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ORIGINAL ARTICLE

# Characteristics and outcomes of out-of-hospital cardiac arrest in a hilly area: Utstein Registry data from the Nagasaki Medical Region, Japan

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## Abstract

**Aim:** To analyze characteristics and investigate prognostic indicators of out-of-hospital cardiac arrest (OHCA) in a hilly area in Japan.

**Methods:** A retrospective population-based study was conducted using the Utstein Registry for 4280 OHCA patients in the Nagasaki Medical Region (NMR) registered over the 10-year period from 2011 to 2020. The main outcome measure was a favorable cerebral performance category (CPC 1–2). Sites at which OHCA occurred were classified into "sloped places (SPs)" (not easily accessible by emergency medical services [EMS] personnel due to slopes) and "accessible places (APs)" (EMS personnel could park an ambulance close to the site). The characteristics and prognosis based on CPC were compared between SPs and APs, and multivariable analysis was performed.

**Results:** No significant improvement in prognosis occurred in the NMR from 2011 to 2020. Prognosis in SPs was significantly worse than that in APs. However, multivariable analysis did not identify SP as a prognostic indicator. The following factors were associated with survival and CPC 1–2: age group, witness status, first documented rhythm, bystander-initiated cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) use, use of mechanical CPR (m-CPR) device or esophageal obturator airway (EOA), and year. Both m-CPR and EOA use were associated with a poor prognosis.

**Conclusion:** In a hilly area, OHCA patients in SPs had a worse prognosis than those in APs, but SPs was not significantly associated with prognosis by multivariable analysis. Interventions to increase bystander-initiated CPR and AED use could potentially improve outcomes of OHCA in the NMR.

KEYWORDS
cardiopulmonary resuscitation, emergency medical system, hilly area, mechanical resuscitation, out-of-hospital cardiac arrest

# INTRODUCTION

Medical needs are not the same worldwide and vary from region to region. Regional characteristics are of great importance especially for emergency medical services (EMS) personnel who treat patients with out-of-hospital cardiac arrest (OHCA). Thus, understanding the characteristics of a medical region is important in establishing an emergency medical system that improves prognosis of patients with OHCA. Nagasaki City, the capital and largest city of Nagasaki Prefecture, has a total area of approximately 456 $km^2$. The population of the Nagasaki Medical Region (NMR), including surrounding towns, is approximately 500,000 citizens.[1] The important geographical characteristic of NMR is that 43% of Nagasaki City's residential area is built on slopes of more than 10 degrees with many narrow roads and steep outdoor stairways, making it unique compared to other major cities in Japan as it has the second highest number of sloping urban areas in the country.[2] Roads leading to the slopes are narrower than those in flat areas. Such features can create unfavorable conditions when EMS personnel need to access patients with OHCA and can lead to a worse prognosis in terms of one-month survival with good neurological outcome.

This study aimed to clarify the factors that may correlate with the prognosis of OHCA patients in the NMR and risk factors for a poor prognosis and to identify measures to improve the EMS system.

# METHODS

## Nagasaki EMS

The 119 emergency telephone number is accessible anywhere in Japan including Nagasaki, and on receipt of a 119 call, an emergency dispatch center sends the nearest available ambulance to the site. Emergency services are provided 24 h every day through a system composed of three stations having a total of 15 ambulance teams. Each ambulance includes a three-person unit providing life support. The most highly trained EMS personnel are called emergency life-saving technicians. They can insert an intravenous line and adjunct airway and can use a semi-automated external defibrillator (AED) to deliver shocks and a mechanical CPR device (m-CPR) for OHCA patients. Specially trained emergency life-saving technicians can perform tracheal intubation and administe epinephrine to OHCA patients. All EMS providers carried out CPR during the study period basically according to the 2010 and 2015 Japanese CPR guidelines. A m-CPR device was initially introduced in 2009, with 2 added in 2009, 1 in 2010, 8 in 2011, 1 in 2012, and 3 in 2014. All m-CPR devices were load-distributing band-type devices (AutoPulse, ZOLL Medical Corporation, Chelmsford, MA, USA). Since 2016, they have been replaced by the Lucas® 2 (Physio-Control Inc., Redmond, WA, USA) with 2 in 2016 and then by the Lucas® 3 with 1 in 2017, 2 in 2018, 1 in2019, and 1 in 2020.

## Study design

This retrospective study used the Utstein Registry of the Fire and Disaster Management Agency (FDMA). The All-Japan Utstein Registry is a prospective, population-based, nationwide registry of OHCA in which data are recorded according to the internationally standardized Utstein style. In this study, only de-identified data of the Utstein Registry in NMR for 10 years (2011–2020) were provided from the Nagasaki EMS office. We included OHCA cases that occurred before and after the arrival of EMS personnel and for which resuscitation was attempted. When bystanders provided public-access defibrillation, the patient's first documented rhythm was regarded as ventricular fibrillation (VF).[3] Causes of OHCA were considered cardiogenic or noncardiogenic (according to physicians' diagnosis).[4]

## Variables

Neurological outcomes were assessed at 1 month after OHCA according to the Glasgow–Pittsburgh Cerebral Performance Categories scale (CPC). Only patients with CPC 1 or 2 were considered to have a good neurological outcome. The research included all ages of the population in the NMR. The analysis included the following variables: year (from 2011 to 2020), age (age groups from 0–9 to 100–109 years), sex (male, female), origin of arrest (cardiogenic, noncardiogenic), place of occurrence (home, public space, others), first documented rhythm on arrival of EMS personnel (asystole, pulseless electrical activity [PEA], VF, pulseless ventricular tachycardia [pVT], others), witness status (witnessed by citizen, witnessed by EMS, unwitnessed), bystander-initiated cardiopulmonary resuscitation (CPR) (yes, no), shock by public-access AED (yes, no), place ambulance parked (sloped place [SP], accessible place [AP]), administration of intravenous fluid or epinephrine by EMS (yes, no), use of esophageal obturator airway [EOA] (yes, no), use of endotracheal intubation (yes, no), use of m-CPR device by EMS (yes, no), time from EMS call to arrival in the field (place where ambulance parked) (minutes), time from EMS arrival to departure (minutes), time from EMS departure to hospital arrival (minutes), time from EMS call to hospital arrival (minutes), and number of hospital inquiries (1, 2, 3, 4, ≥5).

Data on ambulance parking were collected by EMS personnel, which was unique to the NMR. Locations not allowing easy access for EMS personnel due to slopes were classified as a SP, and locations where the ambulance could be parked close to site of OHCA occurrence were classified as an AP. These data were documented according to judgment of the EMS personnel. At SPs, EMS personnel had to carry stretchers and equipment up slopes and stairs on foot.

Use of m-CPR devices (a factor not included in the Utstein Registry) was also recorded.

An Utstein-style flowchart was used to systematize the data of the cases included in this study (Figure 1) according to published data from the FDMA of the Ministry of Internal Affairs and Communications (https://www.fdma.go.jp/publication/rescue/post-4.html).

## Statistical analysis

All normally distributed continuous variable data are presented as mean ± standard deviation or median and interquartile range. Categorical variable data are presented as percentages. Categorical and continuous variables were evaluated with a trend test using logistic or linear regression models, respectively. Continuous variables between two groups were compared with Welch's *t*-test or Mann–Whitney *U* test, and categorical variables were compared with Pearson's chi-square test or Fisher's exact test. Factors associated with one-month survival and favorable neurological outcomes were assessed by multivariable analysis with logistic regression models.

*p*-Values were interpreted as exploratory because this was an exploratory trial, and no confirmatory testing or adjustment for multiplicity was planned. All statistical analyses were performed using JMP Pro 16.0.0 (SAS Institute Inc.). The research was conducted at the Acute and Critical Care Centre of Nagasaki University Hospital, and the study was approved by the Nagasaki University Hospital Clinical Research Ethics Committee (No. 22062022).

# RESULTS

Between January 1, 2011, and December 31, 2020, 7588 OHCA cases were documented in the NMR (Figure 1, Table 1). After OHCA cases with no resuscitation attempt ($n = 3308$) were excluded, in total, 4280 patients were included in the final analysis. Among all cases, 63% (2704) were cardiogenic and more than half of the OHCA cases were unwitnessed (54.7%, $n = 2340$) (Table 1). Witnessed cases were more likely to be witnessed by citizens (37.9%, $n = 1623$). The first documented rhythm was asystole in 62.7% of cases ($n = 2685$), with PEA, VF, pulseless VT, and other rhythms registered in 24.1%, 6.4%, 1.9%, and 6.6% of all OHCA cases, respectively. Ambulance parking was at a SP in 19.8% of cases ($n = 846$) and at an AP in 80.2% ($n = 3434$). Approximately 56% of patients with OHCA received bystander-initiated CPR. Bystander-initiated AED use was registered in 46 cases (1.1%) from 2011 to 2020, and m-CPR devices were used in 52.6% of patients. Mean times were as follows: from EMS call

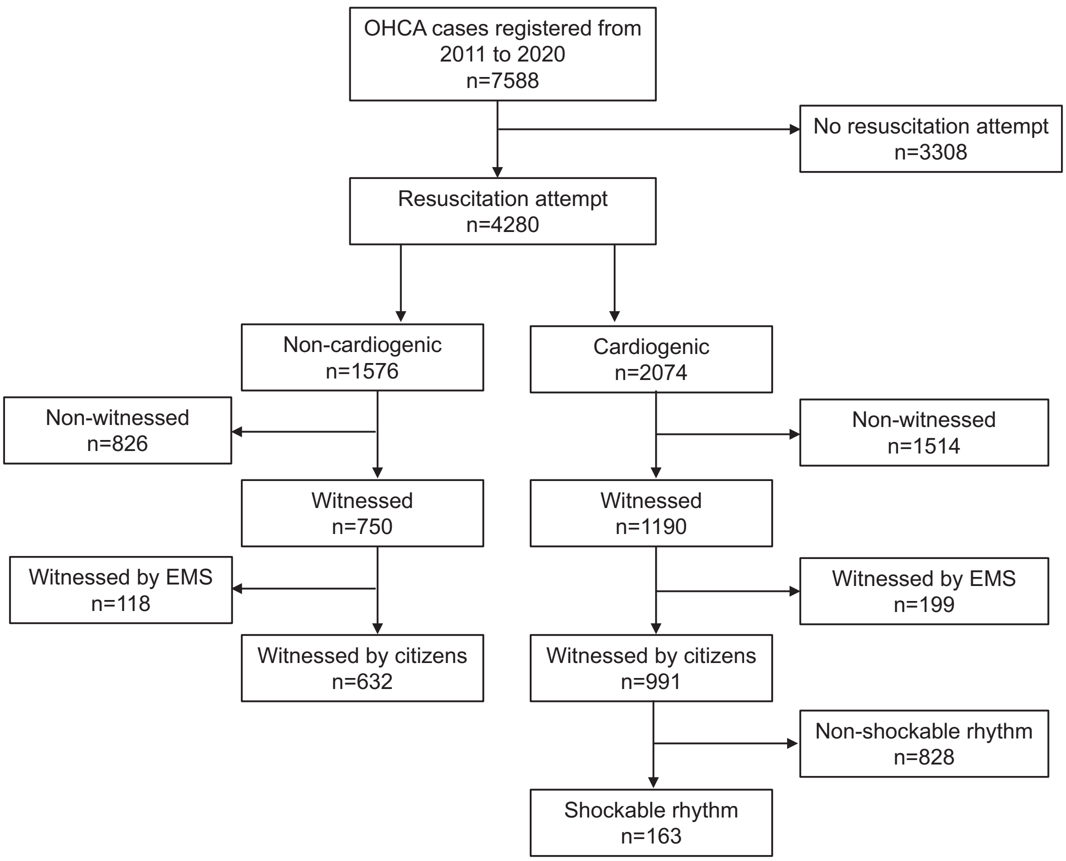


**FIGURE 1** Flowchart of the study cohort. OHCA cases occurring in the NMR between January 1, 2011, and December 31, 2020, were included in this study. EMS, emergency medical services; NMR, Nagasaki Medical Region; and OHCA, out-of-hospital cardiac arrest.

**TABLE 1** Characteristics of OHCA patients in the NMR according to area of residence.

| | Total cases | Sloped places | Accessible places | *p* Value |
|---|---|---|---|---|
| Year, *n* (%) | *n* = 4280 | *n* = 846 | *n* = 3434 | 0.08 |
| 2011 | 422 (9.9) | 96 (11.3) | 326 (9.5) | |
| 2012 | 406 (9.5) | 92 (10.9) | 314 (9.1) | |
| 2013 | 425 (9.9) | 79 (9.3) | 346 (10.1) | |
| 2014 | 421 (9.8) | 83 (9.8) | 338 (9.8) | |
| 2015 | 430 (10.0) | 89 (10.5) | 341 (9.9) | |
| 2016 | 433 (10.1) | 101 (11.9) | 332 (9.7) | |
| 2017 | 492 (11.5) | 91 (10.8) | 401 (11.6) | |
| 2018 | 423 (9.9) | 67 (7.9) | 356 (10.3) | |
| 2019 | 399 (9.3) | 74 (8.7) | 325 (9.5) | |
| 2020 | 429 (10.0) | 74 (8.7) | 355 (10.3) | |
| Male, *n* (%) | 2370 (55.4) | 479 (56.6) | 1891 (55.1) | 0.42 |
| Median age, years (IQR) | 79 (66–86) | 78 (67–85) | 79 (65–87) | 0.15 |
| Age group, years, *n* (%) | | | | **<0.01** |
| 0–9 | 44 (1.0) | 5 (0.6) | 39 (1.1) | 0.16 |
| 10–19 | 28 (0.7) | 4 (0.5) | 24 (0.7) | 0.47 |
| 20–29 | 51 (1.2) | 2 (0.2) | 49 (1.4) | **<0.01** |
| 30–39 | 95 (2.2) | 18 (2.1) | 77 (2.2) | 0.84 |
| 40–49 | 189 (4.4) | 33 (3.9) | 156 (4.5) | 0.42 |
| 50–59 | 330 (7.7) | 69 (8.2) | 261 (7.6) | 0.59 |
| 60–69 | 598 (14.0) | 114 (12.5) | 484 (14.1) | 0.64 |
| 70–79 | 906 (21.2) | 229 (27.1) | 677 (19.7) | **<0.01** |
| 80–89 | 1393 (32.5) | 271 (32.0) | 1122 (32.7) | 0.75 |
| 90–99 | 609 (14.2) | 95 (11.2) | 514 (15.0) | **<0.01** |
| 100–109 | 37 (0.9) | 6 (0.7) | 31 (0.9) | 0.59 |
| Witness status, *n* (%) | | | | **<0.01** |
| Unwitnessed | 2340 (54.7) | 529 (62.5) | 1811 (52.7) | **<0.01** |
| Witnessed by citizens | 1623 (37.9) | 268 (31.7) | 1355 (39.5) | **<0.01** |
| Witnessed by EMS | 317 (7.4) | 49 (5.8) | 268 (7.8) | **0.04** |
| First documented rhythm, *n* (%) | | | | **<0.01** |
| VF | 272 (6.4) | 37 (4.4) | 235 (6.8) | **<0.01** |
| pVT | 8 (1.9) | 1 (0.1) | 7 (0.2) | 1.00 |
| PEA | 1031 (24.1) | 182 (21.5) | 849 (24.7) | 0.05 |
| Asystole | 2685 (62.7) | 595 (70.3) | 2090 (60.9) | **<0.01** |
| Others | 284 (6.6) | 31 (3.7) | 253 (7.4) | **<0.01** |
| Place of occurrence, *n* (%) | | | | **<0.01** |
| Home | 2657 (62.1) | 756 (89.4) | 1901 (55.4) | **<0.01** |
| Public place | 1484 (34.7) | 60 (7.1) | 1424 (41.5) | **<0.01** |
| Others | 139 (3.2) | 30 (3.6) | 109 (3.2) | 0.58 |
| Time from EMS call to arrival in the field, min (SD) | 9.6 (4.3) | 9.7 (4.1) | 9.6 (4.4) | 0.42 |
| Time from EMS arrival to departure, min (SD) | 15.3 (6.8) | 18.6 (7.2) | 14.4 (6.5) | **<0.01** |
| Time from EMS departure to hospital arrival, min (SD) | 10.5 (7.9) | 8.9 (6.6) | 10.9 (8.1) | **<0.01** |
| Time from EMS call to hospital arrival, min (SD) | 36.3 (12.4) | 38.2 (12.0) | 35.9 (12.4) | **<0.01** |
| Bystander-initiated CPR | 2378 (55.6) | 402 (47.5) | 1976 (57.5) | **<0.01** |
| Bystander-initiated AED use | 46 (1.1) | 1 (0.1) | 45 (1.3) | **<0.01** |
| m-CPR device use, *n* (%) | 2252 (52.6) | 519 (61.3) | 1733 (50.5) | **<0.01** |

**TABLE 1** (Continued)

| | Total cases | Sloped places | Accessible places | *p* Value |
|---|---|---|---|---|
| Intravenous fluid administration, *n* (%) | 859 (20.1) | 187 (22.1) | 672 (19.6) | 0.10 |
| Epinephrine administration, *n* (%) | 526 (12.3) | 97 (11.5) | 429 (12.5) | 0.42 |
| EOA, *n* (%) | 773 (18.1) | 196 (23.2) | 577 (16.8) | **<0.01** |
| Endotracheal intubation, *n* (%) | 84 (2.0) | 15 (1.8) | 69 (2.0) | 0.66 |
| ROSC before hospital arrival, *n* (%) | 499 (11.7) | 57 (6.7) | 442 (12.9) | **<0.01** |
| Survival, *n* (%) | 308 (7.2) | 30 (3.6) | 278 (8.1) | **<0.01** |
| CPC 1–2, *n* (%) | 200 (4.7) | 20 (2.4) | 180 (5.2) | **<0.01** |

Abbreviations: AED, automated external defibrillators; CPC, cerebral performance category; CPR, cardiopulmonary resuscitation; EMS, emergency medical services; EOA, esophageal obturator airway; IQR, interquartile range; m-CPR, mechanical cardiopulmonary resuscitation; NMR, Nagasaki Medical Region; OHCA, out-of-hospital cardiac arrest; PEA, pulseless electrical activity; pVT, pulseless ventricular tachycardia; ROSC, return of spontaneous circulation; SD, standard deviation; VF, ventricular fibrillation.

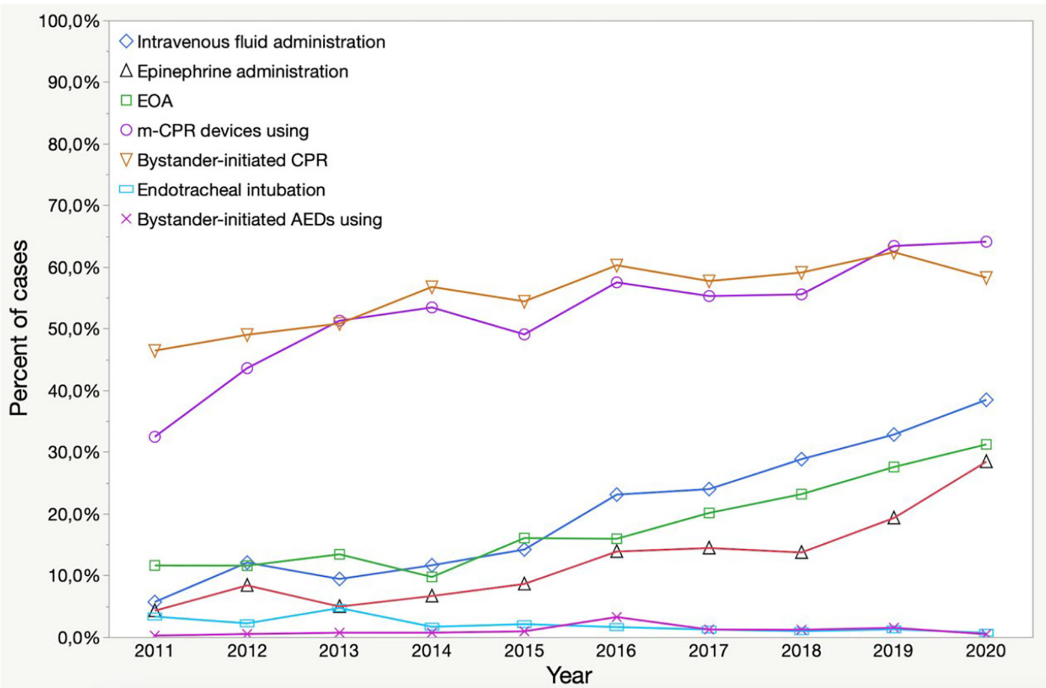


**FIGURE 2** General trends of prehospital care by citizens or EMS in the NMR for the 10-year study period. AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; EMS, emergency medical services; EOA, esophageal obturator airway; m-CPR, mechanical cardiopulmonary resuscitation; NMR, Nagasaki Medical Region.

to arrival in the field, 9.6 ± 4.3 min; from arrival of EMS personnel to departure, 15.3 ± 6.8 min; from departure of EMS personnel to arrival at hospital, 10.5 ± 7.9 min; and from EMS call to arrival at hospital, 36.3 ± 12.4 min. Among the OHCA cases, intravenous fluid was administered in 20.1% and epinephrine in 12.3%, EOA was used in 18.1%, and endotracheal intubation was performed in 2%. The median age increased from 78 years in 2011 to 79 years in 2020, but the increase was not statistically significant (*p* for trend = 0.07) (Table 3). The largest number of cases was registered in the 80-89-year-old age group, which accounted for 31.0%–36.3% of the cases. The number of cardiogenic OHCA cases increased during the 10 years from 52.6% in 2011% to 79.0% in 2020 (*p* for trend <0.01). During the entire study period, the most frequent place of occurrence was the home (58.2%–66.9%). The percentage of witnessed cardiogenic cases increased from 21.1% to 36.4% over the 10-year period (*p* for trend <0.01).

Figure 2 shows the general trends in prehospital care administered by citizens or EMS personnel in the NMR during the 10-year study period. The rate of CPR performed by bystanders changed markedly from 46.5% in 2011 to 58.3% in 2020 ($p < 0.01$). The number of OHCA cases for which m-CPR devices were used increased 1.97 times during the 10-year period, from 32.5% in 2011 to 64.1% in 2020 (*p* for trend <0.01). Significant increases were also observed in rates of epinephrine administration (6.8 times), intravenous fluid administration (6.6 times), and EOA use (2.7 times) (*p* for trend <0.01). Meanwhile, the rate of endotracheal intubation use decreased from 3.3% in 2011 to 0.7% in 2020 (*p* for trend <0.01). Bystander-initiated AED use also remained low (*p* for trend 0.10). No significant improving trend was observed for survival or neurological outcomes during the study period (Table 3).

## Outcomes for SP and AP

Table 1 shows the characteristics of the OHCA patients in the NMR depending on where the ambulance parked. There were no differences in the percentages for each year, sex, age, or time from EMS call to arrival in the field, but witness status, first documented rhythm, and place of occurrence were significantly different between the two groups. More patients went into cardiopulmonary arrest in public places and were witnessed by citizens in APs, whereas asystole was more frequently observed in SPs. We found no differences between the two groups in time from emergency call to arrival of EMS personnel in the field, indicating that there was no disadvantage for SPs until the EMS personnel parked the ambulance, but the times from EMS arrival to departure and EMS call to hospital arrival were significantly longer for SPs. In contrast, time from EMS departure to hospital arrival was shorter for SPs. Rates of bystander-initiated CPR and AED use were significantly lower in SPs, but m-CPR devices (61.3% vs. 50.5%) and EOA (23.2% vs. 16.8%) were used more frequently in SPs. From 2011 to 2020, the one-month survival rate for patients with OHCA that occurred in APs was significantly higher than that for OHCA occurring in SPs: 8.1% vs. 3.6% ($p < 0.01$) (Figure 3, Table 1). The CPC 1–2 rate was also significantly higher for APs ($p < 0.01$).

## Multivariable analysis for one-month survival with good neurological outcome

Table 2 shows factors associated with one-month survival with good neurological outcome. Age groups in the 70s, 80s, and 90s were statistically significant factors. With the 50s age group as a reference, the adjusted odds ratios (ORs) were 0.47, 0.18, and 0.12, respectively. The rate of one-month survival with CPC 1–2 after VF as the first documented rhythm was 23.5%, but that after PEA was 2.7% (adjusted OR, 0.09; 95% confidence interval [CI], 0.05–0.15) and that after asystole was 0.2% (adjusted OR, 0.01; 95% CI, 0.00–0.02). The rate of CPC 1–2 in unwitnessed cases was 1.0% (adjusted OR, 0.29; 95% CI, 0.17–0.50) ($p < 0.01$), but that in cases witnessed by citizens was 8.0%. The ORs and 95% CIs for good neurological outcomes in 2013–2016 and 2018 were >1.0 when 2011 was used as a reference. Bystander-initiated CPR and AED use also correlated with one-month survival with CPC 1–2 in the multivariable analysis ($p < 0.01$). Use of m-CPR or EOA was significantly associated with a poor prognosis. The multivariable analysis showed that the place where the ambulance parked was not significantly associated with CPC 1–2.

## DISCUSSION

The NMR has a distinctive feature of sloping land, and therefore, we collected data on the place where the ambulance parked according to whether the land was sloped or accessible. There were large differences between SPs and APs (Table 1). The number of unwitnessed cases was almost

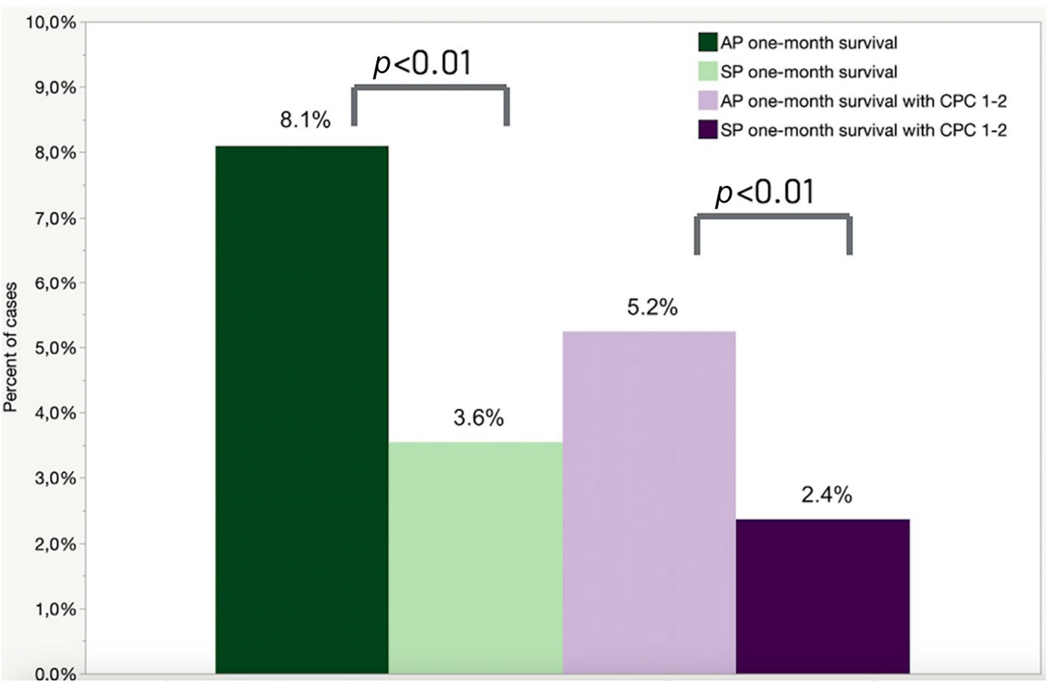


**FIGURE 3** One-month survival and good neurological outcomes depending on the place where the ambulance parked in the NMR during the 10-year study period. AP, accessible place; CPC, cerebral performance category; NMR, Nagasaki Medical Region; SP, slope place.

**TABLE 2** Factors associated with one-month survival with good neurological outcome after OHCA in the NMR during the 10-year study period.

| | CPC 1–2 | | OR | | | |
|---|---|---|---|---|---|---|
| | % | Number/Total number | Crude | 95% CI | Adjusted | 95% CI |
| Age group, years | | | | | | |
| 0–9 | 11.4 | 5/44 | 1.44 | 0.52–3.95 | 0.45 | 0.11–1.91 |
| 10–19 | 14.3 | 4/28 | 1.87 | 0.60–5.79 | 0.24 | 0.05–1.14 |
| 20–29 | 3.9 | 2/51 | 0.46 | 0.11–1.99 | 0.35 | 0.05–2.50 |
| 30–39 | 6.3 | 6/95 | 0.76 | 0.30–1.89 | 0.83 | 0.21–3.35 |
| 40–49 | 11.1 | 21/189 | 1.40 | 0.77–2.56 | 0.46 | 0.19–1.11 |
| 50–59 | 8.2 | 27/330 | Reference | | Reference | |
| 60–69 | 7.7 | 46/598 | 0.94 | 0.57–1.53 | 0.50 | 0.25–1.00 |
| 70–79 | 4.8 | 43/906 | 0.56* | 0.34–0.92 | 0.47* | 0.24–0.91 |
| 80–89 | 2.4 | 33/1393 | 0.27** | 0.16–0.46 | 0.18** | 0.09–0.36 |
| 90–99 | 2.1 | 13/609 | 0.24** | 0.12–0.48 | 0.12** | 0.05–0.29 |
| 100–109 | 0 | 0/37 | 0.00 | – | 0.00 | – |
| Sex | | | | | | |
| Male | 5.6 | 133/2370 | Reference | | Reference | |
| Female | 3.5 | 67/1910 | 0.61** | 0.45–0.83 | 1.21 | 0.80–1.84 |
| Cause | | | | | | |
| Cardiac | 5.2 | 140/2704 | Reference | | Reference | |
| Noncardiac | 3.8 | 50/1576 | 0.72* | 0.53–0.99 | 0.76 | 0.49–1.20 |
| Witness status | | | | | | |
| By citizens | 8.0 | 130/1623 | Reference | | Reference | |
| By EMS | 14.5 | 46/317 | 1.95** | 1.36–2.79 | 0.48* | 0.26–0.87 |
| Unwitnessed | 1.0 | 24/2340 | 0.12** | 0.08–0.18 | 0.29** | 0.17–0.50 |
| Bystander-initiated CPR | | | | | | |
| No | 4.5 | 85/1902 | Reference | | Reference | |
| Yes | 4.8 | 115/2378 | 1.09 | 0.82–1.45 | 1.69* | 1.03–2.76 |
| Bystander-initiated AED use | | | | | | |
| No | 4.1 | 174/4234 | Reference | | Reference | |
| Yes | 56.5 | 26/46 | 30.33** | 16.61–55.40 | 5.13** | 1.81–14.57 |
| m-CPR device use | | | | | | |
| No | 8.8 | 179/2028 | Reference | | Reference | |
| Yes | 0.9 | 21/2252 | 0.10** | 0.06–0.15 | 0.13** | 0.07–0.23 |
| Place ambulance parked | | | | | | |
| Accessible place | 5.2 | 180/3434 | Reference | | Reference | |
| Sloped place | 2.4 | 20/846 | 0.44** | 0.27–0.70 | 0.79 | 0.43–1.46 |
| First documented rhythm | | | | | | |
| VF | 23.5 | 64/272 | Reference | | Reference | |
| pVT | 25.0 | 2/8 | 1.08 | 0.21–5.50 | 0.79 | 0.13–4.92 |
| PEA | 2.7 | 28/1031 | 0.09** | 0.06–0.14 | 0.09** | 0.05–0.15 |
| Asystole | 0.2 | 5/2685 | 0.01** | 0.00–0.02 | 0.01** | 0.00–0.02 |
| Others | 35.6 | 101/284 | 1.79** | 1.24–2.60 | 1.00 | 0.57–1.77 |
| Intravenous fluid administration | | | | | | |
| No | 5.4 | 186/3421 | Reference | | Reference | |
| Yes | 1.6 | 14/859 | 0.29** | 0.17–0.50 | 0.61 | 0.23–1.60 |

(Continues)

**TABLE 2** (Continued)

| | CPC 1–2 | | OR | | | |
|---|---|---|---|---|---|---|
| | % | Number/Total number | Crude | 95% CI | Adjusted | 95% CI |
| Endotracheal intubation | | | | | | |
| No | 4.7 | 199/4196 | Reference | | Reference | |
| Yes | 1.2 | 1/84 | 0.24 | 0.03–1.75 | 0.77 | 0.09–6.64 |
| Epinephrine administration | | | | | | |
| No | 5.1 | 192/3754 | Reference | | Reference | |
| Yes | 1.5 | 8/526 | 0.29** | 0.14–0.58 | 0.46 | 0.14–1.52 |
| EOA | | | | | | |
| No | 5.6 | 196/3507 | Reference | | Reference | |
| Yes | 0.5 | 4/773 | 0.09** | 0.03–0.24 | 0.19** | 0.06–0.58 |
| Place of occurrence | | | | | | |
| Home | 3.4 | 91/2657 | Reference | | Reference | |
| Public place | 6.9 | 102/1484 | 2.08** | 1.56–2.78 | 0.82 | 0.54–1.25 |
| Others | 5.0 | 7/139 | 1.50 | 0.68–3.29 | 1.24 | 0.41–3.71 |
| Number of hospital inquiries | | | | | | |
| 1 | 5.0 | 160/3227 | Reference | | Reference | |
| 2 | 3.9 | 23/598 | 0.77 | 0.49–1.20 | 0.86 | 0.46–1.61 |
| 3 | 4.2 | 12/286 | 0.84 | 0.46–1.53 | 1.57 | 0.70–3.53 |
| 4 | 3.5 | 4/113 | 0.70 | 0.26–1.93 | 2.17 | 0.60–7.87 |
| ≥ | 1.8 | 1/56 | 0.35 | 0.05–2.53 | 0.43 | 0.04–5.19 |
| Time from EMS call to arrival in the field | – | – | 0.95** | 0.91–0.98 | 0.99 | 0.93–1.04 |
| Time from EMS call to hospital arrival | – | – | 1.00 | 0.99–1.02 | 1.01 | 0.99–1.02 |
| Year (for 1-year increment) | | | | | | |
| 2011 | 2.6 | 11/422 | Reference | | Reference | |
| 2012 | 2.5 | 10/406 | 0.94 | 0.40–2.25 | 0.96 | 0.34–2.70 |
| 2013 | 4.2 | 18/425 | 1.65 | 0.77–3.54 | 2.87* | 1.13–7.30 |
| 2014 | 6.2 | 26/421 | 2.46* | 1.20–5.04 | 2.90* | 1.17–7.19 |
| 2015 | 7.0 | 30/430 | 2.80** | 1.39–5.67 | 3.23** | 1.34–7.80 |
| 2016 | 6.9 | 30/433 | 2.78** | 1.38–5.63 | 3.43** | 1.38–8.53 |
| 2017 | 4.7 | 23/492 | 1.83 | 0.88–3.80 | 2.22 | 0.88–5.61 |
| 2018 | 6.6 | 28/423 | 2.65** | 1.30–5.39 | 3.84** | 1.55–9.51 |
| 2019 | 3.3 | 13/399 | 1.26 | 0.56–2.84 | 1.78 | 0.63–5.06 |
| 2020 | 2.6 | 11/429 | 0.98 | 0.42–2.29 | 1.81 | 0.63–5.22 |

Abbreviations: AED, automated external defibrillator; CI, confidence interval; CPC, cerebral performance category; CPR, cardiopulmonary resuscitation; EMS, emergency medical services; EOA, esophageal obturator airway; m-CPR, mechanical cardiopulmonary resuscitation; NMR, Nagasaki Medical Region; OHCA, out-of-hospital cardiac arrest; OR, odds ratio; PEA, pulseless electrical activity; pVT, pulseless ventricular tachycardia; VF, ventricular fibrillation.

*Parameter was statistically significant at $p<0.05$. **Parameter was statistically significant at $p<0.01$.

10% higher in the SP group, likely because the frequency of cases occurring in public places was 5.8 times higher in the AP group ($p<0.01$), whereas almost 90% of cases occurred at home in the SP group. When comparing SPs vs. APs, the first documented rhythm was asystole in 70.3% vs. 60.9% and VF in 4.4% vs. 6.9% of cases (Table 1), and those were significantly associated with one-month survival with good neurological outcome (Table 2). Bystander-initiated CPR was performed in 47.5% of cases in SPs and 57.5% of cases in APs. Given that both survival and good neurological outcome were worse in SPs than in APs, the worse prognosis for SPs may be related to a significantly lower shockable rhythm. Conversely, the respective rates of m-CPR device and EOA use were 61.3% and 23.2% in SPs and 50.5% and 16.8% in APs ($p<0.01$). Considering that the greatest improvement in the prognosis of OHCA resulted from the use of public-access AEDs in the present study (Table 2), devices such as home AEDs may be a future option to improve the prognosis of OHCA in SPs.

Although there was no difference in time from the EMS call to arrival in the field between SPs and APs, the time from

**TABLE 3** Patient characteristics of OHCA cases in the NMR by year.

| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | *p* for trend |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Median age, years, (IQR) | 78 (66–86) | 78 (62.8–84.3) | 79 (65–86) | 79 (65–87) | 78 (63–86) | 79 (65–86) | 79 (66–86.8) | 81 (67–88) | 79 (67–86) | 79 (68–87) | 0.07 |
| Age group, years, *n* (%) | | | | | | | | | | | |
| 0–9 | 3 (0.7) | 6 (1.5) | 7 (1.7) | 4 (1.0) | 3 (0.7) | 6 (1.4) | 5 (1.0) | 6 (1.4) | 0 (0) | 4 (0.9) | 0.36 |
| 10–19 | 1 (0.2) | 5 (1.2) | 1 (0.2) | 3 (0.7) | 7 (1.6) | 5 (1.2) | 0 (0.0) | 1 (0.2) | 1 (0.3) | 4 (0.9) | 0.65 |
| 20–29 | 3 (0.7) | 7 (1.7) | 2 (0.5) | 7 (1.7) | 7 (1.6) | 5 (1.2) | 6 (1.2) | 6 (1.4) | 7 (1.8) | 1 (0.2) | 0.89 |
| 30–39 | 13 (3.1) | 10 (2.5) | 6 (1.4) | 14 (3.3) | 11 (2.6) | 6 (1.4) | 7 (1.4) | 10 (2.4) | 11 (2.8) | 7 (1.6) | 0.29 |
| 40–49 | 22 (5.3) | 19 (4.8) | 16 (3.8) | 17 (4.0) | 25 (5.8) | 16 (3.7) | 31 (6.3) | 16 (3.8) | 11 (2.8) | 13 (3.0) | 0.07 |
| 50–59 | 35 (8.5) | 35 (8.9) | 36 (8.5) | 28 (6.7) | 36 (8.4) | 40 (9.2) | 31 (6.3) | 27 (6.4) | 24 (6.0) | 37 (8.6) | 0.25 |
| 60–69 | 51 (12.4) | 58 (14.8) | 64 (15.1) | 62 (14.7) | 51 (11.9) | 58 (13.4) | 69 (14.0) | 68 (16.1) | 64 (16.0) | 53 (12.4) | 0.55 |
| 70–79 | 98 (23.8) | 82 (20.9) | 93 (21.9) | 80 (19.0) | 89 (20.7) | 94 (21.7) | 105 (21.3) | 68 (16.1) | 86 (21.6) | 108 (25.2) | 0.97 |
| 80–89 | 135 (32.8) | 122 (31.1) | 132 (31.1) | 153 (36.3) | 143 (33.3) | 143 (33.0) | 163 (33.1) | 132 (31.2) | 127 (31.8) | 133 (31.0) | 0.64 |
| 90–99 | 52 (12.6) | 47 (12.0) | 65 (15.3) | 49 (11.6) | 54 (12.6) | 58 (13.4) | 69 (14.0) | 84 (19.9) | 67 (16.8) | 61 (14.2) | **0.01** |
| 100–109 | 2 (0.5) | 2 (0.5) | 3 (0.7) | 4 (1.0) | 4 (0.9) | 2 (0.5) | 6 (1.2) | 5 (1.2) | 1 (0.3) | 8 (1.9) | 0.08 |
| Male, *n* (%) | 223 (52.8) | 234 (57.6) | 215 (50.6) | 228 (54.2) | 242 (56.3) | 241 (55.7) | 277 (56.3) | 243 (57.4) | 226 (56.6) | 241 (56.2) | 0.14 |
| Place of occurrence. *n* (%) | | | | | | | | | | | |
| Home | 270 (64.0) | 262 (64.5) | 265 (62.4) | 245 (58.2) | 268 (62.3) | 255 (58.9) | 289 (58.7) | 261 (61.7) | 255 (63.9) | 287 (66.9) | 0.71 |
| Public place | 132 (31.3) | 128 (31.5) | 145 (34.1) | 165 (39.2) | 143 (33.3) | 167 (38.6) | 186 (37.8) | 149 (35.2) | 132 (33.1) | 137 (31.9) | 0.56 |
| Others | 20 (4.7) | 16 (4.0) | 15 (3.5) | 11 (2.6) | 19 (4.4) | 11 (2.5) | 17 (3.5) | 13 (3.1) | 12 (3.0) | 5 (1.2) | **<0.01** |
| Place ambulance parked | | | | | | | | | | | |
| Sloped place | 96 (22.8) | 92 (22.7) | 79 (18.6) | 83 (19.7) | 89 (20.7) | 101 (23.3) | 91 (18.5) | 67 (15.8) | 74 (18.6) | 74 (17.3) | **<0.01** |
| Accessible place | 326 (77.2) | 314 (77.3) | 346 (81.4) | 338 (80.3) | 341 (79.3) | 332 (76.7) | 401 (81.5) | 356 (84.2) | 325 (81.4) | 355 (82.7) | **<0.01** |
| First documented rhythm | | | | | | | | | | | |
| VF | 28 (6.6) | 29 (7.1) | 27 (6.4) | 23 (5.5) | 30 (7.0) | 26 (6.0) | 34 (6.9) | 28 (6.6) | 22 (5.5) | 25 (5.8) | 0.54 |
| pVT | 1 (0.2) | 1 (0.3) | 1 (0.2) | 1 (0.2) | 0 (0.0) | 1 (0.2) | 1 (0.2) | 1 (0.2) | 1 (0.3) | 0 (0.0) | 0.60 |
| PEA | 101 (23.9) | 109 (26.9) | 106 (24.9) | 100 (23.8) | 97 (22.6) | 107 (24.7) | 113 (23.0) | 103 (24.4) | 87 (21.8) | 108 (25.2) | 0.49 |
| Asystole | 272 (64.5) | 250 (61.6) | 273 (64.2) | 259 (61.5) | 269 (62.6) | 262 (60.5) | 310 (63.0) | 257 (60.8) | 263 (65.9) | 270 (62.9) | 1.00 |
| Others | 20 (4.7) | 17 (4.2) | 18 (4.2) | 38 (9.0) | 34 (7.9) | 37 (8.6) | 34 (6.9) | 34 (8.0) | 26 (6.5) | 26 (6.1) | 0.06 |
| Cardiogenic, *n* (%) | 222 (52.6) | 205 (50.5) | 241 (56.7) | 262 (62.2) | 231 (53.7) | 223 (51.5) | 353 (71.7) | 330 (78.0) | 298 (74.7) | 339 (79.0) | **<0.01** |
| Witnessed | 89 (21.1) | 101 (24.9) | 103 (24.2) | 113 (26.8) | 105 (24.4) | 95 (21.9) | 151 (30.7) | 144 (34.0) | 133 (33.3) | 156 (36.4) | **<0.01** |
| Witnessed by citizens | 72 (17.1) | 83 (20.4) | 79 (18.6) | 95 (22.6) | 89 (20.7) | 81 (18.7) | 128 (26.0) | 117 (27.7) | 113 (28.3) | 134 (31.2) | **<0.01** |
| Shockable rhythm | 21 (4.9) | 22 (5.4) | 12 (2.8) | 16 (3.8) | 19 (4.4) | 18 (4.2) | 17 (3.5) | 21 (5.0) | 15 (3.8) | 18 (4.2) | 0.76 |

(Continues)

**TABLE 3** (Continued)

| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | *p* for trend |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Noncardiac, *n* (%) | 200 (47.4) | 201 (49.5) | 184 (43.3) | 159 (37.8) | 199 (46.3) | 210 (48.5) | 139 (28.3) | 93 (22.0) | 101 (25.3) | 90 (21.0) | **<0.01** |
| Witnessed | 85 (20.1) | 93 (22.9) | 80 (18.8) | 84 (20.0) | 82 (19.1) | 106 (24.5) | 75 (15.2) | 46 (10.9) | 48 (12.0) | 51 (11.9) | **<0.01** |
| Witnessed by citizens | 69 (16.4) | 84 (20.7) | 67 (15.8) | 73 (17.3) | 65 (15.1) | 97 (22.4) | 63 (12.8) | 31 (7.3) | 42 (10.5) | 41 (9.6) | **<0.01** |
| Bystander-initiated CPR, *n* (%) | 196 (46.5) | 199 (49.0) | 216 (50.8) | 239 (56.8) | 234 (54.4) | 261 (60.3) | 284 (57.7) | 250 (59.1) | 249 (62.4) | 250 (58.3) | **<0.01** |
| Bystander-initiated AED use, *n* (%) | 1 (0.2) | 2 (0.5) | 3 (0.7) | 3 (0.7) | 4 (0.9) | 14 (3.2) | 6 (1.2) | 5 (1.2) | 6 (1.5) | 2 (0.5) | 0.10 |
| m-CPR device use, *n* (%) | 137 (32.5) | 177 (43.6) | 218 (51.3) | 225 (53.4) | 211 (49.1) | 249 (57.5) | 272 (55.3) | 235 (55.6) | 253 (63.4) | 275 (64.1) | **<0.01** |
| Intravenous fluid administration, *n* (%) | 24 (5.7) | 49 (12.1) | 40 (9.4) | 49 (11.6) | 61 (14.1) | 100 (23.1) | 118 (24.0) | 122 (28.8) | 131 (32.8) | 165 (38.5) | **<0.01** |
| Epinephrine administration, *n* (%) | 18 (4.3) | 34 (8.4) | 21 (4.9) | 28 (6.7) | 37 (8.6) | 60 (13.9) | 71 (14.4) | 58 (13.7) | 77 (19.3) | 122 (28.4) | **<0.01** |
| EOA, *n* (%) | 49 (11.6) | 47 (11.6) | 57 (13.4) | 41 (9.7) | 69 (16.1) | 69 (15.9) | 99 (20.1) | 98 (23.2) | 110 (27.6) | 134 (31.2) | **<0.01** |
| Endotracheal intubation, *n* (%) | 14 (3.3) | 9 (2.2) | 20 (4.7) | 7 (1.7) | 9 (2.1) | 7 (1.6) | 6 (1.2) | 4 (1.0) | 5 (1.3) | 3 (0.7) | **<0.01** |
| Time from EMS call to arrival in the field, min (SD) | 9.1 (4.3) | 9.6 (4.7) | 9.1 (4.0) | 9.0 (3.9) | 9.4 (4.1) | 9.4 (3.9) | 9.9 (4.7) | 9.9 (4.9) | 10.4 (4.3) | 10.1 (4.1) | **<0.01** |
| Time from EMS arrival to departure, min (SD) | 13.9 (6.2) | 15.4 (7.7) | 14.9 (6.1) | 14.7 (6.5) | 15.9 (7.1) | 16.1 (6.4) | 15.5 (6.9) | 15.3 (6.9) | 15.3 (6.2) | 15.6 (7.9) | **<0.01** |
| Time from EMS departure to hospital arrival, min (SD) | 8.3 (5.9) | 8.8 (7.0) | 10.0 (6.9) | 11.1 (9.2) | 10.6 (7.6) | 11.1 (8.5) | 11.0 (8.1) | 11.7 (8.5) | 10.8 (7.0) | 11.5 (8.7) | **<0.01** |
| Time from EMS call to hospital arrival, min (SD) | 32.3 (10.7) | 34.9 (13.1) | 34.9 (10.9) | 35.8 (13.0) | 37.0 (12.1) | 37.5 (12.5) | 37.4 (13.1) | 37.9 (12.6) | 37.5 (11.3) | 38.0 (12.6) | **<0.01** |
| Number of hospital inquiries | | | | | | | | | | | |
| 1 | 318 (75.4) | 312 (76.9) | 324 (76.2) | 325 (77.2) | 335 (77.9) | 334 (77.1) | 375 (76.2) | 302 (71.4) | 291 (72.9) | 311 (72.5) | **0.04** |
| 2 | 61 (14.5) | 55 (13.6) | 56 (13.2) | 53 (12.6) | 54 (12.6) | 54 (12.5) | 74 (15.0) | 63 (14.9) | 58 (14.5) | 70 (16.3) | 0.19 |
| 3 | 31 (7.4) | 19 (4.7) | 30 (7.1) | 28 (6.7) | 23 (5.4) | 34 (7.9) | 30 (6.1) | 41 (9.7) | 24 (6.0) | 26 (6.1) | 0.61 |
| 4 | 10 (2.4) | 12 (3.0) | 13 (3.1) | 11 (2.6) | 13 (3.0) | 10 (2.3) | 11 (2.2) | 9 (2.1) | 15 (3.8) | 9 (2.1) | 0.78 |
| ≥5 | 2 (0.5) | 8 (2.0) | 2 (0.5) | 4 (1.0) | 5 (1.2) | 1 (0.2) | 2 (0.4) | 8 (1.9) | 11 (2.8) | 13 (3.0) | **<0.01** |
| Outcomes | | | | | | | | | | | |
| ROSC before hospital arrival, *n* (%) | 19 (4.50) | 31 (7.64) | 42 (9.88) | 55 (13.06) | 62 (14.42) | 66 (15.24) | 66 (13.41) | 58 (13.71) | 50 (12.53) | 50 (11.66) | **<0.01** |
| Survival, *n* (%) | 17 (4.0) | 24 (5.9) | 29 (6.8) | 40 (9.5) | 39 (9.1) | 41 (9.5) | 38 (7.7) | 37 (8.8) | 21 (5.3) | 22 (5.1) | 0.65 |
| CPC 1–2, *n* (%) | 11 (2.6) | 10 (2.5) | 18 (4.2) | 26 (6.2) | 30 (7.0) | 30 (6.9) | 23 (4.7) | 28 (6.6) | 13 (3.3) | 11 (2.6) | 0.51 |

Abbreviations: AED, automated external defibrillator; CPC, cerebral performance category; CPR, cardiopulmonary resuscitation; EMS, emergency medical services; EOA, esophageal obturator airway; IQR, interquartile range; m-CPR, mechanical cardiopulmonary resuscitation; NMR, Nagasaki Medical Region; OHCA, out-of-hospital cardiac arrest; PEA, pulseless electrical activity; pVT, pulseless ventricular tachycardia; ROSC, return of spontaneous circulation; SD, standard deviation; VF, ventricular fibrillation.

arrival to departure was significantly longer in SPs because it took longer for EMS personnel to access the patients and return them to the parking location due to the slope. Therefore, total time from EMS call to hospital arrival in SPs was significantly longer than in APs (38.2 vs. 35.9 min, $p<0.01$). Why the time from departure to hospital arrival was shorter in SPs is unclear, but hospitals accepting the patients might be near SPs, or EMS personnel might have started negotiation with the hospital for patient transfer earlier. The difference in time from EMS call to hospital arrival between the SP and AP groups was significant ($p<0.01$). The performance of m-CPR for OHCA has increased in Japan.[5] Especially in the NMR, m-CPR devices were introduced aggressively during the study period because manual chest compressions are sometimes difficult to perform. Thus, it was important to determine the role of m-CPR in prehospital resuscitation as it can be a powerful treatment adjunct in OHCA.[6] Some articles proved that the use of m-CPR led to a similar survival rate as that of manual CPR,[7–9] but others reported negative effects of using m-CPR devices instead of manual CPR.[10–12] Our multivariable logistic regression analysis showed the use of m-CPR devices to be associated with a worse survival prognosis with good neurological outcomes: The one-month survival rate after m-CPR device use was 2.8%, whereas that without its use was 12.1%. Meanwhile, the EMS personnel used m-CPR devices much more frequently in SPs than in APs. It appears that the conditions of OHCA patients on whom m-CPR devices were used were worse than those of patients on whom they were not used.

Prehospital advanced airway management is reported to increase the rate of 72-h survival in adults,[13] whereas other studies reported lower rates of one-month survival and CPC 1–2.[14,15] Our study's findings were in line with the latter studies. The use of EOA was associated with a negative prognosis: The one-month survival rate (with CPC 1–2) was 0.5% when EOA was used and 5.6% when not used. Similar to m-CPR device use, EOA use may be more frequent in patients with worse conditions. EMS personnel tend to use EOA for patients who do not easily return to spontaneous circulation or when it is difficult to perform mask ventilation. Additionally, EOA takes more time to perform and can lead to a delay in hospital arrival. We also need to confirm whether the use of m-CPR devices and EOA was handled appropriately by EMS personnel.

Unfortunately, there was no significant continuous improvement in survival with a good neurological outcome over the 10 years in the NMR ($p$ for trend >0.05). However, the multivariable analysis showed the ORs for survival to be >1.0 from 2013 to 2020 when 2011 was defined as the reference. Therefore, certain aspects of the EMS system may have been improved over the 10 years despite an increase in EMS response time. One example is the increased rate of bystander-initiated CPR, which was higher than that of the nationwide data and was associated with good neurological outcomes (data not shown). However, the rate of factors such as bystander-initiated AED use was low compared to the relatively high rate of bystander-initiated CPR and did not improve significantly during the study period. Although total bystander-initiated AED use was 1.1% (46/4280) of the cases overall in the present study, bystander-initiated use of AEDs accounted for 3.6% (36/991) among the witnessed cardiac arrests of cardiac origin (data not shown). In contrast, data from the Fire and Disaster Management Agency showed a rate of bystander-initiated AED use of 4.3% (10,780/250,526) over the same 10-year period.[16] The results of the present study indicate low AED use considering that NMR is the prefectural capital. The availability of AEDs increased significantly during the study period.[17] AEDs are currently located in several places, not only in public sites such as entertainment centers, railway stations, and sports facilities but also in private firms and schools,[18] but they need to be used more effectively.[19] We suggest that training be provided for citizens to improve their knowledge of how to use AEDs and, consequently, to increase the percentages of bystander-initiated AED use and CPR to improve the prognosis of OHCA in the NMR.

## Limitations

The present study has several limitations. First, we could only access neurological status at 1 month after OHCA, and longer analysis was not available. Second, SP and AP data were collected specifically in the NMR according to the subjective judgment of EMS personnel. Therefore, the definition of place was slightly ambiguous. Third, we did not include the time from witnessing OHCA to CPR in the multivariable analysis. Although this time is considered one of the most important prognostic indicators, the present study included patients with unwitnessed OHCA and cases for which the time of bystander-initiated CPR was unknown. Therefore, the parameter could not be included in the analysis. Finally, a cause-and-effect relationship related to m-CPR device or EOA use could not be clarified; therefore, a randomized controlled study will be necessary in the future.

# CONCLUSIONS

Despite significant increases in bystander-initiated CPR and m-CPR and EOA use, the prognosis of OHCA in the NMR did not significantly improve from 2011 to 2020. Although the percent of patients with CPC 1–2 was significantly smaller in SPs compared to APs, the ambulance parking place was not associated with CPC 1–2 by multivariable analysis. Rather, the factors associated with CPC 1–2 in the multivariable analysis were age group, witness status, first documented rhythm, bystander-initiated CPR, bystander-initiated AED use, use of m-CPR devices or EOA, and year. The rate of AED use was low for the relatively high rate of bystander-initiated CPR performed and showed no significant increase during the study period. Therefore, interventions to increase bystander-initiated CPR and AED use may help to improve outcomes of OHCA in the NMR.

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## CONFLICT OF INTEREST STATEMENT

Dr. Osamu Tasaki is an Editorial Board member of the *Acute Medicine & Surgery* journal and a co-author of this article. To minimize bias, he was excluded from all editorial decision-making related to the acceptance of this article for publication.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

## ETHICS STATEMENT

Approval of the research protocol: Nagasaki University Hospital Clinical Research Ethics Committee (No. 22062022).
Informed consent: N/A.
Registry and the registration no. of the study/trial: N/A.
Animal Studies: N/A.

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