Implementation of a Community-Based Triage for Patients with Suspected Transient Ischemic Attack or Minor Stroke Study: A Prospective Multicenter Observational Study

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Background: Japan has the highest number of magnetic resonance imaging units in the world, and citizens can freely choose medical care at any hospital or clinic. We aimed to investigate the triage of patients with suspected transient ischemic attack (TIA) or minor stroke in this unique Japanese healthcare system. *Methods:* In this cohort study, patients with suspected TIA or minor stroke (National Institutes of Health Stroke Scale score <4) within 7 days after onset were prospectively enrolled and followed for 1 year. The high-risk group was defined as having at least one of the following 5 items at the initial visit: (1) atrial fibrillation, (2) carotid stenosis, (3) crescendo TIA, (4) definite focal brain symptoms, or (5) ABCD2 score of 4 or higher. After the initial assessment, the patients were diagnosed as having acute ischemic cerebrovascular syndrome (AICS) or stroke mimic. AICS was classified into 3 categories including definite, probable, and possible AICS, based on evidence of neurological deficits and brain infarction on the imaging study. *Results:* A total of 353 patients were enrolled and 89.8% of the patients were examined by diffusion-weighted imaging at the initial visit. Kaplan–Meier analyses demonstrated a statistically significant difference in subsequent stroke risk when the patients were triaged by the ABCD2 score ($P = .031$), 5-item high-risk categorization ($P = .032$), or AICS classification ($P = .001$). *Conclusions:* This study demonstrates that hospitals and clinics with imaging facilities play a major role in triage and that the ABCD2 score, 5-item high-risk categorization, and AICS classification are

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useful as triage tools for patients with suspected TIA or minor stroke. **Key Words:** Transient ischemic attack—triage—magnetic resonance imaging—acute ischemic cerebrovascular syndrome—minor stroke.
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Introduction

People with transient ischemic attack (TIA) are at high risk of early stroke, which can be as high as 3.5% within 48 hours and 5.2% within 7 days.[1-3] TIA is a medical emergency. Urgent assessment and intervention reduces the risk of stroke after TIA,[4,5] and a recent study demonstrated the positive effects of the establishment of a daily rapid-access TIA clinic using the ABCD2 score[6] in the United Kingdom.[7] Diffusion-weighted imaging (DWI) is a powerful tool for the detection of acute brain infarction and may be useful for the risk stratification of patients with suspected TIA or minor stroke in addition to the ABCD2 score.[8,9] Japan has the highest number of magnetic resonance imaging (MRI) units in the world with 47 units per million people, which is more than 3.5 times the Organisation for Economic Co-operation and Development average.[10] More than 80% of Japan's hospitals and physician-run offices are privately operated; however, all care is provided under universal health coverage. Citizens can freely choose any hospital or clinic with an MRI unit. Although it is reasonable to assume that such hospitals or clinics might play a major role in the real-world clinics, little work has been done to evaluate their triage function for suspected TIA or stroke. We conducted a prospective multicenter observational study to investigate the triage of patients with suspected TIA or minor stroke in this unique Japanese healthcare system.

Patients and Methods

This study was conducted in Kanagawa prefecture (population of 9,118,334 over 2415.8 km^2) in Japan. In 2011, an ad hoc committee for TIA was established under the Kanagawa Neurosurgeon and Neurologist Association in cooperation with the Kanagawa branch of the Japan Stroke Association. A preliminary study by this committee demonstrated that there were a total of 160 MRI scanners available for DWI examination in various types of hospitals and clinics in this prefecture, suggesting that these hospitals and clinics might play an important role in the triage of patients with suspected TIA or minor stroke. We started a prospective registry of patients with suspected TIA or minor stroke to establish a community-based triage system in cooperation with these hospitals and clinics that had existing imaging facilities. A total of 34 hospitals and clinics participated in this registry. They consisted of 14 large-sized general hospitals (>400 beds), 7 medium-sized hospitals (21-400 beds), and 13 small-sized hospitals (<20 beds) including 11 primary care clinics without beds.

The inclusion criteria for the registry were (1) patients with suspected TIA or minor stroke (National Institutes of Health Stroke Scale [NIHSS] score <4) within 7 days after onset, and (2) age 20 years or older. The classical definition of TIA based on the Classification of Cerebrovascular Diseases III by the National Institute of Neurological Disorders and Stroke[11] was used in the present study. Serious illness (life expectancy <1 year) and moderate-to-severe neurological deficits at the first visit (NIHSS score ≥4) were the exclusion criteria. Patients who met the inclusion and exclusion criteria were consecutively enrolled and a follow-up survey was performed at 3, 6, and 12 months after entry. The enrollment of patients began in April 2013. All data were submitted to our central office in the Department of Neurology, St. Marianna University School of Medicine.

Risk Stratification at Initial Assessment and Diagnosis of Acute Ischemic Cerebrovascular Syndrome (AICS)

When patients met at least one of the following 5 criteria at the initial visit, they were categorized into the high-risk group: (1) history of atrial fibrillation, (2) history of carotid stenosis (≥50% based on the North American Symptomatic Carotid Endarterectomy Trial criteria or peak systolic flow ≥150 cm/second),[12,13] (3) crescendo TIA (2 or more TIAs in a week), (4) definite focal brain symptoms (defined by the National Institute of Neurological Disorders and Stroke Classification of Cerebrovascular Diseases III),[11] or (5) an ABCD2 score of 4 or higher. The remaining patients were categorized as the low-risk group. This practical risk stratification method was based only on expert opinion and without any validation studies. Therefore, urgency for referral to the stroke specialist remained at the discretion of the individual doctor. We planned to explore the validity and reliability of this method after completion of the present study. After the computed tomography (CT) or MRI study, the patients were diagnosed as AICS or not AICS (stroke mimics) as proposed by Kidwell and Warach.[14] AICS was classified into 3 subcategories such as definite, probable, and possible based on the diagnostic certainty afforded by a combination of the clinical features and the supportive neuroimaging data (Fig 1). The CT or MRI study may not be performed on the same day of risk stratification or may be repeated in certain cases. The AICS classification will be reported based on the best imaging data obtained within 7 days after onset.

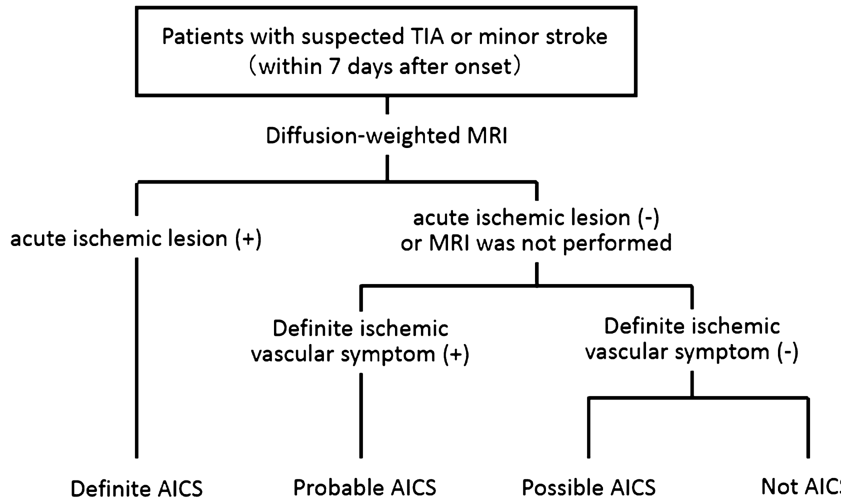

Figure 1. *AICS. Patients were categorized based on the AICS classification proposed by Kidwell and Warach.[14] Abbreviations: AICS, acute ischemic cerebrovascular syndrome; MRI, magnetic resonance imaging; TIA, transient ischemic attack.*

The study protocol was approved by the local ethics committee of the St. Marianna University Bioethics Committee for the primary care clinics. Because the present research belongs to an observational study not using any human biological specimens, written informed consent was not obtained from each patient in accordance with the ethical guidelines for epidemiological research issued by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour, and Welfare, Japan. However, we published all relevant methods regarding this study and provided each patient an opportunity to refuse inclusion in this research by posting the details at every participating clinic and on the home pages of our institutions.

Statistical Analysis

Data are expressed as mean ± standard deviation or median (range). Student's *t*-test or the χ^2 test was used to compare categorical variables, and the Mann–Whitney *U*-test was used for non-normally distributed variables. Several group comparisons were performed with the Kruskal–Wallis test for nonparametric variables or analysis of variance with the post hoc Bonferroni test for continuous variables. Diagnostic accuracy, sensitivity, and specificity were calculated by using receiver operating characteristic curve analysis. Cumulative recurrence-free survival rates were compared between the 2 groups using the Kaplan–Meier method and log-rank statistics. All statistical tests were 2-sided, and probability values less than .05 were considered statistically significant. Statistical analyses were performed using SPSS Statistics for Windows, Version 22.0 software (IBM Corp., Armonk, NY).

Results

A total of 353 patients were enrolled from 34 hospitals and patient characteristics are shown in Table 1. The patients visited clinics or hospitals 36.8 ± 44.0 hours after the onset of symptoms. Seventy-six percent of patients visited within 48 hours after the onset of symptoms. This onset-to-visit time, that is, the patient delay in doctor consultation, varied among AICS categories (analysis of variance, $P = .005$), and this delay in the not AICS category was significantly longer than that in the probable AICS category, 46.6 ± 47.9 hours and 26.1 ± 38.6hours, respectively (post hoc Bonferroni test, $P = .003$). A statistically significant difference in the distribution of major symptoms among the AICS categories was observed in any kind of paresis, dysarthria, vertigo/dizziness/unsteadiness, and transient disturbance of consciousness (Table 1). The latter 2 items were more frequently observed in patients categorized as not AICS.

The majority of patients (89.8%) were examined by DWI and intracranial magnetic resonance angiography was also performed in 82.2% of the patients. In 92.1% of the patients, imaging studies were performed on the same day of risk stratification and categorization of AICS classification was reported. In 99.3% of the patients, AICS categorization was done within 3 days after the risk stratification. Initial diagnoses according to the AICS classification were as follows: 72 definite AICS; 124 probable AICS; 57 possible AICS; and 100 not AICS. Distribution of AICS categories among different hospital sizes was statistically significant (Fig 2, $P = .001$) and most patients (n = 225) were enrolled from primary care clinics without beds.

The ABCD2 score was significantly different among AICS categories. Accuracy of the ABCD2 score for the diagnosis of definite or probable AICS was .757 (95% confidence interval [CI], .707-.808, $P = .001$). Frequencies of AICS categories by tertiles of the ABCD2 score are shown in Figure 3.

At initial triage, high-risk categorization for the diagnosis of definite or probable AICS had a sensitivity of .891, a specificity of .553, a positive predictive value of .715, and a negative predictive value of .798. Subsequent

Table 1. *Patient characteristics*

Characteristics	Total (N = 353)	AICS classification				*P* value
		Definite (n = 72)	Probable (n = 124)	Possible (n = 57)	Not AICS (n = 100)	
Male sex (%)	57.8	63.9	63.7	46.5	54.1	.235
Age (years) (min-max)	68.2 ± 13.3 (25-101)	69.6 ± 11.3 (39-87)	68.9 ± 13.5 (40-101)	65.8 ± 15.9 (27-89)	67.8 ± 12.7 (25-89)	.219
Onset-to-visit time (hour) (min-max)	36.8 ± 44.0 (0-168)	40.8 ± 43.7 (1-168)	26.1 ± 38.6 (0-168)	37.5 ± 44.4 (0-151)	46.6 ± 47.9 (0-168)	.005
Premorbid Rankin Scale (% of score ≤1)	92.0	90.3	95.1	94.7	96.1	.693
Systolic blood pressure (mmHg)	147.6 ± 25.0	152.1 ± 19.6	151.5 ± 27.1	143.2 ± 22.5	153.8 ± 27.1	.255
Diastolic blood pressure (mmHg)	82.8 ± 14.2	86.8 ± 12.3	84.7 ± 16.0	80.1 ± 11.0	84.4 ± 15.0	.229
Major symptom, n (%)						
Any kind of paresis	135 (38.2)	39 (54.2)	65 (52.4)	14 (24.6)	17 (17.0)	.001
Any kind of sensory disturbance	63 (17.8)	12 (16.7)	25 (20.2)	11 (19.3)	15 (15.0)	.828
Dysarthria	80 (22.7)	21 (29.2)	35 (28.2)	16 (28.1)	8 (8.0)	.001
Visual symptom	55 (15.6)	10 (13.9)	17 (13.7)	12 (21.1)	16 (16.0)	.616
Vertigo, dizziness, unsteadiness	94 (26.6)	11 (15.3)	20 (16.1)	18 (31.6)	45 (45.0)	.001
Transient consciousness disturbance	6 (1.7)	0 (.0)	0 (.0)	0 (.0)	6 (6.0)	.007
ABCD2 score total	3.5 ± 1.6 (0-7)	5.2 ± 1.1 (3-7)	4.0 ± 1.7 (0-7)	3.1 ± 1.4 (0-7)	2.2 ± 1.4 (0-5)	.001
High-risk category (+)*, n (%)	247 (70)	67 (93.1)	108 (87.1)	32 (56.1)	40 (40.0)	.001
Comorbidity, n (%)						
Hypertension	177 (50.1)	43 (59.7)	71 (57.3)	30 (52.6)	33 (33.0)	.001
Diabetes mellitus	56 (15.9)	10 (13.9)	22 (17.7)	8 (14.0)	16 (16.0)	.191
Dyslipidemia	115 (32.6)	20 (27.8)	51 (41.1)	18 (31.6)	26 (26.0)	.036
Atrial fibrillation	25 (7.1)	11 (15.3)	8 (6.5)	2 (3.5)	4 (4.0)	.005
Carotid stenosis	12 (3.4)	1 (1.4)	8 (6.5)	2 (3.5)	1 (1.0)	.030
Major intracranial artery stenosis	17 (4.8)	3 (4.2)	10 (8.1)	2 (3.5)	2 (2.0)	.040
History of stroke	65 (18.4)	57 (79.2)	5 (4.0)	2 (3.5)	1 (1.0)	.001
Imaging study, n (%)						
Diffusion MRI	317 (89.8)	71 (98.6)	111 (89.5)	53 (93.0)	82 (82.0)	.002
CT scan	75 (21.2)	17 (23.6)	33 (26.6)	13 (22.8)	12 (12.0)	.052
MRA, intracranial	290 (82.2)	59 (81.9)	100 (80.6)	53 (93.0)	78 (78.0)	.079
MRA, extracranial	182 (51.6)	42 (58.3)	64 (51.6)	32 (56.1)	44 (44.0)	.226
CTA, intracranial	10 (2.8)	3 (4.2)	5 (4.0)	1 (1.8)	1 (1.0)	.454
CTA, extracranial	9 (2.5)	4 (5.6)	4 (3.2)	1 (1.8)	0 (.0)	.127
Carotid echosonography	97 (27.5)	20 (27.8)	55 (44.4)	14 (24.6)	8 (8.0)	.001
Electrocardiogram	183 (51.8)	45 (62.5)	86 (69.4)	26 (45.6)	26 (26.0)	.001
Ultrasound cardiography	44 (12.5)	12 (16.7)	26 (21.0)	5 (8.8)	1 (1.0)	.001
Initial treatment, n (%)						
Aspirin	68 (19.3)	10 (13.9)	37 (29.8)	15 (26.3)	6 (6.0)	.001
Clopidogrel	52 (14.7)	16 (22.2)	27 (21.8)	5 (8.8)	4 (4.0)	.001
Cilostazole	17 (4.8)	4 (5.6)	7 (5.6)	4 (7.0)	2 (2.0)	.313
Warfarin	21 (5.9)	8 (11.1)	7 (5.6)	3 (5.3)	3 (3.0)	.111
NOACs (rivaroxaban)	2 (.6)	0 (.0)	2 (1.6)	0 (.0)	0 (.0)	.230

Abbreviations: AICS, acute ischemic cerebrovascular syndrome; CT, computed tomography; CTA, computed tomography angiography; MRA, magnetic resonance angiography; MRI, magnetic resonance imaging; NOAC, nonvitamin K antagonist oral anticoagulant.

*High-risk category was (1) atrial fibrillation, (2) carotid stenosis, (3) crescendo TIA, (4) definite focal brain symptoms, and (5) ABCD2 score of 4 or higher.

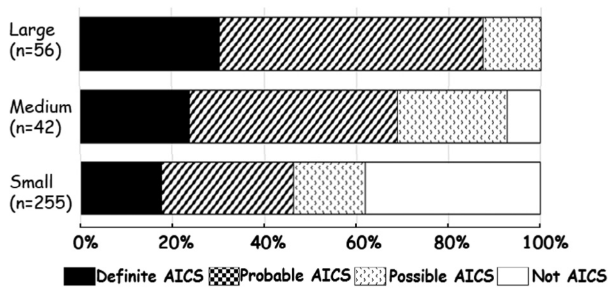

Figure 2. *Type of AICS versus hospital size. Distribution of AICS categories among different hospital sizes was significant* (P = .001). *The vast majority of patients with suspected TIA or minor stroke were triaged by small-sized clinics with an imaging facility, including not AICS (small-sized hospital: <20 beds, medium-sized hospital: 21-400 beds, large-sized hospital: >400 beds). Abbreviations: AICS, acute ischemic cerebrovascular syndrome; TIA, transient ischemic attack.*

stroke risk of patients categorized into the high-risk group using the 5 items proposed by our protocol was significantly higher than that of the low-risk group (Fig 4; $P = .032$, log-rank test). Kaplan–Meier analysis demonstrated a significantly higher early stroke risk in patients with definite AICS (Fig 4; log-rank test, $P = .001$). For the prediction of stroke onset within 3 months, diagnostic accuracy of the ABCD2 score (score ≥ 4), more than 1 item of the 5 high-risk items, and categorization of the definite AICS were .659 (95% CI, .535-.782), .620 (95% CI, .501-.738), and .788 (95% CI .662-.913), respectively.

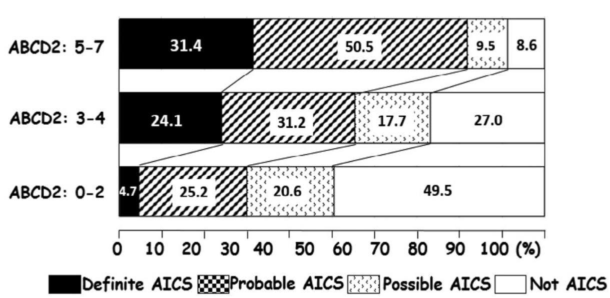

Figure 3. *Type of AICS by tertiles of ABCD2 score. Distribution of AICS subtypes was significantly different among ABCD2 score tertiles* (P = .001, χ^2 *test). Accuracy of the ABCD2 score for the diagnosis of definite AICS was .709 (95% CI, .648-.771) and for the diagnosis of definite or probable AICS was .757 (95% CI, .707-.808). Abbreviations: AICS, acute ischemic cerebrovascular syndrome; CI, confidence interval.*

Discussion

In a nationwide questionnaire of 11,121 Japanese citizens, most people (41.8%) answered "visit the family doctor" as an initial action at the onset of TIA.[15] To establish an effective community-based triage system for TIA, it is important to incorporate primary care physicians into the system. DWI is the most sensitive biomarker for the detection of an acute ischemic lesion and has a better predictive value for subsequent stroke risk than the ABCD2 score alone.[9,16] In Japan, MRI facilities are utilized not only in large hospitals but also in physician-run offices, usually operated by a certified neurosurgeon or a neurologist. Citizens can freely access these hospitals or clinics, and almost 100% of the patients were studied by CT or MRI at the time of initial evaluation. Our study demonstrates that the rate of DWI examination at the initial visit was very high at 89.8% and also DWI with magnetic resonance angiography was performed in 82.2% of the patients. In 92.1% of the patients, imaging studies and AICS categorization were completed on the same day of visit. These figures in real-world clinics in Japan are relatively high; however, the onset-to-visit time varied from 0 to 168 hours. This variability may be caused by difficulties to differentiate symptoms from other benign causes in suspected TIAs. Particularly TIAs originated in the vertebrobasilar artery system are difficult to recognize. In the present study, the onset-to-visit time in the not AICS category, of which symptoms were mainly vertigo, dizziness, unsteadiness, or transient consciousness disturbance (51.0%), was significantly longer than that in the probable AICS category, of which symptoms were characterized by paresis or dysarthria (80.6%). Fortunately, stroke risk for patients categorized as not AICS was significantly low.

Although the ABCD2 score was developed for non-specialists to triage patients with suspected TIA, a validation study has not been performed in Japan.

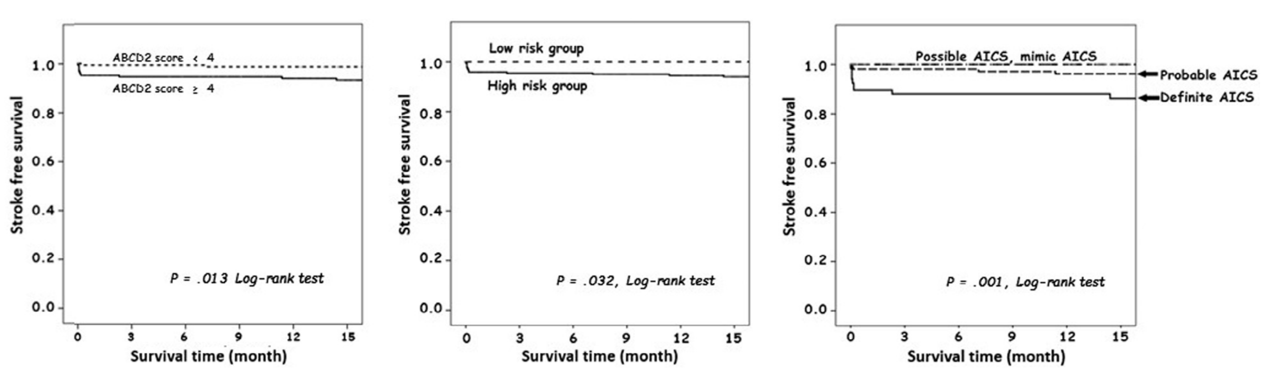

Figure 4. *Kaplan–Meier stroke-free survival curves. Risk stratification by the triage tool (Table 1) is feasible* (P = .032), *but risk stratification based on AICS category is preferable* (P = .001). *Abbreviation: AICS, acute ischemic cerebrovascular syndrome.*

Kaplan–Meier curves demonstrated that risk stratification by either the ABCD2 score (≥4) alone or by the 5-item high-risk categorization (including the ABCD2 score) is feasible. Much higher early recurrence rates were observed in the Kaplan–Meier curve of patients classified as definite AICS, suggesting that such a tissue-based diagnosis may be much more useful for risk stratification. TIAs are now recognized as brief episodes of neurological dysfunction resulting from focal cerebral ischemia not associated with permanent cerebral infarction.[17] When we adopt this tissue-based definition, we should wait to diagnose TIA (or infarction) until obtaining the results of biomarkers sensitive for infarction, such as DWI. In Japan, the AICS classification is feasible at the initial visit and such a tissue-based classification may be useful for community-based triage. All hospitals and clinics with imaging facilities can participate, regardless of the magnet field strength of the magnetic resonance scanner.

Our study had several limitations. First, this was not a complete enumeration study of patients with suspected TIA or minor stroke in the community. However, most of the participating sites were hospitals or physician-run offices with an imaging facility, both of which play an important role in the initial triage of patients with suspected TIA in existing clinical practice. This is the first registry of patients with suspected TIA incorporating such hospitals and clinics. Second, a much larger sample size and longer follow-up may be needed to explore the effectiveness of this community-based triage system.

Conclusions

Our study demonstrates that both hospitals and clinics with imaging facilities play a major role in the triage of patients with suspected TIA or minor stroke in the unique Japanese healthcare system. Although the ABCD2 score, 5-item high-risk categorization, and AICS classification are all clinically useful triage tools, the acute ischemic lesion on DWI, that is, definite AICS, is highly useful for the prediction of early stroke.

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