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COMPARISON OF NEUROLOGICAL OUTCOME BETWEEN TRACHEAL INTUBATION AND SUPRAGLOTTIC AIRWAY DEVICE INSERTION OF OUT-OF-HOSPITAL CARDIAC ARREST PATIENTS: A NATIONWIDE, POPULATION-BASED, OBSERVATIONAL STUDY

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 \Box Abstract—Background: The effect of prehospital use of supraglottic airway devices as an alternative to tracheal intubation on long-term outcomes of patients with out-ofhospital cardiac arrest is unclear. Study Objectives: We compared the neurological outcomes of patients who underwent supraglottic airway device insertion with those who underwent tracheal intubation. Methods: We conducted a nationwide population-based observational study using a national database containing all out-of-hospital cardiac arrest cases in Japan over a 3-year period (2005–2007). The rates of neurologically favorable 1-month survival (primary outcome) and of 1-month survival and return of spontaneous circulation before hospital arrival (secondary outcomes) were examined. Multiple logistic regression analyses were performed to adjust for potential confounders. Advanced airway devices were used in 138,248 of 318,141 patients, including an endotracheal tube (ETT) in 16,054 patients (12%), a laryngeal mask airway (LMA) in 34,125 patients (25%), and an esophageal obturator airway (EOA) in 88,069 patients (63%). Results: The overall rate of neurologically favorable 1-month survival was 1.03% (1426/137,880). The rates of neurologically favorable 1-month survival were

1.14% (183/16,028) in the ETT group, 0.98% (333/34,059) in the LMA group, and 1.04% (910/87,793) in the EOA group. Compared with the ETT group, the rates were significantly lower in the LMA group (adjusted odds ratio 0.77, 95% confidence interval [CI] 0.64–0.94) and EOA group (adjusted odds ratio 0.81, 95% CI 0.68–0.96). Conclusions: Prehospital use of supraglottic airway devices was associated with slightly, but significantly, poorer neurological outcomes compared with tracheal intubation, but neurological outcomes remained poor overall. \oslash 2013 Elsevier Inc.

 \Box Keywords—out-of-hospital cardiac arrest; tracheal intubation; supraglottic airway device; neurological outcome; airway management

INTRODUCTION

Tracheal intubation has long been considered the gold standard for airway management during resuscitation after cardiac arrest. However, this method is now being

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challenged by some experts, especially when the tracheal intubation is performed by inexperienced providers in prehospital settings (1). Critics of the technique cite incorrect placement of the endotracheal tube (ETT) and unnecessary interruption of chest compressions associated with the lengthy procedure as the major disadvantages of prehospital tracheal intubation (2).

Several supraglottic airway devices are currently in clinical use as alternatives to ETT, including the laryngeal mask airway (LMA) and the laryngeal tube, which can be used without the need for elaborate training for airway management (3–7). However, a systematic comparison of the clinical outcomes of ETT and supraglottic airway devices has not been conducted (8).

The aim of the current study was to compare the effects of tracheal intubation and insertion of supraglottic airway devices on neurological outcomes of patients with out-of-hospital cardiac arrest.

MATERIALS AND METHODS

Study Design

This study was approved by the Ethics Committee of Nara Medical University (Authorization Code: 260). We conducted a nationwide population-based observational study using a Japanese national database containing information about out-of-hospital cardiac arrests over a 3-year period from January 1, 2005 to December 31, 2007. The database was compiled by the Fire and Disaster Management Agency (FDMA) in Japan, and contained all outof-hospital cardiac arrest cases that were transferred to hospitals by emergency medical service (EMS) personnel (9). The data set included age, sex, whether the collapse was witnessed, whether bystander cardiopulmonary resuscitation (CPR) was performed, cause of cardiac arrest (cardiac or non-cardiac origin), first documented cardiac rhythm, whether the patient was defibrillated by the EMS, whether epinephrine was administered by the EMS, whether advanced airway devices were used by the EMS, and, if so, the type of advanced airway device used, time course of resuscitation, and outcomes (10).

Setting

Japan contains approximately 128 million residents in an area of $377,914 \text{ km}^2$. A total of 807 fire departments with dispatch centers covered the whole nation as of 2007. The most highly trained prehospital emergency care providers are Emergency Life-Saving Technicians. Among ambulance attendants, only Emergency Life-Saving Technicians are authorized to use supraglottic airway devices other than ETT (11). ETT insertion is conducted only by Emergency Life-Saving Technicians who have received specific training, including a minimum of 30 successful attempts at tracheal intubation in elective surgical patients under anesthesia (11).

The National Protocol for Resuscitation stated that bag-valve-mask ventilation (BVM) was to be used as the first choice for resuscitation, and that an advanced airway device should be considered only when the patient's airway could not be sufficiently secured or a long transportation period was expected (12).

Selection of Participants

We included all out-of-hospital cardiac arrest patients aged 15 years or older who were treated by EMS personnel using advanced airway devices. Patients younger than 15 years of age were excluded from this study because the National Protocol for Resuscitation states that tracheal intubation should be used only for patients aged 15 years or older. We also excluded patients for whom the type of advanced airway device was unknown.

Methods of Measurement

Patients were categorized into three groups according to the advanced airway devices used: ETT group; LMA group; and esophageal obturator airway (EOA) group. Any supraglottic airway devices designed to occlude the esophagus using a balloon were classified as EOAs. The EOAs included a laryngeal tube, a Combitube (an esophageal-tracheal twin-lumen airway device; Kendall Inc., Mansfield, MA), and an esophageal gastric tracheal airway. Cases with unsuccessful advanced airway device insertion and subsequent use of BVM were excluded. Cases in which the airway management method was changed midway were classified according to the airway device in use on arrival at the hospital.

Cardiac arrest was defined as the absence of cardiac mechanical activity, as confirmed by the absence of signs of circulation (10,13,14). The etiology of cardiac arrest was determined clinically by the physician in charge, in collaboration with EMS personnel. Cardiac arrest was presumed to be of cardiac origin unless external causes or any other non-cardiac causes (e.g., respiratory diseases, cerebrovascular diseases, or malignant tumors) were obvious(15). The external causes of out-of-hospital cardiac arrest included trauma, drowning, drug overdose, asphyxia, and hanging. Outcome data such as the 1-month survival and neurological status were collected by EMS personnel from the physicians in charge of the patients (16).

Data Collection and Processing

All the information was entered at local fire departments by EMS personnel using an online entry form, which conformed to the Utstein-style guidelines (10,13,14). The data were verified by EMS personnel and anonymized at the local fire departments, then transferred and stored in the database at the FDMA (17). The data were checked in a logical manner by the computer system at the FDMA. If there were any inconsistencies or missing data, the FDMA consulted the corresponding regional fire department and the data were corrected (9). This is a national database, and the FDMA determines which data are included. There is only one nationwide ambulance service system covering all of Japan, and this service is operated publicly. Thus, the data including the outcome data are collected officially and systematically.

Outcome Measures

The primary outcome measure was the rate of neurologically favorable 1-month survival. Neurologically favorable 1-month survival was defined as Glasgow-Pittsburgh Cerebral Performance Category 1 (good cerebral performance) or 2 (moderate cerebral disability), as evaluated by the physician in charge via a follow-up interview at 1 month after hospital admission (10,13,14). The secondary outcome measures were the return of spontaneous circulation (ROSC) before hospital arrival and 1-month survival.

Statistical Analysis

Patient characteristics were evaluated by analysis of variance (ANOVA) for numerical variables and the chisquared test for categorical variables. The outcomes were evaluated using the chi-squared test and multiple logistic regression analysis. Multiple logistic regression analyses were performed to compare the effects in the LMA and EOA groups with those in the ETT group as a reference, after controlling for potential confounders. Potential confounders were selected by clinical considerations and included age, sex, first documented cardiac rhythm, time between emergency call and initiation of CPR by EMS personnel, time between initiation of CPR by EMS personnel and hospital arrival, etiology of cardiac arrest, witness status, presence of bystander-initiated CPR, first shock by lay people, shock by EMS personnel, and intravenous administration of fluid and epinephrine.

For post hoc subgroup analyses, we divided the eligible patients into internally caused (endogenous) cardiac arrest cases (e.g., cardiac origin, respiratory diseases, cerebrovascular diseases, malignant tumors) and externally caused (exogenous) cardiac arrest cases (e.g., trauma, drowning, drug overdose, asphyxia, hanging), and separately analyzed the effects in the LMA and EOA groups compared with those in the ETT group. The calculated odds ratio was adjusted for the above confounders, except for omission of the etiologies of cardiac arrest among the independent variables in the analyses for the exogenous cardiac arrest group. In addition, similarly, the eligible patients were divided into ventricular fibrillation and pulseless ventricular tachycardia (VF/VT) cases, pulseless electrical activity (PEA) cases, and asystole cases according to first documented rhythms, and post hoc subgroup analyses were then conducted.

All statistical analyses were conducted using PASW version 17 (SPSS Inc., Chicago, IL). The value of $p < 0.05$ was considered statistically significant. We used 95% confidence intervals in the analysis of odds ratios of the outcomes.

RESULTS

Resuscitation was attempted in a total of 308,710 patients aged 15 years and older. Among these patients, cases in which CPR was performed by BVM without an advanced airway device $(n = 167, 953)$, patients in whom it was unclear whether an advanced airway device was used $(n = 2169)$, and patients in whom the type of airway device used was unknown $(n = 340)$ were excluded from the analysis, leaving 138,248 patients eligible for our study. Among these patients, ETTwas used in 16,054 (12%), an LMAwas used in 34,125 (25%), and an EOA was used in 88,069 (63%) (Figure 1). The neurological status at 1 month was not documented in 368 $\left($ <0.3% $\right)$ patients. These cases were excluded from the primary outcome analysis. Secondary outcome was documented in all eligible patients.

Table 1 shows the background characteristics of the patients. Although the three groups seemed to be homogenous in terms of the background characteristics, ANOVA and chi-squared tests revealed significant differences among the three groups for most characteristics.

The overall rate of neurologically favorable 1-month survival was 1.03% (1426/137,880), survival rate at 1 month was 3.84% (5303/138,248), and the rate of ROSC before hospital arrival was 6.90% (9546/138,248).

Table 2 shows the comparisons of outcome measures in the ETT, LMA, and EOA groups. The rates of neurologically favorable 1-month survival were 1.14% (183/ 16,028) in the ETT group, 0.98% (333/34,059) in the LMA group, and 1.04% (910/87,793) in the EOA group. There were no significant differences among the three groups (chi-squared test). After adjustment for confounders, the rates of neurologically favorable 1-month survival were significantly lower in the LMA and EOA groups than in the ETT group.

The 1-month survival rates were 4.19% in the ETT group, 3.64% in the LMA group, and 3.85% in the EOA group. The 1-month survival rates were significantly lower in the LMA and EOA groups than in the ETT group in both the chi-squared test and the multivariable logistic regression analysis.

Figure 1. Flow diagram of the patient inclusion procedure. During the 3 years of the study, 318,141 out-of-hospital cardiac arrests were documented, of which 138,248 were treated with endotracheal tube, laryngeal mask, or esophageal obturator airway. EMS = emergency medical service; BVM = bag-valve-mask.

The rates of ROSC before hospital arrival were 7.24% in the ETT group, 4.90% in the LMA group, and 4.41% in the EOA group. The rates were significantly lower in the LMA and EOA groups compared with the ETT group in both the chi-squared test and the multivariable logistic regression analysis.

SD = standard deviation; CPR = cardiopulmonary resuscitation; PAD = public access defibrillation; AED = automated external defibrillator; VF = ventricular fibrillation; VT = ventricular tachycardia; PEA = pulseless electrical activity; EMS = emergency medical services.

OR = odds ratio; CI = confidence interval; ROSC = return of spontaneous circulation.

Table 3 shows the results of subgroup analyses of the endogenous and exogenous cases. Endogenous cases $(n = 116,071)$ accounted for 84% of the eligible patients. The etiology of cardiac arrest was not documented in 4 patients. These cases were excluded from the analysis. The overall rates of neurologically favorable 1-month survival were 1.13% (1314/115,778) in endogenous cases and 0.51% (112/22,098) in exogenous cases. After adjustment for confounders, in the endogenous subgroup the rates of neurologically favorable 1-month survival were significantly lower in the LMA (1.05%) and EOA (1.15%) groups than in the ETT group (1.25%) . In the exogenous subgroup, the neurologically favorable 1-month survival rates did not differ among the three groups.

Table 4 shows the results of subgroup analyses of the VF/VT cases, PEA cases, and asystole cases. The overall rate of neurologically favorable 1-month survival was 6.47% (725/11,213) in VF/VT cases, 1.1% (348/ 31,512) in PEA cases, and 0.3% (257/91947) in asystole cases. After adjustment for confounders, in the PEA subgroup, the rates of neurologically favorable 1-month survival were significantly lower in the LMA (0.96%) and EOA (1.12%) groups than in the ETT group (1.35%).

DISCUSSION

The current results revealed significantly higher rates of neurologically favorable 1-month survival in the ETT

Table 3. Outcomes of Out-of-Hospital Cardiac Arrest Patients According to Endogenous and Exogenous Causes of Arrest and Types of Advanced Airway Devices Used

	Endotracheal Tube	Laryngeal Mask Airway	p-Value	Esophageal Obturator Airway	p-Value
Endogenous, n	12.992	29,640		73,439	
Neurologically favorable 1-month survival, n (%)	162 (1.25)	310 (1.05)		842 (1.15)	
OR (95% CI)	Reference	$0.84(0.69 - 1.02)$	0.069	$0.92(0.78 - 1.09)$	0.33
Adjusted OR (95% CI)	Reference	$0.77(0.63 - 0.94)$	0.012	$0.81(0.68 - 0.97)$	0.025
1-month survival, n (%)	474 (3.65)	1060 (3.58)		2822 (3.84)	
OR (95% CI)	Reference	$0.98(0.88 - 1.09)$	0.71	$1.06(0.96 - 1.17)$	0.29
Adjusted OR (95% CI)	Reference	$0.96(0.85 - 1.08)$	0.45	$1.04(0.93 - 1.16)$	0.52
ROSC before hospital arrival, n (%)	853 (6.57)	1386 (4.68)		3193 (4.35)	
OR (95% CI)	Reference	$0.70(0.64 - 0.76)$	< 0.001	$0.65(0.60 - 0.70)$	< 0.001
Adjusted OR (95% CI)	Reference	$0.87(0.79 - 0.96)$	0.004	$0.79(0.73 - 0.87)$	< 0.001
Exogenous, n	3062	4483		14,628	
Neurologically favorable 1-month survival, n (%)	21(0.69)	23 (0.52)		68 (0.47)	
OR (95% CI)	Reference	$0.75(0.41 - 1.36)$	0.34	$0.68(0.42 - 1.11)$	0.12
Adjusted OR (95% CI)	Reference	$0.92(0.49 - 1.75)$	0.81	$0.76(0.44 - 1.33)$	0.34
1-month survival, n (%)	199 (6.50)	182 (4.06)		566 (3.87)	
OR (95% CI)	Reference	$0.61(0.50 - 0.75)$	< 0.001	$0.58(0.49 - 0.69)$	< 0.001
Adjusted OR (95% CI)	Reference	$0.69(0.55 - 0.86)$	0.001	$0.67(0.56 - 0.80)$	< 0.001
ROSC before hospital arrival, n (%)	309(10.1)	285 (6.36)		687 (4.70)	
OR (95% CI)	Reference	$0.61(0.51 - 0.72)$	< 0.001	$0.44(0.38 - 0.51)$	< 0.001
Adjusted OR (95% CI)	Reference	$0.91(0.76 - 1.10)$	0.32	$0.67(0.57 - 0.79)$	< 0.001

OR = odds ratio; CI = confidence interval; ROSC = return of spontaneous circulation.

OR = odds ratio; CI = confidence interval; ROSC = return of spontaneous circulation; VF = ventricular fibrillation; VT = ventricular tachycardia; PEA = pulseless electrical activity.

group than in the LMA or EOA groups. However, the differences among the three devices were slight, with rates of neurologically favorable 1-month survival in patients remaining low in all groups, with an overall rate of 1.03% across groups (ETT group, 1.14%; LMA group, 0.98%; EOA group, 1.04%). Accordingly, our study suggests that the choice between ETT, LMA, or EOA as an advanced airway device will not result in major differences in clinical outcomes.

Out-of-hospital endotracheal intubation is a complex procedure with many potential pitfalls, including unrecognized esophageal tube placement that can result in death (1). For this reason, in Japan, when Emergency Life-Saving Technicians perform out-of-hospital tracheal intubation, it is required that they receive specific training, including a minimum of 30 successful tracheal intubations in elective surgical patients under anesthesia. It has been proposed that regular clinical experience is an important element for maintaining tracheal intubation skills and for improved patient survival after outof-hospital tracheal intubation of cardiac arrest patients (18). According to the White Book of the Fire Service in Japan, 7484 cases of out-of-hospital tracheal intubations were performed by 5476 emergency life-saving technicians per annum all over Japan (as of 2007) (19). Thus, the number of cases experienced per capita is only 1.37 per year on average, which is far from sufficient clinical experience. This may have a bearing on the slight improvement in outcome in the ETT group compared with supraglottic airway devices.

A number of previous studies of supraglottic airway devices have examined the rates of successful device insertion, ease of ventilation/oxygenation, and safety issues in comparison with ETTs (2,20–22). However, only a few studies have compared the effects of supraglottic airway devices on clinical outcomes with those of tracheal intubation. In the few studies conducted, no difference in outcome has been reported in patients treated with the Combitube compared with those treated with tracheal intubation (21).

Assuming that outcomes may vary widely among the types of advanced airway devices in limited populations of out-of-hospital cardiac arrest patients, we divided the patients into endogenous and exogenous cases, and separately analyzed the outcomes in the LMA and EOA groups compared with those in the ETT group. In endogenous cases, the ETT group had significantly better outcomes than the LMA and EOA groups after adjustment (Table 3). However, because the differences among the three devices were slight, future studies may produce variable findings among the types of advanced airway devices in other specific populations of out-of-hospital cardiac arrest patients, for example, subjects with witnessed cardiac arrest.

The question of whether the use of any type of advanced airway device improves outcomes compared with BVM should be examined in future studies. However, the probability of serious confounding by the indications for each procedure prevented us from conducting such an analysis. It is known that patients who regain spontaneous circulation during the initial phase of resuscitative intervention (i.e., at the scene) are the strongest candidates for longterm survival. Because such patients also usually regain spontaneous respiration, advanced airway procedures are not indicated, and they are subsequently managed with BVM. Because there were no data regarding the initial intention-to-treat by the Emergency Life-Saving Technicians, we were unable to adjust for this factor.

We used the time from the start of CPR by EMS personnel to the hospital arrival (CPR–hospital time) as one of the independent variables in the regression analyses. However, it is unclear whether this is the most appropriate measure. The CPR–hospital time was approximately 2 min longer in the ETT group than in the other two groups. The delay in the ETT group may have resulted from the more lengthy procedure for tracheal intubation, including the arrangement of equipment or confirmation of correct placement of the tube. If this is the case, the CPR–hospital time could be considered a consequence of choosing tracheal intubation or an ''intermediate variable,'' meaning that CPR–hospital time is not an appropriate independent variable. As such, we also performed regression analyses that did not include the CPR–hospital time (data not shown). However, there were no clear differences in the recalculated odds ratios.

Limitations

Several limitations were involved in the present study. First, the analyses were not conducted with an intention-to-treat principle. The advanced airway devices were classified based on the devices in use upon arrival at the hospital and were not based on the intention-to-treat in the field. This means that cases with failed tracheal intubation attempts were included in either the BVM category (and therefore excluded from the analysis) or in the LMA and EOA groups. In this case, the overall outcome of the LMA and EOA groups might be worse due to the need of conversion. Conversely, cases in which LMA or EOA insertion was attempted but failed to provide sufficient ventilation would be included in either the BVM category or the ETT group. In this case, the overall outcome in the ETT group might be worse. Unfortunately, there were no data available regarding rates of successful insertion by different devices, rates of conversion from one type of airway device to another, or types of complications. Future studies should collect information about these factors. Second, the selection of confounding factors should be examined in more detail. In the current study, we selected potential confounding factors based on clinical considerations. However, it is unclear whether we included all potential confounding factors in the present analysis. In particular, the database did not include information regarding post-resuscitation care (e.g., therapeutic hypothermia or percutaneous coronary intervention). As such, in our multivariate analyses, we were not able to adjust factors related to post-resuscitation care. However, we assumed that the effects of such factors would be similarly distributed among the three groups (LMA, EOA, and ETT groups) because the current database was nationwide and population based. Therefore, we propose that any differences in post-resuscitation care were unlikely to have substantially affected the results. In addition, the Emergency Life-Saving Technicians authorized to insert an ETT receive additional training over the standard training required for non-tracheal-intubation-authorized Emergency Life-Saving Technicians. Consequently, the patients in the ETT group may have been managed by more proficient Emergency Life-Saving Technicians. We were not able to adjust for this potential confounding factor due to a lack of data on the individual profiles of the Emergency Life-Saving Technicians. Future studies should collect information about these factors to enable more detailed analyses. Third, the database did not include information about the timing of advanced airway placement. Fourth, the laryngeal tube, Combitube, and esophageal gastric tracheal airway were combined into a single category (EOA) in the present study. Because data were not available regarding the specific types of airway devices used, their separate effects remain unclear. Fifth, the generalizability of our findings to other countries and ethnicities remains unclear, because the data were solely derived from a national database in Japan. For example, compared with the United States, our sample included a high number of patients presenting with asystole as the initial rhythm, which may have also contributed to the overall poor outcome compared with American studies (23). In Japan, do-not-resuscitate orders and living wills are not generally accepted, and EMS personnel are not allowed to terminate resuscitation out of hospital. Therefore, most patients experiencing out-of-hospital cardiac arrest who were treated by EMS personnel were transported to the hospital and registered in this study, excluding those with decapitation, incineration, decomposition, rigor mortis, or dependent cyanosis (24). This is likely to have resulted in the high number of patients presenting with asystole as the initial rhythm in our database, and to the overall poor outcomes in our sample.

However, despite these limitations, we believe that our current findings are valid, utilizing uniform data collection and consistent definitions based on the Utstein guidelines, a large sample size, and a nationwide, population-based design. In addition, because all consecutive cases of out-of-hospital cardiac arrest patients transferred by the EMS in Japan were included in the database, selection bias was minimal. The results of this study, although limited, suggest that the clinical outcomes associated with the different techniques are at least comparable.

CONCLUSION

The current findings among out-of-hospital cardiac arrest patients arriving to the hospital with an advanced airway device in place revealed that those who were treated by more experienced Emergency Life-Saving Technicians and ultimately underwent ETT were associated with significantly better neurologically favorable survival outcomes compared with patients who were treated by any grade of Emergency Life-Saving Technicians and ultimately underwent LMA or EOA. However, given the low overall rate of neurologically favorable 1-month survival across all groups, these differences do not seem to have major clinical consequences.

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ARTICLE SUMMARY

1. Why is this topic important?

Tracheal intubation is traditionally considered the gold standard for airway management during resuscitation after cardiac arrest, but no systematic comparison of the clinical outcomes of intubation or alternative airway devices has been previously reported.

2. What does this study attempt to show?

To the best of our knowledge, this is by far the largest study to examine the impact of airway management on outcomes after cardiac arrest.

3. What are the key findings?

We found that tracheal intubation was associated with significantly better neurological outcomes compared with prehospital use of alternative airway devices.

4. How is patient care impacted?

Although we found that tracheal intubation was associated with significantly better neurological outcomes compared with prehospital use of alternative airway devices, given the overall low rate of neurologically favorable 1-month survival, these differences do not seem to be of major clinical consequence.