BMJ Open Benefits of adding a physician-staffed ambulance to bystander-witnessed out-of-hospital cardiac arrest: a community-based, observational study in Niigata, Japan

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ABSTRACT

Objective This study aimed to assess the benefits of adding a physician-staffed ambulance to bystander-witnessed out-of-hospital cardiac arrest using a community-based registry.

Design Population-based, retrospective cohort study.

Setting An urban city with approximately 800 000 residents.

Participants Patients aged ≥18 years with bystander-witnessed out-of-hospital cardiac arrests of medical aetiology in Niigata City, Japan, between January 2012 and December 2016, according to the Utstein style.

Primary and secondary outcome measures The primary outcome was 1-month survival with a favourable neurological outcome, defined as a cerebral performance category score of 1 or 2. We used logistic regression analysis to assess the association between favourable neurological outcome and prehospital physician involvement.

Results During the study period, a total of 4172 cardiac arrests were registered; of these, 892 patients with out-of-hospital cardiac arrest were eligible for this analysis, among whom 135 (15.1%) had prehospital physician involvement and 757 (84.9%) did not have prehospital physician involvement. The percentage of favourable neurological outcomes was 20.7% (28 of 135) in those with physician involvement and 10.4% (79 of 757) in those without physician involvement ($p=0.001$). Using multivariable logistic regression, prehospital physician involvement had an OR for a favourable neurological outcome of 3.44 (95% CI 1.64 to 7.23).

Conclusions Among adults with out-of-hospital cardiac arrest, adding a physician-staffed ambulance was associated with significantly greater favourable neurological outcomes than standard emergency medical services.

INTRODUCTION

Out-of-hospital cardiac arrest (OHCA) is a major public health issue in the industrialised world.^{1 2} The rate of survival after an OHCA has continued to increase as improvements

Strengths and limitations of this study

- This study investigated the benefits of adding a physician-staffed ambulance to bystander-witnessed out-of-hospital cardiac arrest using a population-based registry.
- This study assessed the impact of well-established physician-staffed ambulance services that collaborate with emergency medical service (EMS) personnel without variation in EMS provision among different regions in Japan.
- We focused on bystander-witnessed cardiac arrests, which is helpful since this group has the highest survival rate.
- We did not adjust for baseline characteristics such as pre-existing illness.
- We did not adjust for characteristics concerning in-hospital or postresuscitation care.

are made in 'chain of survival' linkages, that is, the early activation of emergency medical services (EMS), early cardiopulmonary resuscitation (CPR), early defibrillation, rapid patient transport to the emergency department and postcardiac arrest care.²⁻⁴

Optimal EMS configurations and staffing for out-of-hospital CPR remain controversial.⁵ Whether prehospital physician-staffed advanced life support services should be provided is still a matter of debate.⁶⁻⁹ Physician-staffed ambulances are in use in many European countries,^{6 7 10 11} while paramedics in the USA are permitted to provide highly advanced support partially because physician-staffed ambulances are considered an inefficient use of physician resources.¹² One meta-analysis showed that EMS physician-guided CPR is associated with improved return of spontaneous circulation (ROSC) rates, hospital admission rates and hospital

discharge rates compared with paramedic-guided CPR in patients with OHCA.⁵ In that meta-analysis, two studies that used data obtained between 2005 and 2010 in Japan comprised almost 90% of the total sample size; therefore, those two studies had undue weight within the overall results.^{13 14} Most EMS in Japan were limited to providing advanced life support during the period between 2005 and 2010 because since July 2004 specially trained emergency life-saving technicians (ELSTs) were permitted to insert tracheal tubes, and since April 2006 they have been permitted to administer intravenous epinephrine under online medical control direction.¹⁵ However, the rate of administration for intravenous epinephrine was low (6.25%) in the non-physician group, as compared with administration of epinephrine in European countries.^{7 14} Moreover, variation in EMS provision among different regions and countries has made it difficult to isolate the effects of physician-staffed advanced life support compared with ELST-delivered advanced life support.

The purpose of this study was to compare the effectiveness of adding a physician-staffed ambulance with that of standard EMS in terms of the outcomes in adults, using a community-based registry.

METHODS

Study design and participants

This study comprised an analysis of the Utstein Registry of the Fire and Disaster Management Agency, a prospective, population-based registry system for OHCA in Niigata City between 2012 and 2016. This study included all patients ≥ 18 years of age with a bystander-witnessed OHCA of medical origin. Based on the international Utstein style, medical origin includes cases in which the cause of the cardiac arrest is presumed to be cardiac, other medical cause (eg, anaphylaxis, asthma, gastrointestinal bleeding) and in which there is no obvious cause of the cardiac arrest.¹⁶ Diagnoses were made by the overseeing physician in collaboration with the EMS rescuers. We excluded OHCA of non-medical origin, unwitnessed OHCA, EMS-witnessed OHCA, OHCA witnessed in long-term care facilities and patients with OHCA who had undergone transfer between hospitals from our analysis.

A physician-staffed ambulance service in Niigata

Whether a physician-staffed ambulance service is implemented depends on the area in Japan because of a shortage of emergency physicians. In limited areas, physician-staffed ambulances are available. Moreover, a helicopter medical service is available in 43 prefectures.^{17–19}

Niigata City, located on the north-west coast of Japan, has a population of 800 000 people. EMS in Niigata City are two-tiered only when it is indicated for the protocol of physician-staffed ambulance service, and the physician-staffed ambulance service is available all day unless active on another emergency call; therefore, a physician-staffed ambulance service cannot be activated if it is being used to treat another patient, if it has been dispatched and

is en route to another patient, or if the emergency call has not been recognised by a dispatch centre as a situation conforming to protocol. In addition, a physician who is in charge of physician vehicle works concurrently in emergency department or intensive care unit in our hospital because we have a few emergency physicians and intensivists. Therefore, a physician-staffed ambulance service cannot be activated if emergency department or intensive care unit is busy. Niigata City has 2 tertiary care hospitals, 25 ambulances and 1 physician-staffed ambulance. Two tertiary care hospitals are certificated as critical care medical centre (CCMC) in Japan. In order to be licensed as a CCMC, a hospital needs to have ≥ 20 beds and an intensive care unit for critically ill patients, and it should be able to provide highly specialised procedures such as extracorporeal membrane oxygenation or percutaneous coronary intervention, and target temperature management 24 hours a day.²⁰ The physician-staffed ambulance comprises one emergency physician with >1 year of experience in an emergency department and three crewmembers trained in rescue, stabilisation, transportation and advanced care in traumatic and medical emergencies. Further, two of the three crewmembers are qualified ELSTs who are permitted to use invasive alternative airways, such as a laryngeal mask airway and the Combitube, to treat patients with cardiac arrest.¹⁷ For those who have completed the Additional National Standard Training course, tracheal intubation is the treatment of choice in the management of patients with cardiac arrest. Authorised ELSTs are able to administer epinephrine. ELSTs are allowed to use advanced airways, intravenous line and epinephrine administration only under online medical control direction. Indications for activating the physician-staffed ambulance service are as follows: bystander-witnessed cardiac arrest, severe trauma, stroke, acute coronary syndrome, anaphylactic shock or a mass casualty incident. Once a dispatch centre receives an emergency call, dispatchers request both a physician-staffed ambulance from an emergency medical centre in Niigata City General Hospital and an ambulance from the nearest emergency medical centre if the patient is suspected to have one of the above emergencies. In the case where an ambulance arrives first on scene, physician-staffed ambulance is sometimes cancelled by the ambulance personnel when the ELSTs do not need physician on scene, for example, the ELSTs consider the low probability of favourable outcome. In contrast, a standard ambulance is staffed with three crewmembers, including at least one ELST. These crewmembers are trained in rescue, stabilisation, transportation and advanced care in traumatic and medical emergencies.

Data collection

Data on patient characteristics (sex and age), bystander characteristics (bystander CPR and bystander defibrillation with automated external defibrillator), cardiac arrest characteristics (first documented rhythm and aetiology of cardiac arrest) and prehospital care characteristics

(intravenous catheter insertion, epinephrine administration, advanced airway management and prehospital physician involvement) were collected from a community-based Utstein registry.

Outcome measures

The primary outcome was 1-month survival with a favourable neurological outcome. Neurological outcome was assessed by inpatient-attending physicians using the Glasgow-Pittsburgh cerebral performance category scores 1 month post-OHCA. A cerebral performance category score of 1 (good performance) or 2 (moderate disability) was considered a favourable neurological outcome, and a cerebral performance category score of 3 (severe disability), 4 (vegetative state) or 5 (death) was considered a poor neurological outcome.²¹ The secondary outcome was 1-month survival rate and ROSC prior to arrival at hospital.

Statistical analysis

Univariate analyses were performed with χ^2 tests and Fisher's exact tests for dichotomous variables and Mann-Whitney U tests for continuous variables.

Multivariable analyses for bystander-witnessed OHCA were used to assess factors associated with 1-month survival with a favourable neurological outcome using logistic regression models, and ORs with 95% CIs were calculated. Potential confounding factors based on biological plausibility and previous studies were included in the multivariable analysis.^{22 23} These variables included age (18–74 years, ≥ 75 years), sex (male, female), cause of cardiac arrest (cardiac, non-cardiac), first documented rhythm (shockable (ventricular fibrillation or ventricular tachycardia), non-shockable), public-access automated external defibrillator use (yes, no), bystander-initiated CPR (yes, no), dispatcher instruction (yes, no), response time, intravenous fluids and epinephrine administration (yes, no), and advanced airway management (yes, no). In the subgroup analyses, we stratified the model according to first documented rhythm, epinephrine administration and advanced airway management. Furthermore, we assessed interactions between a 1-month survival rate with a favourable neurological outcome and the presence of a physician according to first documented rhythm, epinephrine administration and advanced airway management using generalised linear models. We entered the time from call to epinephrine administration as variables into the stratified analysis according to epinephrine administration. The threshold for significance was $p < 0.05$. All statistical analyses were conducted using SPSS V.23.0.

Patient and public involvement

No patients or public were involved in this study design, conduct or analysis.

RESULTS

During the 5-year study period, resuscitation attempts were performed in 4172 cardiac arrests (figure 1). Of the 3146 patients with OHCA of medical origin, 1350 were witnessed by bystanders, and of these 892 patients were eligible for our analyses.

Patient characteristics

Patients' characteristics according to prehospital physician involvement are listed in table 1. A total of 135 (15.1%) patients with OHCA were attended to by a physician prior to hospital arrival, whereas 757 (84.9%) patients were treated by EMS personnel only. When comparing patients who did and did not have prehospital physician involvement, the patients were younger, a greater number of victims had received dispatch CPR instructions, more patients had a shockable rhythm at first rhythm check, more patients received epinephrine administration, and transport time was longer in the physician involvement group. In total, 60.9% of patients received epinephrine administration and $>90\%$ of patients received an advanced airway; however, only few endotracheal intubations were performed in both groups.

The association between physician involvement and outcome

Overall, 20.7% of patients with OHCA with physician involvement and 10.4% of patients with OHCA without physician involvement were alive after 1 month with a favourable neurological outcome (OR=2.25, 95% CI 1.39 to 3.62; adjusted OR=3.44, 95% CI 1.64 to 7.23) (tables 2 and 3). Similar positive associations were observed for the ROSC prehospital arrival and 1-month survival rate (tables 2 and 3).

In the subgroup analyses, physician involvement was positively associated with a favourable neurological

Figure 1 Patients with out-of-hospital cardiac arrests during the study period and patients included in the analysis.

Table 1 Characteristics of patients with witnessed out-of-hospital cardiac arrests of medical origin according to prehospital physician involvement

	All		Physician present		Physician absent		P value*
	N=892	%	n=135	%	n=757	%	
Age, median (IQR)*†	77 (64–85)		66 (57–78)		78 (66–86)		<0.001
18–74	403	45.2	89	65.9	314	41.5	
≥75	489	54.8	46	34.1	443	58.5	
Female sex	295	33.1	48	35.6	247	32.6	0.505
Dispatcher instructions	446	50.0	96	71.1	350	46.2	<0.001
Location							0.494
Home	658	73.8	100	74.1	558	73.7	
Work	29	3.3	7	5.2	22	2.9	
Public area	158	17.7	22	16.3	136	18.0	
Other	47	5.3	6	4.4	41	5.4	
Bystander CPR	453	50.8	81	60.0	372	49.1	0.020
Family	245	27.5	46	34.1	199	26.3	
Acquaintance	37	4.1	10	7.4	27	3.6	
Medical staff	26	2.9	7	5.2	19	2.5	
Passers-by	21	2.4	3	2.2	18	2.4	
Other	124	13.9	15	11.1	109	14.4	
Bystander defibrillation with AED*‡	25	2.8	3	2.2	22	2.9	0.462
Cardiac origin	551	61.8	90	66.7	461	60.9	0.204
Shockable rhythm	205	23.0	51	37.8	154	20.3	<0.001
Response time, min, median (IQR)†	9 (7–11)		8 (7–10)		9 (7–11)		0.021
Time from call to defibrillation by EMS, min, median (IQR)†	10 (8–12)		10 (8–13)		10 (8–12)		0.687
Intravenous catheter insertion	637	71.4	110	81.5	527	69.6	0.005
Epinephrine administration	543	60.9	107	79.3	436	57.6	<0.001
Advanced airway management	837	93.8	128	94.8	709	93.7	0.607
Endotracheal intubation	2	0.2	0	0.0	2	0.3	
Time from call to epinephrine administration, min, median (IQR)†	22 (18–27)		20 (17–26)		22 (18–27)		0.029
Scene time†	23 (18–28)		24 (19–28)		23 (18–28)		0.237
≤15 min	109	12.2	12	8.9	97	12.8	
>15 min to <30 min	629	70.5	97	71.9	532	70.3	
≥30 min	154	17.3	26	19.3	128	16.9	
Transport time†	12 (8–17)		15 (9–19)		12 (8–17)		0.007
Time from call to hospital†	44 (37–52)		45 (39–56)		44 (37–52)		0.056

*Comparisons between the 2 groups were evaluated using Mann-Whitney U test for continuous variables and χ^2 test or Fisher's exact test for categorical variables. The bold P values are statistically significant.

†Mann-Whitney U test.

‡Fisher's exact test.

AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; EMS, emergency medical service.

outcome in terms of shockable rhythm, epinephrine administration and advanced airway management (table 4). In addition, 1-month survival rates with a favourable neurological outcome had a statistically significant association with epinephrine administration and with the presence of a physician.

DISCUSSION

In this community-based, observational study, we found that ROSC prior to hospital arrival, 1-month survival rates and favourable neurological outcomes were positively associated with adding a physician-staffed ambulance.

Table 2 Unadjusted survival rate for ROSC prior to hospital arrival, 1-month survival rate and favourable neurological outcome rate

	n (%)			Unadjusted OR (95% CI)	P value*
	All (N=892)	Presence of physician (n=135)	Absence of physician (n=757)		
ROSC prior to hospital arrival	214 (24.0)	60 (44.4)	154 (20.3)	3.13 (2.14 to 4.59)	<0.001
1-month survival	143 (16.0)	37 (27.4)	106 (14.0)	2.32 (1.51 to 3.57)	<0.001
Neurologically favourable survival	107 (12.0)	28 (20.7)	79 (10.4)	2.25 (1.39 to 3.62)	0.001

*Comparisons between the 2 groups were evaluated using χ^2 test. The bold P values are statistically significant.
ROSC, return of spontaneous circulation.

One significant study finding was the improvement in neurological outcome with adding a physician-staffed ambulance. Several prior studies have reported associations between prehospital physician involvement and improved survival outcomes,^{5,9,14} but these studies did not assess neurological outcomes for surviving patients. The underlying mechanism of our findings may be multifactorial. A previous report showed that the combination of bystander CPR and advanced cardiac life support provided by physicians was the best approach for improving neurological outcome.¹³ Another nationwide study performed in Japan also reported that physician-staffed ambulances were associated with improved favourable neurological outcomes.²⁴ However, in a previous nationwide study, there were wide variations in physician-staffed ambulance services (eg, whether a physician-staffed ambulance was requested from EMS at the scene, and in the skill sets of the attending physicians in the ambulances), compared with

our well-established physician-staffed ambulance services that collaborate with EMS personnel, which might have resulted in our better outcome rates. In addition, physicians are more likely to comply with treatment guidelines and to possess up-to-date knowledge than other ambulance personnel.^{7,25} Physicians are also reportedly more efficient in managing procedures such as ECG analysis and team management.^{7,26} The presence of physicians as a designated team leader, with experience and knowledge to provide oversight during resuscitation, may explain the increased focus on quality of care.¹⁴ On the other hand, another reason is that more personnel on scene might be associated with improved survival of OHCA or favourable neurological outcome rather than the presence of a physician. A prior observational study has shown that having five or more EMS personnel on scene was associated with higher rate of survival to hospital discharge.²⁷ Another observational study in Japan also demonstrated

Table 3 Multivariable associations of prehospital predictors with outcomes

	ROSC prior to hospital arrival	1-month survival rate	Neurologically favourable outcome
	Adjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)
Primary exposure			
Presence of physician	2.69 (1.73 to 4.19)	2.60 (1.41 to 4.78)	3.44 (1.64 to 7.23)
Absence of physician	1 (reference)	1 (reference)	1 (reference)
Covariates			
Age	2.03 (1.39 to 2.97)	2.90 (1.68 to 5.01)	5.70 (2.81 to 11.58)
Sex	1.03 (0.70 to 1.52)	0.79 (0.46 to 1.39)	0.70 (0.36 to 1.38)
Dispatcher instruction	1.34 (0.88 to 2.05)	0.93 (0.52 to 1.65)	0.87 (0.44 to 1.73)
Bystander CPR	0.67 (0.43 to 1.02)	1.28 (0.71 to 2.31)	1.41 (0.69 to 2.87)
Bystander AED	1.72 (0.67 to 4.44)	2.12 (0.66 to 6.85)	2.80 (0.78 to 10.02)
Cardiac origin	1.07 (0.71 to 1.60)	4.73 (2.28 to 9.81)	4.87 (2.00 to 11.86)
Shockable rhythm	3.94 (2.53 to 6.13)	8.39 (4.69 to 15.00)	7.87 (3.82 to 16.21)
Response time	0.93 (0.88 to 0.99)	0.93 (0.86 to 1.01)	0.95 (0.87 to 1.04)
Intravenous fluids	1.30 (0.80 to 2.12)	1.07 (0.56 to 2.03)	0.76 (0.36 to 1.60)
Epinephrine administration	0.53 (0.34 to 0.83)	0.18 (0.09 to 0.33)	0.08 (0.04 to 0.17)
Advanced airway management	0.38 (0.19 to 0.74)	0.12 (0.05 to 0.28)	0.09 (0.04 to 0.24)

AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; ROSC, return of spontaneous circulation.

Table 4 Stratified analyses for outcomes according to first documented rhythm, epinephrine administration and advanced airway management

Stratification	Neurologically favourable outcome		P value for interaction*
		%	Adjusted OR (95% CI)
First documented rhythm			0.159
Shockable			
Physician present	23/51	45.1	4.09 (1.57 to 10.64)*
Physician absent	54/154	35.1	Reference
Non-shockable			
Physician present	5/84	6.0	3.16 (0.86 to 11.68)*†
Physician absent	25/603	4.1	Reference
Epinephrine administration			0.001
Yes			
Physician present	13/107	12.1	3.29 (1.21 to 8.94)†‡
Physician absent	12/436	2.8	Reference
No			
Physician present	15/28	53.6	2.77 (0.73 to 10.52)‡§
Physician absent	67/321	20.9	Reference
Advanced airway management			0.378
Yes			
Physician present	23/128	18.0	3.25 (1.49 to 7.06)§¶
Physician absent	55/709	7.8	Reference
No			
Physician present	5/7	71.4	Not analysed
Physician absent	24/48	50.0	Reference

*The bold P values are statistically significant.

†Adjusted for age, sex, cause of cardiac arrest, public-access AED use, bystander-initiated CPR, dispatcher instruction, response time, intravenous fluids, epinephrine administration and advanced airway management.

‡Adjusted for age, sex, cause of cardiac arrest, first documented rhythm, public-access AED use, bystander-initiated CPR, dispatcher instruction, response time, intravenous fluids, advanced airway management and time from call to epinephrine.

§Adjusted for age, sex, cause of cardiac arrest, first documented rhythm, public-access AED use, bystander-initiated CPR, dispatcher instruction, response time, intravenous fluids and advanced airway management.

¶Adjusted for age, sex, cause of cardiac arrest, first documented rhythm, public-access AED use, bystander-initiated CPR, dispatcher instruction, response time, intravenous fluids and epinephrine administration.

AED, automated external defibrillator; CPR, cardiopulmonary resuscitation.

that on-scene three-ELST group was associated with improved favourable neurological outcome from OHCA compared with on-scene one-ELST group.²⁸ Therefore, more personnel on scene might be more important than the presence of prehospital physician in the current system.

In the subgroup analyses, patients with prehospital physician involvement had neurological outcomes that were more favourable in all situations. However, a significant improvement in outcome was noted when epinephrine was administered. Previous studies have shown that a shorter time to epinephrine administration is associated with better patient outcomes after in-hospital cardiac arrest.^{29–31} Physicians may have more experience in establishing vascular access. In addition, physicians can use intraosseous access, while EMS personnel are

not permitted to establish intraosseous access in Japan. Furthermore, ELSTs are allowed to administer epinephrine and intravenous fluid as well as intubate only after calling a physician, which might create an added delay for EMS drive care. Therefore, extending the procedures done by ELSTs might also be a solution as the paramedics in countries like the USA or Canada are allowed. In our study, there was a significant decrease in the time from the call to epinephrine administration in patients with prehospital physician involvement compared with patients without prehospital physician involvement. In contrast, there was no significant interaction in terms of performing advanced airway management. In Japan, ELSTs are permitted to use supraglottic airway devices. According to our study, more than 90% of patients received an advanced airway, and most of these involved

supraglottic airway devices. Because ELSTs are familiar with supraglottic airway devices,¹⁷ superiority with advanced airway management by physicians may not have been shown.

The baseline characteristics of the patients who did and did not have prehospital physician involvement differed in our study. Unfortunately, we did not know the detailed reason why the physician-staffed ambulance was not dispatched on the 757 cases and the number in which the first arriving ambulance cancelled the physician ambulance. Therefore, selection bias might exist. We also consider that observational studies cannot avoid such selection bias, but we believe our findings provide important suggestions to perform a randomised controlled trial in the future which will reveal the actual impact of physician-staffed ambulance service. On the other hand, the cost and availability of physician ambulance vehicle would need to be considered if physician-staffed ambulance services were proved to be effective. It is impractical to dispatch physicians to all witnessed OHCA patients when considering limited cost and resource; therefore, increasing EMS personnel on scene or extending the procedures done by ELSTs like in North America (eg, administer intravenous epinephrine without online medical control direction or establish intraosseous access) might be a solution.

Limitations

Our study has some limitations. First, our analyses could not adjust for characteristics concerning in-hospital or postresuscitation care. However, it appears likely that most patients with OHCA were transported to specific certified hospitals that perform postresuscitation care in Niigata City. Second, this study could not adjust baseline characteristics such as pre-existing illness, which might affect the outcome of OHCA. Third, although this observational study adjusted for as many covariates as possible, we could not exclude possible residual confounding factors. Finally, some of the basic characteristics were different between patients with and without prehospital physician involvement. Selection bias as mentioned above might exist. However, we adjusted for such factors to the best of our ability and excluded OHCA occurring in long-term care facilities where physician-staffed ambulances are frequently cancelled because of the low probability of a favourable outcome. Moreover, the physician-staffed ambulance service was essentially available 24/7 unless the physicians were attending to other patients, or if they had been dispatched and were en route to other patients, or the dispatch centre did not recognise a witnessed OHCA, or if emergency department or intensive care unit is busy because a physician who is in charge of a physician vehicle works concurrently in emergency department or intensive care unit in our hospital. Furthermore, a randomised controlled study would seem reasonable to adjust the baseline differences between groups and unmeasured confounder, removing some of

the other differences such as the number of personnel on scene or ability to establish intraosseous access.

CONCLUSIONS

In conclusion, this community-based, observational study found that adding a physician-staffed ambulance was positively associated with 1-month survival and with favourable neurological outcomes. Further prospective research such as a randomised controlled trial will be warranted.

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Contributors NS conceived the study. TM, KA, KN and YH supervised the conduct of the trial and data collection. NS managed the data, including quality control. TM and KA provided statistical advice on the study design and analysed the data. NS chaired the data oversight committee. NS, TM and YH drafted the manuscript, and all authors contributed substantially to its revision. NS takes responsibility for the paper as a whole. All authors read and approved the final manuscript.

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Patient consent for publication Not required.

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