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The Perilaryngeal Airway and the Laryngeal Tube in Short Ophthalmic Procedures in Adults: A Prospective Randomized Comparative Study

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Abstract

Objectives: To compare the performance of the perilaryngeal airway and the laryngeal tube in anaesthetized, paralyzed and ventilated adults having ophthalmic surgery.

Methods: Two hundred adults were randomly allocated to receive either the perilaryngeal airway or the laryngeal tube for airway management during general anesthesia. Ease and number of insertions, insertion time, oropharyngeal leak pressure, hemodynamic response to insertion, oxygen saturation and end-tidal CO_2 during and after anesthesia were recorded.

Results: In the laryngeal tube group vs. the perilaryngeal airway group, insertion was considered easy in 90 vs.75, slightly difficult in 6 vs. 13, obviously difficult in 4 vs. 12 patients.

In the laryngeal tube group, the device insertion was 96% successful on the first attempt as compared to 88% in the perilaryngeal airway group. The cumulative insertion success rate increased to 100% for both devices after a second attempt. The time required for the insertion of the perilaryngeal airway was slightly longer than that of the laryngeal tube, but it did not reach statistical significance.

The airway leak pressure was significantly higher in the perilaryngeal airway group in comparison to the laryngeal tube group.

Conclusion: The perilaryngeal airway has insertion characteristics similar to the laryngeal tube but provides better airway sealing pressure. The perilaryngeal airway is a good addition to the airway armamentarium, and might be an important alternative for airway management.

Keywords: Perilaryngeal airway; Cobra PLA; Laryngeal tube; Anesthesia; Ventilation

Introduction

The perilaryngeal airway (PLA) was introduced into clinical practice in 2003 as a single use extraglottic airway device (EGD) [1]. It consists of a breathing tube with a wide cobra shaped distal end and an inflatable cuff just proximal to it [2,3]. When inflated, the cuff serves to seal off the distal end from the upper airway [3,4]. The cobra-shaped distal end is softened and designed to provide passage of the device into the hypopharynx by bending in the direction of the glottis [5]. Once in place, the distal head holds the soft tissues and epiglottis in place and abuts the laryngeal inlet, allowing positive pressure ventilation [6].

The laryngeal tube (LT) was introduced into clinical practice to secure a patent airway during either spontaneous breathing or controlled ventilation [7-11]. It consists of a single-lumen silicon airway tube with a distal small volume cuff (esophageal balloon), median high volume cuff (oropharyngeal balloon). Between these two cuffs, an oval aperture allows for ventilation. The LT is inserted blindly and requires a mouth opening of at least 23 millimeters [12]. The smaller esophageal balloon seals the airway distally, thus preventing aspiration and ventilation of the stomach. The larger oropharyngeal balloon seals the oropharyngeal cavity. Three black lines on the tube near the connector indicate adequate depth of insertion when aligned with the teeth.

Numerous studies compared reusable EGDs with each other or reusable with disposable EGDs, but few compared the disposable PLAs with the reusable LT [3,13-15].

In our hospital the majority of the ophthalmic procedures are performed under local anesthesia (retrobulbar and subtenon), but in certain cases, general anesthesia is indicated, as in uncooperative, demented, anxious or deaf patients. Sometimes, general anesthesia is used per patient request.

Since 2003 is the laryngeal tube one of the most common used extraglottic devices for the airway management during eye operations. Recently we have got the perilaryngeal airway CobraPLA as an addition to the airway armamentarium that has been used also in eye surgery.

This prospective randomized study aimed to determine whether the disposable PLA was as good in the airway management as the reusable LT.

We hypothesized that there would be no difference between groups with regard to the primary study end-points: insertion time, oropharyngeal leak pressure. Secondary study end-points were ease of insertion, hemodynamic responses, peripheral oxygen saturation, end-tidal carbon dioxide and intra-operative and early postoperative adverse events.

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Materials and Methods

A prospective study was conducted on 200 adults scheduled for ophthalmic surgery under general anesthesia at the Jordan University of Science and Technology between the months of August 2010 and June 2011. The study population was divided in to 2 groups to receive either the PLA (Cobra PLA®, Engineered Medical Systems, IN), or the LT (VBM medizintechnik, Sulz am Neckar, Germany) for airway during general anesthesia.

Institutional ethics committee approval was obtained. A written informed consent was signed by all patients, which were blinded to the insertion technique. The exclusion criteria were upper respiratory tract infection, increased risk of aspiration and morbid obesity (body mass index > 35). The choice of airway device was randomized by opening a sealed envelope immediately before induction of anesthesia by the anesthesiologist (M.O.) who was not involved in the insertion of the assigned airway device.

Patients were not premedicated. On arrival to the operating theatre; before induction of anesthesia; intravenous access was obtained and standard monitoring of blood pressure, three-lead electrocardiogram and pulse oximetric oxygen saturation were conducted. After breathing oxygen for 3 minutes via a face mask, anesthesia was induced with propofol 2-2.5 mg/kg, fentanyl 1µg/kg. Neuromuscular blockade was achieved with atracurium 0.2 mg/Kg. Anesthesia was maintained with sevoflurane 1.5-2% in 50% oxygen and air.

After 2 minutes of oxygenation with bag and mask ventilation with 100% oxygen and 2% sevoflurane, either PLA or LT was inserted. The size was based on manufacturer's recommendations, with size 3 PLA for weights between 35 and 70 kgs, and size 4 for weights between 71 and 100 kgs. For the LT, size 4 was used for heights between 155 and 179 cm, and size 5 for heights of ≥ 180 cm.

Before insertion, the cuffs were deflated and a water-based lidocaine gel was applied as a lubricant. Two senior anesthesiologists were involved in the insertions. This was conducted when the eyelash reflex was lost, the jaw had relaxed, and the patient was apnoeic. The patient's head and neck were placed in a sniffing position with the aid of a jelly donut head ring, and the mouth was opened using the non-dominant hand.

The PLA was held by the dominant hand and inserted blindly straight through the mouth until moderate resistance was felt. For the LT, the tip was placed against the hard palate behind the upper incisors and the device was slid down in the center of the mouth until resistance was felt or the device was fully inserted. When the device was judged to be positioned correctly, the cuffs were inflated, using a cuff inflator (cuff pressure gauge, VBM medizintechnik, Sulz, Germany), to a pressure of 60cm H_2O. Mechanical ventilation was performed with controlled positive pressure ventilation, at respiratory rate of 10-14 breaths per minute and with a tidal volume of 8 ml/kg.

The criteria for success of ventilation were adequate chest movement, expired tidal volume of more than 6ml/kg at a peak airway pressure ≤ 15 cm H_2O and presence of end-tidal carbon dioxide square waveform.

If ventilation was inadequate, gentle pushing or pulling of the device, chin lift, jaw thrust, head extension or neck flexion. Adequacy of ventilation was then re-assessed. If the second attempt was unsuccessful, it was to be recorded as a failure and no further data were collected.

An independent observer measured the insertion time from placement of the device in the mouth to the generation of the first satisfactory breath of at least 6ml/kg. The number of attempts and time for successful airway device insertion were recorded.

Ease of airway insertion was evaluated qualitatively, using the following scale: 1 (easy) for insertion on first attempt without any need for adjustment, 2 (slightly difficult) for insertion on first attempt with at least one adjustment maneuver, 3 (obviously difficult) for insertion on a second attempt, 4 (impossible) for more than 3 attempts or no insertion. Once an effective airway was achieved, oropharyngeal cuff leak pressure was obtained by closing the adjustable pressure-limiting valve of the anesthetic circuit. A fixed fresh gas flaw of 3L/min was utilized were the airway leakage pressure was the pressure at which equilibrium was reached. To prevent lung barotraumas, the maximum airway pressure was limited to 40 cm H_2O [16,17]. The direction of gas leaks at the sealing pressure was measured by auscultation with a stethoscope placed on the neck region and on the mouth.

The patient's heart rate, mean blood pressure and oxygen saturation were monitored (Datex-Ohmeda AS/5 Compact Critical Care Monitor; GE Healthcare, Helsinki, Finland) and recorded immediately before airway insertion, immediately after and at 5 minutes after airway insertion, and following the removal of the airway. End-tidal CO_2 was closely monitored and recorded.

At the end of the procedure, anesthesia was discontinued. Patients were allowed to breathe spontaneously, and the EGD removed when the patient responded to simple verbal commands. The cuffs of the EGD were deflated before removal.

After removal of the EGD, the presence or absence of blood on the device was noted, the lips and mouth were inspected for dental or mucosal trauma. Events such as aspiration or regurgitation, desaturation (SpO_2 ≤ 92%), bronchospasm, airway obstruction, coughing, gagging and hiccups were documented.

Thirty minutes after arrival at the post anesthesia care unit, and 4 hours postoperatively, patients were interviewed by a blinded independent investigator. They were asked if they have had sore throat, dysphagia, hoarseness and numbness of the tongue or the oropharynx.

Statistical analysis

The primary variables studied were time to achieve an effective airway and the seal pressures of the CobraPLA™ and LT. Secondary variables were ease of insertion, hemodynamic responses, end-tidal carbon dioxide and intra-operative and early postoperative adverse events.

To estimate appropriate group size, we referred to SDs of time to achieve an effective airway and the seal pressures of the CobraPLA™ obtained in previous study and found them to be within 7 Seconds [26] and 7.9 cm H2O [28]. We considered that a minimal standardized difference (d) of 0.40 would be a clinically important difference. Using these data, sample size was calculated to be 99 patients per group with a power of 80% and a type I error of 0.05. The sample size was increased to 100 patients each to allow for possible failed insertions. We used the two-sided independent Student's t-tests to analyze continuous data, the Mann-Whitney *U*-test for ordinal data, and Fisher's exact test for categorical data.

P value less than 0.05 was considered statistically significant for each comparison.

Statistical analysis was performed with SPSS version 17 (SPSS Inc., Chicago, IL).

Results

The study population included 200 adults (100 in the PLA group and 100 in the LT group) with a physical status category of I to III according to American Society of Anesthesiologists (ASA). Their age ranged between 18 and 80 years. The groups were similar with respect to age, weight, height, gender, ASA physical status and duration of anesthesia (Table 1).

In the LT group vs. the PLA Group, insertion was considered easy in 90 vs.75 patients, slightly difficult in 6 vs. 13, obviously difficult in 4 vs. 12 patients, and impossible in none (Figure 1).

In the LT group, the device insertion was successful in 96 patients on the first attempt and in 4 patients on the second attempt. In the PLA group, a successful primary airway was established in 88 patients on the first attempt, and on the second attempt in the remaining 12 patients. However, the cumulative insertion success rate increased to 100 % for both devices after the second attempt. The time required for the insertion of the PLA was slightly longer than that of the LT, but it did not reach the point of statistical significance (Table 2).

The airway leak pressure was higher in the PLA group (31±6 cm H2O) than in the LT group (24±9 cm H2O). This difference was statistically significant (P < 0.01). There was no difference in the heart rate, mean blood pressure, oxygen saturation and end-tidal CO_2 between the 2 groups (Tables 2,3).

On device removal, blood staining was detected more frequently on the PLA than on the LT airways. The difference was statistically

	LT Group (n = 100)	Cobra-PLA Group (n = 100)	P value
Age (years)	51.57±17.72	54.03±17.51	NS
Weight (kg)	76.05±13.73	79.9±13.57	NS
Height (cm)	166.44±7.12	167.57±8.07	NS
Gender (m/f)	41/59	44/56	NS
ASA I/II/III	36/38/26	28/37/35	NS
Duration of anesthesia (minutes)	44.24±11.16	42.42±9.21	NS

Data are mean ± SD or number of patients
M: Male
F: Female,
LT: Laryngeal tube
PLA: Perilaryngeal airway

Table 1: Demographic data.

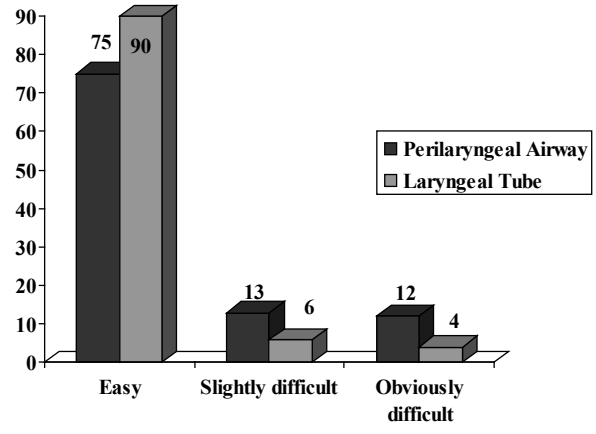

Figure 1: Insertion score details of the 2 devices.

	LT group (n = 100)	PLA group (n = 100)	P value
Device size (3/4/5)	0/57/43	51/49/0	NS
Number of insertions (1/2)	96/4	88/12	NS
Insertion time (seconds)	25.57±7.48	31.8±13.8	NS
Oropharyngeal leak pressure (cm H_2O)	24±3.14	32±2.3	<0.001
$ETCO_2$ (mmHg)	39±4	36±4	NS

Data are mean ± SD or number of patients
LT: Laryngeal tube
PLA: Perilaryngeal airway
ET CO_2: End tidal CO_2

Table 2: Assessment of device placement and ventilation.

	LT group (n = 100)	PLA group (n = 100)	P value
Heart rate (beats/min)			
Before airway insertion	81±7.5 (73-112)	84±11.6 (53-108)	NS
After airway insertion	75±11.9 (60-110)	74±11.4 (54-102)	NS
At 5 minutes after insertion	70±9.8 (47-106)	73±8.3 (62-98)	NS
After removal of the device	82±7.9 (74-122)	79±10.7 (63-117)	NS
MAP (mmHg)			
Before airway insertion	98±11.4 (78-139)	93±10.0 (70-136)	NS
After airway insertion	77±13.5 (56-125)	80±15.4 (55-135)	NS
At 5 minutes after insertion	76±11.7 (60-117)	75±12.0 (61-112)	NS
After removal of the device	86±14.9 (66-135)	84±13.9 (68-133)	NS
SpO_2 (%)			
Before airway insertion	97±1.7 (92-100)	97±1.6 (94-100)	NS
After airway insertion	98±1.4 (96-100)	98±1.6 (95-100)	NS
At 5 minutes after insertion	99±1.0 (97-100)	99±1.7 (92-100)	NS
After removal of the device	96±1.8 (90-98)	95±2.6 (88-98)	NS

Data are mean ± SD (range) or number of patients
LT: Laryngeal tube
PLA: Perilaryngeal airway
MAP: Mean arterial blood pressure

Table 3: Hemodynamic data and peripheral oxygen saturation.

	LT group (n = 100)	PLA group (n = 100)	P value
In the recovery room			
Sore throat (yes/no)	7/93	8/92	NS
Dysphagia (yes/no)	7/93	9/91	NS
Hoarseness (yes/no)	6/94	4/96	NS
Numb mouth (yes/no)	9/91	10/90	NS
Neck pain (yes/no)	2/98	1/99	NS
4 hours after operation			
Sore throat (yes/no)	5/95	5/95	NS
Dysphagia (yes/no)	6/94	5/95	NS
Hoarseness (yes/no)	2/98	1/99	NS
Numb mouth (yes/no)	5/95	4/96	NS
Neck pain (yes/no)	0/100	0/100	NS
Blood on device (yes/no)	4/96	11/89	< 0.001
SpO_2 ≤ 92% during surgery(yes/no)	0/100	2/98	NS

Data are number of patients
SpO_2: Peripheral oxygen saturation.
LT: Laryngeal tube
PLA: Perilaryngeal airway

Table 4: Incidence of complications and adverse events.

significant ($P < 0.01$), but there was no statistically significant difference in the intra-operative and postoperative airway morbidity (Table 4).

Discussion

A number of advantages have been attributed to extraglottic devices over endotracheal tubes. There is an improved hemodynamic stability during induction and emergence, lower incidence of coughing and sore throat and reduced anesthetic requirement for airway tolerance [3,18]. This study demonstrated that the PLA airway is as effective as the laryngeal tube in providing a patent airway during controlled ventilation, and that both devices can be safely used in paralyzed patients.

In this study, first-attempt device insertion was successful in 88% of patients with the PLA, and in 96% with the LT. Furthermore, the overall success rate was 100% for both. This was consistent with other reports, where the success rate of insertion ranged between 92 and 100% for the LT [12,19-24] and between 95 and 100% for the PLA [4-6,25-28]. Despite the high success rate of insertion we found that the PLA was more difficult to insert than the LT. This too was consistent with other studies [25]. In this study, the first attempt success rate of the PLA at 88% was similar to this of Nam et al. [6] at 82%, who used muscle relaxants. The first attempt insertion success rate with the LT was higher at 96%, which was similar to the findings of Wrobel et al. [10] at 90%, who inserted the LT in non-paralyzed patients. In contrast, Kurola et al. [13] found that first time insertion success rates with the PLA were lower than those of the LT.

The average insertion time of the LT was shorter than this for the PLA, which parallels the findings of Gaitini et al. [26] who found that the insertion time for the PLA were longer than that for the Laryngeal Mask Airway Unique (LMA-U). Experience in device insertion may have compounded results. The investigators in a study by Akca et al. [4] performed only 10 PLA insertions before joining the trial and found no differences between the devices in term of insertion time.

In this study, the incidence of postoperative airway morbidities were similar in both groups, except for blood staining, which occurred more frequently with the PLA (11%) than with the LT (4%). Turan et al. [27] compared the PLA, the LMA, and the LT in 90 patients and observed that the PLA was more frequently associated with blood staining in comparison to the LMA and the LT. The rigidity of the PLA head may be the reason for the blood traces and throat soreness [1]. The airway trauma in the LT group is probably due to its design and its low-pressure, high-volume oropharyngeal balloon [12].

In this study, the oropharyngeal leak pressure was higher with the PLA (31±6 cmH_2O) compared to the LT (24±9 cmH2O) ($P < 0.005$). This is consistent with the findings of Andrews et al. [5] who showed that oropharyngeal leak pressure was higher with the PLA than with the LMA. Other studies reported that the oropharyngeal leak pressure was higher with the PLA than with the classic LMA, in addition to its provision of a better airway seal [4,26]. Furthermore, the airway leakage pressure was found to be higher with the LT compared to the LMA [29]. The higher leak pressure with the LT suggests a better airway seal, but this is only safe if the esophageal balloon produces an adequate seal. This may be attributed to the large cuff that improves sealing. Similarly, the higher airway leakage pressure of the PLA may be attributed to a similar cuff structure resulting in better seal of the proximal pharynx [24].

The hemodynamic parameters and the peripheral oxygen saturation before and after induction of general anesthesia were not significantly changed with either PLA or LT. The reason could be due to the lack of tracheal manipulation with the extraglottic airways, in contrast to the conventional endotracheal intubations [23,30].

One of the limitations of this study was the fact that the position of the airway devices was not determined with a fibre-optic bronchoscope.

In conclusion, the PLA has insertion characteristics similar to the LT but provides better airway sealing pressure. The PLA is a good addition to the airway armamentarium, and might be an important alternative for airway management.

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