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Research Communication

COMPARISON OF INTUBATION BY LMA CTRACH VS INTUBATION BY DIRECT LARYNGOSCOPY IN PATIENT WITH NORMAL AIRWAY

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Abstract
Background: *The LMA CTrach™ system is a new device for airway management and endotracheal intubation under direct vision in both anticipated and unexpected difficult intubation situations. This randomized controlled study was undertaken to compare the hemodynamic effects, ease of intubation, time taken for intubation, upper airway morbidity following tracheal intubation through LMA CTrach™ with that of conventional Macintosh laryngoscope.*
Material and Method: *Eighty adult patients of age 16-72 years and ASA I and ASA II grade scheduled to undergo elective surgery under GA were randomly allocated to one of the group i.e. Group A: LMA CTrach™ (Laryngeal Mask Airway CTrach™) and Group B: DLS (Direct Laryngoscopy). The patients were intubated orally using either equipment after induction of general anaesthesia.*
Results: *In both the groups, there was a significant increase in heart rate and blood pressure from base line values after tracheal intubation. The rise in heart rate and SBP was significantly more in group B as compared to group A. The success rate of intubation were comparablein both the groups. The time required for successful intubation was significantly more in group A as compared to group B. The upper airway injury was more in group A than in group B.*
Conclusion: *LMA CTrach™ can be used for tracheal intubation with equal success rate as of DLS in patient with normal airway though it is more time consuming. It offers advantage over DLS for minimizing hemodynamic response to tracheal intubation in normotensive patients.*

Keywords: *LMA CTrach™, endotracheal intubation, hemodynamic response, upper airway morbidity.*

Introduction

Tracheal intubation by direct laryngoscopy is the gold standard procedure for securing the airway. Technical problems with tracheal intubation have been the most frequent cause of anaesthetic death in published analysis from all over the world.[1,2] Anatomical variations of structure around oropharynx are the frequent causes of difficult intubation.

Most cases of unanticipated difficult intubation are managed satisfactorily by direct laryngoscopy (DLS) but associated problems with tracheal intubation are soft tissue damage and marked sympatho-adrenal response due to stimulation of supraglottic tissues.[3] Although these hemodynamic alterations are short lived, they may be undesirable in patients with preexisting myocardial or cerebral insufficiency.[4,5] The incidence of these problems can be reduced by using alternative guiding devices for intubation, such as fiberopticscope,[6] lightwand,[7] intubating laryngeal mask airway (ILMA) etc.

The ILMA was introduced by Dr. Archie Brain in 1997.[8] It is especially designed to aid blind tracheal intubation. The LMA CTrach™ system is further modification of ILMA and has been specially designed for fiberscopic guided tracheal intubation. This new device comprises of an ILMA and a detachable liquid crystal display viewer. The principal features of this system are anatomically curved rigid airway tube with an integrating handle, an epiglottis elevating bar, guiding ramp built into floor of mask aperture and silicon tracheal tube. The rigid airway tube permits the mask to be guided during endotracheal intubation and accommodates normal sized tracheal tube. The tube curvature is specifically designed to fit into the palatopharyngeal arch, producing a firm seal. The insertion technique is simpler and may be achieved by same rotational maneuver from any position that is useful when access is limited.[9] It provides direct view of the larynx and vocal cords during intubation. It has two integrated fiberoptic channels, a light guide to transfer light to illuminate the larynx and a 10,000 pixel image guide to transfer the image of the larynx to the viewer. There is a modified epiglottis elevating bar which optimizes the light source and enables uninterrupted image transmission to the viewer. A lens lies behind the epiglottic elevator and captures an image from in front of the mask aperture which is transmitted to a detachable digital screen with a light source and digital camera. The color viewer is a dedicated system that can only be used with the LMA CTrach™. In contrast to the view of DLS, the viewer of LMA CTrach™ provides visualization of real-time passage of the tube through the glottis from the underside of the tracheal tube.[10,11]

Studies[12,13,14] documenting the experiences of using LMA CTrach™ shows successful insertion at first attempt and ventilation was possible in all cases, larynx was visible in majority of cases with or without manipulation while in very few patients larynx could not be visible even after manipulation but endotracheal intubation was successful in these cases also, none of the patient had any complications and haemodynamic parameters and oxygen saturation remained within normal limits throughout the procedure.

It is an efficient airway device for ventilation and tracheal intubation in case of a difficult airway in morbidly obese patients.[15] However, this is yet to be determined whether ILMA is feasible to use as a primary intubating device in patients with normal airways. Various reports comparing intubation through ILMA with that of direct laryngoscopy have shown that ILMA has no advantage over laryngoscope guided tracheal intubation for adult patients requiring intubation for elective surgery with normal airways, but it is a feasible alternative.[16,17] It gives success rate of tracheal intubation comparable to that of DLS. It also eliminates the need for head and neck manipulations. Studies[18,19] comparing success of tracheal intubation with ILMA Fastrach and CTrach concluded higher first-attempt success rate of tracheal intubation with the LMA CTrach However, more time is required with the LMA CTrach, and its cost effectiveness remains unclear.

Aims and Objective

The present study was carried out to compare intubation by conventional DLS (by using rigid laryngoscope) and intubation using intubating laryngeal mask airway (LMA CTrach™) and compare different aspects i.e.

- Hemodynamic stress response.
- Ease of intubation.
- Success rate of tracheal intubation.
- Time taken for intubation in two techniques.
- Postoperative upper airway morbidity.

Material and Methods

After ethical committee approval and informed and written consent, ASA physical status I and II patients of age 16-72 years scheduled to undergo elective surgery under GA were enrolled after exercising inclusion and exclusion criteria. Patients with cardio-respiratory or cerebrovascular disease, obese patients (BMI>35 kg/m2), patients who had sore throat within 10 days, patients with anticipated difficult airway (Mallampati Class III or IV, thyromental distance < 6cm, inter- incisor distance <3.5 cm), Upper respiratory tract (oropharynx, larynx) pathology and patients at risk of regurgitation and aspiration (previous upper gastro-intestinal tract surgery, known or symptomatic hiatus hernia, oesophageal reflux, peptic ulceration, not fasted and pregnant patients) were excluded. Computer-generated randomization scheme was used to divide these cases into 2 equal numbers of groups and were allocated to either of the group by sealed envelope method: group A where LMA CTrach™ (intubation by LMA CTrach™) was used and group B where DLS (intubation by direct laryngoscopy) was used, each comprising of 40 patients.

All the patients were assessed properly in pre anaesthetic clinic prior to surgery. The detailed history was taken and physical and airway examination was done. Routine investigations were performed in each case and whenever required special tests were asked for. All patients received premedication with Tab. Alprazolam 0.25 mg orally at night before surgery and coming morning. On arrival into operating room (OR) intravenous (IV) access was secured with 18G cannula and standard monitoring was applied. Baseline values of systolic (SBP), diastolic (DBP) and mean blood pressure (MAP); heart rate (HR) and oxygen saturation (SpO_2) were recorded. All the patients received midazolam (0.05mg/Kg), fentanyl (2μg/kg). After preoxygenation for 3 min with 100% oxygen, anaesthesia was induced with Propfol 2mg/kg IV. Vecuronium bromide (0.1mg/kg) IV was given to facilitate tracheal intubation. Adequate mask ventilation was tested before inducing muscle relaxation.

In group 'A', the CTrach™ size and flexible, cuffed, wire reinforced, silicone endotracheal tube (ETT) size was chosen according to patient's weight and following the manufacturer's recommendations as follows

- A size 3 CTrach™ and 7 mm inner diameter ETT was used for patient having body weight < 50 Kg
- A size 4 CTrach™ and 7.5 mm inner diameter ETT was used for patients having body weight 50-70 Kg.
- A size 5 CTrach™ and 8 mm inner diameter ETT was used for patients having body weight >70 Kg.

Before the insertion of the LMA CTrach™, the viewer was attached to it and focused by obtaining a sharp image of a sheet of text held 1 cm in front of the fibreoptic channel port. Then the viewer was detached. The posterior surface of it was lubricated, for ease of insertion. The head and neck were then placed in neutral position and the LMA CTrach™ was inserted with minimal neck movement without attaching the viewer. The cuff was inflated and then the ventilation was checked. Once satisfactory ventilation was achieved, the viewer was attached to obtain view of the larynx. Ventilation was maintained throughout this duration. If the larynx could not be viewed, the LMA CTrach™ was manipulated to obtain the view. The aim was to see the vocal cords and laryngeal inlet in the centre of the viewer. After getting the best possible view, ETT was passed through it into the trachea under vision and correct intubation was thereafter confirmed by chest auscultation and capnography. The viewer was then detached, ETT connector was removed, cuff was deflated and the CTrach™ was removed over the ETT. When tracheal intubation was not successful after three attempts, the patients were intubated with conventional laryngoscopy.

In the group 'B' direct laryngoscopy was done with Macintosh laryngoscope (size 3, 4) and intubation was done with cuffed ETT of appropriate size with head and neck in sniffing position. Intubation was done by same person in all the patients of both the groups. In both the study groups, maintenance of anesthesia was done with nitrous oxide and oxygen (70/30) and isoflurane with atracurium as muscle relaxant. At the end of the surgery, neuromuscular blockade was reversed with a mixture of glycopyrolate (0.01 mg/kg) and neostigmine (0.05 mg/kg) and extubation was done. Hemodynamic parameters recorded were HR, SBP, DBP, MAP and SpO2 after induction and at 1 min interval for 5 min after intubation. The other parameters studied were success rate and ease of intubation, time taken for intubation, oesophageal intubation, desaturation (Spo2<92%), upper airway morbidity like dental injury, mucosal injury, sore throat and hoarseness (after 2 hours in postoperative period) were observed and recorded.
The intubation was considered to be successful if it was accomplished within 3 min and was considered failed if it could not be done within 3 min or if all adjusting maneuvers had failed. Ease of intubation was assessed by recording the number of attempts required to intubate the patients' trachea. Intubation was considered to be difficult if it could not be accomplished in 3 attempts, the patients were intubated with conventional laryngoscopy. Time taken for intubation was accessed as follows- in group LMA CTrach™ time between removal of face mask for CTrach™ insertion and removal CTrach™ following successful tracheal intubation. In group DLS the time between removal of face mask and successful tracheal intubation. The sample size was determined as 40 in each group, allowing an alpha-error of 0.05 and beta-error of 0.2 (power

80%) to detect a difference of 60 s for the intubation time between the devices. SPSS software version 17.0 (SPSS Inc, Chicago, Illinois, USA) was used for statistical analysis. Parametric data were analysed with the unpaired t-test and non-parametric data were analysed with the x2-test. Unless otherwise stated, data are presented as mean (SD). Significance was taken as P <0.05.

Results

There were no statistically significant differences in either the demographic data or the baseline vitals between the two groups (Table-1). A significant rise in heart rate (HR) from base line value occurred after intubation in both the groups but the rise was significantly more in group B as compared to group A at postintubation and at 1 min postintubation (p value <0.05) (Table-2). There was a significant rise in SBP at post intubation in group B (23.73%) as compared to group A (16.06%) (p value <0.05) (Figure-1).

Table 1:
Demographic and Pre-Operative Data of Patients in Two Groups

	Group A	**Group B**	**p-value**
Age	43.15±16.43	41.5±14.96	>0.05
Weight (kg)	61.22±6.77	65±5.8	>0.05
BMI (kg/m^2)	27.42±2.90	27±3.23	>0.05
Sex M/F	23/17	29/11	>0.05
ASA I/II	24/16	32/8	>0.05
MPG I/II	32/8	36/4	>0.05
HR (per min)	83.75±8.72	81.17±11.05	>0.05
SBP (mmHg)	126.5±12.88	121.97±21.16	>0.05
DBP (mmHg)	82.75 ±6.89	83.82±6.63	>0.05
MAP (mmHg)	97.18±7.95	96.41±9.09	>0.05

Table 2:
Changes in Heart Rate (Beats/Min) at Different Time Intervals

	Group A	**Group B**	
TIME	Mean±SD	Mean±SD	P Value
Post Induction	77.6±8.30	80.7±10.90	>0.05
Post Intubation	110.15±7.71	120.22±11.55	0.0001*
1 Min	106.52±7.63	111.82±10.98	0.0413*
2 Min	104.6±14.44	104.47±10.73	>0.05
3 Min	99.35±7.17	97.95±10.78	>0.05
4 Min	96.45±7.90	93.3±10.03	>0.05
5 Min	92.37±6.96	90.87±9.14	>0.05

Figure with * shows significant p val

Table 3:
No. of Attempts Required for Successful Intubation in Two Groups

NO. OF ATTEMPTS	GROUP A		GROUP B	
	No. of Patients	Percentage	No. of Patients	Percentage
1st Attempt	30	75	36	90
2nd Attempt	8	20	4	10
3rd Attempt	2	5	0	0
TOTAL	40	100	40	100

In group A, postintubation rise in DBP was 21.5% while in the group B rise was 18.7%. The rise in mean DBP was statistically not significant (p>0.05) (Figure-1). In group A, postinubation rise in MAP from the base line value was 19.16% while in group B postinubation rise in MAP from the base line value was 20.81%. However, the rise in MAP between the two groups was insignificant as 'p' value was >0.05(Figure-1). Thereafter there was a fall in HR, SBP, DBP and MAP in both the groups up to 5 minutes post intubation.

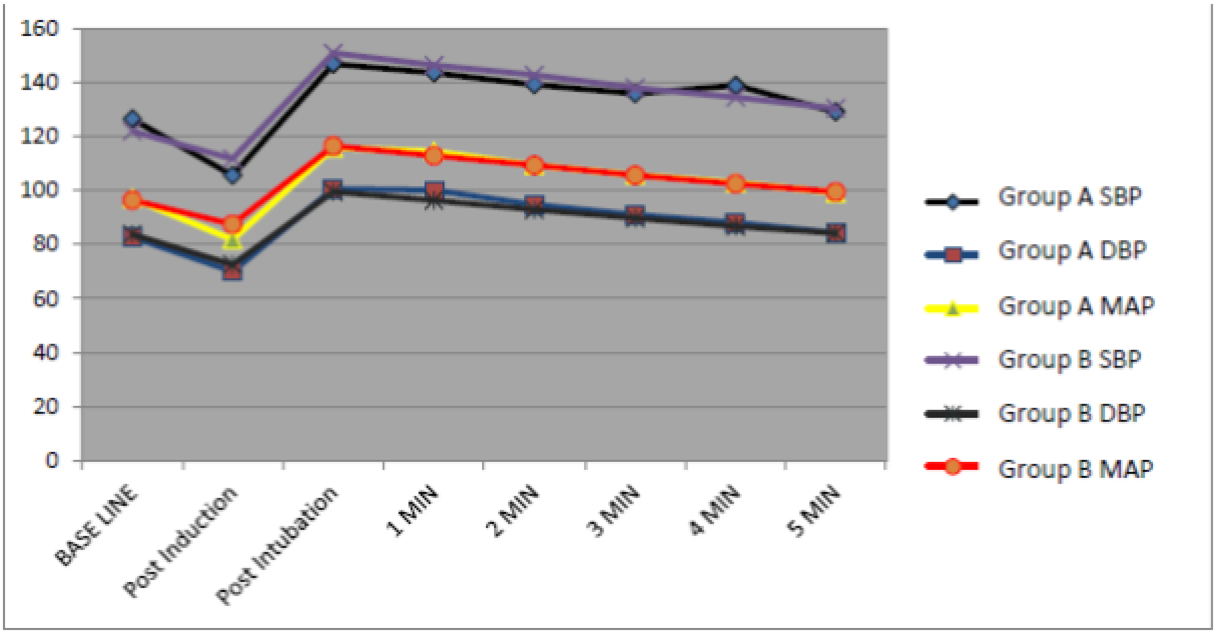

Figure1: Changes in SBP, DBP AND MAP (mm Hg) at Different Time Intervals

Tracheal intubation was successful in all 40 (100%) patients in both groups. In group A 30 (75%) patients were intubated in the first attempt, 8 (20%) patients were intubated in second attempt while 2 (5%) patients were intubated in third attempt. In group B 36 (90%) patients were intubated in first attempt and 4 (10%) patients were intubated in second attempt (Table-3). In present study the mean time required for intubation in group A was 80.6±19.47 sec and it was significantly more than time required for intubation with DLS i.e. 29.92±4.84 sec (p value <0.05) (Table-4).

Table 4:
Mean Time (Sec) Taken For Intubation in Two Groups

	Group A	Group B
MEAN TIME (sec)	80.6	29.92
SD	19.47	4.84
SEM	3.08	0.765
p Value	<0.0001	

None of the patients in both the group desaturated and suffered any type of dental injury. The frequency of mucosal trauma (detected by blood on the LMA CTrach™ or laryngoscope) was comparatively more in group A (25%) than the group B (10%). Oesophageal intubation occurred in none of the patient in both groups (Table-5). In our study 5% patients in group A and 10% patients in group B had sore throat. Fifteen percent patients in group A and 10% patient in group B developed hoarseness (Table-5).

Table 5:
Percentage of Complications in Two Groups

S. No.	COMPLICATION	Group A	Percentage	Group B	Percentage
1.	Dental Injury	0	0	0	0
2.	Mucosal injury	10	25	4	10
3.	Oesophageal Intubation	0	0	0	0
4.	Sorethroat	2	5	4	10
5.	Desaturation	0	0	0	0
6.	Hoarseness	6	15	4	10

Discussion

Tracheal intubation is gold standard for securing the airway and providing oxygenation and ventilation but it can leads to undesirable hemodynamic stress response. Laryngoscopic stimulation of oropharyngolaryngeal structures is an important factor in the hemodynamic stress response associated with tracheal intubation.[20,21] The hemodynamic stress response to tracheal intubation can precipitate adverse cardiovascular events in patients with [22] and without [23] cardiovascular diseases. Intubating laryngeal mask offers a new approach for orotracheal intubation and is expected to produce less cardiovascular stress responses. [24] ILMA had been proved useful in cases of failed and difficult intubation. [25] LMA CTrach™ is a modification of ILMA with integrated fiberoptics. It provides a direct view of the larynx with real time visualization of tracheal tube passing through vocal cords and thus minimizes the technical efforts required by the user. LMA CTrach™ is expected to increase ease of intubation and produce less hemodynamic stress response. Although there are various reports comparing endotracheal intubation through ILMA and DLS, we are unable to found any report comparing intubation through LMA CTrach™ and DLS. Thus the purpose of this study was to compare intubation with LMA CTrach™ and with DLS, taking into account hemodynamic response, ease of intubation, time taken for intubation, success rate, and upper airway morbidity.

In present study, SBP, DBP, MAP and HR significantly increased immediately after intubation compared to the base line. The rise in HR and SBP compared to base line was significantly more in group B as compared to group A (p value <0.05). In the study of Joo and Rose, [26] MAP was higher in the patients receiving laryngoscopic orotracheal intubation than in those receiving ILMA-guided orotracheal intubation. In study of Wilson et al [27] the mean maximum increase in systolic blood pressure after laryngoscopy and tracheal intubation was significantly more in DLS as compared with LMA insertion (51.3% vs 22.9%). Similar finding was also observed by Neerja Bharti et al. [28]

Some studies (Zhang guo-hua et al, [29] Kavitha et al, [30] Choyce et al [31]) had shown that tracheal intubation using ILMA & DLS under GA lead to similar hemodynamic responses. Hemodynamic response depends on magnitude and duration of airway manipulation and duration of apnea. A meticulous technique in which care is taken for minimum stimulation of oropharyngeal structures, proper continuous ventilation should produce less hemodynamic response. ILMA guided intubation is blind procedure and requires greater manipulation of endotracheal tube, ILMA and patients head neck and jaw position. Intubation of trachea with LMA CTrach™ is done under direct vision. Hence it should require less manipulation and stimulation of the oropharyngeal structure although more time is required for adjustment and visualization of the laryngeal inlet.

Theoretically, ILMA guided intubation should produce less hemodynamic stress response as there is less stimulation of base of the tongue, epiglottis and pharyngeal mucosa compared to DLS. The present study confirms these findings.

The ease of intubation was assessed by success rate and no. of attempts required to intubate trachea. Tracheal intubation was successful in all 80(100%) patients. It was successful in the first attempt in 90% of patients in group B and 75% in patients group A. In previous studies success rate of intubation through ILMA varied from 76 to 99.3% and success rate in first attempt varies from 56-87%.[10,32-35] It is difficult to compare the studies due to inter study differences in type of tracheal tube, anaesthesia technique, selection criteria of patients etc.

In present study all the patients were successfully intubated with LMA CTrach™ probably because present study incorporates patients with normal airway. Only 75% patients were intubated in first attempt, this could be because of lack of experience with this device. Mean time required for intubation in group A was significantly more than that of time required in group B (80.6±19.47 vs 29.92 ±4.84). It may be due to greater time required to obtain best possible view of LMA CTrach™. In a study by Kavitha et al [30] the mean time taken for intubation was 63.66 ± 14.10 seconds in group where ILMA was used for tracheal intubation. Thus intubation by LMA CTrach™ is more time consuming than intubation by DLS.

In present study there were no episodes of desaturation (<92%) in both the groups emphasizing the fact that LMA CTrach™ can maintain an airway and oxygenation of the patient throughout the intubation procedure. The frequency of mucosal trauma (detected by blood on the LMA CTrach™ or laryngoscope) was comparatively more with LMA CTrach™ than the laryngoscope (2.5% to 10%). Neerja Bharti et al [28] also observed more frequency of mucosal trauma in ILMA group than DLS group (15% vs 7.5%). Higher incidence of mucosal trauma may be because of high pressure exerted by LMA CTrach™ against pharyngeal mucosa or easier detection of bleeding with LMA CTrach™ due to cuff collecting supra cuff material.

In present study 5% patients in group A and 10% patients in the group B had sore throat and 15% patients in the group A and 10 % patients in group B developed hoarseness in postoperative period. Frequency of sore throat and hoarseness in different studies varies from 17- 36% several factors like anaesthesia technique drugs and their doses used and duration LMA CTrach™ use may affect frequency of sore throats and hoarseness.

Implication

Our study is able to demonstrate that the use of LMA CTrach™ could be alternative to direct laryngoscopy for endotracheal intubation in patient with normal airway. However, there is need for further RCT with proper sample size to replicate the findings of our study. So that LMA CTrach™ can become standard of care for securing the airway in patients with normal airway.

Conclusion

Thus it could be concluded that DLS is comparatively faster method of tracheal intubation than LMA CTrach™. LMA CTrach™ can maintain airway and oxygenation of the patient despite taking more time than DLS. LMA CTrach™ can be used with equal success rate for tracheal intubation in patients with normal airway. LMA CTrach™ offers advantage over DLS for minimizing hemodynamic response to tracheal intubation in normotensive patients.

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