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ORIGINAL ARTICLE

Endotracheal intubation with Intubating Laryngeal Mask Airway (ILMA)^{TM}, C-Trach^{TM}, and Cobra PLA^{TM} in simulated cervical spine injury patients: a comparative study

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Abstract
Purpose The aim of our study was to evaluate the success rate of fiberoptic-guided endotracheal intubation through an Intubating Laryngeal Mask Airway (ILMA), a Cobra Perilaryngeal Airway (Cobra PLA), and a C-Trach Laryngeal Mask Airway (C-Trach) in patients whose necks are stabilized in a hard cervical collar.
Methods One hundred and eighty ASA I–II patients were randomized to undergo endotracheal intubation after general anesthesia via an ILMA (group ILMA), a C-Trach (group C-Trach) or a Cobra PLA (group CPLA) with the application of an appropriately-sized hard cervical collar. A fiberoptic bronchoscope was used for intubation via the ILMA and Cobra PLA. Rate of successful insertion of an endotracheal tube through the three devices was the primary aim. Other parameters compared were time taken for device insertion, endotracheal intubation, hemodynamic changes, incidence of hypoxia, and mucosal injury during the procedure. The incidence of postoperative sore throat was also compared between the three groups.
Results The success rates of intubation in the ILMA, C-Trach, and CPLA groups were 100, 100, and 98 % respectively. The first-attempt success rate was significantly better with the C-Trach compared to Cobra PLA (100 vs 85 %, $p < 0.05$). The time taken for device insertion was significantly more with the Cobra PLA as compared to that taken with an ILMA or a C-Trach (35.7 vs 30.3 and 27.5 s, respectively). Intubation through a C-Trach took the least amount of time (84.4 s) as compared to an ILMA (117.9 s) or a Cobra PLA (139.2 s). The incidence of hypoxia and airway morbidity was similar between the groups.
Conclusion The success rates of fiberoptic-guided endotracheal intubation through an ILMA and a Cobra PLA are similar to the success rate of intubation using a C-Trach in patients whose cervical spines are immobilized with a hard cervical collar.

Keywords Hard cervical collar · ILMA^{TM} · C-Trach^{TM} · Cobra PLA^{TM} · Endotracheal intubation

Introduction

Airway management in patients with cervical spine immobilization using a hard collar may be required for various purposes like intensive care management for neurological obtundation, respiratory distress, or hemodynamic instability and elective or emergency operative and diagnostic procedures. The presence of a cervical collar during direct laryngoscopy has been shown to be associated with decreased mouth opening [1] and an increased risk of difficult laryngoscopy, which may result in higher rates of failed intubation [2]. Awake fiberoptic-guided intubation is a gold standard in securing airways in these patients [3], but it requires a conscious and co-operative patient, and the inability to maintain ventilation during intubation attempts is a major drawback. These disadvantages, along with the fact that this technique requires some amount of skill with a long learning curve, prompted a look into the more

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attractive option of supraglottic airway devices for more complex airway management.

Supraglottic airways (SGAs) have been found to be useful for ventilation as well as intubation in patients with difficult airways, including those with cervical spine disorders [4]. The Intubating Laryngeal Mask Airway™ (ILMA) (The Laryngeal Mask Company, Ltd., Le Rocher, Seychelles) and the Cobra Perilaryngeal Airway™ (Cobra PLA) (Pulmodyne, USA) are two such devices that allow endotracheal intubation through the lumen. The ILMA has been shown to have higher success rates of intubation if used with a fiberoptic scope to guide intubation in patients whose necks are immobilized using manual in-line stabilization [5]. The Laryngeal Mask Airway C-Trach™ (C-Trach) (The Laryngeal Mask Company, Ltd., Le Rocher, Seychelles) has an incorporated fiberoptic system to allow a direct view of the glottis during endotracheal intubation. C-Trach thus has all the advantages of a supraglottic airway with 'fiber-optic vision'. We thus considered the C-Trach to be the 'gold standard' and hypothesized that adding the advantage of a fiberoptic view to the other two SGAs will make them equally as efficacious as the C-Trach for intubation in patients with an immobilized cervical spine. The primary aim of the study was to find the success rate of endotracheal intubation with the use of a fiberoptic bronchoscope through either the ILMA or Cobra PLA as compared to the C-Trach in patients whose neck has been stabilized by use of a hard cervical collar. The study was planned as a non-inferiority study with the C-Trach as the gold standard. The secondary aims of the study were to compare the number of attempts needed for endotracheal intubation, time taken to achieve intubation, as well as complications, hemodynamic responses, and postoperative morbidity associated with the use of all three devices.

Materials and methods

The trial has been registered with the Clinical Trials Registry-India, CTRI/2012/04/002585. Formal approval from our institute's ethical committee (All India Institute of Medical Sciences, Delhi, India) was obtained. Informed written consent was obtained from all the patients recruited to the study. According to the protocol, recruitment into the study was done until 60 patients each were allocated to group ILMA, group C-Trach, and group Cobra PLA (CPLA). Allocation into groups was done only in the preoperative holding area according to a computer-generated randomization sequence, and patients were blinded to the same. Inclusion criteria consisted of consent, ASA I and II patients with age more than 18 years and weight more than 30 kg, and being posted for elective surgery under general anesthesia. Exclusion criteria included anticipated difficult intubation (Mallampati class >3, thyromental distance <6 cm and/or neck circumference >35 cm), high risk of gastric content aspiration, any pharyngeal or laryngeal pathology, surgery involving neck, oral cavity, pharynx or larynx, and intended use of nasogastric tube or throat pack.

Patients were kept nil per orally overnight. All patients were premedicated with oral diazepam 0.1 mg/kg the night before and on the day of surgery. In the operation theater, routine pre-induction monitoring was performed, including pulse oximeter, non-invasive blood pressure and electrocardiography, and intravenous access was secured. An appropriately-sized Philadelphia hard cervical collar was then applied to the patient. General anesthesia was induced with 2 μg/kg of fentanyl and 1.5–2 mg/kg of Propofol. In addition, 100 μg/kg of vecuronium was given for muscle relaxation. Post-induction monitoring included partial pressure of carbon dioxide in expired gases ($EtCO_2$). Ventilation was assisted/controlled with 100 % O_2 and anesthesia was maintained with isoflurane to achieve a minimal alveolar concentration of 1.0–1.2. In group ILMA, an appropriately-sized ILMA was selected for each patient according to the manufacturer's recommendations (size 3 for <50 kg, size 4 for 50–70 kg and size 5 for >70 kg) and was introduced by a rotational motion in the sagittal plane. Successful insertion was defined as adequate ventilation confirmed by square waves on capnography. Appropriate maneuvers, as described in the literature [6], were done if the insertion of ILMA did not result in adequate ventilation. A fiberoptic scope loaded with the prelubricated, dedicated endotracheal tube (ETT) (size 7.0 for ILMA size 3, 7.5 for ILMA size 4) was then inserted through the airway. Once the scope tip reached the epiglottic elevating bar, it was negotiated paramedial to it and the fiberoptic scoring of the glottis view was done using a previously proposed system (1—vocal cord not visible, 2—vocal cord plus anterior epiglottis visible, 3—vocal cord plus posterior epiglottis visible, and 4—only vocal cords visible) [7]. The scope was inserted into the trachea, the ETT was guided into the trachea, and the fiberscope was removed. The ILMA was removed subsequently with the use of a stabilizing rod and the proper placement of the ETT was confirmed clinically, as well as by $EtCO_2$ trace.

In group C-Trach, the C-Trach was inserted by the same method used for the ILMA. The viewer screen was then connected to the C-Trach and the glottic view was noted. An appropriately-sized ETT was passed under guidance into the trachea and the C-Trach was removed once the ETT was stabilized with the help of a stabilizing rod.

In group CPLA, an appropriately-sized Cobra PLA, as described by the manufacturer (size 3 for 35–70 kg, size 4 for 70–100 kg, size 5 for >100 kg), was first prepared by dilating the gap between the middle two grills of the Cobra

PLA using the lubricated ETT. This prepped Cobra PLA was then inserted. After inflation of the cuff, proper placement was confirmed by auscultation and $EtCO_2$ tracing. The fiberoptic bronchoscope was railroaded with the appropriately-sized polyvinyl chloride (PVC) ETT (size 6.5 ETT for size 3 Cobra PLA or size 7.5 ETT for size 4 Cobra PLA) and then inserted through the device, and as the tip of the bronchoscope passed between the anterior grills, fiberoptic scoring of the glottic view was performed, as described above. Subsequently, thefibreroptic scope was inserted into the trachea and the ETT was guided under vision. The fibreoptic scope was then removed and the Cobra PLA was removed while stabilizing the ETT using the stabilizing rod.

The time taken to insert the supraglottic device (removal of facemask to the appearance of $EtCO_2$ tracing in capnography after device insertion) and the time taken for endotracheal intubation (time from disconnection of the device from the anesthesia circuit until the reappearance of capnographic tracing upon attachment to ETT, after removal of airway device) were noted. Successful endotracheal intubation was defined as a well-placed endotracheal tube in the trachea after removal of the airway device. In all of the groups, a maximum of three attempts each were performed for both the insertion of the airway device and insertion of the ETT through the device. If the endotracheal intubation could not be performed within these three attempts, the procedure was abandoned and the trachea was intubated under direct laryngoscopic view after removal of the cervical collar and optimal positioning of the head and neck of the patients. An ongoing attempt was abandoned if the oxygen saturation of the patient fell below 93 % at any point of time. The number of insertion attempts of the airway device and the number of insertion attempts of the endotracheal tube were also noted.

Hemodynamic parameters (heart rate, systolic and diastolic blood pressure) were measured at 1 min prior to induction, immediately post-induction, and every minute until 5 min after endotracheal intubation.

Any gum or lip injury was noted after removal of the device. Mucosal injury was defined as the presence of blood on the supraglottic airway upon removal of the device. Sore throat was defined as the subjective sensation of throat discomfort or dysphagia noticed by the patient during the first 24 h post-surgery.

The primary outcome was the success rate of intubation via the three airway devices within the stipulated attempts. The secondary parameters compared were time and number of attempts taken for insertion of devices and intubation through the device, fiberoptic scores seen through the devices, hemodynamic parameters during the insertion and intubation attempts, and complications seen during and after the insertion and intubation attempts, which included hypoxia (defined as SpO_2 <93 %), lip, dental and mucosal injury, and sore throat.

Statistical analysis

The difference in success rates of intubation through the C-Trach and ILMA in the first attempt was found to be 25 % [8]. Since the non-inferiority margin with the advantage of the fiberoptic bronchoscope needs to be lower than this, we chose a difference in success rate of 18 % for our power analysis. With this margin, and with 80 % power and a 5 % level of significance, the estimated sample size was 56 in each group. Statistical analysis was performed using STATA 9.0 (College Station, TX, USA). Data is presented as the number (%) or mean (standard deviation, SD), as appropriate. The success rate of intubation was compared using Fisher's exact test. Successful insertion and intubation in various attempts, as well as the incidence of complications were also compared using Fisher's exact test. The time taken for insertion of the device and time taken for endotracheal intubation were compared using one-way analysis of variance (ANOVA), as were demographic data, age, and weight. Sex distribution and Mallampati class were compared using the chi-squared test. Fiberoptic grading was compared using the chi-squared test for trends. To calculate the confidence interval, fiberoptic grading was further categorized with grades 3 and 4 as good alignment and grades 1 and 2 as poor alignment of the device. A p value less than 0.05 was considered significant.

Results

On completion of final allocation, 336 patients had been screened for eligibility and 206 were invited for participation, 20 of whom declined. The study could not include six patients after allocation into groups due to non-availability of group allocation protocol at the time of induction of anesthesia. Thus, the final analysis was performed with 60 patients in each group (Fig. 1).

The baseline parameters like age, sex, ASA physical status, weight, and Mallampati class were similar among the three study groups (Table 1). Regarding the primary outcome, out of the 180 patients in the study, endotracheal intubation was possible in 179 patients and there was one failure in group CPLA. The success rate with both ILMA and C-Trach were 100 %, whereas that of Cobra PLA was 98 % (Table 2). Hence, the intubation method using ILMA was non-inferior to intubation using C-Trach. The upper limit of the confidence interval of difference between intubation success rates with the C-Trach and the Cobra PLA was 0.05, which is less than the non-inferiority margin (0.18) set by us for the study. Hence, we infer that

Table 1 Demographic data, ASA physical status, and Mallampati classification of patients into three groups

	C-Trach ($N = 60$)	ILMA ($N = 60$)	Cobra PLA ($N = 60$)	p value
Age in years (SD)	42.4 (13.0)	42.8 (13.3)	41.7 (15.0)	0.9
Gender (M/F), *N*	19/41	20/40	27/33	0.2
Weight in kg (SD)	59 (9.8)	57.3 (10.1)	59.9 (10.3)	0.3
ASA (1/2), *N*	41/19	44/16	50/10	0.1
MMP (1/2), *N*	29/31	26/34	25/35	0.6

SD standard deviation, *ASA* Anesthesiologists Society of America Physical Status Grading, *MMP* Mallampatti classification of patients
$P < 0.05$—significant

fiberoptic-guided intubation with the Cobra PLA is also non-inferior to endotracheal intubation through the C-Trach in patients with an immobilized cervical spine.

The number of attempts taken for endotracheal intubation through the device, however, was significantly more with the Cobra PLA as compared to the C-Trach ($p = 0.013$, with $p < 0.018$ considered as significant after Bonferroni correction). All the patients in group C-Trach were intubated successfully in the first attempt. In group ILMA, five patients required a second attempt for insertion of the endotracheal tube, while in group CPLA only 51 patients could be successfully intubated on the first attempt, seven patients required a second attempt, and one patient required a third attempt.

The mean device insertion time between these three airway devices was significantly different ($p < 0.05$) (Table 2). Post-hoc analysis of the insertion times showed that insertion of the Cobra PLA took significantly more time than both the ILMA and C-Trach ($p < 0.05$). The difference in mean time taken for intubation between the three groups was significant (Table 2). Post-hoc analysis of the intubation times showed that intubation time with the C-Trach was significantly less than that observed with both the ILMA and Cobra PLA. There was a statistically significant difference in the grading of the fiberoptic view of the glottis, with the C-Trach providing a superior view than both the ILMA and Cobra PLA. The incidences of hypoxia, presence of mucosal, gum, and lip injury, and postoperative sore throat are given in Table 3.

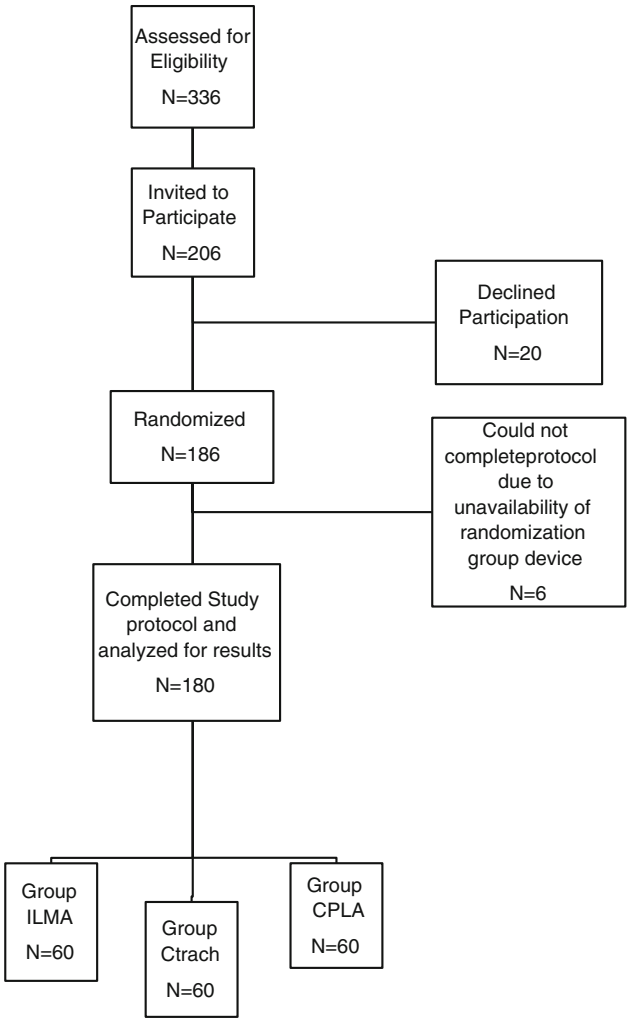

Fig. 1 Flow diagram for allocation of patients into various groups. *ILMA* Intubating Laryngeal Mask Airway, *C-Trach* C-Trach Laryngeal Mask Airway, *CPLA* Cobra Perilaryngeal Airway

Discussion

Our study shows that fiberoptic-guided intubation through the ILMA and Cobra PLA will provide an equivalent success rate for intubation as is achieved through a C-Trach in patients with a hard cervical collar in situ. The use of supraglottic airways, though previously thought to be impossible to use in patients with the cervical spine immobilized in a hard cervical collar [1, 9], is now an acceptable modality of airway management in these patients [10–13]. SGAs can be used for immediate and intermediate securing of an airway without removing the cervical collar and subjecting the patient to possible secondary neurological injury. Our study shows that if visual guidance in the form of either an inbuilt visualization system or fiberoptic bronchoscopy is possible through the device, then endotracheal intubation has a high success rate in these patients. The use of a fiberoptic bronchoscope for intubation improves the first attempt success rate of intubation through an ILMA in patients with normal [14] and difficult [15] airways, and in patients with simulated [16] and actual cervical spine instability [5, 17]. Fiberoptic-guided intubation through an ILMA, in fact, has been reported to be more successful than direct laryngoscopic bougie-guided intubation in patients with manual in-line stabilization [18]. In our study, the success rate of

Table 2 Parameters of insertion of airway device, and intubation through the device in the three groups

Parameter	Supraglottic Airway	Result	Difference (95 % CI)	Inference
Successful intubation, *n* (proportion)	C-Trach	60 (1.0)		
	ILMA	60 (1.0)	-	
	Cobra PLA	59 (0.98)	0.02 ($-\infty$, 0.05)	Non-inferior to gold standard[a]
Insertion time in seconds, mean ± SD	C-Trach	27.5 ± 9		
	ILMA	30.3 ± 11.9	2.8 (−1.01, 6.6)	$P = 0.15$
	Cobra PLA	35.7 ± 10.9	8.2 (4.6, 11.8)	$P < 0.0001$[†]
Intubation time in seconds, mean ± SD	C-Trach	84.4 ± 19.2		
	ILMA	117.9 ± 56.6	33.5 (18.2, 48.8)	$P < 0.0001$[†]
	Cobra PLA	139.2 ± 74.6[b]	54.8 (35.1, 74.5)	$P < 0.0001$[†]
Fibreoptic grading, poor alignment: good alignment ratio (proportion of good alignment)	C-Trach	15:45 (0.75)		
	ILMA	30:30 (0.50)	0.25 (0.08, 0.42)	$P = 0.005$[†]
	Cobra PLA	38:22 (0.37)	0.38 (0.22, 0.54)	$P < 0.0001$[†]

Secondary outcomes were not analyzed as per the non-inferiority statistical procedure

CI confidence interval, *SD* standard deviation

[a] Upper limit of CI (0.05) is less than non-inferiority margin of 0.18

[b] Data from 59 patients who were intubated

[†] *p* value <0.05 considered as significant

Table 3 Incidence of various complications in the three groups

Complications	C-Trach	ILMA	Cobra PLA	*p* value
Hypoxia, *N* (%)	0	2 (3.3)	5 (8.3)	0.06
Lip and gum injury, *N* (%)	8 (13.3)	6 (10)	8 (13.3)	0.81
Mucosal injury, *N* (%)	8 (13.3)	10 (16.6)	12 (20)	0.61
Sore throat, *N* (%)	10 (16.67)	13 (21.67)	14 (23.33)	0.64

p value for ANOVA <0.05 significant

intubation in the first attempt was 91 % with an ILMA, which is similar to the reports of previous studies in which fiberoptic-guided intubation has been done through the ILMA in patients with simulated cervical spine immobilization [15, 18].

The C-Trach provides an advantage over the ILMA because of an integrated viewing system, such that ventilation of the lungs can be continued while maneuvers for optimal positioning of the device to locate the glottis are done, thus effectively reducing the apnea time during endotracheal intubation. The first-attempt success rate of the C-Trach was reported as 96.7 % in its first evaluation study in human patients [19]. The C-Trach has been used for intubation in patients with actual and simulated cervical spine injury [20, 21]. The first-attempt success rate with the C-Trach in various trials in patients with simulated cervical spine instability has also been reported to be between 83–93 %, and all these studies quote an overall 100 % success rate of intubation [22, 23]. Since the end point of termination for an attempt at intubation was a fall in SpO_2 level to <93 %, more time was available in the C-Trach group for the actual intubation process than with the other two devices. Thus, in our study, the first-attempt success rate as well as the intubation times of the C-Trach were better as compared to other two devices. Although fiberoptic-guided intubation through the ILMA is more cumbersome and is associated with greater intubation times, it provides the added advantage of visual confirmation of the exact position of the endotracheal tube above the carina, which is not possible with the C-Trach.

Endotracheal intubation through the Cobra PLA had the lowest first-attempt success rate (85 %). We found that the closely-placed epiglottic grills on the ventral surface of the Cobra head hampers the smooth passage and deflects the path of both the fiberoptic scope and the endotracheal tube.

Intubation times with use of the ILMA have been reported to be much lower than those recorded by us [7, 24, 25]. However, all these studies have either not used any cervical spine stabilization technique [24, 25] or used a manual in-line stabilization for immobilizing the cervical spine [7]. The definition of intubation time was also different in our study: where we removed the supraglottic airway before connecting the ETT to the circuit, most of the studies connected the circuit with the supraglottic airway in situ [7, 12] and calculated the time

accordingly. We considered the former definition because the time of intubation refers to the time to secure the airway, and accidental extubation during removal of the supraglottic airway may occur, in which case the significance of successful intubation is lost.

None of the patients in the C-Trach group had hypoxic episodes. The incidence of hypoxia was insignificant in the other two groups, and the degree of desaturation was also mild (minimum SpO_2 88 % seen in one patient, between 90 and 93 % in the other six patients). However, we feel that all methods of oxygenation should be actively pursued when fiberoptic guidance is used, since the longer times of intubation can lead on to hypoxia, especially in patients with poor respiratory reserve. The highest incidence rates of mucosal injury and sore throat (20 %) were observed with the Cobra PLA. This can be attributed to the stiffer 'cobra head' of the Cobra PLA compared to the soft ILMA cuff, and due to the use of a PVC endotracheal tube for intubation, which is more traumatic than the soft Tuohy-tipped, dedicated ILMA endotracheal tube [26].

Our study may have been limited by the fact that an active control (fiberoptic-guided intubation without SGA) was not used to compare the devices. A fluoroscopic view to evaluate the cervical spine movement during the insertion of SGA and intubation through them may also have shed light on the utility of these devices.

To conclude, our study shows that the use of supraglottic airway devices with either mechanism for direct visualization of the glottis or with the help of a fiberoptic bronchoscope for endotracheal intubation has a high success rate in patients whose cervical spine is immobilized with a hard cervical collar. The overall performance in terms of the success rate of intubation through the ILMA, C-Trach, and Cobra PLA in this regard was similar. Intubation through the C-Trach, however, took a significantly lower number of attempts and less time for completion of the procedure, and thus can be recommended above the other two devices.

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Conflict of interest The authors declare that they have no conflicts of interest.

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