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Clinical paper

Current termination of resuscitation (TOR) guidelines predict neurologically favorable outcome in Japan☆

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ABSTRACT

Background: It is unclear whether the basic life support (BLS) and advanced life support (ALS) pre-hospital termination of resuscitation (TOR) rules developed in North America can be applied successfully to patients with out-of-hospital cardiac arrest (OHCA) in other countries.
Objectives: To assess the performance of the BLS and ALS TOR in Japan.
Methods: Retrospective nationwide, population-based, observational cohort study of consecutive OHCA patients with emergency responder resuscitation attempts from 1 January 2005 to 31 December 2009 in Japan. The BLS TOR rule has 3 criteria whereas the ALS TOR rule includes 2 additional criteria. We extracted OHCA patients meeting all criteria for each TOR rule, and calculated the specificity and positive predictive value (PPV) of each TOR rule for identifying OHCA patients who did not have neurologically favorable one-month survival.
Results: During the study-period, 151,152 cases were available to evaluate the BLS TOR rule, and 137,986 cases to evaluate the ALS TOR rule. Of 113,140 patients that satisfied all three criteria for the BLS TOR rule, 193 (0.2%) had a neurologically favorable one-month survival. The specificity of BLS TOR rule was 0.968 (95% CI: 0.963–0.972), and the PPV was 0.998 (95% CI: 0.998–0.999) for predicting lack of neurologically favorable one-month survival. Of 41,030 patients that satisfied all five criteria for the ALS TOR rule, just 37 (0.1%) had a neurologically favorable one-month survival. The specificity of ALS TOR rule was 0.981 (95% CI: 0.973–0.986), and the PPV was 0.999 (95% CI: 0.998–0.999) for predicting lack of neurologically favorable one-month survival.
Conclusions: The prehospital BLS and ALS TOR rules performed well in Japan with high specificity and PPV for predicting lack of neurologically favorable one-month survival in Japan. However, the specificity and PPV were not 1000 and we have to develop more specific TOR rules.

1. Introduction

Sudden cardiac arrest remains a major public health problem in the industrialized world.[1] Despite improvements in resuscitation practices including the chain of survival, outcomes from out-of-hospital cardiac arrest (OHCA) remain poor.[2–4] In many industrialized countries, pre-hospital termination of resuscitation (TOR) for OHCA have been implemented to allow for better utilization of hospital health care resources.[5–8]

Both the American Heart Association (AHA) and European Resuscitation Council (ERC) 2010 cardiopulmonary resuscitation (CPR) guidelines recommend that emergency medical services (EMS) personnel consider TOR for OHCA patients that have failed to respond to basic life support (BLS) and/or advanced life support (ALS) treatment efforts. TOR is preferred instead of transporting these patients to the hospitals for ongoing resuscitation because of their poor survival and heavy economic burdens.[9,10]

Recently, several studies have independently validated the BLS and ALS TOR rules which were originally developed in North America. These studies have shown that these rules have a high specificity and positive predictive value (PPV) and performed well in identifying patients with OHCA who had little or no chance of survival.[5,6,8,11] However, we thought that it was important to evaluate whether this 'North American TOR rules' was acceptable in

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not only the different EMS systems but also areas where different races lived. In Japan, EMS personnel are not legally permitted to terminate resuscitation for OHCA patients in the pre-hospital setting. Therefore, EMS personnel in Japan are required to transport almost all OHCA patients to a hospital regardless of the success or failure of their resuscitation efforts.[12] In this study, we aimed to investigate whether BLS and ALS TOR rules can predict neurologically favorable one-month survival for OHCA patients in Japan using a large population based registry covering the whole of Japan.

2. Methods

2.1. Study design and settings

The All-Japan Registry of the Fire and Disaster Management Agency (FDMA) is a nationwide, population-based registry of OHCAs that is based on the standardized Utstein style.[2] This study enrolled all patients aged ≥ 18 years who had an OHCA of presumed cardiac origin, were treated by EMS personnel, and were transported to medical institutions from January 1, 2005 to December 31, 2009. The ethics committee at Kyoto University Graduate School of Medicine approved the study. The requirement of written informed consent was waived. Cardiac arrest was defined as the cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation.[13,14] The arrest was presumed to be of cardiac origin unless it was caused by cerebrovascular disease, respiratory disease, malignant tumor, external causes including trauma, hanging, drowning, drug overdose, and asphyxia, or any other non-cardiac cause. These diagnoses of presumed cardiac or non-cardiac origin were determined clinically by the physician in charge in collaboration with the EMS personnel.

Do-not-resuscitate orders or living wills are generally not used in Japan,[12] and EMS providers are not legally permitted to terminate resuscitation in the field. Therefore, most patients with OHCA treated by EMS personnel were transported to hospital and registered in this cohort. The cohort excluded cases with obvious signs of death on EMS arrival such as decapitation, incineration, decomposition, rigor mortis, or dependent lividity.

2.2. The EMS system in Japan

Japan has an area of approximately 378,000 km^2 and with a population of approximately 127 million in 2005.[2] EMS is provided by municipal governments through a fire department model. There were 804 fire departments with dispatch centers in 2009. Usually, a fire department ambulance has a crew of three emergency providers, including at least one emergency lifesaving technician (ELST). ELSTs are trained to insert an intravenous line, place adjunct airways and to use semi-automated external defibrillators. ALS measures in Japan are limited to advanced airway management and epinephrine. Under the online medical control, specially trained ELSTs can also insert endotracheal tubes (since July 2004), and administer intravenous epinephrine (since April 2006). All EMS providers perform CPR according to the Japanese CPR guidelines which are based on the AHA and the International Liaison Committee on Resuscitation (ILCOR) recommendations. AHA Guidelines 2000 were in effect until September 2006 and the AHA 2005 Guidelines were followed thereafter.[12] In Japan, approximately 1.6 million citizens participate each year in community CPR programs which includes training in chest compressions, mouth-to-mouth ventilation, and the use of an automated external defibrillator (AED).[2]

2.3. Data collection and quality control

Data were collected with the use of a form based on the Utstein-style guidelines for reporting OHCA,[11,12] and included details on sex, age, witness status, initial cardiac rhythm, time course of resuscitation, bystander-initiated CPR, advanced airway management, intravenous epinephrine, as well as pre-hospital return of spontaneous circulation (ROSC), one-month survival, and neurological status one month after the event. The time course of resuscitation included details on the time the call was received, vehicle arrival at the scene, contact with patient, initiation of CPR, defibrillation by EMS, and hospital arrival. All survivors were evaluated at one month after the event for their neurological function by the EMS personnel in charge.

The data form was filled out by the EMS personnel in cooperation with the physicians in charge of the patients, and the data were integrated into the registry system on the FDMA database server. They were logically checked by the computer system and were confirmed by the implementation working group. If a data form was incomplete, the FDMA would return it to the respective fire station for completion and follow up on the missing data.

2.4. Main outcome measurement

Neurological outcome was clinically determined by the physician caring for the patients one month after successful resuscitation, using the cerebral performance category (CPC) scale: category 1, good cerebral performance; category 2, moderate cerebral disability; category 3, severe cerebral disability; category 4, coma or vegetative state; and category 5, death. The primary outcome measure was neurologically favorable one-month survival, defined as CPC category 1 or 2.[13,14] The secondary outcome measure was one-month survival.

2.5. Patient eligibility

OHCA patients aged ≥ 18 years of presumed cardiac etiology who had resuscitation attempted by EMS personnel were included in these analyses. We classified that level from EMS personnel's activity on the scene. The cases who received only BLS were classified into the BLS group (eligible OHCA patients for the BLS TOR rule) and the cases who received BLS plus ALS were classified into the ALS group (eligible OHCA patients for the ALS TOR rule).[6] The BLS TOR rule has 3 criteria (not witnessed by EMS, no public-access AED use or shock by EMS, and no pre-hospital ROSC) while the ALS rule added 2 additional criteria (not witnessed by bystanders and no bystander-initiated CPR).

2.6. Statistical analysis

We extracted OHCA patients meeting the criteria for each TOR rule and calculated the sensitivity, specificity, PPV, and negative predictive value (NPV) and their respective 95% confidence intervals (CI) for identifying OHCA patients without one-month survival and neurologically favorable one-month survival. Statistical analyses were performed using the SPSS statistical package version 15.0J (SPSS, Inc, Chicago, IL). A p-value < 0.05 was considered statistically significant.

3. Results

From Jan 2005 to December 2009, 537,519 adult OHCAs in Japan were documented (Fig. 1). Out of 530,084 patients with resuscitation attempts, 294,193 were presumed to be of cardiac origin. Of these, 151,659 received only BLS care by EMS personnel, while

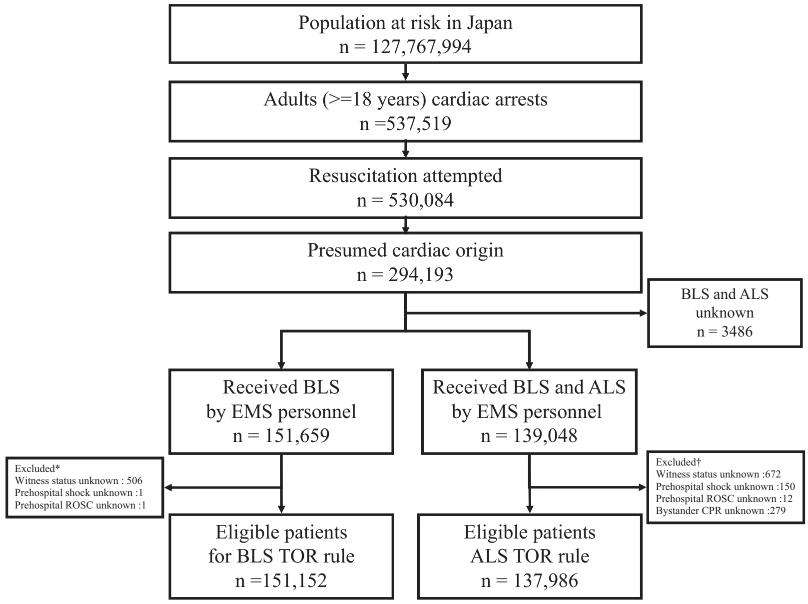

Fig. 1. Flow chart of patients. EMS, emergency medical service; BLS, basic life support; ALS, advanced life support; TOR, termination of resuscitation; ROSC, return of spontaneous circulation; CPR, cardiopulmonary resuscitation. *One case was unknown in multiple subjects. †Fifty-one cases were unknown in multiple subjects.

139,048 received both BLS and ALS care by EMS personnel. Excluding cases without complete data, 151,152 were eligible to evaluate the BLS TOR rule, and 137,986 to evaluate the ALS TOR rule.

3.1. The BLS TOR rule

Table 1A shows clinical characteristics and outcomes among OHCA patients eligible for the BLS TOR rule. Mean age was 75.5 years old, and 56.8% were male. The percentage of arrests witnessed by bystanders, receiving bystander CPR, or having VF as an initial rhythm were 29.8%, 36.3%, and 11.1%, respectively. The mean time interval from call to ambulance arrival on the scene and from call to hospital arrival was 7.1 min and 29.9 min, respectively. The proportion of patients with pre-hospital ROSC, one-month survival, and one-month survival with favorable neurological outcome was 7.2%, 6.6%, and 4.0%, respectively.

Among 151,152 eligible patients, 113,140 (74.9%) satisfied all three criteria for the BLS TOR rule (Fig. 2A). Neurologically

Table 1A
Characteristics and outcomes among eligible OHCA patients for BLS TOR rule.

	Eligible OHCA patients for BLS TOR rule (n = 151,152)
Age (years), mean (SD)	75.5 (14.4)
Male, *n* (%)	85,791 (56.8)
Witness status, *n* (%)	
Arrest not witnessed	90,256 (59.7)
Arrest witnessed by bystanders	45,017 (29.8)
Arrest witnessed by EMS	15,879 (10.5)
Bystander-initiated CPR, *n* (%)	54,970 (36.3)
VF as an initial rhythm, *n* (%)	16,859 (11.1)
EMS care interval (min), mean (SD)	
Call to ambulance arrival on the scene	7.1 (3.7)
Call to hospital arrival	29.9 (11.8)
Clinical outcomes, *n* (%)	
Prehospital ROSC	10,933 (7.2)
One-month survival	9516 (6.3)
One-month survival with neurologically favorable outcome	6001 (4.0)

OHCA, out-of-hospital cardiac arrest; BLS, basic life support; TOR, termination of resuscitation; EMS, emergency medical service; CPR, cardiopulmonary resuscitation; VF, ventricular fibrillation; ROSC, return of spontaneous circulation.

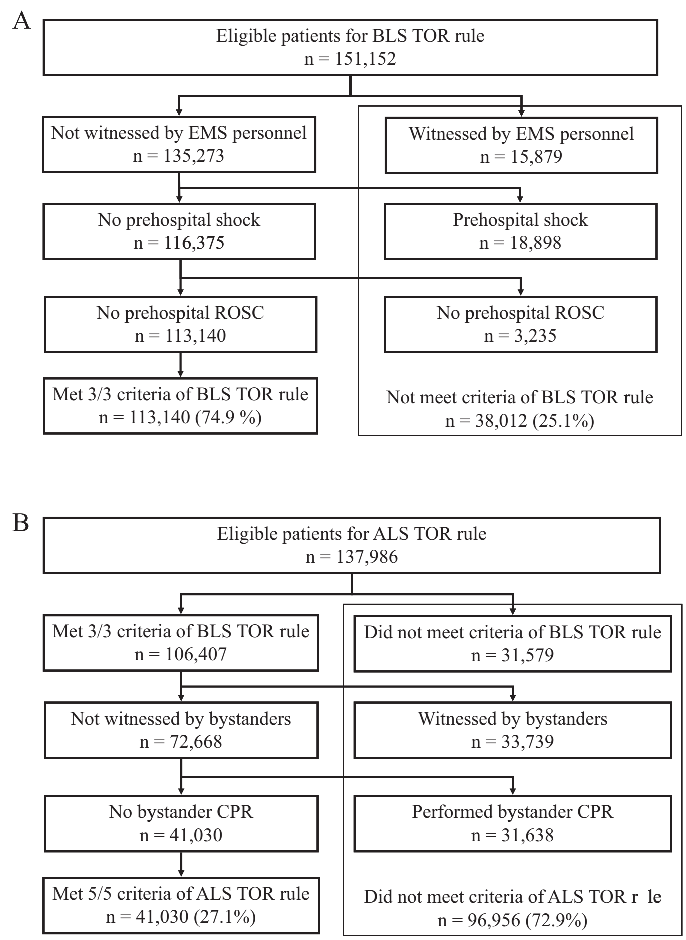

Fig. 2. Sampling OHCA patients meeting criteria for (A) the BLS TOR rule and (B) the ALS TOR rule. EMS denotes emergency medical service; BLS, basic life support; ALS, advanced life support; TOR, termination of resuscitation; ROSC, return of spontaneous circulation; CPR, cardiopulmonary resuscitation.

Table 1B
Characteristics and outcomes among eligible OHCA patients for ALS TOR rule.

	Eligible OHCA patients for ALS TOR rule (n = 137,986)
Age (years), mean (SD)	74.4 (14.1)
Male, n (%)	82,696 (59.9)
Witness status, n (%)	
Arrest not witnessed	81,992 (59.4)
Arrest witnessed by bystanders	49,640 (36.0)
Arrest witnessed by EMS	6354 (4.6)
Bystander-initiated CPR, n (%)	57,704 (41.9)
VF as an initial rhythm, n (%)	16,562 (12.0)
EMS care interval (min), mean (SD)	
Call to ambulance arrival on the scene	7.3 (3.7)
Call to hospital arrival	33.5 (11.5)
Outcomes, n (%)	
Prehospital ROSC	7076 (5.1)
One-month survival	5455 (4.0)
One-month survival with neurologically favorable outcome	1902 (1.4)

OHCA, out-of-hospital cardiac arrest; ALS, advanced life support; TOR, termination of resuscitation; EMS, emergency medical service; CPR, cardiopulmonary resuscitation; VF, ventricular fibrillation; ROSC, return of spontaneous circulation.

favorable outcome among OHCA patients meeting criteria for the BLS TOR rule are summarized in Table 2A. Of 113,140 patients who satisfied all three criteria, 193 (0.2%) had one-month survival with neurologically favorable survival. The specificity of BLS TOR rule was 0.968 (95% CI: 0.963–0.972), and the PPV was 0.998 (95% CI: 0.998–0.999) for predicting lack of neurologically favorable one-month survival. For one-month survival, the specificity of BLS TOR rule was 0.878 (95% CI: 0.872–0.884), and the PPV was 0.990 (95% CI: 0.989–0.990) (Table 2C).

3.2. The ALS TOR rule

Table 1B shows characteristics and outcomes among eligible OHCA patients for the ALS TOR rule. Mean age was 74.4 years old and 59.9% were male. The proportion of arrests witnessed by bystanders, receiving bystander CPR, and having VF as an initial rhythm were 36.0%, 41.9%, and 12.0%, respectively. The mean time interval from call to ambulance arrival on the scene and from call to hospital arrival was 7.3 min and 33.5 min, respectively. The proportion of patients with pre-hospital ROSC, one-month survival, and one-month survival with favorable neurological outcome was 5.1%, 4.0%, and 1.4%, respectively.

Among 137,986 eligible patients, 41,030 (27.1%) satisfied all five criteria for the ALS TOR rule (Fig. 2B). Neurologically favorable outcome among OHCA patients meeting criteria for the ALS TOR rule are noted in Table 2B. Of 41,030 patients satisfying all five criteria, only 37 (0.1%) had one-month survival with neurologically favorable survival. The specificity of ALS TOR rule was 0.981 (95% CI: 0.973–0.986), and the PPV was 0.999 (95% CI: 0.998–0.999) for predicting lack of neurologically favorable one-month survival. For one-month survival, the specificity of ALS TOR rule was 0.923 (95% CI: 0.916–0.930), and the PPV was 0.990 (95% CI: 0.989–0.991) (Table 2D).

4. Discussion

Using a nationwide population-based Utstein registry of OHCA in Japan, we investigated whether BLS and ALS TOR rules can predict neurologically favorable one-month survival for OHCA patients in Japan, and demonstrated that both rules had high specificity and PPV in this population.

The prior studies on the validation of TOR rules were conducted in limited geographic areas of North American, Europe and Singapore,[5–7,10,15] and it is not clear whether latest BLS and ALS TOR rules can predict neurologically favorable one-month survival for OHCA patients in Japan.[5,6] This clearly demonstrates the effectiveness of BLS and ALS TOR rules for predicting neurologically favorable outcome in over 300,000 OHCAs in Japan. This suggests that these TOR rules would be of considerable helpful to detect refractory OHCA patients.

In this study, we note that the specificity and PPV of both BLS and ALS TOR rules for predicting non-survival in this population was high. Our results were consistent with those of previous studies.[5,6] The PPV (0.998) of the BLS TOR rule in this study was very similar to that in Ontario (0.995)[5] and in the CARES study (0.998),[6] and the PPV of the ALS TOR rule was also similar to previous studies. Therefore, these findings suggest that BLS and ALS TOR rule are valid beyond North American could possibly be introduced to the pre-hospital settings of the industrialized world. An important difference between this study and prior validation studies is that there was no termination of resuscitation protocols in place since EMS personnel in Japan are not legally permitted to do this. In the other preceding studies, 17.2% in the CARES study received the declaration of TOR on the scene.[6] In addition, the prevalence of OHCA patients satisfying the ALS TOR rule was higher than that in the CARES study (27% vs 22%),[6] and it might suggest differences in ALS procedures between Japan and North America. Of note, the proportion of patients satisfying the ALS TOR rule was higher in this study then in the validation study using the CARES registry. The reasons for this difference are not clear but may be related to differences in ALS capabilities between Japan and North America. For example, ALS measures in Japan are limited to advanced airway management and epinephrine whereas more interventions are performed in North America. These differences require further study.

Currently, both AHA and ERC recommend permitting the termination of resuscitation efforts that have failed for selected OHCA patients in the pre-hospital setting. However, one report showed that the adherence to these recommendations is variable in that guidelines were used in only 44% for eligible patients,[16] and as much as 40% of EMS personnel felt that resuscitation efforts should be continued even if the chances of survival were poor.[17] In addition, some experts suggest that rapid transportation of OHCA patients who have little or no chance of survival simply adds additional costs to the system while also increasing the risk of ambulance/motor vehicle crashes, vehicle-pedestrian collision, and occupational exposure to blood contamination and body secretions.[18,19] However, most people in North America still desire to be transported to a hospital when they collapse in pre-hospital settings, and implementation of the TOR rule is still under vigorous debates.[20] The increasing number of transportation of

Table 2A
Neurologically favorable outcome among out-of-hospital cardiac arrest patients meeting criteria for the BLS TOR rule.

	CPC ≥ 3	CPC 1 or 2	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
BLS TOR rule						
Met 3/3 criteria	112,947	193	0.778	0.968	0.998	0.153
Did not meet criteria	32,204	5808	(0.776–0.780)	(0.963–0.972)	(0.998–0.999)	(0.149–0.156)

BLS, basic life support; TOR, termination of resuscitation; CPC, cerebral performance category; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

Table 2B
Neurologically favorable outcome among out-of-hospital cardiac arrest patients meeting criteria for the ALS TOR rule.

	CPC ≥ 3	CPC 1 or 2	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
ALS TOR rule						
Met 5/5 criteria	40,993	37	0.301	0.981	0.999	0.019
Did not meet criteria	95,091	1865	(0.299–0.304)	(0.973–0.986)	(0.998–0.999)	(0.018–0.020)

ALS, advanced life support; TOR, termination of resuscitation; CPC, cerebral performance category; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

Table 2C
One-month survival among out-of-hospital cardiac arrest patients meeting criteria for the BLS TOR rule.

One-month survival	Died	Survived	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
BLS TOR rule						
Met 3/3 criteria	111,980	1160	0.791	0.878	0.990	0.220
Did not meet criteria	29,656	8356	(0.790–0.791)	(0.872–0.884)	(0.989–0.990)	(0.218–0.221)

BLS, basic life support; TOR, termination of resuscitation; CPC, cerebral performance category; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

Table 2D
One-month survival among out-of-hospital cardiac arrest patients meeting criteria for the ALS TOR.

One-month survival	Died	Survived	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
ALS TOR rule						
Met 5/5 criteria	40,612	418	0.306	0.923	0.990	0.052
Did not meet criteria	91,919	5037	(0.306–0.307)	(0.916–0.930)	(0.989–0.991)	(0.052–0.052)

ALS, advanced life support; TOR, termination of resuscitation; CPC, cerebral performance category; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

out-of-hospital patients by ambulances is a serious social and medical issue in Japan.[4,21] We should, therefore, consider the introduction of the TOR rule in the pre-hospital settings in Japan to concentrate limited resources for people who have more chance of survival. The verification and implementation of the TOR rule for OHCA patients in Japan would be an important topic in any revisions of the Japanese CPR guidelines in near future.

In this study, both the BLS and ALS TOR rules could detect refractory OHCA patients but the specificity and PPV were not 1.000. Although the North American TOR rules had the specificity and PPV of 1.000 in United States and Canada,[5,6] these studies were conducted in limited areas and populations. Therefore, our findings were also important because these TOR rules could not show the specificity and PPV of 1.000 for predicting lack of neurologically favorable outcome and one-month survival among the whole Japanese population. These results suggest that we have to consider whether these TOR rules should be used and to develop more specific TOR rules that could be applied successfully in each area.

These data also suggest that TOR rules cannot be always correct (i.e., TOR rules might be going to terminate potential survivors in the fields), and we need to develop a strong argument for the cost-effectiveness. To improve survival from OHCA, we must consider limited medical resources and the cost-effectiveness of treatment for OHCA patients. National organizations such as the AHA and the National Association of EMS Physicians have promoted guidelines that allow for termination of futile cardiac resuscitation efforts in the out-of hospital setting. Both organizations recognize that rapid transport of patients who have little or no chance of survival poses risks and generates needless costs.[6] The time has come for discussion of the TOR rule including the cost-effectiveness with all citizens. In addition, we must consider that the citizens might have different religious and ethical views regarding the implementation of the TOR rule. Therefore, consultation on the introduction of the TOR rule to our pre-hospital settings should be done with the public, administrative bodies, and the police and fire authorities.

5. Limitations

As with any study, there are several limitations that deserve mention. First, this study used neurologically favorable survival at one-month as the primary outcome for the TOR rules, unlike survival to discharge from hospital that was used in the prior validation studies. This makes direct comparison to other validation studies more challenging but we feel that neurologically favorable survival is a more important survival outcome. Second, these study subjects were classified by BLS or ALS depending on the level of EMS personnel's activity on the scene. Although it might influence our results, All-Japan Utstein registry did not obtain information on the EMS rescuer level. Third, our data does not address potential variability in in-hospital post-arrest care (hemodynamic support, induced hypothermia, and coronary interventional therapies).[22] Fourth, as with all epidemiological observational studies, data integrity, validity, and ascertainment bias are potential limitations. The use of uniform data collection based on Utstein-style guidelines for reporting cardiac arrest, large sample size, and a nationwide population-based design to cover all known adult OHCA in Japan were intended to minimize these potential sources of biases.

6. Conclusion

The BLS and ALS TOR rules had high specificity and PPV for predicting lack of neurologically favorable one-month survival and both rules could be used to identify cases of OHCA unlikely to benefit from transport to the hospital for further attempts at resuscitation in Japan. However, the specificity and PPV were not 1.000 and we have to develop more specific TOR rules. The implementation of TOR rules in Japan merits further discussion.

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Conflict of interest statement

There are no conflicts of interest to declare.

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