CobraPLA™ Insertion by anesthetists and non-anesthetists wearing unconventional protective gear: A prospective study in humans

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Summary

Background: The threat of a mass casualty unconventional attack has challenged the medical community to devise means for providing rapid and reliable emergent airway control under chaotic conditions by inexperienced medical personnel dressed in self protective gear. Since endotracheal intubation may not be feasible under those conditions, other extraglottic devices should be considered. We assessed the performance of anesthesia and non-anesthesia residents in inserting the CobraPLA™, a supraglottic airway device, on consecutive anesthetized patients, to assess its potential use under simulated conditions.

Material/Methods: Anesthesia and non-anesthesia residents wearing either surgical scrubs or complete anti-chemical gear inserted the CobraPLA™ in anesthetized patients. If post-trial positive pressure ventilation via the CobraPLA™ was unsuccessful, an LMA™ or endotracheal tube was inserted in its stead.

Results: It took anesthesia residents 57±23 sec and 43±13 sec (P<0.05) to place the CobraPLA™ while wearing anti-chemical gear and surgical scrubs, respectively. Non-anesthesia residents wearing anti-chemical gear performed worse than anesthetists in their first insertion (73±9 sec, P<0.05), but after the brief training period they performed as well as their colleagues anesthetists (58±10 sec, P=NS). Post-trial, twenty-one CobraPLA™ (42%) leaked, preventing adequate positive-pressure ventilation: 13 devices (26% of the total) required replacements.

Conclusions: Anti-chemical protective gear slowed the insertion of the CobraPLA™ by anesthetists, and more so by other residents inexperienced in airway management. In 26% of the cases CobraPLA™ was inadequate for positive pressure ventilation.

key words: airway management • CobraPLA™ • unconventional protective gear

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BACKGROUND

Recent threats to civilian populations from conventional [1,2] and unconventional [3,4] toxic agents have challenged medical personnel to devise means for providing rapid and reliable emergent airway control. Airway control is a crucial step in the management of any medical emergency, regardless of its cause [5–7]. Exposure of a civilian population to any airborne toxic agent is expected to injure large and varied populations of all ages and health conditions [4,8]. In the case of chemical warfare with multiple victims, some with combined conventional and chemical injuries, strict adherence to protocols and triage criteria is mandatory [9]. However, there is always the concern of how rapid and reliable airway management will be if the first medical provider approaching the victim is not experienced in airway management. Another problem is the need to treat as many victims as possible in a chaotic environment while at the same time maintaining self-protection. This subject was recently reviewed by our group [7,9].

New equipment that does not require extensive experience in airway management has recently become a part of the armamentarium of anesthesiologists, intensivists and paramedics. [10] We have previously studied the use of the laryngeal mask airway (LMA™) by experienced anesthesia residents and by inexperienced surgery residents, with and without full anti-chemical protective gear [11]. We demonstrated that LMA™ insertion was faster than tracheal intubation by anesthesiologists wearing protective gear, and that it was a suitable device for initial airway control when the caregiver’s level of expertise was limited and when, for any reason, tracheal intubation was not feasible.

Importance

Whereas direct laryngoscopy and insertion of an endotracheal tube (ETT) is the first choice for airway control in the described situation [6], caregiver’s self-protection by anti-chemical gear limits breathing, field of vision during laryngoscopy, movement, kneeling, holding small objects, and fine motor control necessary to perform delicate tasks such as insertion of an intravenous line, and performance of laryngoscopy and intubation [7,12]. It is thus necessary to make available alternative and handy airway control devices in addition to the LMA, such as the CobraPLA™. Importantly, elevated work of breathing is frequent during airborne gas attacks, which mandate the use of positive pressure ventilation; the tested device needs to enable positive airway ventilation.

The perilyngeal airway (CobraPLA™, Engineered Medical Systems, Indianapolis, IN) is a supraglottic, cuffed airway device. It consists of a breathing tube with a wide distal end positioned in the hypopharynx and a cuff attached just proximal to the wide part. The cuff, when inflated, serves to seal off the distal end from the upper airway. The wide end holds both soft tissues and the epiglottis away from the distal portion of the CobraPLA™. Inside the distal end, a continuation of the breathing tube angles upwards [13]. The CobraPLA™ requires a smaller mouth opening for insertion than the LMA [13].

Goals of this investigation

The primary purpose of the current study was to assess suitability and efficacy of CobraPLA™[13,14], when used by CobraPLA™ inexperienced anesthesia residents and non-anesthesia residents; the latter also inexperienced in airway management. Secondarily, ease of training of the non-anesthesia personnel in this technique was assessed. Since the CobraPLA™ has been found to be as efficient as the LMA™ during general anesthesia in an outpatient setting [13], we also assessed the post-trial positive pressure ventilation usefulness of CobraPLA™ under the projected circumstances.

MATERIAL AND METHODS

Setting; selection of participants

Fifteen anesthesia residents (2nd–3rd year residency) experienced in airway management, but not in the use of the CobraPLA™, and ten other residents (similar year of residency), inexperienced in airway management, participated in this prospective study. All the participating physicians passed the Advanced Cardiac Life Support and Advanced Trauma Life Support courses (lectures and hands-on practice of airway management on mannequins) and were currently on call in the tertiary university-affiliated hospital’s emergency department or on their own ward 1–2 times/week.

The patients studied were consecutive consenting, ASA I–2, adults, scheduled for various elective surgical procedures under general anesthesia. Exclusion criteria were concomitant indication to the use of an extraglottic device, indication for endotracheal intubation, suspected difficult intubation, bad dentition, pulmonary disease, obesity, cervical spine pathology, and maxillofacial abnormality.

Anti-chemical gear and airway control devices

The anti-chemical protective gear is a complete suit that is currently used by the medical staff according to the regulations of the Israeli Defense Force Medical Corps. It includes butyl rubber boots (Hamegapher, Tel Aviv, Israel), a nylon shirt and pants covered by a khaki vest and pants (Chemoplast, Afula, Israel), butyl rubber gloves (Supergum, Tel Aviv, Israel) and a gas mask with an active filter (Shalon, Tel Aviv, Israel).

The CobraPLA™ is a supraglottic airway device. It consists of a breathing tube with a wide distal end. A cuff proximal to the wide end may be inflated and thus seal the distal end from the upper airway. The wide end retracts the epiglottis out of the airway and holds the soft tissue away from the distal portion of the CobraPLA™. We used device size number 3 for women and 4 for men [14]. The airway device was lubricated with a water-based lubricant.

Study design

This Tel Aviv Medical Center’s institutional review board-approved study consisted of two phases. In the first, we randomly assessed the performance of anesthesia residents that...
were unfamiliar with the CobraPLA™. Each anesthetist inserted the device once while wearing regular surgical scrubs and once while wearing full anti chemical gear, in random sequence. Randomization was performed using sealed envelopes that were opened in the holding area just before the patient was brought to the OR. In the second phase of the study, we evaluated the performance of non-anesthesia residents untrained in management of an airway. This part was not random: each participant inserted the CobraPLA™ device once while wearing complete anti chemical gear. He then inserted the CobraPLA™ device three times with the guidance of an anesthesiologist, while wearing surgical scrubs. In the fifth case, the study resident inserted the device again while wearing complete anti-chemical gear. This latter protocol followed our previous data in LMA™ placement, showing that non-anesthesia residents benefited from brief (4–6) LMA™ training sessions to perform as well as anesthesia residents [11]. The study patients were thus divided into five groups:

Group 1: Fifteen patients in whom a CobraPLA™ was inserted by anesthesia residents wearing surgical scrubs.

Group 2: Fifteen patients in whom a CobraPLA™ was inserted by anesthesia residents wearing complete anti-chemical gear.

Group 3: Ten patients in whom a CobraPLA™ was inserted by non-anesthesia residents wearing complete anti-chemical gear before a brief training period: first case.

Group 4: Thirty patients in whom a CobraPLA™ was inserted by non-anesthesia residents wearing surgical scrubs (brief, three-patient-training period): cases 2–4.

Group 5: Ten patients in whom a CobraPLA™ was inserted by non-anesthesia residents wearing complete anti-chemical gear after brief training period: fifth case.

Interventions; methods of measurement

In the preoperative holding area, each patient received 1mg of midazolam IV. In the OR, the patient was connected to a routine multimodal vital sign monitor, including end tidal CO₂ (Cardiocap-5, Datex-Omeda, Helsinki, Finland), and 500 ml crystalloid solution was infused. After pre-oxygenation with 100% O₂ for 3min, anesthesia was induced with fentanyl 100mcg followed by propofol 2 mg/kg IV. After loss of consciousness and the verification, by the supervising anesthesia attending physician, that mask ventilation was easy, the study physician stepped in and briefly mask-ventilated the patient. The CobraPLA™ was then inserted without the assistance of a neuromuscular blocking agent; when deemed, by the resident, to be in place, its balloon was inflated with 35–60 ml of air according to the manufacturer’s instructions. The patient was then manually ventilated. Proper position of the CobraPLA™ was subsequently confirmed by the supervising anesthesiologist, based on lung auscultation, capnography curve and value, and auscultation at the neck for air leak, while ventilating the patient with a tidal volume of 4–5 ml/kg, and generating an inspiratory pressure of up to 22 cmH₂O. Failure in placement was defined as inability to record normal capnography. If CobraPLA™ placement failed, the same resident would repeat the procedure until properly placed. The CobraPLA™ was then secured by the resident, using a cotton lace. Measurement of the time for device insertion began when the study physician grabbed the device until the supervising anesthetist confirmed proper position. Time to its fixation was measured from the time of proper positioning to proper fixation.

Vital signs were recorded every 3min during the tested procedures. Unsuccessful post trial controlled ventilation via the CobraPLA™ due to air leak mandated its replacement by an LMA™ or ETT.

Primary data analysis

The analyses were performed at the Statistical Laboratory of the School of Mathematics, Tel Aviv University, Tel Aviv, Israel, using SPSS for Windows (version 11.01, 2001; Chicago, IL). All values are given as mean ±SD. The study was based on a 90% power, aimed at detecting a mean difference of 10s between the groups when inserting the device with and without the anti-chemical outfit, at an alpha value of 0.05. The study size was thus determined to be n=10 per group.

A ln transformation of the data was used to reach a normal distribution of the time values of the various groups. The time to successful insertion or fixation of the CobraPLA™ and the demographic and background values were analyzed using the analysis of variance followed by the post hoc Tukey’s test. The rates of failure or of hypoxicemic events were analyzed using the χ² test. ASA physical class and Mallampatti score evaluation were assessed using the Kruskal-Wallis test. P<0.05 was considered significant.

Results

There was no difference in the demographic data between the five study groups (Table 1). The vital signs, recorded throughout the cases, were comparable between the groups as well (Table 2). There was no desaturation event in any of the cases studied, nor were there any other side effects or complications (data not shown).

The anti-chemical gear significantly hampered the performance of the anesthesia residents. It took them ~25s longer to properly place and twice as long to secure the CobraPLA™ while wearing the anti-chemical gear compared to while wearing surgical scrubs (Table 3).

The non-anesthesia residents on their first case, wearing anti-chemical gear, performed worse than their anesthesia colleagues wearing the gear, in both inserting and fixing the CobraPLA™ (Table 3); they took 28% more time to insert and fix the device than their anesthetist counterparts. After the three drills wearing surgical scrubs, their performance while wearing anti-chemical gear was as good as the anesthesia residents, both in inserting and securing the device (Table 3, Figure 1).

Three cases of failed insertion of the device were recorded, all among the non-anesthesia residents (Table 3).

Independent of the outfit, the CobraPLA™ had a high occurrence of leak (Table 3). Forty-two percent of the devic-
es, mostly those placed by non-anesthesia residents, prior to their brief training period, had significant air leaks. Eight of these patients were adequately maintained with spontaneous ventilation whereas 13 required removal of the Cobra PLA™.

In all these latter cases replacement by an LMA™ proved adequate for positive pressure ventilation.

**Discussion**

This study indicates that anti-chemical protective gear slowed the insertion of the Cobra PLA™ by anesthesia residents, but made no large difference in success rate. In contrast, non-anesthesia residents untrained in airway management achieved success rates comparable to anesthesia residents.

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**Table 1.** Demographic data of patients treated by the various residents wearing different outfits (mean ±SD).

<table>
<thead>
<tr>
<th>Patients treated by residents in</th>
<th>Age (yr)</th>
<th>Weight (kg)</th>
<th>M/F</th>
<th>ASA class</th>
<th>Mallampatti score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia + Scrubs (n=15)</td>
<td>38±18</td>
<td>72±10</td>
<td>11/4</td>
<td>1.3±0.6</td>
<td>1.8±0.6</td>
</tr>
<tr>
<td>Anesthesia + Gear (n=15)</td>
<td>41±17</td>
<td>73±12</td>
<td>9/6</td>
<td>1.4±0.6</td>
<td>1.4±0.6</td>
</tr>
<tr>
<td>Non-Anesthesia + Gear before training (n=10)</td>
<td>38±13</td>
<td>76±8</td>
<td>7/3</td>
<td>1.4±0.5</td>
<td>1.9±1.0</td>
</tr>
<tr>
<td>Non-Anesthesia + Scrubs during training (n=30)</td>
<td>40±12</td>
<td>75±11</td>
<td>20/10</td>
<td>1.3±0.3</td>
<td>1.7±1.1</td>
</tr>
<tr>
<td>Non-Anesthesia + Gear after training (n=10)</td>
<td>32±11</td>
<td>72±9</td>
<td>6/4</td>
<td>1.3±0.5</td>
<td>1.6±0.5</td>
</tr>
</tbody>
</table>

No significant differences were found among the various parameters.

**Table 2.** Vital signs before and immediately after Cobra PLA™ insertion (mean ±SD).

<table>
<thead>
<tr>
<th>Time</th>
<th>Parameter</th>
<th>Anesthesia residents</th>
<th>Non-Anesthesia residents in gear</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Scrubs</td>
<td>Gear</td>
</tr>
<tr>
<td>Pre-insertion</td>
<td>SBP (mmHg)</td>
<td>129±12</td>
<td>130±15</td>
</tr>
<tr>
<td></td>
<td>DBP (mmHg)</td>
<td>82±9</td>
<td>85±12</td>
</tr>
<tr>
<td></td>
<td>HR (bpm)</td>
<td>79±8</td>
<td>81±9</td>
</tr>
<tr>
<td></td>
<td>SpO₂ (%)</td>
<td>98±0.9</td>
<td>97±1</td>
</tr>
<tr>
<td></td>
<td>EtCO₂ (mmHg)</td>
<td>25.2±4.1</td>
<td>27.8±4.1</td>
</tr>
<tr>
<td>Post-insertion</td>
<td>SBP (mmHg)</td>
<td>131±12</td>
<td>125±12</td>
</tr>
<tr>
<td></td>
<td>DBP (mmHg)</td>
<td>81±13</td>
<td>77±9</td>
</tr>
<tr>
<td></td>
<td>HR (bpm)</td>
<td>73±9</td>
<td>72±10</td>
</tr>
<tr>
<td></td>
<td>SpO₂ (%)</td>
<td>97±0.8</td>
<td>98±2</td>
</tr>
<tr>
<td></td>
<td>EtCO₂ (mmHg)</td>
<td>34.2±3.0</td>
<td>37.3±5.9</td>
</tr>
</tbody>
</table>

SBP – systolic blood pressure; DBP – diastolic blood pressure; HR – heart rate; bpm – breaths per min; SpO₂ – finger-tipped pulse oxygen saturation; EtCO₂ – end-tidal (end expired) carbon dioxide pressure. No significant differences were found among the various parameters.

**Table 3.** Time (sec) required to insert and secure the Cobra PLA™, and rates of failure to insert it and post-study occurrence of excessive leak when used for pressure (>22 cmH₂O) ventilation (mean ±SD or absolute numbers).

<table>
<thead>
<tr>
<th>Groups</th>
<th>Surgical scrubs</th>
<th>Anti-chemical gear</th>
<th>Failure of insertion (n)</th>
<th>Excessive leak (n [%])</th>
<th>Exchange to LMA™ (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Insertion</td>
<td>Fixation</td>
<td>Insertion</td>
<td>Fixation</td>
<td>Total</td>
</tr>
<tr>
<td>Anesthesia residents (n=15)</td>
<td>43±13</td>
<td>21±10</td>
<td>57±23*</td>
<td>43±22*</td>
<td>0</td>
</tr>
<tr>
<td>Non-Anesthesia residents, attempt #1 (n=10)</td>
<td>73±9**</td>
<td>54±10</td>
<td>2</td>
<td>10 [100]**</td>
<td>8**</td>
</tr>
<tr>
<td>Non-Anesthesia residents, attempt #5 (n=10)</td>
<td>58±10</td>
<td>38±11</td>
<td>1</td>
<td>4 [40]</td>
<td>2</td>
</tr>
</tbody>
</table>

* P<0.05 vs. the scrubs data, ** P<0.05 vs. the corresponding anesthesia residents’ data and the same group’s data during the 5th insertion of the device while wearing an anti-chemical gear.
may be nearly impossible, especially when the oral cavity to nerve agent intoxication. Laryngoscopy and visualization of the vocal cords in an individual lying on the floor may be nearly impossible, especially when the oral cavity is filled with vomitus, as may be expected in the described situation. The insertion of an ETT may also require intravenous access for the administration of sedative drugs, but we believe that in most of these victims the insertion of an IV line would be impossible (i.e., patient hypovolemia, profuse sweating, the need for cumbersome gear to protect the caregiver). It is therefore important that airway devices other than the ETT be evaluated.

The extraglottic airway device of choice for resuscitation has not yet been established. The laryngeal mask airway (LMA-Classic™; Laryngeal Mask Company Limited, Gensia Pharmaceuticals, San Diego, CA), the most commonly used and most studied extraglottic device [18], has gained popularity as an airway management device, in a variety of situations including surgical and internal medicine wards and trauma situations [19–21]. In the latest guidelines for adult advanced life support, published by the European Resuscitation Council [22], only the LMA™ and the esophageal-tracheal Combitube™ (Kendall Company, Mansfield, MA) were mentioned as alternatives to the ETT. In addition, the LMA™ has a well-deserved status in the American Society of Anesthesiologist’s difficult airway algorithm [23]. As we have previously demonstrated, the LMA™ is an alternative to the ETT when used by physicians wearing anti-chemical gear, since the time for insertion is shorter compared to that required for the insertion of the ETT [24]. Several extraglottic airway devices have become available more recently, including the Combitube™, and two newer versions of the classic LMA™ (ProSeal™ [Laryngeal Mask Company Limited, San Diego, CA], and the intubating laryngeal mask [ILMA Fastrack™, Intavent, Berkshire, UK]). Mark et al. [20] evaluated the performance of corpsmen in inserting an ETT, a LMA™, and a Combitube™ under combat-like conditions. Although the three devices were found to be suitable for emergency settings, the study did not include a mass casualty pattern, nor did it involve the unconventional outfit that we describe. The Cobrapla™ was recently evaluated for use during anesthesia and was found to be very efficient and even provided a better seal compared to the LMA™ [13]. We now demonstrate that the Cobrapla™ is easy to use even by untrained personnel and the learning period is relatively short. Nevertheless, 26% of the Cobrapla™s had to be replaced compared to none of the LMA™s in our previous study [11]. Each time, the LMA™ proved to be acceptable for positive pressure ventilation of >22 cmH2O and successfully replaced the Cobrapla™. This observation contradicts that of Akca et al. [13] who suggested that the Cobrapla™ provided a better fit compared to the LMA™ but conforms to the data provided recently by Gaitini et al. who like us found that Cobrapla™ poses minimal setback to the airways during spontaneous ventilation [25] and is supported by the suggestion that the Cobraperilaryngeal airway needs caution against airway trauma [26]. Finally, the finding that leakage rate was much higher before training implies that skill affects degree of leak.

**Limitations**

Although this study was designed to assess the use of the Cobrapla™ as a device for airway management during mass casualty, chemical warfare conditions, the only condi-
tions mimicked here is the dress and the incentive to control the airway quickly. Airway management was conducted in a controlled setting in the operating theatre, as mandated by the Institutional Helsinki Committee. Still, the negative results stand, as the results would only have been worsened by the pulmonary trauma and chaos expected in an attack. Using medics in addition to residents might have added interesting data for a more general emergency scenario. Additional studies are currently under way to directly compare the performance of different medical and para-medical personnel using a range of available extraglottic devices in an emergency setting.

**CONCLUSIONS**

Anti-chemical protective gear slowed the insertion of the CobraPLA™ by anesthetists, and more so by other residents inexperienced in airway management. Since a significant number of CobraPLA™ proved inadequate for positive pressure ventilation, and since the occurrence of lung injury is expected to be high, and so is the need for high pressure ventilation in the addressed individuals, our data emerging from this study suggest that the CobraPLA™ may not be a good extraglottic device in such conditions. When bad comes to worse, if used, once the injured individual is transported to a medical center, the supraglottic device should be replaced by an ETT if continued ventilatory support is indicated.

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