Use of an intubating laryngeal mask airway on out-of-hospital cardiac arrest patients in a developing emergency medical service system

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Background/Purpose: An intubating laryngeal mask airway (ILMA) is an alternative device for airway control, capable of providing effective ventilation in various situations. The purpose of this study is to compare the effects of the ILMA and bag-valve-mask (BVM) ventilation devices on out-of-hospital cardiac arrest (OHCA) patients.

Methods: An ILMA training course was conducted by emergency medical technicians (EMTs). Before training, OHCA patients had received BVM ventilation; these patients were defined as the BVM group. After training, all EMTs in the area being served were instructed to immediately use an ILMA on OHCA patients when possible; these patients were defined as the ILMA group. Demographics, transport time, first arterial blood gas data, and the short-term outcomes of these two groups were analyzed.

Results: A total of 398 OHCA patients (89 in the BVM group and 309 in the ILMA group) were analyzed. All of the EMTs passed the training course, and ILMAs were used in the emergency settings. The ILMA was applied to each OHCA patient for a longer-than-average field time than the BVM (9.5 vs. 7.8 minutes, p = 0.006). The 24-hour survival rate of the ILMA-treated patients was significantly higher than BVM-treated patients (36.2% vs. 24.7%, p = 0.033).
Conclusion: Well-trained EMTs were able to insert the ILMA and ventilate OHCA patients properly in prehospital settings, and ILMA-treated OHCA patients had better short-term outcomes than BVM-treated patients.

Introduction

Airway control is usually necessary during prehospital resuscitation in order to provide adequate oxygenation and ventilation to a patient in cardiac arrest. Prehospital endotracheal intubation (ETI) is considered the optimal method of securing the airway. The 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care recommends emergency ETI as a class I method. However, in areas without adequateprehospital medical care, sufficient training, or sufficient equipment to ensure that prehospital ETI is a routine procedure, other methods of airway control are legal and practical options. Bag-valve-mask (BVM) ventilation of a nasal or oral airway has traditionally been considered an effective alternative for prehospital airway and breathing control. However, BVM ventilation has some shortcomings, including gastric inflation, regurgitation, and pulmonary aspiration. Another problem not frequently mentioned is the difficulty of affixing the mask while transporting the patient to the hospital. In addition, BVM ventilation is difficult when the patient has a severe facial injury or is being moved.

On the other hand, both prehospital ETI and paramedic-performed rapid sequence intubation (RSI) have recently been criticized because they offer no decrease in mortality, regardless of whether they are used on patients undergoing cardiac arrest or those who present with a severe head injury. Because prehospital ETI is often time consuming, laborious, and difficult in areas with shortages of prehospital medical resources, a randomized trial of its efficacy for out-of-hospital cardiac arrest (OHCA) patients is practically impossible.

In Taiwan, the emergency medical service (EMS) system is still developing, and emergency medical technicians (EMTs) operate strictly from protocol, without the guidance of real-time, on-line medical control. EMS does not allow EMTs to liberally perform prehospital ETI or to give prehospital sedatives to patients because the distance between the emergency scene and the nearest hospitals is often short. The average transport time from the scene to the hospital is often less than 8 minutes in most urban and suburban areas. Following basic life support (BLS) guidelines, EMTs are not equipped with endotracheal tubes and are restricted to a few methods of establishing airway control outside of hospitals. In addition to monitoring the patient’s vital signs, they are instructed to use BVMs with a nasal or oral airway as the standard mode of ventilation on all patients who require airway management. Prehospital ETI has only been performed in very few cases, and EMTs using BVM have discovered the difficulty of maintaining the proper mask position while transporting patients. Furthermore, ETI without medication is considered difficult by all healthcare professionals, and alternative methods for airway control without medication are still needed.

Since its introduction into clinical practice in 1985, the laryngeal mask airway (LMA) has been advocated as a useful option for airway management during outpatient operations, thoracotomies, and elective Cesarean sections under proper anesthesia, or as a back-up option when dealing with a difficult airway in an emergency. The role of the LMA in resuscitation and its potential prehospital role have been described, but no serial studies have been performed to determine its clinical effects.

Affixing an LMA during the transportation of a patient is a concern. One type of LMA, called an “intubating laryngeal mask airway” (ILMA or LMA-Fastrach), has been designed to facilitate tracheal intubation. Instead of a flexible silicon tube, an ILMA has a stiff handle and a rigid stainless steel tube, which provides more stability during transportation (Fig. 1). ILMAs have been successfully
provided to injured patients to provide adequate prehospital ventilation and oxygenation.\textsuperscript{19} Although it is considered an effective alternative for airway control, the ILMA has not been compared with the BVM in prehospital settings.

Before this study, the EMS in Taiwan followed the BLS guidelines for prehospital settings. Performing BLS procedures within the limited timeframe before arrival at a hospital were the main tasks. However, EMTs in Tainan City have reported that BVMs are ineffective for airway and ventilation control.

The aims of this study are to understand the feasibility of training EMTs to use the prehospital ILMA and determine its effectiveness for managing airway control in OHCA patients in comparison with BVM.

**Methods**

**Study design**

Based on review articles and pioneering experiences in prehospital airway control,\textsuperscript{19–21} the Tainan City EMS advisory committee suggested\textsuperscript{20} that EMTs be given the option to use an ILMA at emergency scenes in order to manage the airways of patients in cardiac arrest or those without vital signs. The committee thought that the ILMA is minimally invasive and that it is easier to maintain the position of the mask and, thus, ventilate the patient. The Tainan City Fire Department accepted the suggestion and enrolled all EMTs into an ILMA-insertion training course. Preliminary EMT operational guidelines for OHCA patients were enacted during the ILMA-insertion training course. Preliminary EMT operational guidelines for OHCA patients were enacted during the induction period, and EMTs were encouraged to use the ILMA without any neuromuscular-blocking or sedative agents when initially establishing an airway in an OHCA patient. Before this prehospital ILMA-insertion program was implemented, OHCA patients had been managed with BVMs.

**Study setting and population**

National Cheng Kung University Hospital (NCKUH) is a university-based medical center in the study region of Tainan City. The director of the NCKUH Department of Emergency Medicine is also the regional EMS director and holds a monthly quality-assessment meeting.

A before-and-after controlled study of OHCA patients was performed throughout the Tainan area under an EMS program with medical direction and six base hospitals. Approximately 750,000 residents are served by the Tainan City Ambulance Dispatch Center and Tainan EMS system, which provided dispatch information about all of the OHCA patients who were transported by ambulance during the study period (from September 1, 2004 through June 30, 2007). Prehospital care was documented on the EMT run sheet, which recorded specific data such as the call code, time of events, and procedures performed. The study population included all adult patients whom the EMTs had found lifeless at the scene. All patients in Taiwan, except those who expire a certain amount of time before the EMTs arrival and are declared dead on the scene, are transported to a hospital. Terminal patients with a malignancy, patients who had already signed a do-not-resuscitate (DNR) form, and patients with jaw stiffness or rigor mortis were excluded from this study. Because this prehospital emergency service was regulated by the city’s fire department, regular institutional review board processes and informed consent were waived.

During the study period, emergency medical services were supplied by the EMTs who had previously been trained to provide all BLS measures, including oxygen, BVM ventilation, and automated external defibrillation, if indicated. For this study, all EMTs completed the 4-hour training course, which included an introduction, an explanation of the structure of the ILMA, practice on an intubation mannequin (an airway training model), and a performance test. The objective of the training was to enable the trainee to properly insert the ILMA and ventilate the mannequin within 1 minute. EMTs were instructed to insert the ILMA directly in the case of a confirmed OHCA and then report to the dispatch center. The dispatch center would then inform the on-duty physician at the appropriate emergency department while the ambulance was on route to the hospital. Immediately after the ILMA had been inserted, EMTs started to provide ventilation using an adult resuscitation bag that delivered oxygen 12 times per minute and was capable of delivering a total of 15 L/minute.

Before the training course on the insertion of the ILMA, the local EMS followed an OHCA algorithm developed by the central fire department (Fig. 2). A patent airway, no
spontaneous breathing, and no carotid pulse were three criteria used to classify a patient as OHCA in this study.

All 175 EMTs who attended the ILMA training course learned how to proficiently insert the ILMA and properly start ventilating the mannequin within 1 minute (37.2 ± 14.6 seconds). No obvious air leaks were observed, and all EMTs passed the examination.

After the ILMA training course, when the EMTs were called out for prehospital medical resuscitation, they first confirmed the OHCA conditions upon arrival by following the OHCA procedure. They performed cardiopulmonary resuscitation (CPR) with a BVM for 1 minute and then inserted the ILMA, which was affixed to the proper position using tape in order to maintain the airway and provide proper ventilation while the ambulance was en route to the hospital.

Following the standard CPR procedure, the patient’s medical history and present illness were recorded after the primary survey and resuscitation. Study data were provided by EMS and a review of hospital records—ambulance call reports, computer-based dispatch reports, hand-written EMS sheets, and hospital charts—was compiled by assistants blind to this study. Because the reasons that the OHCA patients survived were associated with the etiology of their physiological collapse and underlying comorbidities, the patients survived were associated with the etiology of their in the hospital.

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Data analysis

All data were analyzed using SPSS for Windows 10.0 (SPSS Inc., Chicago, IL, USA). Numerical data are presented as medians ± standard deviations (SD) unless otherwise indicated. Differences between BVM and ILMA groups were analyzed using two-sample t-tests or χ² tests. The significance was set at p < 0.05 or a 95% confidence interval (CI) < 1.

Results

From September 1, 2004 through June 30, 2005, the BVM-group patients (n = 113) were ventilated with a BVM, but 24 of these patients were excluded from the analysis because of incomplete data. From July 1, 2005 through June 30, 2007, the ILMA-group patients (n = 332) were ventilated with an ILMA, but 23 of these patients were excluded from the analysis because of incomplete data. Demographic data were not significantly different between the two groups (Table 1). The ILMA-group patients spent significantly more time at the scene of the accident than the BVM group patients (9.5 ± 4.8 minutes vs. 7.8 ± 6.1 minutes, p = 0.006) and required more CPR (11.6 ± 4.0 minutes vs. 8.75 ± 5.1 minutes, p < 0.001). Several laboratory parameters, such as arterial blood gas testing (e.g., pH, PaO₂, and HCO₃ levels) were not significantly better for the ILMA-group patients compared with the BVM-group patients (Table 2). However, the ILMA group had a significantly higher percentage of ROSC (47.6% vs. 36.4%, p = 0.05) and a significantly higher 24-hour survival rate (36.2% vs. 24.7%, 95% CI: 0.01–0.22, p = 0.043) than the BVM group.

Discussion

We evaluated the effects of the ILMA on OHCA patients in a prehospital setting. The preliminary results seem promising and strongly suggest that the ILMA is a feasible alternative to the BVM for prehospital airway control. Our preliminary results show that the ILMA is a minimally invasive option for airway control of OHCA patients in a developing EMS system with limited prehospital ETI training and without ETI resources or enough on-line medical direction. Reinhart et al.²² showed that the mean time to successful ventilation with the LMA was less than 1 minute (38.9 ± 1.9 seconds); our study shows a slightly longer field time for the ILMA group compared with the BVM group (9.5 ± 4.8 minutes vs. 7.8 ± 6.1 minutes, p = 0.006) in prehospital settings.

Several EMT-related ILMA studies²³–²⁵ have reported positive results when using ILMAs on mannequins with airways that are difficult to intubate, but before 2008 no study has shown how much more time it takes to insert an ILMA in a prehospital setting and compare the arterial blood gas data and outcomes. This inclusive study on OHCA

<table>
<thead>
<tr>
<th>Table 1 Demographic data of ILMA and BVM groups.</th>
<th>BVM (n = 89)</th>
<th>ILMA (n = 309)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>53 (59.6%)</td>
<td>193 (62.5%)</td>
<td>0.368</td>
</tr>
<tr>
<td>Age* (y)</td>
<td>63.2 ± 18.5</td>
<td>63.2 ± 18.2</td>
<td>0.932</td>
</tr>
<tr>
<td>Trauma</td>
<td>21.3%</td>
<td>14.2%</td>
<td>0.058</td>
</tr>
<tr>
<td>Chronic comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>57.3%</td>
<td>56.9%</td>
<td>0.711</td>
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<tr>
<td>Cerebrovascular</td>
<td>33.7%</td>
<td>32.4%</td>
<td></td>
</tr>
<tr>
<td>Pulmonary</td>
<td>13.5%</td>
<td>4.2%</td>
<td></td>
</tr>
<tr>
<td>Uremia</td>
<td>1.1%</td>
<td>6.1%</td>
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<tr>
<td>Diabetes</td>
<td>28.1%</td>
<td>16.9%</td>
<td></td>
</tr>
<tr>
<td>Liver cirrhosis</td>
<td>1.1%</td>
<td>1.9%</td>
<td></td>
</tr>
<tr>
<td>Malignancy</td>
<td>6.7%</td>
<td>8.1%</td>
<td></td>
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<tr>
<td>* Values are the means ± standard deviations.</td>
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</tbody>
</table>
values are the means

looking the risk of gastroesophageal reflux was another.

CPR quality, off-chest time, or quality of chest compression

are low in OHCA patients.

methods used for resuscitation. Long-term survival rates
diseases and chronic conditions than on the effects of the

outcome depends more on the patient’s underlying

compared 24-hour survival rates instead of functional or

effect on the outcomes of this study. Second, we

believe that these sampling problems had no significant

OHCA patients before they arrived at the hospital. We

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Before this study, EMTs in Taiwan were limited in their

more critical condition than those in the BVM group.

it is also possible that the ILMA group included patients in

treating a patient in a more critical condition. Therefore,

BVM group; and, (2) on the other hand, the EMTs would

included patients in less critical condition than those in the

least two implications: (1) the ILMA group might have

study still had several limitations. First, it was not a

randomized clinical trial. Case selection is an issue with at

least two implications: (1) the ILMA group might have

included patients in less critical condition than those in the

BVM group; and, (2) on the other hand, the EMTs would

have been more likely to use the ILMA than BVM when

treating a patient in a more critical condition. Therefore,

it is also possible that the ILMA group included patients in

more critical condition than those in the BVM group. Before this study, EMTs in Taiwan were limited in their

ability to maintain oxygenation and ventilation in critical

patients. This study is pioneering because it allowed EMTs
to provide more effective ventilation management to

OHCA patients before they arrived at the hospital. We

believe that these sampling problems had no significant

effect on the outcomes of this study. Second, we

compared 24-hour survival rates instead of functional or

long-term outcomes. We did so because the long-term

outcome depends more on the patient’s underlying
diseases and chronic conditions than on the effects of the

method used for resuscitation. Long-term survival rates

are low in OHCA patients.

In this before-and-after study, it was difficult to measure

CPR quality, off-chest time, or quality of chest compression

at the scene, which are undoubtedly limitations. Over-

looking the risk of gastroesophageal reflux was another.

Although this has been reported when using an LMA,26 no

serious regurgitation was reported in our study population.

While gastroesophageal reflux might have been under-

reported in these patients, BVM also involves the risk of

gastroesophageal reflux.

In Taiwan, it is difficult to compare the effectiveness

and efficiency of ILMA and ETI outside of hospitals.

However, some recent studies6,7 have already questioned

the appropriateness of the laborious prehospital ETI as

a method of airway management for certain types of crit-

ical patients, such as those with a severe head injuries. The

failure rate of ETI and the high incidence of misplaced

endotracheal tubes in prehospital settings27–30 motivated

our EMS system to develop a new strategy: using a non-ETI

alternative in urban areas. This experiment yielded higher

pH levels and other arterial blood gas data in the ILMA

group compared with the BVM group, in accordance with

the significantly higher ROSC and 24-hour survival rates of

the ILMA-group patients. Some criticisms can be made

about the various underlying etiologies as confounding

factors. In fact, EMTs in some cases had difficulty deter-

mining the cause of airway collapse at first inspection.

Although ETI is generally considered the prehospital gold

standard for airway management, here we show that the

ILMA provides a better short-term survival rate than BVM for

OHCA patients who need to be transported only a short
distance to a hospital.

Conclusion

Our results demonstrate significantly better physiological

data in the ILMA group than the BVM group and a better 24-

hour survival rate for the ILMA group. We conclude that

more in-depth studies on the use of ILMA as the optimal

method of prehospital airway control, rather than BVM or

ETI, are necessary. ILMA proved to be an efficient and

effective alternative means of providing airway manage-

ment in prehospital settings, especially in regions where an

EMS system is still being developed.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Clinical data of ILMA and BVM groups.</th>
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<tbody>
<tr>
<td></td>
<td>BVM (n = 89)</td>
</tr>
<tr>
<td>Total transport time*</td>
<td>16.7 ± 8.6</td>
</tr>
<tr>
<td>Dispatch time*</td>
<td>4.6 ± 2.8</td>
</tr>
<tr>
<td>Field time*</td>
<td>7.8 ± 6.1*</td>
</tr>
<tr>
<td>Delivery time*</td>
<td>4.9 ± 3.1</td>
</tr>
<tr>
<td>Time of CPR†</td>
<td>8.8 ± 5.1†</td>
</tr>
<tr>
<td>pH</td>
<td>7.0 ± 0.23</td>
</tr>
<tr>
<td>PaO2†</td>
<td>110.9 ± 122.6</td>
</tr>
<tr>
<td>PaCO2 †</td>
<td>74.3 ± 37.1</td>
</tr>
<tr>
<td>HCO3 †</td>
<td>16.5 ± 10.0</td>
</tr>
<tr>
<td>SaO2 (%)</td>
<td>62.2 ± 36.5</td>
</tr>
<tr>
<td>ROSC (%)</td>
<td>36.0%</td>
</tr>
<tr>
<td>24-hour survival rate (%)</td>
<td>24.7%</td>
</tr>
</tbody>
</table>

* Values are the means ± standard deviations, in minutes.
† Values are the means ± standard deviations, in mmHg.
‡ Values are the means ± standard deviations, in mmol/L.
ILMA in OCHA patients

References


