# Stroke Risk in Patients with Suspected Transient Ischemic Attacks with Focal and Nonfocal Symptoms: A Prospective Study

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*Objectives:* The aim was to investigate triage methods for suspected transient ischemic attacks (TIAs) with focal or nonfocal symptoms. *Materials and methods:* In total, 350 patients with suspected TIAs were enrolled and followed for one year. Potential high-risk factors for TIAs, such as atrial fibrillation, carotid artery stenosis, crescendo TIA, and ABCD2 score ≥ 4, were evaluated. Patients were classified into 3 groups according to the initial neurological symptoms: focal, nonfocal, and mixed (both focal and nonfocal) groups. Stroke-free survival rates were compared via Kaplan-Meier analysis. *Results:* Diffusion-weighted MRI (DWI) was performed for 89.8% of the patients within 7 days, and the frequency of acute brain infarction on DWI was significantly lower in the nonfocal group (focal, 24.1%; nonfocal, 7.2%; mixed, 22.2%; $P < .01$). There was no significant difference in the one-year event-free survival rates across the groups.

Significantly higher stroke risk was observed in patients with one or more high-risk categories or the ABCD2 score (≥ 4) in the focal group ($P = .021$ and .26, respectively), whereas no significant difference was observed in the other groups. Across all symptom groups, significantly higher stroke risk was observed in patients showing acute infarcts on DWI evaluated within 7 days. *Conclusions:* Both high-risk categorization (≥ 1 potential high-risk factors) and ABCD2 score (≥ 4) alone were useful tools for identifying higher stroke risk in patients with focal symptom but not with nonfocal symptoms in isolation. Further studies are warranted in triage methods for TIA with nonfocal in isolation in conjunction with DWI.

**Key Words:** Transient ischemic attack—Nonfocal neurologic symptom—Triage—Magnetic resonance imaging—Acute ischemic cerebrovascular syndrome



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## Introduction

Transient ischemic attacks (TIAs) have been defined as brief episodes of focal loss of brain function lasting < 24 h, thought to be due to ischemia,[1] whether or not any new infarct area is confirmed by computed tomography (CT) or magnetic resonance imaging (MRI). However, since diffusion-weighted MRI (DWI) has made it easy to diagnose acute brain infarctions within a few hours after onset, a tissue-based definition, by which infarction and TIA are distinguished based on the condition of ischemic brain tissue, began to be recognized as a valid definition. In 2009, the American Heart Association (AHA) and the American Stroke Association (ASA) abolished the traditional time-based definition and adopted a new definition that defines TIA as "a transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction".[2] That is to say, TIA, which used to be clinically diagnosed based on the presence or absence of focal neurological symptoms, is now diagnosed based on transient neurological attacks (TNAs) caused by ischemia, whether they are focal or nonfocal, and imaging results. The urgency of the initial response to suspected TIA depends on the risk of developing cerebral infarction after the attack. However, the risk of developing infarction in TIA diagnosed according to the new definition that includes nonfocal neurological symptoms is unknown. Japan has the highest number of MRI units in the world, with 55.2 units per million people,[3] and citizens can freely choose any hospital or physician-run office with an MRI unit under universal health coverage.[4] Investigation of real-world triage of patients with suspected TIA in this unique healthcare system provides an opportunity to clarify the optimal initial management based on the tissue-based definition of TIA. The objectives of the present study were to clarify the risk of developing infarction in patients with suspected TIA according to their symptom type based on the follow-up data from the COMBAT-TIA study (Community-based triage for patients with suspected transient ischemic attack or minor stroke study community-based study)[5] conducted to explore real-world risk stratification and triage of patients with suspected TIA or minor stroke.

## Materials and methods

This study analyzed individual patient data from the COMBAT TIA Study,[5] a prospective multicenter observational study. Data are available on request from the corresponding author.

This prospective follow-up study was planned in 2011 by the TIA committee founded by the Kanagawa Neurosurgeon and Neurologist Association of the Kanagawa Prefecture Medical Association, as a joint project with the Kanagawa branch of the Japan Stroke Association and was conducted at 34 sites in Kanagawa Prefecture (population of 9,118,334 over 2415.8 $km^2$) in Japan. As previously reported,[5] the subjects and methods were as follows. The patient inclusion criteria were (1) those with transient neurological symptoms of a presumed ischemic cause, *i.e.*, suspected TIA or mild stroke (National Institutes of Health Stroke Scale [NIHSS] score < 4), within 7 days after onset and (2) men and women aged 20 years or older. Serious illness (life expectancy < 1 year) and moderate-to-severe neurological deficits at the first visit (NIHSS score ≥ 4) were the exclusion criteria.

The physicians first consulted and started the treatment of these patients with suspected TIA or minor stroke and enrolled them using the acute ischemic cerebrovascular syndrome (AICS) classification proposed by Kidwell and Warach,[6] based on the diagnostic certainty afforded by a combination of symptoms and neuroimaging data. Accordingly, patients are classified into "definite AICS" (*i.e.*, cerebral infarction) if fresh infarction is confirmed on imaging at the initial visit, or "probable AICS" (with focal neurological symptoms) or "possible AICS" (without focal neurological symptoms) if there is no infarct area or no imaging has been performed (and, thus, no confirmation of infarction) (Fig. 1). Because of the collaboration with local clinics with MRI devices, as many as 89.8% of the patients were examined by DWI at the initial visit.[5] The following expert opinion was provided to participating physicians, although they were allowed to exercise their own discretion: (1) patients should be classified by their risk of developing infarction by high-risk categorization (atrial fibrillation, carotid stenosis, crescendo TIA, or ABCD2 score ≥ 4) into high-risk AICS (classified in one or more high-risk category) and low-risk AICS (not classified in any high-risk category); (2) hospitalization is appropriate for patients rated as "definite AICS" and "probable AICS;" (3) for patients rated as "possible AICS," hospitalization is usually recommended if they are classified into any of the high-risk categories, and outpatient treatment is possible for those not classified in any of the categories; and (4) treatment of the present illness should be continued if AICS was ruled out ("not AICS") at the initial visit. For all patients, the course of treatment and presence or absence of onset of cerebral infarction were investigated 3, 6, and 12 months after enrollment.

In this study, the patients' symptoms were classified into 3 groups, focal (hemiplegia, aphasia, homonymous hemianopia, amaurosis, diplopia, and hemilateral sensory abnormality), nonfocal (*e.g.*, dizziness, vertigo, transient impairment of consciousness, transient vague neurological symptoms), and mixed (mixture of focal and nonfocal symptoms) according to the Rotterdam study.[7,8] Recurrence of cerebral infarction was defined as appearance of a new cerebral infarction confirmed not only based on clinical findings, but also by MRI performed in all patients. Then, we compared the one-year event-free survival rate by symptom

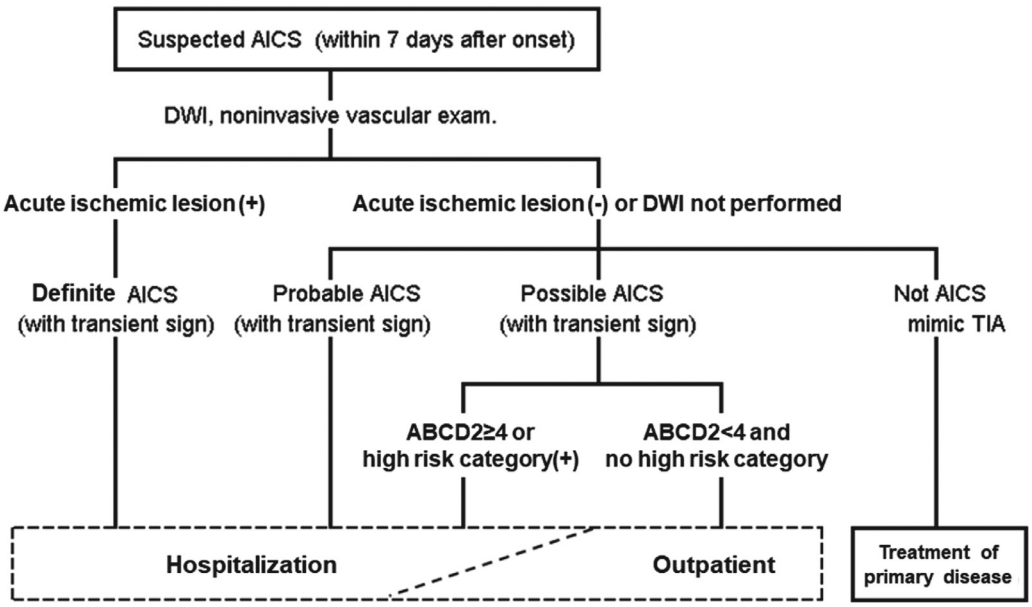


**Fig. 1.** *Flow diagram of treatment recommended in guidelines based on the acute ischemic cerebrovascular syndrome (AICS) classification, ABCD2 score, and high-risk categorization.*

classification. The aim of our study is to evaluate if the use of the high-risk categories including ABCD2 score, along with symptom type (focal, non-focal or mixed) examined by the physicians at the initial visit helped to identify patients at higher risk of cerebral infarction.

The study protocol was approved by the St. Marianna University School of Medicine Bioethics Committee (Approval No. 3293; Approval date, October 12, 2016). All data were registered at the Department of Neurology, St. Marianna University School of Medicine, which was the central secretariat for this study.

### *Statistical analysis*

Unless otherwise specified, values are summarized as means and standard deviation. The unpaired Student's *t*-test was used for comparisons between two groups, and the $\chi^2$ test was used for comparisons of proportions. For comparison of nonparametric data, the Mann-Whitney test was used. The one-year event-free survival rate by symptom classification was compared by the Kaplan-Meier method. Moreover, for each symptom classification, a significant difference in the event-free survival rate by AICS classification, ABCD2 score ($\geq$ 4 or not),[9,10] and classification into any of the high-risk categories[5] in addition to clinical symptoms was tested by the log-rank test. Statistical analyses were performed using IBM SPSS Statistics for Windows version 25 software (Chicago, IL, USA), at a significance level of 0.05.

## Results

Of the 353 patients with suspected TIA enrolled in the COMBAT-TIA Study, 3 patients with inadequate symptom data were excluded, and the remaining 350 patients were examined. The patients' background characteristics are presented in Table 1. The mean ABCD2 score was significantly higher in the focal group and the mixed group than in the nonfocal group (3.8 ± 1.6, 3.9 ± 1.7, and 2.6 ± 1.3, respectively; $P < .001$). By symptom classification, 59 patients (24.1%) in the focal group, 8 patients (22.2%) in the mixed group, and 5 patients (7.2%) in the nonfocal group were assessed as definite AICS (*i.e.*, acute ischemic lesion was confirmed on DWI), indicating significantly fewer patients in the nonfocal group ($P < .01$).

Cerebral infarction recurred during the follow-up period in 20 patients. The one-year event-free survival rate was 0.969, 0.881, and 0.930 in the focal, mixed, and nonfocal groups, respectively. There was no significant difference in the Kaplan-Meier curves by symptom classification ($P = .390$, Fig. 2). When Kaplan-Meier curves were compared by the AICS classification in each symptom group, the risk for cerebral infarction was significantly higher for definite AICS (patients whose infarct area was confirmed by MRI at the initial visit) in any of the symptom groups ($P < .001$, Fig. 3). When Kaplan-Meier curves were compared by ABCD2 score ($\geq$ 4 or not) and whether patients were classified into one or more high-risk categories (atrial fibrillation, carotid stenosis, crescendo TIA, and ABCD2 score $\geq$ 4), the risk for infarction was significantly higher for higher ABCD2 scores and classification into one or more high-risk categories in the focal group, whereas no significant difference was observed in the other groups (Figs. 4 and 5).

## Discussion

In the present study, the mean ABCD2 score was higher in the focal group and the mixed group. This is probably

**Table 1.** *Patients' characteristics.*

| | | Symptom classification | | | |
|---|---|---|---|---|---|
| | Total ($n$ = 350) | Focal ($n$ = 245) | Mixed ($n$ = 36) | Nonfocal ($n$ = 69) | $p$ value |
| Male sex (%) | 57.8 | 57.5 | 51.4 | 60.9 | 0.599 |
| Age (y) | 68.2 ± 13.3 | 69.6 ± 11.3 | 68.9 ± 13.5 | 65.8 ± 15.9 | 0.097 |
| (min-max) | (25−101) | (30−93) | (39−101) | (25−89) | |
| Systolic blood pressure (mmHg) | 147.6 ± 25.0 | 148.5 ± 25.5 | 156.0 ± 26.4 | 140.9 ± 20.5 | 0.043 |
| Diastolic blood pressure (mmHg) | 82.8 ± 14.2 | 79.1 ± 13.1 | 84.0 ± 12.1 | 83.7 ± 14.6 | 0.109 |
| Major symptom | | | | | |
| Any kind of paresis | 135 (38.2%) | 116 (47.3%) | 16 (44.4%) | 2 (2.9%) | 0.001 |
| Sensory disturbance | 63 (17.8%) | 49 (20.0%) | 9 (25.0%) | 0(0.0%) | 0.001 |
| Dysarthria | 80 (22.7%) | 69 (28.2%) | 11 (30.6%) | 0 (0.0%) | 0.001 |
| Visual symptom | 55 (15.6%) | 51(20.8%) | 6 (16.7%) | 0 (0.0%) | 0.001 |
| Vertigo, dizziness, unsteadiness | 94 (26.6%) | 0(0.0%) | 35 (97.2%) | 56 (81.1%) | 0.001 |
| Transient consciousness disturbance | 6 (1.7%) | 0(0.0%) | 0 (0.0%) | 6 (8.7%) | 0.001 |
| ABCD2 Score, total | 3.5 ± 1.6 (0−7) | 3.8 ± 1.6 (0−7) | 3.9 ± 1.7 (0−7) | 2.6 ± 1.3 (0−6) | 0.001 |
| High-risk category ≥ 1* | 245 (70.0%) | 186 (75.9%) | 30 (83.3%) | 29 (42.0%) | 0.001 |
| Comorbidity | | | | | |
| Hypertension | 177 (50.1%) | 125 (51.0%) | 23 (63.9%) | 28 (40.6%) | 0.070 |
| Diabetes mellitus | 56 (15.9%) | 36 (14.7%) | 8 (22.2%) | 12 (20.3%) | 0.485 |
| Dyslipidemia | 115 (32.6%) | 83 (33.9%) | 14 (38.9%) | 17 (24.6%) | 0.244 |
| Atrial fibrillation | 25 (7.1%) | 19 (7.8%) | 1 (2.8%) | 5 (7.2%) | 0.556. |
| Carotid artery stenosis | 12 (3.4%) | 8 (3.3%) | 2 (5.6%) | 2 (2.9%) | 0.752 |
| Major intracranial artery stenosis | 17 (4.8%) | 11 (4.5%) | 2 (5.6%) | 4 (5.8%) | 0.886 |
| History of Stroke | 65 (18.4%) | 38 (15.5%) | 4 (11.1%) | 6 (5.8%) | 0.310 |

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

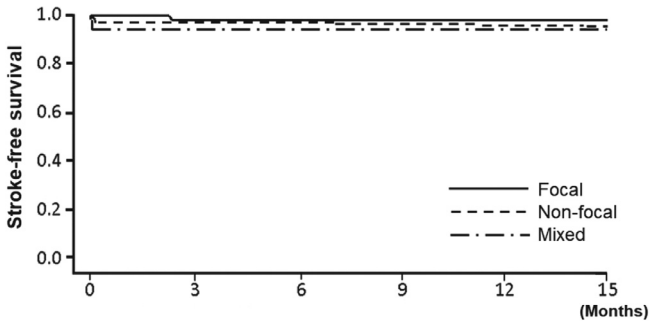


**Fig. 2.** *Recurrence rate of cerebral infarction by symptom classification. There is no significant difference in the outcome among the groups of initial symptoms.*

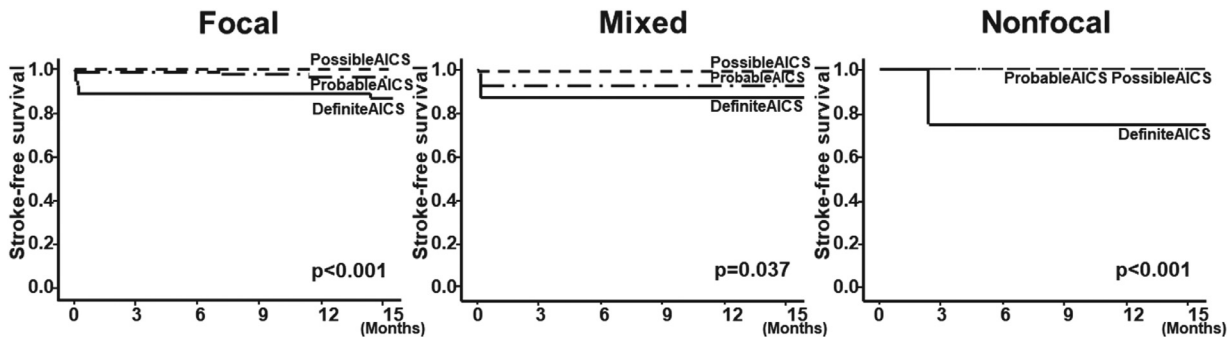


**Fig. 3.** *The recurrence rate of cerebral infarction by AICS classification is shown for each symptom classification. Cerebral infarction recurs significantly more frequently within 1 year in patients rated as definite AICS* (i.e., *positive on diffusion-weighted head MRI at the initial visit), regardless of the type of symptoms.*

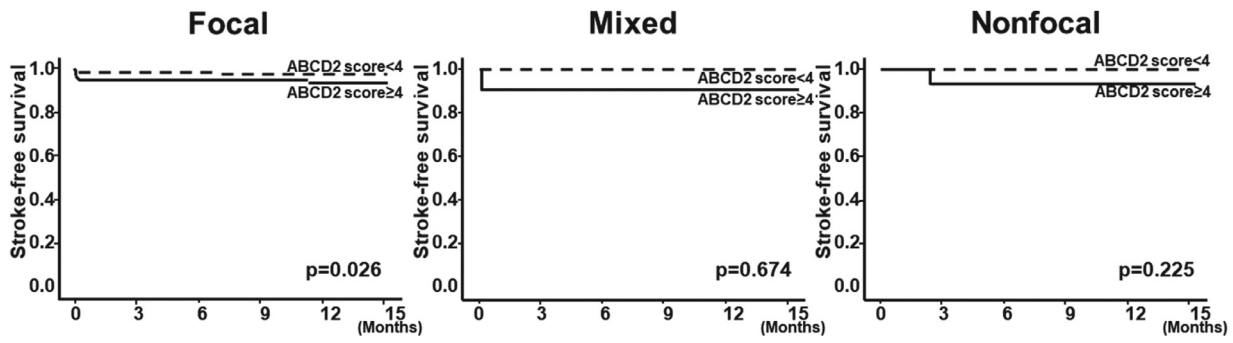


**Fig. 4.** *The recurrence rate of cerebral infarction by ABCD2 score (≥ 4 or < 4) is shown for each symptom classification. The recurrence rate of cerebral infarction is higher in patients with ABCD2 score ≥ 4 in the focal group, whereas there is no significant difference in the mixed and nonfocal groups.*

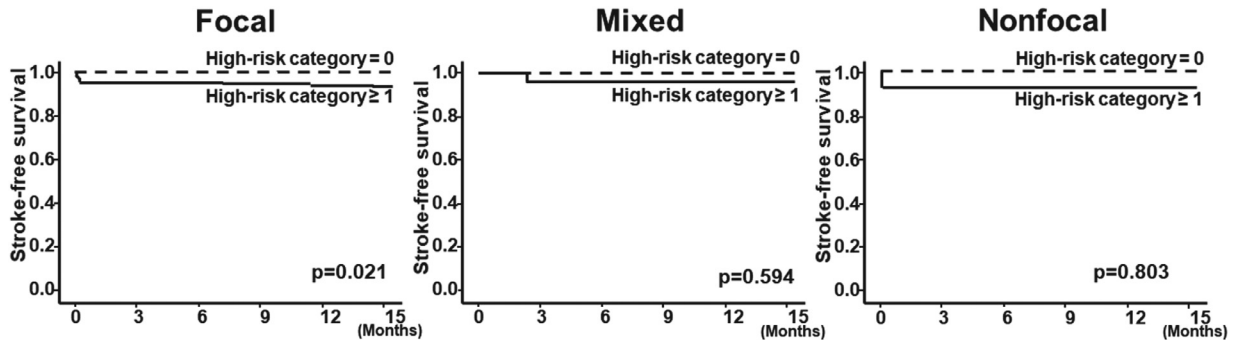


**Fig. 5.** *The recurrence rate of cerebral infarction was compared between patients with high-risk categorization and those without high-risk categorization. The recurrence rate of cerebral infarction is significantly higher in patients with high-risk categorization (≥ 1) in the focal group, whereas there is no significant difference in the mixed and nonfocal groups.*

because focal neurological symptoms such as hemiplegia and speech disturbance were included in the assessment of the ABCD2 score. The presence of significantly fewer patients assessed as definite AICS in the nonfocal group is thought to reflect that the occurrence of focal neurological symptoms is useful for selection of patients with cerebral infarction. However, the one-year event-free survival rate by symptom group did not show any significant difference, suggesting that stratification of risk for developing cerebral infarction only by initial symptoms is difficult.

The PROMISE-TIA Study, which was a Japanese prospective registry of 1362 patients with TIA diagnosed by the time-based definition, demonstrated that ischemic stroke risk during the one-year follow-up period after TIA onset was similar in patients with focal symptom and those with both focal and nonfocal symptoms (7.5% vs. 8.1%, $P$ = .762).[11] Recently, similar results were reported by Santos and Canhão as the frequency of the composite outcome event of stroke, TIA, myocardial infarction or vascular death in the first year of follow-up (17.0% vs. 15.7%, $P$ = .430).[12] These reports were well agree with our results showing that one-year prognosis of TIA in the focal and the mixed groups were similar. However, it should be noted that a considerable fraction of TIAs may be overlooked among clinically nonfocal TNAs. In fact, some studies have reported that cerebellar infarction manifested as isolated vertigo in approximately 10% of patients, and that only 8% of patients with ischemia in the posterior circulation developed a TIA accompanied by focal neurologic deficit symptoms within 90 days prior to onset.[13,14] Hoshino et al. also demonstrated that TNAs with nonfocal symptom in isolation were preceded in 42.0% of patients with ischemic stroke in the vertebrobasilar circulation system.[15] Furthermore, in supratentorial infarction, unilateral infarction in the vestibular cortical network has been reported to manifest solely as dizziness in some cases.[16] Practical guidelines should be established to select high risk patients exhibiting nonfocal symptom in isolation.

Amort et al. reported that memory loss, headache, and blurred vision are symptoms indicative of TIA mimics, and that stroke, TIA, and ischemic heart disease did not occur in any of the patients with these symptoms during follow-up.[17] In the present study, cerebral infarction did not recur during the follow-up period in any of the patients assessed as "not AICS" (*i.e.*, TIA mimics) at the initial visit. Therefore, for patients who are considered, based on the symptoms, course, and high-risk categorization, to definitely have TIA mimics, immediate MRI may be spared.

In the study preceding the present study, the recurrence rate of cerebral infarction was high in the group with ABCD2 score ≥ 4 and the group classified into ≥ 1 high-risk categories.[5] It would be appropriate to interpret these

findings not as denying the significance of the ABCD2 score or high-risk categorization in the other symptom groups, but as suggesting that, in suspected TIA cases with focal neurological symptoms, those with ABCD2 score ≥ 4 or those classified into ≥ 1 high-risk categories are at particularly greater risk of developing infarction.

In recent years, it has been considered problematic to limit the hospitalization of patients with suspected TIA or immediate use of imaging for these patients based on low ABCD2 scores. Policy statements of the American College of Emergency Physicians recommended that one should not rely solely on the ABCD2 score for determining whether adult patients with suspected TIA can be safely discharged from the emergency department,[18] indicating that the ABCD2 score should be used carefully. Guidelines for stroke and TIA in the United Kingdom[19] stated that, since the ABCD2 score insufficiently stratifies the post-TIA risk when it is used alone, and ABCD2-I and ABCD3-I have only minimally improved discriminating capability, it is harmful to delay the diagnosis based on these tools with low levels of discriminating capability. The ABCD2 score is reported to be less sensitive for the detection of posterior circulation stroke than anterior circulation stroke.[20,21]

The COMBAT-TIA Study, which was conducted with the participation of physician-run offices and hospitals with imaging devices, was the only prospective study in Japan that examined how triage during the initial visit of TIA cases should be under the tissue-based definition. We believe that the results of the COMBAT-TIA study reflect the real-world level of treatment of TIA in Japan. Recently, the Japan Stroke Society officially adopted the tissue-based definition of TIA on October 12, 2019, and the present results may help to develop new practical guidelines using the tissue-based definition.

In the present study, the presence or absence of high-risk categorization and ABCD2 score (≥ 4) were shown to be useful for risk stratification in the focal group, whereas their utility in risk stratification in TIA patients showing nonfocal neurological symptoms was not confirmed. This could be attributed to the small numbers of subjects and the fact that the ABCD2 score may be less sensitive for the detection of posterior circulation stroke than anterior circulation stroke.[20,21] Significantly higher risk for brain infarction in patients rated as definite AICS, which was observed in all symptom groups in this study, indicates that, in patients with suspected TIA, diffusion-weighted MRI at the initial visit and prompt diagnosis of definite AICS, *i.e.*, cerebral infarction according to the new definition, would help in the evaluation of the risks of developing infarction. Further studies are necessary to explore the triage methods of patients classified as possible AICS, that is considered to be relatively low risk because of low ABCD2 score, nonfocal symptoms, or lack of high-risk categories. The triage methods other than the high-risk categorization and ABCD2 score as shown in Fig. 1 and the timing of referral to specialist including neuroimaging are needed to be explored.

Certain limitations of the present study have to be considered. First, the findings were based on an observational investigation of real-world triage in the unique Japanese health care system, which may not be generalizable to a more ethnically diverse population and to different types of universal health care systems. Second, some patients in the nonfocal group without DWI evidence of acute ischemic lesion could have had a nonvascular cause for their symptoms. However, this is inevitable when exploring the best triage method to improve the posterior probability of high-risk TIA exhibiting nonfocal symptoms.

## Conclusions

Stroke risk was similar among patients with transient ischemic attack who developed focal, mixed, or nonfocal neurological symptoms. High-risk categorization and ABCD2 score (≥ 4) were found to be useful for risk stratification only in the focal group. Further studies are warranted in triage methods for TIA with nonfocal in isolation in conjunction with DWI.

## Sources of funding

None.

## Declaration of Competing Interest

The authors have reported their conflict of interest to the Japan Stroke Society, and there is no conflict of interest that should be disclosed for the publication of this paper.

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