Laryngeal Mask Airway Insertion by Anesthetists and Nonanesthetists Wearing Unconventional Protective Gear

A Prospective, Randomized, Crossover Study in Humans

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Background: Mass casualty situations impose special difficulties in airway management, even for experienced caregivers. The laryngeal mask airway is part of the difficult airway algorithm. The authors evaluated the success rate and the time to secure airways by mask by anesthetists, surgeons, and novices when wearing either surgical attire or full antichemical protective gear that included butyl rubber gloves and a filtering anti-gas mask.

Methods: Twenty anesthetists and 22 surgeons with 2–5 yr of residency inserted a laryngeal mask airway in 84 anesthetized patients, and 6 novices repetitively inserted masks in 57 patients under both conditions in a prospective, randomized, crossover manner. The duration of insertion was measured from the time the device was first grasped until a normal capnography recording was obtained.

Results: Anesthetists needed $39 \pm 14$ s to insert the masks when wearing surgical attire and $40 \pm 12$ s with protective gear. In contrast, surgery residents needed $64 \pm 40$ and $102 \pm 40$ s ($P = 0.0001$), respectively. Anesthetists inserted masks in a single attempt, whereas the surgeons needed up to four attempts with no hypoxia or failure associated. The initial attire-wearing novices' insertions took as long as the surgeons'; three of them then reached the mean performance time of the anesthetists after four (protective gear) and two (surgical attire) trials, with only one occurrence of hypoxia and a failure rate similar to that of the surgeons.

Conclusions: Anesthesia residents insert laryngeal mask airways at a similar speed when wearing surgical attire or limiting antichemical protective gear and two to three times faster than surgical residents or novices wearing either outfit. Novices initially perform at the level of surgical residents, but their learning curve was quick under both conditions.

RECENT threats to civilian populations from conventional combustion of toxic agents, such as sulfuric acid,1,2 or from unconventional nerve agents3,4 have challenged medical personnel to devise means for providing rapid and reliable emergent airway control. Airway management is a crucial step in the management of any medical emergency, regardless of whether it is associated with trauma or toxic injury to the respiratory system5,6 or is combined with unconventional trauma.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.8,9 In the case of chemical warfare with multiple victims, some with conventional plus chemical injuries, strict adherence to protocols and triage criteria is mandatory to prevent the chaotic phase of the event.9 However, there is always the concern of how rapid and reliably airway management will be if the first medical providers arriving in the area are surgeons or general practitioners, if their number is limited, and if they must rush to treat as many victims as possible in a chaotic environment while protecting themselves at the same time.

Direct laryngoscopy and the insertion of an endotracheal tube has thus far been the classic and safest approach for airway control under any circumstances.6 We have previously reviewed bioterrorism-related conditions in which large populations were the theoretical target of trauma and unconventional intoxication and raised the question of how well an anesthetist or any other caregiver could succeed in managing individuals’ airways in such conditions while wearing full antichemical gear. This kind of cumbersome outfit limits breathing, field of vision during laryngoscopy, movement, kneeling, holding small objects, and performing delicate tasks such as insertion of an intravenous line.10

New equipment that does not require experience in airway management has recently become commercially available and is now a part of the armamentarium of the anesthetist as well as of paramedics.11 The most familiar airway device, the laryngeal mask airway, which can be inserted in victims without the need for laryngoscopy, both in humans and in monkeys,12,13 has gained popularity in emergency situations outside the operating room,6,14 and has been successfully used by paramedical...
personnel. The laryngeal mask has even become a part of the difficult airway algorithm so that under certain circumstances, it may be the step-down solution in cases when laryngoscopy and tracheal intubation have become impossible or inadvisable despite the need for airway control.

The purpose of the current study was to assess the speed and success rate by which inexperienced medical personnel who are supposed to be the first caregivers in times of disaster, especially after unconventional attack, would insert laryngeal masks under normal conditions, i.e., wearing surgical attire, compared with wearing full antichemical protective gear. We evaluated their performances as well as those of anesthesia residents under both conditions. Based on preliminary results that indicated longer insertion time for the surgical residents, we added a third group that consisted of novices who also inserted laryngeal masks under both apparel conditions. We hoped that the data retrieved from this latter group would serve as their learning curve, i.e., that it would indicate the number of attempts that would be needed before successful insertion was completed in the mean time level of the anesthesia residents.

Materials and Methods

Physician and Patient Recruitment

Twenty-two general surgery residents and 20 anesthesia residents participated in this prospective, randomized, crossover study. They had respectively completed 3.0 ± 0.9 and 2.9 ± 0.7 (2–5) years of residency; had, without exception, passed the Israeli Defense Forces (Tel Aviv, Israel) Medical Corps’ Advanced Cardiac Life Support and Advanced Trauma Life Support courses (lectures and hands-on practice of airway management on mannequins) within the 12 months before starting their residency; and were currently on call in the hospital’s emergency department or in their own ward one or two times/week. Based on draft plans, the former physicians may be deployed on site where ordinary medical as well as airway management are necessary, whereas, according to current protocols of a mass casualty scenario of a unconventional attack in the catchment area of the Tel Aviv Medical Center, Tel Aviv, Israel, the latter physicians are the ones to perform these measures when the victims arrive at the hospital’s decontamination area for treatment (see ANESTHESIOLOGY Web site). The third group of physicians comprised six novices who would also be deployed on the site of a disaster, who had no experience in inserting laryngeal masks in anesthetized patients, and whose sole experience in airway management was the aforementioned Israeli Defense Forces Medical Corps’ Advanced Cardiac Life Support and Advanced Trauma Life Support courses.

Consecutive patients with American Society of Anesthesiologists physical status I–III who were scheduled for various surgical or orthopedic interventions under general anesthesia were considered suitable to participate in this study, which was approved by the institutional human investigation committee of the Tel Aviv Sourasky Medical Center, Tel Aviv, Israel. All compliant subjects signed a Helsinki Committee-approved informed consent after having been given a detailed explanation of the study. Exclusion criteria were allergy to latex, history of chronic pain or of psychiatric disorders, and the use of centrally acting drugs of any sort. Patients younger than 18 yr, pregnant women; individuals who had experienced severe trauma to the central nervous system or to the face; patients who had undergone maxillofacial, head, or neck surgery; and patients who had a Mallampati score of 4 were also excluded from the study.

Antichemical Gear and Airway Control Devices

The antichemical protective gear is a complete set 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 an antigas mask with an active filter (Shalon, Tel Aviv, Israel).

A size 4 laryngeal mask airway (Gensia Pharmaceuticals, San Diego, CA) was used for all patients; our experience is that this size has a lower rate of postoperative pharyngeal discomfort, as was the observation by Grady et al. All devices were lubricated with 2% lidocaine in aqueous jelly (Rafa Laboratories, Jerusalem, Israel).

Study Protocol

In the operating room, all nonpremedicated patients were connected to a multimodal monitor (AS/3; Datex-Ohmeda, Helsinki, Finland), which enabled the recording of cardiovascular and respiratory parameters. These consisted of measurements of heart rate by a five-lead electrocardiograph, systolic and diastolic blood pressures, respiratory rate, pulse oximetry, and exhaled (sidestream) capnography. The patients were first allowed to breathe 100% oxygen via a facemask. When all parameters reached normal and/or satisfactory values, 1–2 mg midazolam and 100 µg fentanyl were injected intravenously, followed by 2–2.5 mg/kg propofol injected over 30 s for the induction of anesthesia. We usually refrain from using muscle relaxants during laryngeal mask airway insertion and instead use the jaw thrust as the indicator for the proper time for insertion. We also had to bear in mind that toxic nerve agents act pharmacologically at the same site as suxamethonium. We and others have recommended that nerve agent victims should not be given any drug that further inhibits acetylcholine esterase activity.

After manual ventilation was confirmed as being effec-
Table 1. Patients’ Demographic, Hemodynamic, and Respiratory Data

<table>
<thead>
<tr>
<th></th>
<th>Anesthesia Residents (n = 20)</th>
<th>Surgical Residents (n = 22)</th>
<th>Novices (n = 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Surgical Attire</td>
<td>Protective Gear</td>
<td>Surgical Attire</td>
</tr>
<tr>
<td>Age, yr</td>
<td>38.7 ± 18.1</td>
<td>36.3 ± 14.3</td>
<td>45.2 ± 18.9</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>69.1 ± 16.5</td>
<td>75.4 ± 13.2</td>
<td>79.3 ± 19.4</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>7/13</td>
<td>9/11</td>
<td>8/14</td>
</tr>
<tr>
<td>Vital signs immediately before insertion of the LMA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart rate, beats/min</td>
<td>83.1 ± 13.1</td>
<td>81.7 ± 16.0</td>
<td>72.9 ± 12.0</td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td>131.4 ± 18.7</td>
<td>130.7 ± 15.7</td>
<td>137.5 ± 22.7</td>
</tr>
<tr>
<td>Diastolic blood pressure, mmHg</td>
<td>83.0 ± 10.9</td>
<td>82.1 ± 7.1</td>
<td>83.9 ± 11.1</td>
</tr>
<tr>
<td>SpO₂, %</td>
<td>98.8 ± 1.0</td>
<td>98.3 ± 0.9</td>
<td>98.4 ± 0.9</td>
</tr>
<tr>
<td>Vital signs immediately after capnography-confirmed LMA insertion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart rate, beats/min</td>
<td>75.0 ± 10.7*</td>
<td>77.3 ± 14.7</td>
<td>71.7 ± 10.7</td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td>115.0 ± 20.5*</td>
<td>111.4 ± 14.3*</td>
<td>121.1 ± 19.4*</td>
</tr>
<tr>
<td>Diastolic blood pressure, mmHg</td>
<td>71.6 ± 15.3*</td>
<td>69.2 ± 19.7†</td>
<td>73.1 ± 13.3†</td>
</tr>
<tr>
<td>SpO₂, %</td>
<td>98.5 ± 1.0</td>
<td>97.9 ± 1.4</td>
<td>98.1 ± 1.1</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD.

*P = 0.01, †P = 0.005 vs. pre-LMA insertion values. ‡P ≤ 0.02 vs. the surgeons’ own attire group values or vs. fellow anesthetists’ values. LMA = laryngeal mask airway; SpO₂ = oxygen saturation measured by pulse oximetry.

The proper position of the laryngeal mask was later reconfirmed by lack of oropharyngeal airway leaking as verified by the supervising anesthesiologist, who used a stethoscope to detect any audible noise over the epiglottis, laterally to the thyroid cartilage, and over the mouth. To obtain this verification as well as to assure equal bilateral lung expansion, the patient was manually ventilated with a generated peak inspiratory pressure of 22 cm H₂O.

Any untoward effect during the study was treated immediately, and its occurrence was recorded. The study was concluded when the airway device was properly placed and secured; anesthesia was then administered in the usual way. No additional data were recorded after this time.

Statistics

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, Chicago, IL). All values are given as mean ± SD. Based on the results of a pilot study, a power analysis for the two groups of the residents was conducted before the study was opened. The test was based on a 90% power, aimed at detecting a mean difference of 10 s between the groups when inserting the masks with and without the antichemical outfit, at an α value of 0.05. The study size was thus determined as being 10.

In transformation of the data was used to reach a normal distribution of the time values of the various groups. The time to successful insertion and demographic and background values were analyzed using analysis of variance (with repeated measures wherever required) followed by post hoc Tukey test. The rates of failure or of hypoxic events were analyzed using the Fisher exact test. P ≤ 0.05 was considered significant.
Results

Table 1 shows the demographic data of the patients who were enrolled in the study; these and the mean American Society of Anesthesiologists physical status classifications and Mallampati scores (data not shown) were similar among the three study groups.

Figure 1 depicts the performances of each of the residents in inserting the laryngeal masks under each condition. Insertions were accomplished at a similar speed by the anesthesia residents when wearing either type of apparel. With one exception, all anesthetists accomplished the task within 60 s. Their insertions were successful on their first attempt under both conditions. There was an overall significant difference ($P < 0.001$) in the performances of the anesthetists and nonanesthetists: the surgery residents were almost two times ($P < 0.001$) slower than the anesthetists in properly placing the masks. This result was associated with a significant interaction (group × gear; $P = 0.001$) between the performances recorded among the surgeons who wore protective gear compared with the score when they wore surgical attire. Overall, their mean levels of skill during the first attempts while wearing surgical attire were similar to those of both the anesthetists and the surgical residents (in between the values of the two groups). When protected by the gear, their initial mean time to successfully first insert the masks was the slowest among all three groups of physicians (figs. 1 and 2). They significantly improved their practice with time under both conditions (time effect; $P < 0.0001$) and reduced their failure rates, with their learning curve improving in parallel under both conditions. Three of them reached the mean insertion time of the anesthetists after four attempts in both conditions, whereas the other three needed six to seven attempts. The number of failed insertions among the gear-protected novices was signif-

Table 2. LMA Insertion Data

<table>
<thead>
<tr>
<th></th>
<th>Anesthesia Residents (n = 20)</th>
<th>Surgical Residents (n = 22)</th>
<th>Novices (n = 6)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Surgical Attire</td>
<td>Protective Gear</td>
<td>Surgical Attire</td>
</tr>
<tr>
<td>Attempts to successful insertion, No. (1/2/3/4)</td>
<td>20/0/0/0</td>
<td>20/0/0/0</td>
<td>18/2/2/0‡</td>
</tr>
<tr>
<td>Failed attempts of LMA insertion, No.</td>
<td>0</td>
<td>0</td>
<td>6*</td>
</tr>
<tr>
<td>Time to secure LMA to patient’s face, s</td>
<td>23 ± 7</td>
<td>39 ± 9‡</td>
<td>37 ± 13*</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD or absolute values.

* $P < 0.05$, † $P < 0.001$ vs. the fellows anesthetists’ values. ‡‡ $P < 0.01$ vs. own attire or respective anesthetists’ values.

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The results of this study, which is the first of its kind, emphasize a well-known and accepted notion from a new aspect. Although physician expertise is an important factor in the management of medical emergencies in general and the management of airways in particular, it is also relevant for the achievement of successful insertion of laryngeal mask airways in humans, especially under toxic or unconventional stressful conditions. The laryngeal mask is the second-best choice for airway management. It requires less expertise than tracheal intubation and is practiced by paramedical personnel and other medical providers. Nevertheless, inserting it properly took almost twice as long for the surgical resident compared with the anesthetist counterpart when each wore surgical attire. This difference was even greater when both groups were dressed in antichemical gear, when it took surgical residents almost three times longer to correctly place the mask compared with the anesthetists. Furthermore, whereas the antichemical gear did not affect the success rate of laryngeal mask insertion by the anesthesia residents who consistently achieved successful insertion in a single attempt under both dress conditions, the number of attempts required by the surgical residents and their rate of failure were higher (22–44%), leading to a much lower rate of success. This raised the question of whether an antecedent practice program would benefit nonanesthetists when they are deployed and need to manage patients’ airways during a mass casualty event; we found the answer to be yes.

Obtaining the novices’ performance profile added an essential aspect to the current study by indicating the number of attempts, i.e., the amount of practice, that they needed before their rate and time of successful laryngeal mask insertion reached the anesthesia residents’ level of skill. The resultant learning curves (both with and without the protective gear) unexpectedly indicated that no more than eight attempts would be needed for them to reach an equivalent level of skill. This rapid gain in the level of skill between the novices’ initial scores and their final ones, similar to those of surgical residents, might be that the former had more recently completed the Advanced Cardiac Life Support and Advanced Trauma Life Support courses (including hands-on practice of airway management) as part of their training in the Israeli Defense Forces Medical Corps, a phenomenon probably unique to Israel. Moreover, the opportunity to manage patients’ airways during a surgical residency program is limited because the residents in our tertiary medical center customarily call the emergency team and do not deal with airway management by themselves. This, and the longer time distance from the Advanced Cardiac Life Support and Advanced Trauma Life Support courses, may explain the relatively narrow gap in their performance and that of the novices. As for the time necessary for the various groups to secure the laryngeal mask to a patient’s face, which was the longest among the novices but later shortened, we suggest that this may be related to the fact that it is not a task worked
out during the courses. This is an issue we have recently brought up to the appropriate authorities.

Inhalation of toxic vapor induces acute lung injury,5,22,23 whereas nerve gas intoxication causes muscle paralysis8 or upper airway obstruction and bronchorrhea.7 In an event of any intoxication that afflicts the airway and the lungs, securing the airway is by far the most important step for preventing respiratory failure and asphyxia.5,23 The time factor is crucial. The respiratory and oxygenation reserves of the victims is minimal, and they are inevitably frightened and in precarious physical and mental condition due to hypoxia, such that any delay in providing proper respiratory support reduces survival.5,7,23 Although the laryngeal mask airway does not provide the same degree of safety and ventilation as obtained by preferred tracheal intubation,6,24–26 it is a viable alternative device for medical providers who are inexperienced in intubation or when intubation is difficult or impossible.12,14,21 Our data show how use of the laryngeal mask airway could be implemented in humans, whereas a possible role of other extraglottic airway devices (e.g., esophageal tracheal Combitube (Kendall Company, Mansfield, MA), cuffed oral pharyngeal airway, or ProSeal™ (Laryngeal Mask Company Limited, San Diego, CA)) await future investigations. Our MEDLINE search did not provide more specific data on airway management of the victims we describe, with the exception of reports of paramedics using the device in emergency situations.6,11,14,21 Therefore, we designed an algorithm (fig. 3) based on personal expertise in airway management that displays what steps should be taken by caregivers in cases of gas-intoxicated victims. We suggest that when tracheal intubation is impossible because of the victim’s state, the caregiver’s limited experience, or any other restricting conditions at the scene, laryngeal mask placement is an acceptable alternative for successful airway management. However, because time is crucial during mass casualty resuscitation, victims’ conditions are precarious, and the duration of each attempt is approximately 100 s, the total number of attempts to successfully insert the mask by the nonanesthetists would be limited (up to two attempts).

This study had a number of limitations. It was performed under safe and secure conditions for the patients, as stipulated by the Tel Aviv Sourasky Medical Center Helsinki Committee Directives. The study patients were relatively healthy, had secured intravenous access, and were fully anesthetized, hemodynamically stable, and preoxygenated. The physicians were not subject to any undue stress, the environmental conditions of the operating room and the available equipment were ideal (e.g., lubricated laryngeal mask airway), and a single patient was being cared for at any time. In an actual mass casualty biologic or chemical warfare situation, the conditions would clearly be much less favorable.4,5,7 For example, physicians would have to provide emergent medical support to a large number of people of variable ages and health conditions who would be highly likely to have problematic upper airway characteristics and hypoxia, some of whom would be in a critical state.4,7,8 They could also have multiple injuries and seizures and have copious secretions, vomit, and edema overwhelming their upper airways, especially if they had inhaled toxic vapors. Venous access might be difficult to achieve7,10; therefore, the administration of sedatives or relaxants to facilitate airway management would be impossible. The caregiver would not use a stethoscope because of caveats regarding the personnel’s safety (uncovering the head), and qualified assistance might be unavailable.7 We tried to simulate a scenario involving caregivers under
pressure (in this case, that of time) who were required to protect themselves by two layers of clothing, rubber boots, thick rubber gloves, and an antigas mask, all of which induce profuse sweating and hamper breathing, movement, kneeling, vision, and dexterity,7 and showed that they directly caused a delay in airway management and patient care by anesthetists, surgeons, residents, and novices. Because we hypothesized that laryngoscopy and tracheal intubation would be almost impossible under these adverse conditions,7 we studied the insertion of a laryngeal mask, the second-best choice in the algorithm of difficult airway management.6,16,17,24,25 We assumed that the time required for successful insertion of the mask would be longer and the rate of success would be lower for inexperienced residents compared with anesthetists: our results showed this to be the case and probably highly underestimated.

We conclude that the laryngeal mask airway is a suitable device for initial airway control when the caregiver’s level of expertise in ventilatory support is limited and when, for any reason, tracheal intubation is not applicable. The reassessment of the appropriateness and the efficacy of the device to maintain sustained airway patency should be done later, at a medical facility, by physicians who are experts in airway management. We also call on the authorities who are responsible for the medical care of the civilian population to consider periodic courses (hands-on) on the use of the laryngeal mask for nonanesthetists. Training programs on cadavers and anesthetized patients for nonanesthetists to reach a level of skill comparable to that of anesthetists are highly recommended. Novices should also be considered as suitable candidates for on-site care giving. Their deployment in such conditions would not disrupt clinical work, but their previous military training could enhance their capability in providing airway support to victims at a level of success and skill similar to that of the surgical and even some of the anesthesiology residents.

The authors thank Perla Eckstein, M.D. (Staff Anesthesiologist, Department of Anesthesiology and Critical Care Medicine, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel), for intellectual input. Esther Estkol, M.A. (Institutional Medical and Scientific Copyeditor, Tel Aviv Sourasky Medical Center), is thanked for editorial assistance.

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