ORIGINAL ARTICLE

Awake intubation using lightwand-guided ILMA versus LMA CTrach™ in patients with simulated cervical spine injury

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ABSTRACT

Background and Aims: To study and compare the time taken, success and ease of awake tracheal intubation using lightwand-guided ILMA and LMA CTrach™ after application of manual in-line stabilization, in adult patients with simulated cervical spine injury.

Methodology: Eighty adult patients were randomized into two groups. In ILMA–LW group trachea was intubated using lightwand-guided ILMA and in LMA CTrach™ group using CTrach™ LMA. After anesthetizing patient's airway with topical local anesthetic, manual in-line stabilization was applied by an assistant, study device was inserted and trachea was intubated through it. The time taken, success and ease of tracheal intubation was noted. The observations of the study were compiled and analyzed statistically. Fischer´s exact test and Chi-square test were used for qualitative data. Quantitative data within groups was analyzed using paired t-test and non-parametric Wilcoxon signed rank test and for quantitative data between groups, Student´s t-test and Wilcoxon Mann Whitney test was used. The level of statistical significance was taken as $p < 0.05$.

Results: The mean time required for tracheal intubation was 47.86 ± 11.76 sec in ILMA–LW group as compared to 64.84 ± 15.97 sec in LMA CTrachTM group ($p < 0.001$). Success of tracheal intubation was 87.5% and 80% in group ILMA-LW and group LMA CTrach™ respectively ($p = 0.363$). Ease of intubation, number of adjusting maneuvers and intubation attempts, hemodynamic parameters, post-operative oropharyngolaryngeal morbidity and patient's experience of the procedure were comparable between the two groups.

Conclusion: In patients with simulated cervical spine injury after application of manual in-line stabilization, awake tracheal intubation through lightwand-guided ILMA (ILMA-LW) was significantly faster than LMA CTrach™ with comparable success and ease of intubation.

Key words: Intubation, Endotracheal; Awake intubation; Lightwand-guided ILMA; LMA CTrach™

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INTRODUCTION

Airway management in patients with cervical spine injury presents a challenge to the anesthesiologist. These patients may require immediate control of airway or may later present for elective surgical procedures. Awake intubation in patients with cervical spine injury is safe and does not cause neurological deterioration.[1] The splinting action of normal cervical muscle tone, in awake patients is protective.[2]

In patients of blunt trauma, the incidence of cervical spine injury has been reported as two to five percent.[2]Airway maneuvering during laryngoscopy may cause significant movement at the cervical

spine and aggravate the injury, necessitating the need to avoid or minimize this movement. Manual in line stabilization provided by an assistant reduces the cervical spine movement during laryngoscopy but increases the difficulty in visualizing the larynx.

The Intubating Laryngeal Mask Airway (ILMA) and LMA CTrach™ can be inserted in neutral position of head and neck and facilitate intubation in these patients.[3,4] ILMA can be used for guided tracheal intubation either blindly or using visualizing techniques like fibreoptic bronchoscope or lightwand. LMA CTrach™ is a modification of ILMA with a fibreoptic system and a detachable LCD viewer. This system enables real time viewing of the glottis to guide tracheal intubation via laryngeal mask conduit.

To the best of our knowledge, awake intubation through ILMA-LW and LMA CTrach™, has not been compared in patients with simulated cervical spine injury. Hence, we undertook this study to compare these two devices for awake tracheal intubation in patients with simulated cervical spine injury with application of manual in line stabilization.

Hypothesis: The study hypothesis is that LMA CTrach™ , which enables real time viewing of the glottis to guide tracheal intubation via laryngeal mask conduit, should result in faster tracheal intubation with a greater success and ease as compared to ILMA-LW.

METHODOLOGY

We conducted this prospective, randomized study, over a period of one year, in 80 adult patients, after obtaining approval of the institutional ethical committee and informed consent.

Patients in the age group 18 to 60 years, of either gender, belonging to ASA physical status I or II, scheduled for elective surgical procedure requiring general anesthesia with oro-tracheal intubation were included in the study. Exclusion criteria included patient's refusal, risk of aspiration, known sensitivity to lignocaine, weight < 30 kg, mouth opening < 2.5 cm, oropharyngeal pathology, surgery of oropharynx or larynx and surgical procedures greater than two hours duration.

Patients were randomly allocated using computer generated random number table to either group ILMA–LW (n = 40), when tracheal tube (ETT) was inserted using lightwand-guided ILMA or group LMA CTrach™ (n = 40), when ETT was inserted through LMA CTrach™. Concealment of allocation was done using sequentially numbered, opaque, sealed envelopes, that were numbered in advance, opened sequentially, after the participant's name and other details were written on the appropriate envelope. The study device was inserted by the same anesthesiologist, who had successfully intubated the trachea in more than twenty patients using each of the two devices.

Size of the ILMA (Laryngeal Mask Company, Singapore) or LMA CTrach™ (Laryngeal Mask Company, Singapore) was selected as per the manufacturer's recommendation (size 3, 4 and 5 for weight of patient 30 to 50 kg, 50 to 70 kg and > 70 kg respectively). Silicone wire reinforced cuffed ILMA ETT size 7 mm for female and size 8 mm for male patients was used for the initial attempt. After selecting the appropriate sized ILMA or LMA CTrach™, the ILMA ETT was lubricated and tested whether it passed to and fro through the shaft of the mask. Lightwand used in this study was Trachlight™ (Laerdal Medical AS, Tanke Svilandsgate Stavanger, Norway).

In the ILMA-LW group, lightwand (without its metal stylet) was lubricated and inserted into the ETT, with its tip positioned just at the bevel of the tube. This whole assembly was then loaded into the ILMA with the tip of the assembly just at the epiglottis elevating bar, the transverse marking on the ETT (at 15 cm) also acting as a guide to the final position of the assembly. This fully loaded gadget was the study device for group ILMA-LW. For group LMA CTrach™, antifog solution was applied to the lens and a well lubricated ETT was loaded into LMA CTrach™, with the tip of the ETT just at the epiglottic elevating bar. This was the study device for group LMA CTrach™. Modified grip was used in both the groups where index finger was used to stabilize the gadget, as shown in figure 1 and 2. The tip of the posterior surface of both the devices was lubricated using Lubic jelly (Neon laboratories limited, Mumbai, India).

Patients were kept fasting overnight and pre-medicated with tab alprazolam 0.25 mg and tab ranitidine 150 mg on the night before and two hours prior to surgery. Pre-operatively Mallampati class, mouth opening and thyromental distance were noted. Intramuscular glycopyrrolate (0.2 mg) was administered 45 minutes before the procedure. Patient's airway was anesthetized topically with 2% lignocaine viscous gargles, 10% lignocaine spray and 4% topical lignocaine using ultrasonic nebulizer. In the operating theater, standard monitors (electrocardiogram, non-invasive blood pressure, pulse oximeter) were

applied. Fentanyl 2 μg/kg and midazolam 0.03 mg/kg were given intravenously. With head in neutral position, manual in-line stabilization (MILS) was provided by another anesthesiologist, who stood beside the patient in front of the intubator, with hands placed on the sides of the patient's head and forearms resting on the patient's chest. The same anesthesiologist applied MILS in all patients. Patient was asked to open his mouth and protrude the tongue; thereafter the study device was inserted and its cuff inflated with recommended volume of air.

In group ILMA-LW, after reducing room lighting, lightwand with pre-loaded ETT was advanced while observing the glow in the neck. A bright glow in the midline at the level of laryngeal prominence, that continued with the downward movement and disappeared at the level of suprasternal notch, indicated correct placement of ETT in the trachea. Adjusting maneuvers,[5] (Table 1) were performed, if glow was not visualized in midline or resistance was felt during insertion of ETT. After tracheal intubation, the lightwand was removed and tracheal intubation confirmed by capnography. Auscultation of bilateral lung fields was done. ILMA was removed using a stabilizer rod.

In group LMA CTrach™, we attached a fully charged viewer to LMA CTrach™. If the glottis was visible in the center of the screen, the ETT was inserted into the glottic aperture under vision. If a centralized glottic image was not seen, adjusting maneuvers[6-10] (Table 2) were performed. ETT was inserted and confirmed by capnography. Auscultation of bilateral lung fields was done. LMA CTrach™ was subsequently removed using a stabilizer rod.

During insertion of any of the devices, if patient had gagging or complained of discomfort (demonstrated by raising his right hand as instructed), the device was withdrawn and reinserted after optimizing sedation and/or topical anesthesia. Maximum of two trials of optimization were done.

If the patient was not co-operative even after optimization of topical anesthesia/sedation or SpO_2 fell below 90% or there was more than 30% change in baseline parameters; the procedure was abandoned. The trachea was intubated using Macintosh laryngoscope after induction of general anesthesia and the case was excluded from the study.

We allowed a maximum of two attempts for study device insertion, four attempts for study device maneuvering and five attempts for ETT insertion. If these attempts were exhausted or tracheal intubation was not achieved within 120 sec, general anesthesia was induced and trachea was intubated using Macintosh laryngoscope. These cases were taken as failed intubation.

After successful intubation, the ease of intubation was rated on a VAS score of zero to ten (ten being easiest). The time required for tracheal intubation was defined as the time from the device entering between the incisors to the time when tracheal intubation was confirmed by capnograph tracing. An intubation attempt was defined as forward or backward movement of ETT through the ILMA or LMA CTrach™ for intubation of trachea.

Table 1: Maneuvers performed in ILMA-LW group, to facilitate ETT insertion, depending on position of glow in the neck

Glow Position	Maneuvers performed
Midline (above laryngeal prominence)	ILMA handle flexion; extension; up-down maneuver; try smaller size ETT
Midline (below laryngeal prominence)	ILMA handle is withdrawn partially; extended; withdrawn partially and extended
Lateral (right or left)	ILMA handle is twisted
No glow	ILMA handle is withdrawn partially and extended; check the bulb

Table 2: Adjusting maneuvers performed in group LMA CTrach™ to obtain a centralized glottic image on the viewer-

Glottic image	Adjusting maneuver
In center of viewer	Not required
Image partially visible or nonvisible; not in center of viewer	Up-down maneuver; Side-to-side maneuver; Chandy maneuver
Image obscured by epiglottis or other structures (red-out)	Up-down maneuver
Image obscured by fogging; secretions/ lubricant (white-out	LMA CTrach™ removed, cleaned and reinserted; applied antifog solution if fogging
Image dark (black-out)	Increase light intensity on viewer; increase depth of insertion

Failed intubation was defined as intubation achieved after exhaustion of allowable time or number of attempts. In case of esophageal intubation, if the number of attempts had not exhausted, the ETT was withdrawn till the epiglottic elevating bar and reinserted.

Vital parameters such as pulse rate, blood pressure and SpO_2 were noted before and after insertion of the device and every minute till five minutes post-intubation. Post-operatively, an independent observer blinded to the method of intubation assessed oro-pharyngo-laryngeal morbidity at 24 hours, trauma to lips, oral mucosa or dental injury and patient's experience during the procedure.

Statistical Analysis: The observations of the study were compiled and analyzed statistically. Fischer´s exact test and chi-square test were used for qualitative data. Quantitative data within groups was analyzed using paired t-test and non-parametric Wilcoxon signed rank test and for quantitative data between groups, Student´s t-test and Wilcoxon Mann Whitney test was used. The level of statistical significance was taken as $p < 0.05$. The sample size was estimated as 40 in each group, to detect an assumed difference of 60s between the two groups from the effect size of 0.65 with alpha error of 0.05 and power 80%.

RESULTS

The patient characteristics such as age, gender, ASA class, weight, height, body mass index, Mallampati class, mouth opening and thyromental distance were comparable in both the study groups (Table 3). Hemodynamic parameters were comparable between the two groups. In both the groups none of the patients had desaturation.

Study device insertion was successful at first attempt in all 40 patients in ILMA-LW group as compared to 37 patients in LMA CTrach™ group. Three patients in group LMA CTrach™ required two insertion attempts (Table 4). Number of adjusting maneuvres required in both groups was as depicted in Table 4. Adjusting maneuvres were not required in 14 patients of each group.

The number of intubation attempts required was comparable between the two groups (Table 4). Intubation was successful in first attempt in 24 (60%) and 22 (55%) patients in ILMA-LW and LMA CTrach™ groups respectively. Tracheal intubation was significantly faster in ILMA-LW group with mean time required for tracheal intubation being 47.86 ± 11.76 sec as compared to 64.84 ± 15.97 sec in LMA CTrach™ group ($p < 0.001$).

Success of tracheal intubation was statistically comparable between the two groups (Table 4). Intubation was successful in 35 of 40 (87.5%) patients in group ILMA-LW and in 32 of 40 (80%) patients in LMA CTrach™ group. Ease of intubation was similar between the two groups with p value being 0.809 (Table 4).

Oro-pharyngo-laryngeal morbidity in form of sore throat and hoarseness was comparable between the two groups. None of the patients in either group had dental injury. However, lip and mucosal injuries were noted in one (2.5%) and six (15%) patients in ILMA-LW and three (7.5%) and four

Table 3: Characteristics of patients in ILMA-LW and LMA CTrach™ groups. Values are expressed as Mean (SD) or number (proportion).

Patient characteristics		ILMA – LW	LMA CTrach™	p value
Age (years)		34.50(10.96)	34.88(12.22)	0.885
Gender	Male	33(82.5%)	29(72.5%)	0.284
	Female	7(17.5%)	11(27.5%)	
ASA*	Class I	34(85%)	34(85%)	1.000
	Class II	6(15%)	6(15%)	
Weight (kg)		55.38 (11.65)	55.60(11.26)	0.930
Height (cm)		156.00 (7.72)	158.60 (7.62)	0.134
BMI† (kg/m2)		22.73 (4.10)	22.05 (3.78)	0.446
MPC‡	Class I	13(32.5%)	15(37.5%)	0.605
	Class II	24(60%)	20(50%)	
	Class I III	3 (7.5%)	5(12.5%)	
Mouth opening (cm)		4.21(0.39)	4.40 (0.48)	0.06
TMD§ (cm)		7.26 (0.85)	7.45(0.99)	0.356

*ASA: American Society of Anesthesiologists; †BMI: Body Mass Index; ‡MPC: Modified Mallampati Class; §TMD: Thyromental Distance

Table 4: Comparative intubation characteristics in ILMA-LW and LMA CTrach™ groups. Values are expressed as median (IQR [range]) or n (%).

Variables		ILMA – LW (n = 40)	LMA CTrach™ (n = 40)	p value
Insertion attempts of study device 1/2		40(100)/0	37(92.5)/3(7.5)	0.241
Number of adjusting maneuvers	0	14(35)	14(35)	0.833
	1	8(20)	7(17.5)	
	2	9(22.5)	6(15)	
	≥ 3	9(22.5)	13(32.5)	
Number of intubation attempts	1	24(60)	22(55)	0.884
	2	6(15)	7(17.5)	
	3	6(15)	6(15)	
	≥ 4	4(10)	5(12.5)	
Successful intubation		35(87.5)	32(80)	0.363
Time required for intubation (s)		47.86 ± 11.76	64.84 ± 15.97	< 0.001
Ease of intubation (VAS score)		8 [7-9(0-10)]	8 [7-9(0-10)]	0.809
Complications (injury)	Lip	1(2.5)	3(7.5)	0.172
	Mucosal	6(15)	4(10)	
	Dental	0(0)	0(0)	
Patient's experience of the procedure	1-no recall	20(50)	20(50)	0.695
	2-not unpleasant	19(47.5)	17(42.5)	
	3- unpleasant,	1(2.5)	2(5)	
	4-distressing	0(0)	1(2.5)	

(10%) patients in LMA CTrach™ group respectively.

Regarding patient's experience of the procedure, 20 (50%) patients in each group had 'no recall' of the procedure. Nineteen (47.5%) and 17 (42.5%) patients in ILMA-LW and LMA CTrach™ groups respectively, did not find the procedure unpleasant. While, one (2.5%) and two patients (5%) in ILMA-LW and LMA CTrach™ groups respectively found the procedure 'unpleasant'. One patient (2.5%) in the LMA CTrach™ group found the procedure to be distressing.

DISCUSSION

Awake tracheal intubation in patients with cervical spine injury permits neurological monitoring[2] and examination following the intubation procedure. This may be important from a medico legal point of view, as it can be documented that no new neurological deficit has occurred due to the procedure. The cervical muscle tone is protective,[2] and awake patients can maintain their airway and respiration adding to the safety. A fiberscope may be used for awake tracheal intubation but this may not always be available. Both devices, LMA CTrach™ and ILMA can be introduced in neutral position of head and neck.[3,4] They may be used to facilitate tracheal intubation in patients with cervical spine injury, in whom movement at cervical spine is not desirous.

This study describes the performance of ILMA-LW and LMA CTrach™ for awake tracheal intubation in patients with simulated cervical spine injury after application of MILS. The ILMA-LW could be successfully inserted in all 40 (100%) patients in the first attempt. Other authors have also observed similar results in placement of ILMA.[11-15] We could successfully insert the LMA CTrach™ in the first attempt in 37 of 40 (92.5%) patients. Three patients required two insertion attempts. One of these patients' had gagging and required optimization of topical anesthesia. While, excessive secretions had required device removal and reinsertion after cleaning, in other two patients. Lopez et al. in their study on awake intubation in patients with difficult airway using the LMA CTrach™ found 95% success rate at first attempt placement of LMA CTrach™.[8] Supplemental sedation and topical anesthesia was required to facilitate insertion in one of their patients. Some authors have reported

100% successful insertion of LMA CTrach™ in first attempt.[15-18] However, these studies were conducted in anesthetized patients. Patient preparation and co-operation plays an important role in successful placement of a device in awake patients.

We needed to perform one or more adjusting maneuvers in 26 of 40 (65%) patients in both ILMA-LW and LMA CTrach™ groups (Table 4). Lopez et al. performed corrective maneuvers in 12 of 21 (57.14%) patients undergoing awake intubation through LMA CTrach.[8] Liu et al. applied optimization maneuvers with LMA CTrach™ in (97 of 134) 72.4% patients.[19] However, some authors have reported requirement of optimization maneuvers with LMA CTrach™ in lesser number of patients.[20] Dimitriou et al. required adjusting maneuvers in 45.45% (20 of 44) cases of lightwand-guided tracheal intubation via ILMA.[21] As compared to the conventional blind intubation through ILMA, light-guided intubation required fewer adjusting maneuvers.[5,12]

Our success rate of tracheal intubation was 87.5% (35 of 40) in ILMA-LW group. Of the five subjects in whom tracheal intubation was considered a failure, in two patients number of attempts in device maneuvering had exhausted, while in three patients the allowed time limit had elapsed. Asai et al. also successfully performed light-guided tracheal intubation through ILMA in 9 of 10 (90%) patients.[22] A higher success rate has been reported by some authors.[21] Kihara et al.[12] and Dimitriou and Voyagis[5] have reported 100% success in light wand-guided tracheal intubation via ILMA.

We found 80% (32 of 40) success rate of tracheal intubation through LMA CTrach. Tracheal intubation failed in eight subjects. In two patients number of attempts for device maneuvering had exhausted, in five patients the allowed time had elapsed and in one patient both number of allowed maneuvers and time limit were exceeded. Malik et al. observed 90% success rate in tracheal intubation with LMA CTrach.[9] While, some authors have reported 100% intubation success rate through LMA CTrach™ .[15,17,19,20] In our study, the success of tracheal intubation was comparable ($p = 0.363$) between ILMA-LW (87.5%) and LMA CTrach (80%) groups. Most of the previous studies involving ILMA-LW or LMA CTrach™ have recorded higher intubation success than ours, probably because these were performed in paralyzed patients as against awake patients in our study. In a paralyzed patient, placement of the device and maneuvering is easier. In awake patients more resistance is encountered due to tone of pharyngeal muscles and maneuvers done at the handle may not get fully transmitted to the mask. The results obtained in paralyzed patients may not apply to non-paralyzed patients.[21]

The mean time required for tracheal intubation in our study was 47.86 ± 11.76 sec for ILMA-LW which is close to that observed by Kihara et al., 46 ± 28 sec in lightwand-guided tracheal intubation through ILMA.[12] However, Dimitriou et al. recorded a lesser time of 31 ± 8 sec in light-guided tracheal intubation through ILMA.[5] In our study, the mean time required for tracheal intubation through LMA CTrach™ was 64.84 ± 15.97 sec. This was significantly longer than that observed with use of ILMA-LW ($p < 0.001$). Arslan et al. recorded a mean time of 66.3 ± 29.3 sec required for tracheal intubation through LMA CTrach™ which is close to our study.[23] The time required for tracheal intubation in studies involving LMA CTrach™ varies considerably from 40.8 sec to 347.75 sec.[9,15,17-19,23-25] This wide variation is probably because various

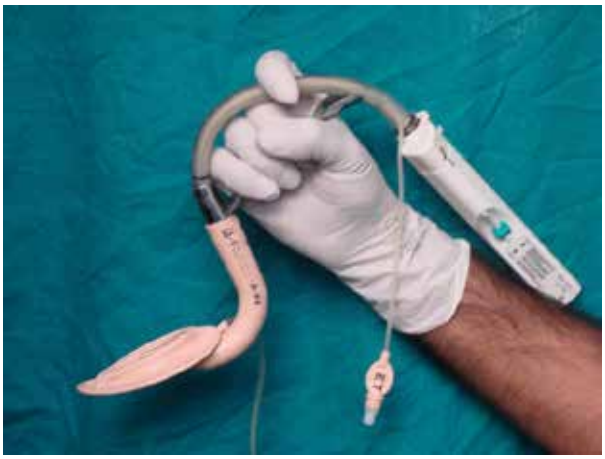

Figure 1: Awake intubation using lightwand guided ILMA

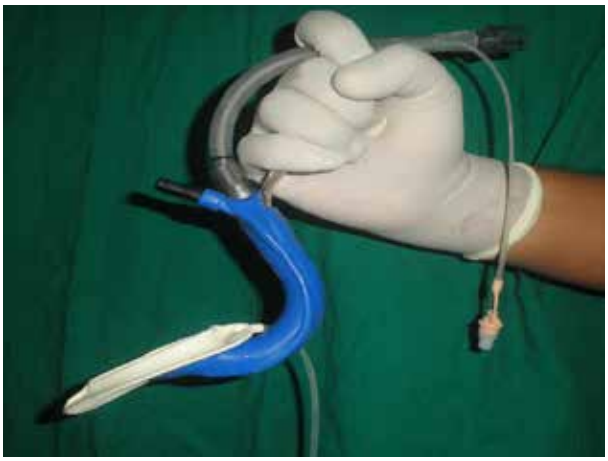

Figure 2: Awake intubation using LMA CTrach™

investigators have used different study designs and definition of time required for tracheal intubation in their studies.

Ease of intubation was a subjective parameter which was assessed by operator throughout the process of intubation. It was comparable between the two groups. In a study by Yousef et al., median (interquartile range) VAS score for overall subjective intubation difficulty (0, very easy; 100, major difficulty or impossible) with LMA CTrach™ was 12 (1-45).[26] In our study, handling of the device was slightly more cumbersome in group ILMA-LW than group CTrach™ due to the dangling lightwand handle. This problem was managed by grip modification as shown in Figure 1. The index finger was used to stabilize the dangling lightwand handle with preloaded ETT. Similar modification was used in LMA CTrach™ group where index finger was used to stabilize the ETT as shown in Figure 2.

We observed significantly longer intubation time in LMA CTrach™ group due to excess time required in optimizing view of the glottis on the viewer. Similar results have been obtained by other investigators as well.[19,24] Malik et al. observed that the prolongation of tracheal intubation times was not due to the positioning of the LMA CTrach™, rather it was due to the time required to optimize the view of the glottis.[9] Liu et al. also found failure to obtain satisfactory view of larynx despite using multiple maneuvers as a major limitation of LMA CTrach™.[19] We faced difficulty in getting good picture quality and obtaining a satisfactory view in some patients, despite using adjusting maneuvers, focusing using visual test card, antisialagogue preparation and use of antifog solution with LMA CTrach™. Other authors have also experienced difficulties with LMA CTrach™ such as red-out due to lens touching epiglottis/mucosa or presence of blood, white-out because of secretions or lubricants, black-out due to low light intensity or insufficient depth of insertion.[7] Deterioration of light intensity and sharpness of image over the course of applications,[7,10] lens getting obstructed by secretions, lubricants and fogging,[8,9] deterioration in fiber-optic quality after repeated sterilization[9,19] and small visual field, confined within the boundaries of the mask aperture leading to poor views[8] have been reported with use of LMA CTrach™.

There were some limitations in our study. It was impossible to blind the investigator to the device they were using. Application of MILS is subjective; the provider was not blinded and could have been biased towards a technique. It was not a crossover study; the investigator could have performed a particular technique better with fewer complications due to his personal preference. Our study was performed on awake patients and our data may not apply to paralyzed patients.

CONCLUSION

We conclude that performing awake tracheal intubation using lightwand-guided ILMA was significantly faster than LMA CTrach™ with comparable success and ease of intubation, in patients with simulated cervical spine injury after application of manual in-line stabilization.

Conflict of interest: Nil

Authors' Contribution:

DS & AK - Concept, Conduction of Study work, Manuscript editing
MS - Conduction of Study work, Manuscript editing

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