Abstract

Objective: Few studies have compared airway management via laryngeal masks (LM) or laryngeal tubes (LT) in patients with out-of-hospital cardiac arrest (OHCA). This study evaluated whether LT insertion by emergency medical service (EMS) personnel affected ventilation and outcomes in OHCA patients (vs. the standard LM treatment).

Methods: This prospective, cluster-randomized, and open-label study evaluated data that were collected by the Sapporo Fire Department between June 2012 and January 2013. We selected the 14 EMS teams that treated the greatest number of OHCA patients in Sapporo, Japan during 2011, and randomized the teams into Groups A and B. In the first study period (June 2012 to September 2012), Group A treated OHCA patients via LT and Group B treated OHCA patients via LM. In the second period (October 2012 to January 2013), Group A treated OHCA patients via LM and Group B treated OHCA patients via LT. If necessary, both groups were allowed to use an esophageal obturator airway (EOA) kit. The primary endpoints were time from cardiopulmonary resuscitation to device insertion and the rate of successful pre-hospital ventilation. The secondary endpoints were return of spontaneous circulation and survival and favorable neurological outcomes at 1 month after cardiac arrest.

Results: LT was used in 148 OHCA patients and LM was used in 165 OHCA patients. Our intention-to-treat analyses revealed no significant differences in the primary and secondary outcomes of the LT- and LM-treated groups.

Conclusion: Prehospital advanced airway management via LT provides similar outcomes to those of LM in OHCA patients.

Introduction

Effective airway management is an important technical skill in the treatment of patients with out-of-hospital cardiac arrest (OHCA). For many years, the optimal method for airway management was considered to be endotracheal intubation (ETI), because it provided better airway control and protection against upper airway obstruction, with a decreased risk of gastric aspiration and control of carbon dioxide removal. However, the performance of ETI by emergency medical services (EMS) personnel has been questioned recently.[1, 2] In addition, the 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science[3] and the 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care[4] have reduced the level of urgency for early ETI unless it can be performed by highly skilled medical personnel with minimal interruption of chest compressions. Furthermore, several studies[5-9] have compared the efficacy of endotracheal tube (ETT) to that of other supraglottic airway devices (SGAs) in patients with OHCA, and reported no improvements in the survival or outcomes of the patients who were treated with ETT. Moreover, the failure rate of ETI that is performed by EMS personnel in the prehospital setting can be as high as 30%.[10] Therefore, because attempted ETI typically requires the interruption in chest compressions during cardiac arrest (which can increase detrimental outcomes),[11] correct ETI administration requires continuous training and advanced skills.[12-14]

In this context, various SGAs have become preferred to ETT for the advanced airway management of patients with OHCA. Recently developed examples of SGAs include the esophageal obturator airway (EOA), laryngeal mask (LM), laryngeal tube (LT), and i-gel devices. In 1991, Brain reported the invention of the LM,[15] which is easy to insert and provides effective management of difficult airways. Since that time, various reports have compared LM and ETT, and have confirmed the effectiveness of LM.[7-9] In addition, Samarkandi et al.[16] have reported that LM is a good alternative to ETT in cases that require cardiopulmonary resuscitation. Similarly, LT was recently introduced as an alternative device for managing difficult airways, and numerous reports[17-20] have emphasized the benefits of LT during resuscitation in the emergency department, because the LT insertion procedure is very simple (even for inexperienced individuals) and requires minimal instruction prior to its first use.[21, 22] Furthermore, LT has been successfully used by paramedics to treat cases of OHCA.[23-25] Therefore, although no studies have directly compared LM and LT, it is possible that the time for LT insertion might be shorter than that for LM insertion, which might improve the prognosis and outcomes for patients with OHCA. Before this study, EMS personnel in Sapporo, Japan used EOA and LM (rather than LT) as the standard treatment for patients with OHCA. Thus, we hypothesized that EMS personnel might be able to skillfully use LT after short-term training, and that the shorter time for LT insertion might improve the rate of successful ventilation and prognosis of patients with OHCA, compared to LM.

Methods

Study design

This study used a prospective, cluster-randomized, and open-label design, which was reviewed and approved by the institutional review committee of Hokkaido University Hospital. The Sapporo Fire Department kindly performed the data collection. In Sapporo, LM and EOA are the standard of care for OHCA, and LT was only introduced after a week-long training period, which involved lectures and practical exercises to improve LT insertion into a mannequin.

Figure 1 shows the study protocol. First, we selected the 14 EMS teams that had treated the greatest number of patients with OHCA during the past year in Sapporo. We then randomized these teams into Groups A and B (using sealed envelopes). During the first part of this study (4 months), Group A treated patients with OHCA via LT, while Group B treated the patients via LM. During the second part of this study (4 months), we exchanged the treatment methods for each group (Group A used LM and Group B used LT). If necessary, both groups were permitted to use EOA.

EMS system and procedures

The EMS system in Sapporo has been described previously.[26] In brief, each patient is transported in an ambulance with three EMS personnel. When cardiac arrest is detected, chest

compressions and ventilation by bag valve mask are immediately started by two of the EMS personnel, and cardiopulmonary resuscitation (CPR) is provided according to the 2010 International Guidelines. Before this study, the standard advanced airway devices were EOA or LM, and ETT was only permitted when rescue breathing via the bag valve mask or SGA was not sufficient, due to foreign bodies in the respiratory tract. The EMS personnel apply an automated defibrillator (AED) if necessary, and attempt to gain peripheral venous access and administer intravenous adrenaline every 4 min until the return of spontaneous circulation (ROSC) or arrival at the hospital. If necessary, the EMS personnel can request that an emergency physician be transported directly to the scene, instead of transporting the patient.

Data collection

For this study, we enrolled consecutive OHCA patients from June 2012 to January 2013. The data that was collected included the patient's sex and age, cardiac rhythm at CPR initiation and upon hospital arrival, the time course of resuscitation, if a bystander had witnessed the cardiac arrest and/or initiated CPR, if the patient had been intubated, if adrenaline had been administered, if an AED had been used, if an emergency physician had been requested, or if ROSC had been achieved before arrival at the hospital. Follow-up data (i.e., survival rates) were also collected at 1 month after the events, during a meeting between the EMS personnel who had treated the patient and the hospital's medical control director.

Study endpoints

The primary endpoints were the time from CPR initiation to device insertion and the rate of successful ventilation upon arrival at the hospital. A positive outcome was confirmed if the EMS personnel could observe sufficient chest elevations and assess the degree of oropharyngeal leakage, based on their professional judgment. The EMS personnel also examined the patients' respiratory sounds by using a stethoscope to confirm whether the ventilation was adequate. The secondary endpoints were defined as the rate of ROSC, survival, and favorable neurological outcomes at 1 month after cardiac arrest. A favorable neurological outcome was defined as a cerebral performance category score of 1 (good performance) or 2 (moderate disability), and an unfavorable neurological outcome was defined as a score of 3 (severe cerebral disability), 4 (vegetative state), or 5 (death).

Statistical analyses

All outcomes were reported and evaluated using the intention-to-treat approach. The patient characteristics and outcomes were compared between the two groups using Student's *t*-test for numerical variables and using the chi-square test for categorical variables. Unless otherwise indicated, all data were expressed as number (percentage) or mean ± standard deviation. All statistical analyses were performed using SPSS software (version 15.0J; SPSS Inc., Chicago, IL, USA), and a P-value of <0.05 was considered statistically significant.

Results

Patient selection

A total of 357 patients with OHCA were treated during the study period. Among these patients, we excluded 27 patients for missing data and 17 patients who had not experienced cardiac arrest or whose spontaneous circulation had been restored spontaneous or bystander assisted ROSC had been achieved before the EMS arrived. After these exclusions, the 313 remaining patients were divided into two groups, including 148 patients who were treated via LT and 165 patients who were treated via LM.

Patient characteristics

Table 1 describes these patients' characteristics. Significant differences between the two groups were observed in the rates of bystander-initiated CPR (LM: 44.8%, LT: 28.4%, $P = 0.017$) and EOA use (LM: 41.8%, LT: 10.1%, $P < 0.001$). However, no significant differences were observed in the outcomes when we compared the two treatments using our intention-to-treat approach.

Patient outcomes

Table 2 describes the patients' outcomes. No significant differences were observed in the outcomes when we compared the two treatments using our intention-to-treat approach.

Discussion

To the best of our knowledge, this is first study to compare the efficacy of LM and LT

as advanced airway management for patients with OHCA. In this study, we hypothesized that LT would provide better outcomes, because several reports have indicated that LT insertion is very easy.[21,22] Therefore, we aimed to determine whether the speedy insertion might shorten the interruption of chest compressions and thereby improve the prognosis of patients with OHCA. However, when we compared LM and LT, we did not observe any significant differences in the time from CPR initiation to device insertion or the rates of successful ventilation upon hospital arrival, ROSC, or 1-month neurological outcomes. Nevertheless, we believe that our findings are useful to EMS personnel, as they confirm that LT and LM are both effective for advanced airway management in patients with OHCA.

In the present study, EMS personnel underwent 1 week of training regarding LT insertion, although these personnel have much more experience using LM or EOA as an advanced airway device. However, the similar outcomes, despite the different experiences with the two techniques, appear to confirm the belief that LT insertion is very easy. Furthermore, we observed that EOA insertion was significantly more common in the LM group, compared to the LT group, and this finding appears to indicate that LM insertion was more difficult than LT insertion. Similarly, Brimacombe et al.[27] have reported that the major complication of LM usage is failed insertion, which can necessitate re-insertion and re-positioning. Moreover, EOA has a high frequency of complications when used in the prehospital environment,[28] and these complications include airway bleeding, esophageal laceration, esophageal perforation, and

mediastinitis.[29] Therefore, based on those findings and our results, it appears that LT may be more appropriate in patients with OHCA, despite the similar prognosis of patients who are treated with LT or LM and EOA.

Our study has several limitations. First, the assessment of successful ventilation upon hospital arrival was performed subjectively by the EMS personnel, which creates that possibility that the assessments were not identical for each patient. We think a tidal volume and minute ventilation volume could be effective and objective data to assess the successful ventilation so these data should have been collected. Second, our data did not include information regarding the duration of the chest compression interruption (for the LT or LM insertions), and we cannot determine whether the use of LT actually shortened this period. Future studies should be designed to collect data regarding this parameter. Third, we were unable to analyze the effects of any in-hospital procedures that were performed, and it is possible that post-arrest hypothermia or percutaneous coronary interventions may have affected the patients' prognoses.

Conclusion

In this study, we found that the choice of LT or LM for advanced airway management in patients with OHCA did not affect the time from CPR initiation to device insertion or the rates of successful ventilation, ROSC, 1-month survival, and 1-month favorable neurological outcomes. Although it is possible that the use of LT may reduce the need for EOA,

and thereby decrease the risk of prehospital complications, further research is needed to evaluate the use of LT in the prehospital setting.

Conflicts of interest

None.

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Figure legend

Figure 1. Study flow chart

We selected 14 emergency medical services (EMS) teams. In the first part, Group A treated using laryngeal tubes (LT), and Group B treated using laryngeal masks (LM). In the second part, the two groups switched their treatment methods.

Figure1.

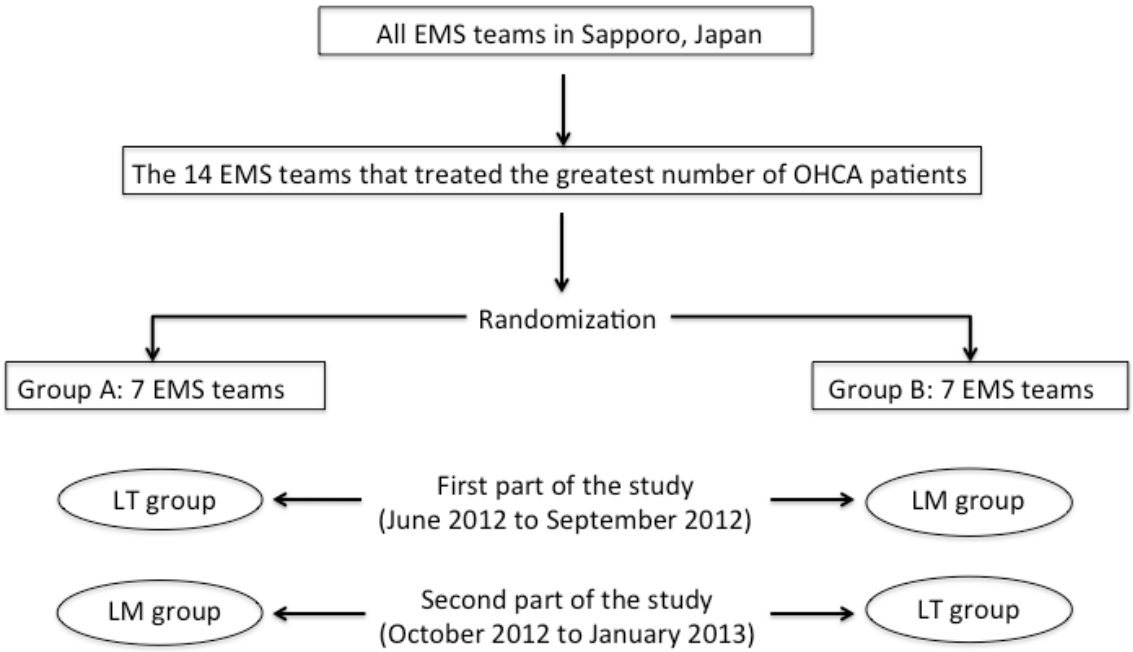
All EMS teams in Sapporo, Japan
The 14 EMS teams that treated the greatest number of OHCA patients
Randomization
Group A: 7 EMS teams
Group B: 7 EMS teams
LT group
First part of the study
(June 2012 to September 2012)
LM group
LM group
Second part of the study
(October 2012 to January 2013)
LT group

Table 1. Characteristics of patients with out-of-hospital cardiac arrest according to supraglottic airway device

	Laryngeal Tube (n = 148)	Laryngeal Mask (n = 165)	P-value
Age, years (mean ± standard deviation)	72.41 ± 17.3	75.84 ± 16.1	0.071
Male sex	90 (60.8)	101 (61.2)	0.942
Bystander eyewitness	52 (35.1)	63 (38.2)	0.577
CPR initiated by bystander	42 (28.4)	74 (44.8)	0.017
Primary ECG rhythm			
VF/VT	17 (11.5)	8 (4.8)	0.031
Non - VF/VT (PEA or asystole)	131 (88.5)	157 (95.2)	
Defibrillation by EMS personnel (AED)	22 (14.9)	12 (7.3)	0.031
ECG rhythm at arrival of hospital			
ROSC	21 (14.2)	18 (10.9)	
VF	9 (6.1)	4 (2.4)	0.162
Non - VF (PEA or asystole)	118 (79.7)	143 (86.7)	
Time, mean (standard deviation), min			
Time from call to CPR initiation	8.4 (2.7)	8.7 (3.3)	0.468
Time from CPR initiation to departure the spot	14.6 (4.8)	14.6 (4.9)	0.989
Time from departure to arrival at the hospital	13.3 (7.7)	12.2 (6.5)	0.199
Inserted device			
Laryngeal tube	120 (81.1)	2 (1.2)	
Laryngeal mask	12 (8.1)	92 (55.8)	
Esophageal obstructive airway	15 (10.1)	69 (41.8)	
Endotracheal tube	1 (0.7)	2 (1.2)	< 0.01

Data are expressed as number (%), unless otherwise indicated, and were analyzed using the intent to treat approach (a total of 313 patients). CPR, cardiopulmonary resuscitation; ECG, electrocardiography; VF, ventricular fibrillation; VT, ventricular tachycardia; PEA, pulseless electrical activity; EMS, emergency medical services; AED, automated external defibrillator; ROSC, return of spontaneous circulation.

Table 2. Outcomes of the intention-to-treat analyses

	LT (n = 148)	LM (n = 165)	P-value
Time from CPR initiation to inserted device, mean (standard deviation), min	4.8 (2.5)	5.8 (7.2)	0.126
Successful ventilation	110 (74.3)	128 (77.6)	0.501
ROSC	37 (25.0)	38 (27.7)	0.6
1-month survival	9 (6.1)	7 (4.2)	0.461
1-month favorable neurological outcome	2 (1.4)	2 (1.2)	0.913

Data are expressed as number (%). LT, laryngeal tube; LM, laryngeal mask; ROSC, return of spontaneous circulation.