different endpoints for calculating the intubation time. This has led to publishing of variable reports. We conclude that Blind oro-tracheal intubation with ILMA is equally efficacious and successful method compared to conventional direct laryngoscope guided intubation with Macintosh laryngoscope. The pressor response with use of ILMA is clinically insignificant and gives no added advantage over direct laryngoscopy guided tracheal intubation in patients with normal airway. The removal of ILMA over ILMA-ETT generates maximum pressor response and hence proper measures and technique needs to be applied particularly at this stage to minimize it. It needs to be further investigated whether ILMA holds any haemodynamic advantage over Macintosh laryngoscope in cases with difficult airway where pressure response due to direct laryngoscopy is proved to be deleterious. Use of ILMA requires longer time for intubating trachea compared to direct laryngoscopy. Oro-pharyngo-laryngeal complications associated with both the methods are rare and comparable in anticipated non difficult airway. Thus in patients with normal airway blind intubation with ILMA offers a good alternative to conventional direct laryngoscopy with equal success, similar haemodynamic advantage and insignificant oropharyngolaryngeal morbidity. Hence, we recommend that anaesthesiologists must master this technique with more frequent use in elective surgeries requiring tracheal intubation and general anaesthesia so that it may be utilized in certain anticipated or unanticipated clinical situations if they arise with more perfection and greater confidence.

Abbreviations

Group-L = Group intubated with Macintosh laryngoscope
Group-I = Group intubated with intubating laryngeal mask airway
IT = Intubation time
IA2 = One intubation attempt (with adjusting maneuver)
IA3 = Two intubation attempt

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