Comparison of Outcomes After Use of Biphasic or Monophasic Defibrillators Among Out-of-Hospital Cardiac Arrest Patients: A Nationwide Population-Based Observational Study

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Background—The use and popularity of the biphasic waveform defibrillator as a replacement for the monophasic waveform defibrillator are increasing, but it is unclear whether this can improve the rate of survival among out-of-hospital cardiac arrest patients. This study aimed to verify the hypothesis that the outcome of out-of-hospital cardiac arrest patients who received defibrillation shock with the biphasic waveform defibrillator was better than that of patients who received defibrillation shock with the monophasic defibrillator.

Methods and Results—This prospective, nationwide, population-based, observational study included 21,172 out-of-hospital cardiac arrest patients with initial ventricular fibrillation or pulseless ventricular tachycardia from January 1, 2005, through December 31, 2007. Defibrillation shock was performed by monophasic defibrillator on 8,224 (39%) patients and by biphasic defibrillator on 12,948 (61%) patients. The rate of survival at 1 month with minimal neurological impairment was 11.6% (951/8,192) in the monophasic defibrillator group and 12.8% (1,653/12,928) in the biphasic defibrillator group. Hierarchical logistic regression analysis using a generalized estimation equation showed no significant difference between the biphasic and monophasic groups in 1-month survival with minimal neurological impairment (adjusted odds ratio, 1.07; 95% confidence interval, 0.91–1.26; P=0.42). Confirmatory propensity score analyses showed similar results.

Conclusions—Although monophasic defibrillators are being replaced by biphasic defibrillators, our nationwide population-based observational study failed to demonstrate a statistically significant association between defibrillation waveform and 1-month survival rate with minimal neurological impairment. (Circ Cardiovasc Qual Outcomes. 2012;5:689-696.)

Key Words: cardiopulmonary resuscitation ⋆ defibrillation ⋆ heart arrest ⋆ registries

Sudden cardiac arrest is a major public health problem in the industrialized countries of the world, and the outcome of patients with out-of-hospital cardiac arrest (OHCA) remains poor. Early defibrillation is critical for survival from OHCA. There are currently 2 types of defibrillator, according to the type of waveform used to shock the patients: the monophasic defibrillator and the biphasic defibrillator. Defibrillation with a biphasic waveform shock has been reported to be safer and more effective than a monophasic waveform shock in a controlled laboratory, in-hospital, and out-of-hospital. A biphasic defibrillator has lower energy requirements and is smaller and lighter in weight than a monophasic defibrillator and thus has the advantage of portability to the scene of a medical emergency. Accordingly, almost all defibrillators currently available commercially are biphasic defibrillators and out-of-hospital defibrillators are gradually being changed from the traditional monophasic defibrillators to biphasic defibrillators. However, it is not yet clear whether the outcome of patients with OHCA has improved by replacement of the monophasic defibrillators with the biphasic defibrillators.

In January 2005, the Fire and Disaster Management Agency (FDMA) of Japan started enrollment of patients with OHCA in a prospective nationwide population-based study. This study, using a large Japanese nationwide OHCA database, aimed to verify the hypothesis that the
survival of patients at 1 month with minimal neurological impairment who received defibrillation shock with the biphasic defibrillator is better than the survival of patients who received defibrillation shock with the monophasic defibrillator.

**WHAT IS KNOWN**

- Defibrillation with a biphasic waveform shock has been reported to be safer and more effective than a monophasic waveform in a controlled laboratory, in-hospital, and out-of-hospital.
- Accordingly, defibrillators are gradually being changed from the traditional monophasic defibrillators to biphasic ones. However, it is not yet clear whether the outcome of patients with out-of-hospital cardiac arrest has been improved by this conversion effort.

**WHAT THE STUDY ADDS**

- Leveraging a prospective registry of out-of-hospital cardiac arrest in Japan, we sought to examine whether or not survival was improved in patients treated with newer, biphasic defibrillators compared with traditional monophasic ones.
- This study found no significant advantage of biphasic defibrillators over monophasic defibrillators on meaningful clinical outcomes. Although some EMS systems may replace monophasic defibrillators with biphasic ones because of their lighter weight and increased portability, there is no outcome-based reason to do so.

**Methods**

**Study Design**

The all-Japan Utstein Registry is a prospective, nationwide, population-based registry system of OHCA patients who are transferred to hospital by the emergency medical services (EMS). This observational study enrolled all OHCA patients ≥18 years old, who were transported to hospital by EMS personnel during 3 consecutive years from January 1, 2005, to December 31, 2007. The Japanese EMS system for OHCA is a government-provided, nationally standardized system. Registration of OHCA patients in the registry is mandatory.

Cardiac arrest is defined as the cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation. EMS personnel generally confirm the absence of signs of circulation by palpating the patient’s carotid artery. Almost all patients who have an OHCA who are treated by EMS personnel are transported to hospital, excluding those with decapitation, incineration, decomposition, rigor mortis, or dependent cyanosis. Therefore, patients in the present study are representative of cardiac arrest patients in Japan. The study was approved by the Institution Review Board in Nara Medical University (Approval No. 260).

**EMS System in Japan**

Japan has 128 million residents (2010) in an area of 378,000 km². The population is served by 807 fire stations (2007). The universal emergency telephone number of 119 is directly connected to the dispatch center of the regional fire defense headquarters. Upon acceptance of an emergency call, the nearest available ambulance is dispatched to an incident. All expenses of the EMS system are covered by the local government, so there is no charge to the patient for emergency treatment and transportation. The EMS system in Japan is a 1-tiered response system, except for limited areas, where physician-manned ambulances or helicopters are available. Each ambulance has 3 staff, who can perform cardiopulmonary resuscitation (CPR) according to the Japanese guidelines, which, until September 2006, were based on the International Liaison Committee on Resuscitation and the American Heart Association 2000 guidelines. Since October 2006, CPR has been based on the respective 2005 guidelines.

Do-not-resuscitate orders or living wills are not generally accepted, and EMS personnel are not allowed to terminate or withhold resuscitation out of hospital. Therefore, most patients who have an OHCA who are treated by EMS personnel are transported to hospital, excluding those with decapitation, incineration, decomposition, rigor mortis, or dependent cyanosis.

**Automated External Defibrillator Descriptions**

Most ambulances have only 1 defibrillator. Either a biphasic defibrillator or a monophasic defibrillator was applied to the OHCA patients, according to the type of defibrillator supplied in the EMS ambulance. All ambulance vehicles used to have a monophasic defibrillator until biphasic defibrillators became available, when monophasic defibrillators were gradually (one by one) replaced by biphasic defibrillators. Biphasic defibrillator models used in the study were Heart Start MRxE, Heart Start FR2/FR2+, Heart Start 4000, Heart Start HS1, Heart Start XL (Philips Medical Systems, Seattle, WA), automated external defibrillator (AED)-9200/9210, AED-9231/9211/9201, AED-1200, TEC-2312/2313 (Nihon Kohden, Tokyo, Japan), LIFEPAK 500B, and LIFEPAK 12B (Medtronic, Minneapolis, MN). All the biphasic defibrillators adopted the biphasic truncated exponential waveform.

The monophasic defibrillator models used in the study were Heart Start 3000/3000QR (Laerdal Medical, Stavanger, Norway), LIFEPAK 12A (Medtronic), and TEC 2212/2213 (Nihon Kohden). The monophasic defibrillator delivered either monophasic truncated exponential or monophasic damped sine defibrillation waveforms, depending on the model used in each ambulance. EMS personnel are not allowed to use defibrillators in manual mode. Both monophasic and biphasic defibrillators are used in AED mode. The energy dose of the monophasic defibrillator was initially 200 J and, thereafter, 360 J. The energy dose of the biphasic defibrillator was set at the level recommended by the manufacturer.

**Data Collection and Quality Control**

All information was collated at local fire departments by EMS personnel using an online entry form, which conformed to the Utstein form. With some additions. Data on the characteristics of the OHCA patients were collected, including age, sex, whether the collapse was witnessed by a bystander, whether bystander CPR was performed, whether the patient was defibrillated by the EMS, type of waveform of defibrillation shock, the cause of the cardiac arrest such as cardiac or noncardiac origin, whether the patient was intubated, whether epinephrine was administered, the first documented cardiac rhythm, and the time course of resuscitation. In addition, outcome data, such as information on whether spontaneous circulation was restored before hospital arrival, survival, and neurological status 1 month after the event, were also collected. One-month survival and neurological status data were collected by EMS personnel from the discharge summaries of hospitals that received the patients, in cooperation with the physicians in charge of the patients. To collect 1-month follow-up data, EMS personnel had a face-to-face meeting with the hospital physician in charge at the hospital to which the OHCA patient was transferred or sent a questionnaire form asking the physician in charge to provide outcome data. If the patient was discharged from the hospital within 1 month, the EMS personnel conducted a follow-up search. This registry system is operated by the FDMA.
Thus, the data regarding 1-month follow-up (1-month survival and neurological status) are collected systematically. Survival at 1 month with minimal neurological impairment was not documented for 52 (≤0.3%) patients, 32 in the monophasic group and 20 in the biphasic group. They were excluded for subsequent analyses of the primary outcome measures. Survival at 1 month was documented in all eligible patients.

The times of the emergency call receipt and hospital arrival were recorded according to the times on the clock used by the EMS that responded to the call. Information on witness status and bystander CPR was collected by EMS personnel by interviewing the bystander. The cause of cardiac arrest was determined by the physician in charge based on physical, laboratory, and radiological findings, together with scene information obtained from EMS crew. It was presumed to be cardiac in origin unless unequivocal evidence suggested respiratory diseases, cerebrovascular diseases, external causes (trauma, hanging, drowning, drug overdose, asphyxia), or any other noncardiac cause. Data were verified by EMS personnel and anonymized at the local fire stations, then transferred and stored in the database at the FDMA. The data were checked by computer, and if there were any inconsistencies or missing data, the FDMA consulted the corresponding regional fire stations and the data were corrected when necessary.

Study Targets and End Points

In the present study, we focused on patients whose first documented rhythms were ventricular fibrillation (VF) or pulseless ventricular tachycardia. The primary outcome measure was survival at 1 month with minimal neurological impairment, which was defined as Glasgow-Pittsburgh cerebral performance category 1 (good cerebral performance) or 2 (moderate cerebral disability); 17,25 as evaluated by the physician in charge at 1 month after the event. The secondary outcome measures were survival at 1 month and return of spontaneous circulation before hospital arrival.

Statistical Analysis

The time from the emergency call to CPR by the EMS was subdivided into the following 3 categories: early response (0–6 minutes), moderate response (7–12 minutes), and late response (13–18 minutes). The cause of the cardiac arrest was categorized into cardiac or noncardiac origin subgroups. Patients received CPR based on 2 American Heart Association CPR guidelines (2000 and 2005 American Heart Association Guidelines). Patient characteristics were evaluated using the unpaired Student t test for numerical variables and the χ² test for categorical variables. The outcomes were compared between the subgroups using χ² tests.

To identify the association between defibrillator type (monophasic or biphasic) and outcomes, we performed multivariate logistic regression analyses with adjustment for age, sex, cause of arrest, the type of bystander CPR performed (no bystander CPR, compression only CPR, or conventional CPR), the type of guideline-based CPR performed (2000 Guideline-based or 2005 Guideline-based), time from emergency call to CPR by EMS (early, moderate, or late response), whether the collapse was witnessed by a bystander, whether an advanced airway device was inserted, whether epinephrine was injected, and calendar year. We assumed that data were structured hierarchically into 2 levels: communities and patients. We accounted for clustering of outcomes within communities using a generalized estimation equation (GEE). This is commonly used in place of a basic regression approach because outcomes of patients in the same community may be correlated, thus violating independence assumptions made by traditional regression procedures. 26 We also performed logistic GEE regression analyses focusing on the following subgroups: (1) early response subgroup (0–6 minutes from the time of the emergency call to CPR by the EMS) (n=7036), (2) cardiac origin subgroup (n=18 173), and (3) 2005 Guideline-based subgroup (n=9024).

We performed additional confirmatory logistic GEE regression analyses for all patients with adjustment for propensity to receive biphasic defibrillation. The propensity score approach addresses selection bias that is inherent in retrospective observational studies, where outcomes can reflect a lack of comparability in treatment groups rather than the effects of treatment. 27 To estimate the propensity score, we fitted a logistic regression model for the receipt of biphasic defibrillation as a function of the reported covariates. The c-statistic for evaluating the goodness of fit was calculated. First, we added the estimated propensity scores to the logistic GEE models as a covariate (ie, propensity-score–adjusted analyses). Second, we performed a one-to-one matching between the monophasic and biphasic defibrillation groups on the basis of estimated propensity scores of each patient using a nearest neighbor matching within a caliper. The caliper size was set as a quarter of an SD of the sample estimated propensity scores. The covariate imbalance was checked using the standardized differences in covariates in the matched samples. 27 All statistical analyses were conducted using SAS version 9.2 (SAS, Cary, NC). All tests were 2-tailed, and P<0.05 was regarded as significant.

Results

The documented number of OHCA patients ≥18 years of age was 312322. We excluded patients who had no attempted resuscitation by the EMS (n=4500), whose initial rhythms were not VF nor pulseless ventricular tachycardia (n=284 843), who were not shocked by the EMS (n=1606), and who lacked information on receiving defibrillation shock (n=25). Consequently, the number of VF/pulseless ventricular tachycardia patients who were shocked for defibrillation by the EMS at least once before their arrival at the hospital was 21 348. Patients who underwent defibrillation by a public-access AED by bystanders (n=175) and patients shocked with an unknown type of defibrillator (n=1) were then excluded, leaving 21 172 patients eligible for inclusion in the study. Figure 1 shows a flow diagram of the study. Of the eligible patients, 8224 (39%) patients were shocked with a monophasic defibrillator and 12 948 (61%) patients were shocked with a biphasic defibrillator.

Table 1 presents the demographic and medical characteristics of the included patients. Figure 2 shows the annual changes in the number of patients by defibrillator type. The proportion of patients who were shocked with the monophasic defibrillator decreased each year. Figure 3 shows the cerebral performance category status of survivors by defibrillator type (monophasic/biphasic).

Table 2 shows the outcomes by type of defibrillator of eligible patients and of subgroups of patients. χ² tests showed significant differences in survival at 1 month with minimal neurological impairment (11.6% versus 12.8%) and return of spontaneous circulation before hospital arrival (21.2% versus 22.3%) between monophasic and biphasic groups.

Table 3 shows the results of logistic GEE regression analyses. There were no significant differences between the monophasic and biphasic groups in all outcome measures of eligible patients, including return of spontaneous circulation before hospital arrival (odds ratio, 1.03; 95% confidence interval, 0.91–1.16; P=0.64), survival at 1 month (odds ratio, 1.02; 95% confidence interval, 0.92–1.14; P=0.69), and survival at 1 month with minimal neurological impairment (odds ratio,
1.07; 95% confidence interval, 0.91–1.26; \( P = 0.42 \). No significant association between defibrillator type and outcomes was shown in any of the 3 subgroup analyses (ie, early response subgroup, cardiac origin subgroup, or 2005 Guideline-based subgroup).

Table 3 also shows the results of the propensity-score–adjusted analyses and propensity-score–matched analyses for all patients. The c-statistic for goodness of fit was 0.641 in the propensity score model. By one-to-one propensity-score matching, 7293 pairs of the monophasic and biphasic groups were selected (\( n = 14586 \)). The standardized differences in covariates in the matched samples were all <0.1. Again, there were no significant differences between the monophasic and biphasic groups in all outcome measures.

**Discussion**

In our study, no significant difference was observed in multivariate logistic regression analyses between the patients who were shocked with a biphasic defibrillator or with a monophasic defibrillator, either in the primary outcome or in the secondary outcomes. To date, it has been indicated that biphasic defibrillator group

\[
\text{Type of defibrillator unknown} \quad n=1
\]

No shock by EMS

\( n=1,506 \)

Unknown if shocked or not

\( n=25 \)

Shock by bystanders with public-access AEDs

\( n=175 \)

Not shockable rhythm

\( n=284,843 \)

- Asystole (Flatline) 205,670
- PEA 65,925
- Other 13,248

First documented rhythm

\( \text{VF/Pulseless VT} \quad n=22,979 \)

Shock by EMS

\( n=21,348 \)

Eligible patients

\( n=21,172 \)

Monophasic defibrillator group

\( n=8,224 \)

Biphasic defibrillator group

\( n=12,948 \)

Cardiac arrests (≥18 yr)

\( n=312,322 \)

Resuscitation attempted by EMS

\( n=307,822 \)

Type of defibrillator unknown

\( n=1 \)

No resuscitation attempted by EMS

\( n=4,500 \)

No shock by EMS

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**Discussion**

In our study, no significant difference was observed in multivariate logistic regression analyses between the patients who were shocked with a biphasic defibrillator or with a monophasic defibrillator, either in the primary outcome or in the secondary outcomes. To date, it has been indicated that biphasic waveform shock is superior to monophasic waveform shock with respect to safety and efficacy under controlled laboratory and in-hospital conditions. An observational study of subjects with OHCA indicated that biphasic waveform shock afforded a higher probability of terminating VF than monophasic waveform shock. With regard to the long-term outcome, no significant difference was observed between the 2 types of waveform for defibrillation in any of the 4 randomized trials. These studies focused on differences in the waveforms among defibrillators. However, compared with the monophasic defibrillator, the commercialized biphasic defibrillator not only has a different waveform but also has differences in the amount and duration of defibrillation energy. Furthermore, the equipment is smaller and lighter. Sellers of defibrillators seem to consider that biphasic defibrillators are equal to or better than the monophasic defibrillator in improving outcomes of OHCA patients. Purchasers are also assumed to expect improved outcomes of OHCA patients with the biphasic defibrillator, and this may be a factor in replacing the monophasic defibrillator with the biphasic defibrillator. The FDMA of Japan has encouraged fire stations nationwide to replace the monophasic defibrillators with biphasic defibrillators by assisting each fire station with the expense of purchasing new defibrillators. Consequently, a majority of the patients underwent shock by biphasic defibrillator (Figure 2).

Biphasic defibrillators have several advantages compared with monophasic defibrillators, including a lower burden for EMS personnel because of their lower weight and greater portability. However, despite theoretical advantages of biphasic waveforms and some limited evidence about their better surrogate outcomes, the present study showed no significant advantage of biphasic defibrillators over monophasic defibrillators on meaningful clinical outcomes. Although some EMS systems may replace monophasic defibrillators with biphasic ones because of their lighter weight and increased portability, there is no patient-safety, outcome-based reason to do so. There are mainly 2 reasons why no significant association could be confirmed. First, there was no difference in the association with outcome of OHCA
patients between monophasic and biphasic defibrillators. Second, because many factors contribute to the outcome of 1-month cerebral function, such as where cardiac arrest occurs, bystander treatment, prehospital EMS treatment, and intensive care at the admitting hospital, any association may be decreased to an extent that it cannot be detected. When the second case was considered, although good neurological outcome is the ultimate desired outcome of all resuscitations, as an index to measure the direct effects of different defibrillators, we consider it would be desirable to include whether a defibrillation terminated VF. However, because we did not collect data on whether VF was terminated by each shock, we could not compare the probability of terminating VF and the number of shocks necessary to terminate VF between the different types of defibrillators. Our study was an observational study that compared the association of the biphasic defibrillator and monophasic defibrillator with outcome in a large number of OHCA patients. Because the monophasic defibrillator is being replaced by the biphasic defibrillator in Japan (Figure 2), as in other developed countries, this study may be the last large-scale observational study to compare outcomes by type of defibrillator—monophasic and biphasic—and provide a valuable comparison in OHCA patients.

Table 1. Characteristics of the Study Participants

<table>
<thead>
<tr>
<th></th>
<th>Total (n=21,172)</th>
<th>Monophasic (n=8,224)</th>
<th>Biphasic (n=12,948)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>65.3 (15.2)</td>
<td>64.8 (15.1)</td>
<td>65.6 (15.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>16,400 (77.5)</td>
<td>6,468 (78.6)</td>
<td>9,932 (76.7)</td>
<td>0.001</td>
</tr>
<tr>
<td>Witnessed by laypersons, n (%)</td>
<td>14,962 (70.7)</td>
<td>5,862 (71.3)</td>
<td>9,100 (70.3)</td>
<td>0.12</td>
</tr>
<tr>
<td>Type of bystander-initiated CPR*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No CPR, n (%)</td>
<td>12,599 (60.1)</td>
<td>4,974 (60.9)</td>
<td>7,625 (59.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Compression-only CPR, n (%)</td>
<td>4,393 (21.0)</td>
<td>1,594 (19.5)</td>
<td>2,799 (21.9)</td>
<td></td>
</tr>
<tr>
<td>Conventional CPR, n (%)</td>
<td>3,963 (18.9)</td>
<td>1,599 (19.6)</td>
<td>2,364 (18.5)</td>
<td></td>
</tr>
<tr>
<td>Advanced airway management†, n (%)</td>
<td>10,616 (50.5)</td>
<td>4,209 (51.5)</td>
<td>6,407 (49.9)</td>
<td>0.025</td>
</tr>
<tr>
<td>Adrenalin‡, n (%)</td>
<td>907 (4.4)</td>
<td>257 (3.2)</td>
<td>650 (5.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Call to CPR by EMS, min, mean (SD)§</td>
<td>8.8 (5.5)</td>
<td>8.8 (5.5)</td>
<td>8.8 (5.4)</td>
<td>0.68</td>
</tr>
<tr>
<td>0–6 min, n (%)</td>
<td>7,036 (34.6)</td>
<td>2,719 (34.4)</td>
<td>4,317 (34.8)</td>
<td></td>
</tr>
<tr>
<td>7–12 min, n (%)</td>
<td>11,527 (56.8)</td>
<td>4,526 (57.3)</td>
<td>7,001 (56.4)</td>
<td></td>
</tr>
<tr>
<td>13–18 min‖, n (%)</td>
<td>1,748 (8.6)</td>
<td>654 (8.3)</td>
<td>1,094 (8.8)</td>
<td></td>
</tr>
<tr>
<td>CPR by EMS to hospital arrival, min, mean (SD)#</td>
<td>22.2 (10.1)</td>
<td>22.4 (10.0)</td>
<td>22.0 (10.2)</td>
<td>0.012</td>
</tr>
<tr>
<td>Origin of cardiac arrest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac, n (%)</td>
<td>18,173 (85.8)</td>
<td>7,130 (86.7)</td>
<td>11,043 (85.3)</td>
<td>0.004</td>
</tr>
<tr>
<td>Noncardiac, n (%)</td>
<td>2,999 (14.2)</td>
<td>1,094 (13.3)</td>
<td>1,905 (14.7)</td>
<td></td>
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<tr>
<td>CPR guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000 AHA Guideline-based, n (%)</td>
<td>12,148 (57.4)</td>
<td>5,786 (70.4)</td>
<td>6,362 (49.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2005 AHA Guideline-based, n (%)</td>
<td>9,024 (42.6)</td>
<td>2,438 (29.6)</td>
<td>6,586 (50.9)</td>
<td></td>
</tr>
<tr>
<td>No. of shocks administered to patients who had ROSC before hospital arrival, Median (25%–75%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>6,797 (32.1)</td>
<td>3,642 (44.3)</td>
<td>3,155 (24.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2006</td>
<td>7,183 (33.9)</td>
<td>2,783 (33.8)</td>
<td>4,400 (34.0)</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>7,192 (34.0)</td>
<td>1,799 (21.9)</td>
<td>5,393 (41.7)</td>
<td></td>
</tr>
</tbody>
</table>

AHA indicates American Heart Association; CPR, cardiopulmonary resuscitation; and EMS, Emergency Medical Services.
*Two hundred seventeen (1.0%) patients with missing data were excluded. Percentages were calculated on the basis of the total number of events, including those excluded.
†One hundred sixty-three (0.8%) patients with missing data were excluded. Percentages were calculated on the basis of the total number of events, including those excluded.
‡Three hundred sixty-four (1.7%) patients with missing data were excluded. Percentages were calculated on the basis of the total number of events, including those excluded.
§Twenty-six (0.1%) patients whose data were missing were excluded. The mean value and SD were calculated without the excluded data.
‖Eight hundred thirty-five (3.9%) patients in whom there was >18 min between the time of call to CPR by EMS were excluded. Percentages were calculated on the basis of the total number of events, including the excluded data.
#Twenty-three (0.1%) patients whose data were missing were excluded. The mean value and SD were calculated without the excluded data.
Study Limitations
This study has several limitations. First, bias on the basis of its observational design is a potential limitation. It is possible that EMS personnel who used the monophasic defibrillator were less well supported by public funds, thus received a lower frequency of training, and this could have influenced the results. Second, as mentioned above, data on whether VF was terminated by shock were not collected, so we could not directly compare the probability of terminating VF. However, to investigate the association of replacing the monophasic defibrillator by the biphasic defibrillator, a comparison of the survival at 1

Table 2. Outcomes of All Patients and Subgroups

<table>
<thead>
<tr>
<th></th>
<th>ROSC Before Hospital Arrival</th>
<th>Survival at 1 mo</th>
<th>Survival at 1 mo With Minimal Neurological Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>P</td>
<td>n (%)</td>
</tr>
<tr>
<td>All patients (n=21172)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=8224)</td>
<td>1740 21.2%</td>
<td>0.043</td>
<td>1641 20.0%</td>
</tr>
<tr>
<td>Biphasic (n=12948)</td>
<td>2892 22.3%</td>
<td></td>
<td>2713 21.0%</td>
</tr>
<tr>
<td>Time from emergency call to CPR by EMS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early response (0–6 min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=2719)</td>
<td>706 26.0%</td>
<td>0.046</td>
<td>694 25.5%</td>
</tr>
<tr>
<td>Biphasic (n=4317)</td>
<td>1215 28.1%</td>
<td></td>
<td>1179 27.3%</td>
</tr>
<tr>
<td>Moderate response (7–12 min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=4526)</td>
<td>809 17.9%</td>
<td>0.17</td>
<td>744 16.4%</td>
</tr>
<tr>
<td>Biphasic (n=7001)</td>
<td>1323 18.9%</td>
<td></td>
<td>1247 17.8%</td>
</tr>
<tr>
<td>Late response (&gt;12 min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=654)</td>
<td>123 18.8%</td>
<td>0.70</td>
<td>102 15.6%</td>
</tr>
<tr>
<td>Biphasic (n=1094)</td>
<td>197 18.0%</td>
<td></td>
<td>152 13.9%</td>
</tr>
<tr>
<td>Origin of cardiac arrest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=7130)</td>
<td>1574 22.1%</td>
<td>0.007</td>
<td>1505 21.1%</td>
</tr>
<tr>
<td>Biphasic (n=11043)</td>
<td>2629 23.8%</td>
<td></td>
<td>2516 22.8%</td>
</tr>
<tr>
<td>Noncardiac</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=1094)</td>
<td>166 15.2%</td>
<td>0.30</td>
<td>136 12.4%</td>
</tr>
<tr>
<td>Biphasic (n=1950)</td>
<td>263 13.8%</td>
<td></td>
<td>197 10.3%</td>
</tr>
<tr>
<td>CPR guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000 Guideline-based</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=5786)</td>
<td>1189 20.5%</td>
<td>0.66</td>
<td>1097 19.0%</td>
</tr>
<tr>
<td>Biphasic (n=6362)</td>
<td>1287 20.2%</td>
<td></td>
<td>1175 18.5%</td>
</tr>
<tr>
<td>2005 Guideline-based</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monophasic (n=2438)</td>
<td>551 22.6%</td>
<td>0.080</td>
<td>544 22.3%</td>
</tr>
<tr>
<td>Biphasic (n=6586)</td>
<td>1605 24.4%</td>
<td></td>
<td>1538 23.4%</td>
</tr>
</tbody>
</table>

ROSC indicates return of spontaneous circulation; CPR, cardiopulmonary resuscitation; and EMS, Emergency Medical Services.
month with minimal neurological impairment is considered to be a good index. Third, because of the lack of data, we were unable to account for several potential confounders, including body mass index and preshock pause of chest compressions (time for ECG analysis and energy charge). In particular, postcardiac arrest care (eg, therapeutic hypothermia and percutaneous coronary intervention) that became increasingly adopted over the study period deserves attention as one of the major confounders. However, we believe this was partly, if not completely, accounted for by incorporating the calendar year in our multivariable logistic regression analysis. Furthermore, considering that the use of a biphasic defibrillator also increased over the study period, improvement of postcardiac arrest care would have affected the odds ratio in favor of the biphasic defibrillator, but we still failed to find a statistically significant difference in the primary outcome. Fourth, the present study did not compare individual defibrillator types but rather collapsed the defibrillator models into 2 groups according to the type of waveform. Fifth, this study is based on a retrospective observational design and, therefore, more susceptible to bias and confounding when compared with randomized controlled trials. However, we believe our study has strength in that it reflects daily clinical practice more closely than randomized controlled trials, as well as in that it includes a large number of patients. Sixth, accuracy of the recorded cerebral performance category scores was not confirmed. Despite these limitations, we believe that our results are valid, given the use of uniform data collection and consistent definitions based on the Utstein guidelines.\textsuperscript{14,15,20} the large sample size, and the nationwide, population-based design. In addition, because all consecutive cases of OHCA patients transferred by the EMS in Japan were included in the database, selection and reporting bias was minimal.

Conclusions

Although monophasic defibrillators are being replaced by biphasic defibrillators, our nationwide population-based observational study could not confirm a parallel improvement in survival at 1 month with minimal neurological impairment.

Acknowledgments

We thank all the Emergency Medical Service personnel and participating physicians in Japan and the Fire and Disaster Management Agency for their generous cooperation in establishing and maintaining the database.

Disclosures

None.

References


Comparison of Outcomes After Use of Biphasic or Monophasic Defibrillators Among Out-of-Hospital Cardiac Arrest Patients: A Nationwide Population-Based Observational Study

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