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Monophasic versus biphasic defibrillation for pediatric out-of-hospital cardiac arrest patients: a nationwide population-based study in Japan

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Abstract

Introduction: Conventional monophasic defibrillators for out-of-hospital cardiac-arrest patients have been replaced with biphasic defibrillators. However, the advantage of biphasic over monophasic defibrillation for pediatric out-of-hospital cardiac-arrest patients remains unknown. This study aimed to compare the survival outcomes of pediatric out-of-hospital cardiac-arrest patients who underwent monophasic defibrillation with those who underwent biphasic defibrillation.

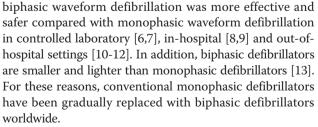
Methods: This prospective, nationwide, population-based observational study included pediatric out-of-hospital cardiac-arrest patients from January 1, 2005, to December 31, 2009. The primary outcome measure was survival at 1 month with minimal neurologic impairment. The secondary outcome measures were survival at 1 month and the return of spontaneous circulation before hospital arrival. Multivariable logistic regression analysis was performed to identify the independent association between defibrillator type (monophasic or biphasic) and outcomes.

Results: Among 5,628 pediatric out-of-hospital cardiac-arrest patients (1 through 17 years old), 430 who received defibrillation shock with monophasic or biphasic defibrillator were analyzed. The number of patients who received defibrillation shock with monophasic defibrillator was 127 (30%), and 303 (70%) received defibrillation shock with biphasic defibrillator. The survival rates at 1 month with minimal neurologic impairment were 17.5% and 24.4%, the survival rates at 1 month were 32.3% and 35.6%, and the rates of return of spontaneous circulation before hospital arrival were 24.4% and 27.4% in the monophasic and biphasic defibrillator groups, respectively. Hierarchic logistic regression analyses by using generalized estimation equations found no significant difference between the two groups in terms of 1-month survival with minimal neurologic impairment (odds ratio (OR), 1.57; 95% confidence interval (CI), 0.87 to 2.83; P = 0.14) and 1-month survival (OR, 1.38; 95% CI, 0.87 to 2.18; P = 0.17).

Conclusions: The present nationwide population-based observational study could not confirm an advantage of biphasic over monophasic defibrillators for pediatric OHCA patients.

Introduction

Ventricular fibrillation (VF) accounts for 5% to 15% of out-of-hospital cardiac arrests (OHCAs) in children [1-4]. In such patients, early defibrillation may improve the outcome [4,5]. Depending on the wave pattern used in the defibrillation shock for VF, two types of defibrillator are used: monophasic and biphasic. It was reported that



However, human studies comparing the two types of defibrillators have been performed only with adult patients. Even in a controlled laboratory setting or in-hospital



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setting, to our knowledge, no data compare the outcomes of defibrillation with different waveforms for pediatric OHCA patients. Thus, the advantage of a biphasic over a monophasic defibrillator for pediatric OHCA patients remains unknown.

In the present study, we used the nationwide OHCA registry database in Japan [14] to compare neurologically intact survival outcomes of pediatric OHCA patients who underwent defibrillation with a monophasic or biphasic defibrillator.

Materials and methods

Study design and data source

Our study used the All-Japan Utstein Registry database, which is a prospective, nationwide, population-based registry system of OHCA patients who are transferred to hospital by emergency medical service (EMS) providers [14]. Because only one nationwide emergency transport service system exists in Japan, all OHCA cases in which the patients were transported to hospital are registered in this database. Except for those with decapitation, incineration, decomposition, rigor mortis, or dependent cyanosis, almost all OHCA patients who are treated by EMS personnel are transported to hospital [14]. Therefore, patients in this database are representative of all OHCA patients in Japan.

The present study enrolled all pediatric patients aged 1 to 17 years who were transported to hospital by EMS personnel during 5 consecutive years from January 1, 2005, through December 31, 2009. In this period, because EMS personnel are allowed to perform defibrillation only on patients aged 1 year or older, the subjects in this study were those aged 1 year or older. Given the anonymous nature of the data, informed consent was waived. The study was approved by the Ethics Committee of Nara Medical University.

EMS system in Japan

Japan has approximately 128 million residents (as of 2007) in an area of approximately 378,000 km², and residents aged 17 years or younger account for 16% (21 million) of the population. The universal emergency telephone number of 119 directly connects to the regional fire defense headquarters. On acceptance of an emergency call, the nearest available ambulance is dispatched to a scene. All expenses are covered by the local government; the patient does not bear emergency treatment or transportation expenses. Except for limited areas where physicianmanned ambulances or helicopters are available, the EMS system is a one-tiered response system [15].

Each ambulance has three EMS staff who can all perform cardiopulmonary resuscitation 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 [16]. Since October 2006, resuscitation has been based on the respective 2005 Guidelines [14,17]. In Japan, EMS personnel can give only epinephrine and cannot give amiodarone.

Automated external defibrillator

Each ambulance is equipped with one automated external defibrillator (AED). Either a monophasic or a biphasic defibrillator is applied to OHCA patients, according to the type of defibrillator on the EMS ambulance. The monophasic defibrillator models used in the present study were Heart Start 3000/3000QR (Laerdal Medical, Stavanger, Norway), LIFEPAK 12A (Medtronic), TEC 2202/2203/2212/2213, and AED-9100/9110 (Nihon Kohden). The monophasic defibrillators delivered either monophasic damped sine defibrillator waveforms or monophasic truncated exponential waveforms, according to the type of defibrillator on each EMS ambulance.

Biphasic defibrillator models were Heart Start MRxE/ MRx, Heart Start FRx, Heart Start FR2/FR2+, Heart Start 4000, Heart Start HS1, Heart Start XL (Philips Medical Systems, Seattle, WA, USA), AED-9200/9210, AED-9231/9211/9201, AED-1200, AED-2100, TEC-2312/2313, TEC-2503/2513 (Nihon Kohden, Tokyo, Japan), or LIFE-PAK 500B, LIFEPAK 1000, LIFEPAK 12B, and LIFEPAK CR-Plus (Medtronic, Minneapolis, MN, USA). All biphasic defibrillators in this study delivered the biphasic truncated exponential waveform.

EMS personnel used the both monophasic and biphasic defibrillators in AED mode, not manual mode. The defibrillation energy dose was set at the level for adults. The recommended adult dose of the monophasic defibrillator was initially 200 J, and thereafter, 360 J. The biphasic defibrillator energy dose was set at the level recommended by the manufacturer. For children aged 1 to 8 years, defibrillation was performed by using self-adhesive pad electrodes with pediatric attenuator systems. For children aged 9 to 17 years, a self-adhesive pad without pediatric attenuator systems was used in the same way as in adults.

Data collection and quality control

All OHCA patient information was input by using an online entry form by EMS personnel, which basically conformed to the Utstein form, with some additions. The data were anonymized at the local fire departments and then transferred to the Fire and Disaster Management Agency (FDMA) and stored [18,19]. The data were checked, and if any were missing, the FDMA informed the corresponding regional fire department, and the data were corrected [18].

The main database items included patient age, sex, bystander-witness status, receipt of bystander CPR, receipt of defibrillation by the EMS, type of defibrillator, and the etiology of the cardiac arrest (cardiac or noncardiac origin). Outcome data included return of spontaneous circulation before arrival at the hospital, survival at 1 month, and neurologic status 1 month after the OHCA [20,21].

The etiology of cardiac arrest was determined by the physician in charge based on physical, laboratory, or radiologic findings, together with scene information obtained from EMS crew [22]. 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. One-month survival and neurologic- status data were collected by EMS personnel from the hospitals that received the patients, in cooperation with the physicians in charge of the patients through a follow-up interview at 1 month after hospital admission [14,20,23].

Study targets and end points

In this study, we focused on pediatric patients who had confirmed shockable rhythms (ventricular fibrillation or pulseless ventricular tachycardia) and received defibrillation shock by EMS personnel. The primary outcome measure was survival at 1 month with minimal neurologic impairment, which was defined as Glasgow-Pittsburgh Cerebral Performance Category 1 (good cerebral performance) or 2 (moderate cerebral disability) [24,25]. The secondary outcome measures were survival at 1 month and the return of spontaneous circulation (ROSC) before hospital arrival.

Statistical analysis

We compared the outcomes of pediatric OHCA patients receiving defibrillation shock with a monophasic waveform defibrillator with those receiving shock with a biphasic waveform defibrillator. Age was dichotomized into children aged 1 through 11 years (children) and 12 through 17 years (adolescents). The time from emergency call to CPR by EMS was divided into the following three categories: early response (0 to 6 minutes), moderate response (7 to 12 minutes), and late response (13 to 18 minutes). Based on the CPR type, the subjects were categorized into 2000 Guideline-based subgroup and 2005 Guideline-based subgroup. Patient characteristics were evaluated by using unpaired Student *t* tests for numeric variables and χ^2 tests for categoric variables. Outcomes by type of defibrillator were compared by using χ^2 tests.

To identify the association between defibrillator type (monophasic or biphasic) and outcomes, we performed multivariate logistic regression analyses with adjustment for age, sex, bystander-witness status, the type of bystander CPR (no bystander CPR, compression-only CPR or conventional CPR), time from emergency call to CPR by EMS (early, moderate, or late response), cause of arrest (cardiac or noncardiac), the type of guideline-based CPR performed (2000 Guideline based or 2005 Guideline based), and calendar year. We assumed that our data were structured hierarchically into two levels of patients and communities. We accounted for clustering of patients within communities by using a generalized estimation equation (GEE). This method is commonly used instead of a traditional regression analysis because patients in the same community may be correlated, thus violating independence assumptions made by traditional regression procedures [26]. All statistical analyses were conducted by using PASW ver. 17.0J (SPSS, Inc., Chicago, IL, USA). All tests were two-tailed, and a P value < 0.05 was regarded as significant.

Results

The total number of OHCA patients (aged 1 through 17 years) was 5,628 during the study period. Patients who had no attempted resuscitation by EMS (n = 283), patients not shocked by EMS (n = 4848), patients lacking information on whether defibrillation shock was done or not (n = n)43; < 0.8%), and patients who underwent defibrillation by a public-access AED by bystanders (n = 24; < 0.4%) were excluded. Consequently, the number of OHCA patients who were shocked for defibrillation by EMS was 430. These 430 patients were eligible for this study. Of the eligible patients, 127 (30%) received shocks with a monophasic defibrillator, and 303 (70%) received shocks with a biphasic defibrillator. Table 1 shows the demographic characteristics of the included pediatric patients. The proportion of patients receiving biphasic waveform defibrillation increased yearly.

Table 2 shows outcomes by type of defibrillator of eligible patients and of subgroups. Neurologic status was not documented for one patient in the monophasic waveform group. Chi-square tests showed no significant differences in any outcome measures between monophasic and biphasic groups in all patients and all subgroups.

Table 3 shows the results of logistic GEE regression analyses. No significant differences were found between the monophasic and biphasic groups in any outcome measures of eligible patients, including ROSC before hospital arrival (odds ratio (OR), 1.46; 95% confidence interval (CI), 0.8 to 2.63; P = 0.20), survival at 1 month (OR, 1.38; 95% CI, 0.87 to 2.18; P = 0.0.17), and survival at 1 month with minimal neurologic impairment (OR, 1.57; 95% CI, 0.87 to 2.83; P = 0.14).

Discussion

Our study showed no significant differences in outcomes between the pediatric OHCA patients who were shocked with a biphasic defibrillator and those who were shocked with a monophasic defibrillator. So far, effective waveform

Table 1 Patient characteristics of the study participants

	Total		Mono	phasic	Biphasic		Р
Number of cases	(n = 4	430)	(<i>n</i> = 127)		(<i>n</i> = 303)		
Year							< 0.001
2005, n (%)	89	(20.7)	48	(37.8)	41	(13.5)	
2006, n (%)	74	(17.2)	30	(23.6)	44	(14.5)	
2007, n (%)	90	(20.9)	26	(20.5)	64	(21.1)	
2008, n (%)	92	(21.4)	15	(11.8)	77	(25.4)	
2009, n (%)	85	(19.8)	8	(6.3)	77	(25.4)	
Age, mean (SD)	12.8	(4.2)	13.3	(3.7)	12.6	(4.4)	0.08
Children (1 to 11 years old), n (%)	119	(27.7)	35	(27.6)	84	(27.7)	0.97
Adolescents (12 to 17 years old), n (%)	311	(72.3)	92	(72.4)	219	(72.3)	
Boys, <i>n</i> (%)	293	(68.1)	84	(66.1)	209	(69.0)	0.56
Witnessed by laypersons, n (%)	287	(66.7)	87	(68.5)	200	(66.0)	0.62
Type of bystander-initiated CPR ^a							0.05
No-CPR, <i>n</i> (%)	193	(45.2)	63	(50.0)	130	(43.2)	
Compression-only CPR, n (%)	97	(22.7)	19	(15.1)	78	(25.9)	
Conventional CPR, n (%)	137	(32.1)	44	(34.9)	93	(30.9)	
Call to CPR by EMS, minutes, mean (SD) ^b	8.9	(5.3)	8.8	(5.3)	9.0	(5.4)	0.34
0 to 6 minutes, <i>n</i> (%)	137	(32.0)	46	(36.5)	91	(30.1)	
7 to 12 minutes, <i>n</i> (%)	236	(55.1)	67	(53.2)	169	(56.0)	
13 to 18 min, <i>n</i> (%)	55	(12.8)	13	(10.4)	42	(13.9)	
CPR by EMS to hospital arrival, minutes, mean (SD)	21.3	(10.5)	21.6	(10.6)	21.1	(10.4)	0.66
Type of origin							0.72
Cardiac, n (%)	272	(63.3)	82	(64.6)	190	(62.7)	
Noncardiac, n (%)	158	(36.7)	45	(35.4)	113	(37.3)	
External causes, n (%)	92	(21.4)	24	(18.9)	68	(22.4)	
Respiratory diseases, n (%)	10	(2.3)	4	(3.1)	6	(2.0)	
Cerebrovascular diseases, n (%)	7	(1.6)	2	(1.6)	5	(1.7)	
Others, n (%)	49	(11.4)	15	(11.8)	34	(11.2)	
CPR guidelines							< 0.001
2000 Guideline based, n (%)	146	(34.0)	74	(58.3)	72	(23.8)	
2005 Guideline based, n (%)	284	(66.0)	53	(41.7)	231	(76.2)	
Number of shocks administered to patients who had ROSC before hospital arrival							
Median (25% to 75%)	1	(1-2)	1	(1-2)	1	(1-2)	0.76

CPR, cardiopulmonary resuscitation. ^aThree (0.7%) patients with missing data were excluded. Percentages were calculated based on the total number of events, excluding those missing data. ^bTwo (0.5%) patients with missing data were excluded. Percentages were calculated based on the total number of events, excluding those missing data. AHA, American Heart Association; CPR, cardiopulmonary resuscitation; SD, standard deviation; EMS, emergency medical service.

types for defibrillation of pediatric VF have not been well determined. Only studies based on animal models report the potential effectiveness of certain types [27-29]. In an animal model of pediatric defibrillation with "infant" and "child" piglets, biphasic were more effective than monophasic waveforms [29]. Regarding human studies, previous studies with adult patients reported that biphasic waveform shock was superior to monophasic waveform shock in terms of safety under controlled laboratory and in-hospital conditions [6,8,9]. Regarding long-term outcomes, no significant difference was detected between the two types of waveform for defibrillation in any observational studies or in four randomized trials for adults [30-34]. In pediatric patients, no studies compared biphasic and monophasic waveforms, even in controlled laboratory or in-hospital settings. To the best of our knowledge, the present study is the first to verify the association of the outcomes and defibrillation with different defibrillator waveforms in pediatric OHCA.

Owing to the results of adult studies comparing the two defibrillators in laboratory and in-hospital settings, or the greater portability of biphasic defibrillators, most monophasic defibrillators were replaced with biphasic defibrillators in ambulances in Japan. This tendency is common worldwide. Biphasic defibrillators may reduce the physical burden on EMS personnel because of their greater portability. With respect to effectiveness, however, the present study showed no significant advantage of biphasic over monophasic defibrillators on meaningful clinical outcomes for pediatric patients.

Table 2 Outcomes of all patients and subgroups.

	ROSC before hospital arrival			Surv mon	ival at 1 th		Survival at 1 month with minimal neurologic impairment					
	n	(%)	Р	n	(%)	Р	n	(%)	Р			
All patients ($n = 430$)												
Monophasic ($n = 127$)	31	24.4%	0.52	41	32.3%	0.50	22	17.5%	0.12			
Biphasic ($n = 303$)	83	27.4%		108	35.6%		74	24.4%				
Age category												
Children (1 to 11 years)												
Monophasic $(n = 35)$	6	17.1%	0.10	9	25.7%	0.51	3	8.6%	0.72			
Biphasic ($n = 84$)	6	7.1%		17	20.2%		9	10.7%				
Adolescents (12 to 17 years)												
Monophasic ($n = 92$)	25	27.2%	0.17	32	34.8%	0.27	19	20.9%	0.11			
Biphasic ($n = 219$)	77	35.2%		91	41.6%		65	29.7%				
Time from emergency call to CPR by EM	S											
Early response (0 to 6 minutes)												
Monophasic ($n = 46$)	13	28.3%	0.35	19	41.3%	0.65	11	24.4%	0.37			
Biphasic ($n = 91$)	33	36.3%		34	37.4%		29	31.9%				
Moderate response (7 to 12 minutes	5)											
Monophasic ($n = 67$)	17	25.4%	0.93	21	31.3%	0.20	10	14.9%	0.12			
Biphasic ($n = 169$)	42	24.9%		68	40.2%		41	24.3%				
Late response (13 to 18 minutes)												
Monophasic ($n = 13$)	1	7.7%	0.33	1	7.7%	0.53	1	7.7%	0.84			
Biphasic ($n = 42$)	8	19.0%		6	14.3%		4	9.5%				
Origin of cardiac arrest												
Cardiac												
Monophasic ($n = 82$)	25	30.5%	0.61	32	39.0%	0.53	19	23.2%	0.059			
Biphasic ($n = 190$)	64	33.7%		82	43.2%		66	34.7%				
Noncardiac												
Monophasic ($n = 45$)	6	13.3%	0.59	9	20.0%	0.68	3	6.8%	0.95			
Biphasic ($n = 113$)	19	16.8%		26	23.0%		8	7.1%				
CPR Guidelines												
2000 Guideline based												
Monophasic ($n = 74$)	17	23.0%	0.12	24	32.4%	0.64	12	16.4%	0.50			
Biphasic ($n = 72$)	25	34.7%		26	36.1%		15	20.8%				
2005 Guideline based												
Monophasic ($n = 53$)	14	26.4%	0.84	17	32.1%	0.64	10	18.9%	0.31			
Biphasic ($n = 231$)	58	25.1%		82	35.5%		59	25.5%				

CPR, cardiopulmonary resuscitation; ROSC, return of spontaneous circulation.

Study limitations

Several limitations of this study should be considered. First, because of the relatively small sample size (n = 430), the present study may have been too underpowered to detect true differences in outcomes between the groups. For example, to detect the true difference in 1-month survival with minimal neurologic impairment (17.5% versus 24.4%), the necessary sample size was estimated to be 1,321 on the basis of a two-sided α value of 0.05 and a β error of 0.20 [35].

Second, the inherent bias in an observational study is a potential limitation. For example, the monophasic EMS users were possibly less well supported by public funds, and received a lower frequency of training and retraining. If true, this could have influenced the results.

Third, data on whether VF was terminated by defibrillation were not collected, so our study could not directly compare the probability of terminating VF after defibrillation. However, 1-month survival with minimal neurologic impairment is considered to be a better outcome measure than the probability of terminating VF.

Fourth, the neurologic outcome in the database was not defined by pediatric Cerebral Performance Category [36].

However, despite these limitations, we believe that our study is valid, given the use of uniform data collection

	ROSC before hospital arrival						ival month				Survival at 1 month with minimal neurologic impairment				
	OR	(95% C	I)		Р	OR	(95% C	I)		Р	OR	(95% C	I)		Р
Age (1-year increase)	1.13	1.06	to	1.21	0.009	1.05	0.98	to	1.11	0.17	1.11	1.03 to		1.20	0.01
Sex															
Boys	Ref.					Ref.					Ref.				
Girls	1.19	0.71	to	1.98	0.51	1.58	1.05	to	2.36	0.03	1.50	0.89	to	2.51	0.13
Witness status															
Witness	Ref.					Ref.					Ref.				
No witness	0.75	0.48 to	to	1.17	0.20	0.55	0.34 to		0.89	0.02	0.40	0.23	to	0.71	0.002
Type of bystander-initiated CPR															
No CPR	Ref.					Ref.					Ref.				
Compression-only CPR	0.81	0.50	to	1.31	0.40	0.85	0.50	to	1.45	0.56	1.32	0.72	to	2.41	0.37
Conventional CPR	1.34	0.87	to	2.06	0.18	1.38	0.91	to	2.08	0.13	1.54	0.87	to	2.73	0.14
Call to CPR by EMS															
0 to 6 minutes	Ref.					Ref.					Ref.				
7 to 12 minutes	0.68	0.44	to	1.06	0.09	1.00	0.65	to	1.53	0.99	0.67	0.36	to	1.27	0.22
13 to 18 minutes	0.46	0.21	to	1.01	0.05	0.26	0.12	to	0.58	0.001 >	0.35	0.12	to	0.97	0.04
Cause of arrest															
Cardiac origin	Ref.					Ref.					Ref.				
Noncardiac origin	0.48	0.28	to	0.83	0.01	0.51	0.31	to	0.85	0.01	0.23	0.11	to	0.49	0.001 >
Type of guideline-based CPR performed															
2000 Guideline based	Ref.					Ref.					Ref.				
2005 Guideline based	0.58	0.17	to	1.95	0.37	1.09	0.41	to	2.89	0.86	1.24	0.34	to	4.47	0.74
Year															
2005	Ref.					Ref.					Ref.				
2006	1.24	0.71	to	2.16	0.45	1.09	0.59	to	2.02	0.78	0.90	0.38	to	2.12	0.81
2007	1.65	0.36	to	7.45	0.52	0.84	0.30	to	2.34	0.74	1.13	0.27	to	4.75	0.86
2008	1.63	0.42	to	6.31	0.48	1.08	0.36	to	3.22	0.89	1.42	0.34	to	5.85	0.63
2009	1.98	0.55	to	7.12	0.29	0.92	0.29	to	2.86	0.88	1.32	0.33	to	5.22	0.70
Defibrillator															
Monophasic	Ref.					Ref.					Ref.				
Biphasic	1.46	0.81	to	2.63	0.20	1.38	0.87	to	2.18	0.17	1.57	0.87	to	2.83	0.14

Table 3 Odds ratios of outcomes for biphasic vs. monophasic defibrillators in the logistic regression models

All models included age, sex, whether the collapse was witnessed by a bystander, the type of bystander CPR performed (no bystander CPR, compression-only CPR, or conventional CPR), time from emergency call to CPR by the EMS (early response, moderate response, or late response), cause of arrest, the type of guideline-based CPR performed (2000 AHA Guideline based or 2005 AHA Guideline based), calendar year and the type of defibrillator (monophasic or biphasic). Regression analyses did not include patients with missing data. OR, odds ratio; CI, confidence interval.

and consistent definitions based on the Utstein guidelines [24,25] and the relatively large sample size as an observational study of pediatric OHCA in a nationwide population-based setting.

Conclusions

Our nationwide population-based observational study did not confirm an advantage of biphasic defibrillator over a monophasic defibrillator for 1-month survival with minimal neurologic impairment of pediatric OHCA patients.

Key messages

• No significant differences in neurologic outcomes was found between the pediatric OHCA patients

who were shocked with a biphasic defibrillator and those who were shocked with a monophasic defibrillator.

• Biphasic defibrillators may reduce the physical burden on EMS personnel because of their greater portability. With respect to effectiveness, however, the present study showed no significant advantage of biphasic over monophasic defibrillators on meaningful clinical outcomes for pediatric patients.

Abbreviations

AED: automated external defibrillator; CPC: cerebral performance category; CPR: cardiopulmonary resuscitation; EMS: emergency medical service; FDMA: Fire and Disaster Management Agency of Japan; GEE: generalized estimation

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Authors' contributions

ST and TI designed the study. TO and ST conducted data cleaning. HY, HH, and TH provided statistical advice on the study design and analyzed the data. ST drafted the manuscript, and ST, HY, TH, HY, TO, MA, and SK contributed substantially to its revision. ST takes responsibility for the article as a whole. All authors approved the manuscript before submission.

Competing interests

The authors declare that they have no competing interests.

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