

Stroke Outcomes of Japanese Patients With Major Cerebral Artery Occlusion in the Post-Alteplase, Pre-MERCI Era

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This study examined outcomes of patients with acute ischemic stroke (AIS) with major cerebral artery occlusion after the approval of intravenous recombinant tissue-type plasminogen activator (IV rt-PA) but before approval of the MERCI retriever. We retrospectively enrolled 1170 consecutive patients with AIS and major cerebral artery occlusion (496 women; mean age, 73.9 ± 12.3 years) who were admitted within 24 hours after the onset of symptoms to 12 Japanese stroke centers between October 2005 and June 2009. Cardioembolism was a leading cause of AIS in this group (68.2%). The occlusion sites of the major cerebral arteries included the common carotid artery and internal carotid artery (ICA; 29.6%), middle cerebral artery (52.2%), and basilar artery (7.6%). Recanalization therapy (RT) was performed in 32.0% of patients (IV rt-PA, 20.0%; neuroendovascular therapy, 9.4%; combined, 2.5%). Symptomatic intracerebral hemorrhage within 36 hours with a ≥ 1 -point increase in the National Institutes of Health Stroke Scale score occurred in 5.3% of the patients. At 3 months (or at hospital discharge), 29.3% of the patients had a favorable outcome (based on a modified Rankin scale score of 0-2), 23.8% were bedridden, and 15.6% died. After multivariate adjustment, RT was positively associated with a favorable outcome and negatively associated with death, whereas age, baseline National Institutes of Health Stroke Scale score, and ICA occlusion were negatively associated with a favorable outcome and positively associated with death. One-third of the patients with AIS and major cerebral artery occlusion were treated with RT, which was independently associated with favorable outcomes and death. However,

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40% of the patients became bedridden or died during the post-alteplase, pre-MERCI era in Japan. **Key Words:** Acute ischemic stroke—thrombolysis—t-PA—endovascular treatment.

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Although the age-adjusted annual incidence of acute ischemic stroke (AIS) has gradually decreased,^{1,2} the prognosis for many patients with AIS and major cerebral artery occlusion remains poor. Intravenous (IV) recombinant tissue-type plasminogen activator (rt-PA) can be administered within 3–4.5 hours of symptom onset, but is not very effective for patients with occlusion of the internal carotid artery (ICA)³ or proximal middle cerebral artery (MCA).⁴ Intra-arterial thrombolysis is another strategy for treating acute major cerebral artery occlusion, but its value is limited as well.^{5,6} The effects of percutaneous transluminal angioplasty or intracranial stenting are unclear, given the lack of adequate clinical trials. New neuroendovascular devices to remove clots from occluded arteries, such as the MERCI retriever,^{7,8} PENUMBRA System,⁹ or Solitaire stent,¹⁰ have been introduced worldwide; however, these have yet to be examined in randomized control trials. A concern surrounding the use of these devices is the possible high mortality rate if recanalization is not achieved.

In Japan, a council was established in 2009 to consider approval for such devices, and clinical data on patients with AIS and major cerebral artery occlusion who were not treated with these devices are required. In advance of the council, a joint research task force derived from the JR-NET2 (Japanese Registry of NeuroEndovascular Therapy 2) and SAMURAI (Stroke Acute Management with Urgent Risk Factor Assessment and Improvement) study groups on stroke medicine conducted a multicenter observational study to determine the current domestic status of AIS with major cerebral artery occlusion in the post-alteplase, pre-MERCI era.

Patients and Methods

We retrospectively registered 1170 consecutive patients (496 women; mean age, 73.9 ± 12.3 years) who were admitted within 24 hours of AIS onset with major cerebral artery occlusion to 12 stroke centers in Japan between October 2005 and June 2009. During the study period, a total of 5213 patients were admitted within 24 hours after the onset of any type of AIS to these stroke centers. The local Ethics Committees approved the retrospective collection of clinical information from databases and submission of the data to our central office. The major occluded cerebral arteries included the common carotid artery (CCA), ICA, anterior cerebral artery (ACA), MCA, posterior cerebral artery (PCA), basilar artery (BA), and vertebral artery (VA). Data from magnetic resonance angiography,

computed tomography angiography, digital subtraction angiography, or carotid ultrasonography obtained on admission were examined to identify occlusion sites. Because most of the patients had occlusion of the ICA (including the CCA), MCA, and BA, subgroups comprising patients with occlusion of these 3 arteries were analyzed. Baseline data, including sex, age, onset-to-arrival time, and baseline neurologic deficits (based on National Institutes of Health Stroke Scale [NIHSS] score) were collected from medical records. Clinical stroke subtypes were determined by the consensus of vascular neurologists or neurosurgeons according to the TOAST subtype classification system.¹¹ Recanalization therapy (RT) initiated immediately after admission included IV rt-PA and/or neuroendovascular therapy, such as intra-arterial urokinase,^{5,6} percutaneous transluminal angioplasty, and intracranial stenting. Mechanical thrombectomy devices were not yet approved for use in Japan during the study period.

The outcomes were as follows: symptomatic intracerebral hemorrhage (sICH) within the initial 36 hours with neurologic deterioration corresponding to an increase of ≥ 1 point from the baseline NIHSS score, a favorable outcome corresponding to a modified Rankin scale (mRS) score of 0–2 at 3 months after stroke onset, death at 3 months, and an unfavorable outcome corresponding to an mRS score of 5–6 at 3 months. The mRS score at 3 months was investigated as thoroughly as possible from reviews of outpatient clinic medical records and from face-to-face or telephone interviews. The mRS score at hospital discharge was used when data from the 3-month assessment were unavailable.

Data were statistically analyzed with JMP Pro 9.0.2 statistical software (SAS Institute, Cary, NC). Clinical characteristics of the patients were compared using the Student *t* test, χ^2 test, and Mann-Whitney *U* test as appropriate. Factors that were independently associated with each outcome were determined using multivariate analyses with adjustment for sex, age, cardioembolism, onset-to-arrival time, ICA occlusion, baseline NIHSS score, and RT (forced-entry method). A *P* value $< .05$ was considered significant.

Results

Table 1 presents the baseline characteristics of the patients. Cardioembolism was the leading stroke subtype (68.2%), the MCA was the most frequently occluded artery (52.2%), and 32.0% of the patients underwent RT of some type.

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