Three Cases of Middle Cerebral Artery Occlusion Emergently Revascularized with A Balloon-expandable Coronary Bare Stent After Intravenous Tissue Plasminogen Activator

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> Background: Revascularization with emergency stent placement in patients with acute middle cerebral artery occlusion is still controversial in Japan. Methods: We placed balloon-expandable coronary bare stents in 3 patients in whom revascularization was not obtained after intravenous tissue plasminogen activator therapy (IV t-PA) for acute ischemic stroke (middle cerebral artery M1 occlusion). Results: Patient 1 was an 87-year-old woman with left hemiplegia. Her National Institutes of Health Stroke Scale score (NIHSS) was 12, and her magnetic resonance imaging diffusion-weighted image Alberta Stroke Programme Early Computed Tomography Score (MRI DWI-ASPECTS) was 8. Adequate revascularization was not obtained with IV t-PA and adjunctive percutaneous transluminal angioplasty (PTA) for right M1 occlusion, and a stent was placed 368 minutes after onset. Her Thrombolysis in Myocardial Infarction Trial (TIMI) score was 2. After 90 days, her modified Rankin scale (mRS) score was 4. Patient 2 was a 65-year-old woman with left hemiplegia. Her NIHSS score was 16, and MRI DWI-ASPECTS was 9. A stent was placed 337 minutes after onset after IV t-PA and adjunctive PTA for right M1 occlusion. Her TIMI score was 3. After 90 days, her mRS score was 3. Patient 3 was a 61-year-old woman with left hemiplegia. Her NIHSS score was 18, and MRI DWI-ASPECTS score was 7. Arterial dissection was found after IV t-PA and adjunctive PTA for the right M1 occlusion, so a stent was placed 312 minutes after onset. Her TIMI score was 2. After 90 days, her mRS score was 0. Conclusions: Revascularization with emergency stent placement seems likely to be successful in patients with acute middle cerebral artery occlusion, but clinical symptoms do not always improve in some cases and care is needed in selecting patients for the procedure. Key Words: Acute ischemic stroke-adjunctive percutaneous transluminal angioplastyballoon-expandable stent-tissue plasminogen activator. © 2012 by National Stroke Association

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Intravenous tissue plasminogen activator (IV t-PA) is widely used in cases of hyperacute ischemic stroke, but revascularization rates are low in cases of major artery occlusion.¹ In the Japan Alteplase Clinical Trial II (J-ACT II) study, the revascularization rate for the middle cerebral artery (MCA) with IV t-PA (0.6 mg/kg) was shown to be 51.7% at 6 hours after administration and 69.0% after 24 hours.² In recent years, concurrent endovascular treatment has been applied in cases when revascularization is not obtained using IV t-PA.^{3,4}

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There are reports from many countries of intracranial stent placement in the MCA for acute MCA infarction,⁵⁻²⁰ but stent devices for intracranial use have not been approved in Japan, and reports on their use are scarce.^{21,22}

With the approval of the ethics committee at our hospital, we have been conducting combined endovascular treatment including stent placement in cases of hyperacute cerebral infarction in which early revascularization is not obtained after IV t-PA therapy, and we begin antithrombotic therapy within 24 hours in these endovascular treatment patients after IV t-PA. Here we report stent placement in 3 patients who did not achieve revascularization after IV t-PA therapy for acute ischemic stroke caused by MCA occlusion.

Case 1

The patient was an 87-year-old woman who was brought to a local doctor with sudden left hemiplegia. A subtly high-intensity area was seen from the right corona radiata to the basal ganglia on diffusion-weighted imaging (DWI) of the head, and occlusion of the M1 segment of the right magnetic resonance angiography (MRA) was seen. Mer magnetic resonance imaging diffusion-weighted image Alberta Stroke Programme Early Computed Tomography Score (MRI DWI-ASPECTS) was 8. With a National Institutes of Health Stroke Scale (NIHSS) score of 12, IV t-PA therapy was performed at 130 minutes, while the patient was being transported to our hospital. On admission, she had remaining right conjugate deviation, left hemiplegia, and impaired articulation. Endovascular treatment was started in our hospital with her NIHSS score still at 12. A 4-Fr catheter introducer (Supersheath; Medikit, Tokyo, Japan) was inserted from the right inguinal region, and a 4-Fr diagnostic catheter (JB2; Medikit) was introduced. Occlusion of the proximal right MCA was confirmed (Thrombolysis in Myocardial Infarction Trial [TIMI] score, 0). The sheath size was changed to a 6.2-Fr catheter introducer (Supersheath) for the purpose of endovascular treatment, and a 6-Fr guiding catheter (Envoy; Cordis, Miami, FL) was placed in the right internal carotid artery. Systemic heparinization was achieved by infusing 2500 units of heparin. After advancing a microguidewire (300 cm, 0.014 inch; Asahi Chikai, Aichi, Japan) through the occlusion site to distal M2, a microcatheter (Renegade HI-FLO 150 cm; Boston Scientific, Natick, MA) was guided to the distal side of the thrombus. The microcatheter was changed to a PTA Dilatation Catheter (Gateway 2.0 mm \times 9 mm; Boston Scientific), and percutaneous translumial angioplasty (PTA) was carefully performed. However, only a very slight recanalization was seen (TIMI 1). PTA was performed twice, but adequate revascularization was not obtained. A balloon-expandable coronary bare stent (Micro Driver stent 2.25 mm \times 8 mm; Medtronic, Minneapolis, MN) was then placed, and good revascularization was obtained (TIMI 2). Immediately before stent placement, aspirin 100 mg/day and cilostazol 200 mg/ day were administered via a nasal tube. A tendency for tachycardia appeared from the second day in hospital, so cilostazol was discontinued and clopidogrel was added at 50 mg/day. The time until revascularization was 368 minutes after onset. On the fourth day in the hospital, infarction of the right frontal lobe and basal ganglia was seen, but infarction in the temporal and parietal lobes was avoided. Figure 1 shows the imaging findings for this patient. After 30 days, her NIHSS score was 15. After 90 days, her modified Rankin scale (mRS) score was 4. From postoperative week 4, clopidogrel alone was administered as an antiplatelet agent.

Case 2

The patient was a 65-year-old woman. Disturbances of consciousness, left hemiplegia, and impaired articulation appeared suddenly, and she was transported by ambulance to the hospital. On admission, neurologic findings were Japan coma scale (JCS) I-1, left hemiplegia, impaired articulation, and right conjugate deviation, and her NIHSS score was 16. A subtly high-intensity area from the corona radiata to the basal ganglia was seen on a DWI of the head, and the MRA was occluded in the right proximal M1 segment. Her MRI DWI-ASPECTS score was 9. IV t-PA therapy was started 135 minutes after onset, and angiography was performed. A 4-Fr catheter introducer (Supersheath) was inserted from the right inguinal region, after which a 4-Fr diagnostic catheter (JB2; Medikit) was introduced. After confirming occlusion in the right proximal MCA, IV t-PA therapy was started with TIMI 1, and neurologic symptoms had not improved 1 hour after IV t-PA. The sheath size was changed to a 6.2-Fr catheter introducer (Supersheath) for the purpose of endovascular treatment, and a 6-Fr guiding catheter (Envoy) was placed in the right internal carotid artery. Systemic heparinization was achieved by infusion of 2500 units of heparin. After advancing a microguidewire (300 cm 0.014 inch; Asahi Chikai) through the occlusion site to the distal M2, a microcatheter (Renegade HI-FLO 150 cm; Boston Scientific) was guided to the distal side of the thrombus. The microcatheter was changed to a PTA Dilatation Catheter (Gateway 2.0 mm \times 9 mm; Boston Scientific), and PTA was carefully performed. However, only very slight recanalization was seen (TIMI 2). PTA was conducted twice, but adequate recanalization was not obtained, so a balloon-expandable coronary bare stent (Micro Driver stent 2.5 mm \times 12 mm; Medtronic) was placed after the administration of aspirin at 100 mg/day and cilostazol at 200 mg/day, and good revascularization was obtained (TIMI 3). Postoperative administration of argatroban was started at 60 mg/day. High intensity areas from the corona radiata to the basal ganglia were confirmed on DWI on day 2 of hospitalization. No reocclusion occurred in the MRA, and cerebral

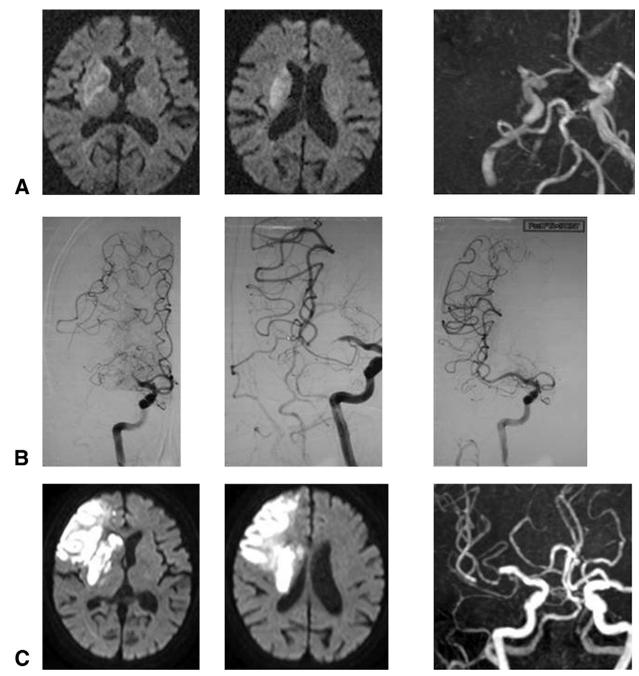


Figure 1. Radiologic findings in case 1. (A) Diffusion-weighted imaging and magnetic resonance angiography on arrival. (B) Cerebral angiographic findings. Left: After t-PA (before cerebral vessel treatment). Middle: Simultaneous imaging from the guiding catheter and microcatheter. Right: After stent placement. (C) Magnetic resonance imaging and magnetic resonance angiography on day 4 in the hospital.

blood flow was good. Figure 2 shows imaging findings for this patient. After 30 days, her NIHSS score was 7. After 90 days, her mRS score had improved to 3. From postoperative week 4, cilostazol alone was administered as an antiplatelet agent.

Case 3

The patient was a 61-year-old woman. Left hemiplegia and impaired consciousness appeared suddenly, and she

was transported by ambulance to the hospital. On admission, her NIHSS score was 18, and a subtly high-intensity area was identified from the right basal ganglia to the insular cortex and opercular part of the frontal lobe. Her MRI DWI-ASPECTS score was 7. Occlusion was apparent in the right proximal M1 on MRA. Administration of t-PA was started 114 minutes after onset, followed by angiography. A 4-Fr catheter introducer (Supersheath) was inserted from the right inguinal region, followed by a 4-Fr diagnostic catheter (JB2; Medikit). Recanalization of the

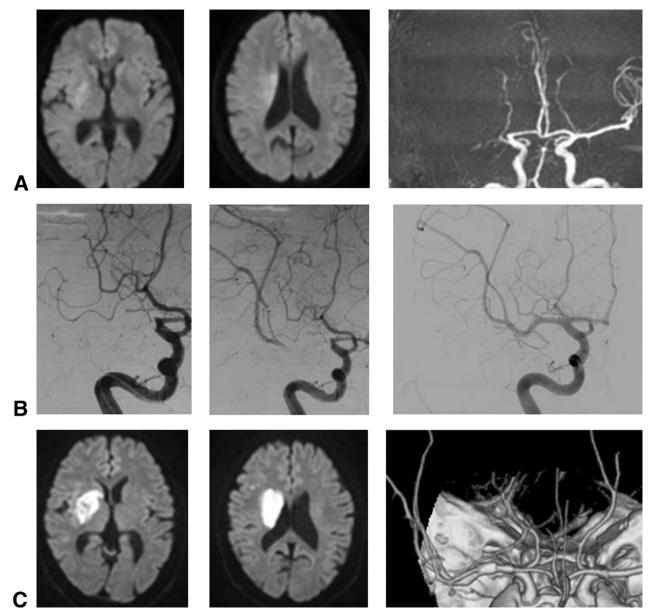


Figure 2. Radiologic findings in case 2. (A) Diffusion-weighted imaging and magnetic resonance angiography on arrival. (B) Cerebral angiographic findings. Left: After t-PA (before cerebral vessel treatment). Middle: Simultaneous imaging from the guiding catheter and microcatheter. Right: After stent placement. (C) Magnetic resonance imaging and magnetic resonance angiography on day 2, 3-dimensional computed tomographic angiography on day 8 in the hospital.

occlusion in the proximal right MCA was not achieved, and TIMI remained at 1. Neurologic findings had not improved by 1 hour after the start of IV t-PA. The sheath size was changed to a 6.2-Fr catheter introducer (Supersheath) for the purpose of endovascular treatment, and a 6-Fr guiding catheter (Envoy) was placed in the right internal carotid artery. Systemic heparinization was achieved using 2500 units of heparin. After advancing a microguidewire (300 cm 0.014 inch; Asahi Chikai) through the occlusion site to the distal M2, a microcatheter (Renegade HI-FLO 150 cm; Boston Scientific) was guided to the distal side of the thrombus. The catheter was changed to a PTA Dilatation Catheter (Gateway 2.0 mm \times 9 mm; Boston Scientific) and PTA was carefully performed, but TIMI remained at 1. PTA was performed twice, but adequate revascularization was not obtained, and findings suggested partial vascular dissection. After the administration of aspirin at 100 mg/day and cilostazol at 200 mg/ day via a nasal tube, a balloon-expandable coronary bare stent (Micro Driver stent 2.75 mm \times 12 mm; Medtronic) was placed. After placement, her TIMI score was 2. Time until recanalization was 312 minutes from onset. High-intensity areas were confirmed from the right basal ganglia to the frontotemporal lobe on DWI on day 2 of hospitalization. No reocclusion occurred in the MRA, and her blood flow was good. Figure 3 shows imaging findings for this patient. After 30 days, her NIHSS score was 0. Both on discharge and after 90 days, her mRS score



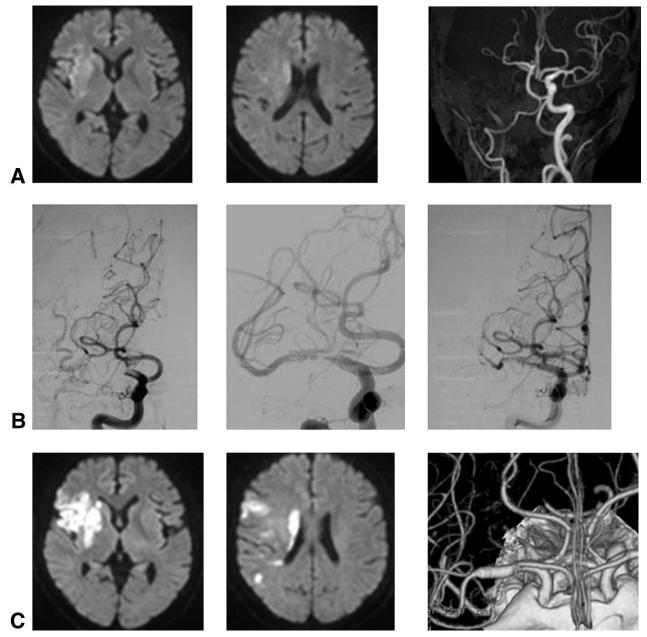


Figure 3. Radiologic findings in case 3. (A) Diffusion-weighted imaging and magnetic resonance angiography on arrival. (B) Cerebral angiographic findings. Left: After t-PA (before cerebral vessel treatment). Middle: Simultaneous imaging from the guiding catheter and microcatheter. Right: After stent placement. (C) Magnetic resonance imaging and magnetic resonance angiography on day 2, 3-dimensional computed tomographic angiography on day 7 in the hospital.

was 0. From postoperative week 4, cilostazol alone was administered as an antiplatelet agent.

Discussion

We placed cerebral artery stents in 3 patients after IV t-PA therapy had been performed. PTA was conducted, but sufficient recanalization was not obtained in 2 cases, and PTA was accompanied by cerebral vascular dissection in the remaining case. The result was that while patency was maintained in all 3 cases, outcomes by day 90 were mRS scores of 3, 4, and 0.

Many reports have already appeared in other countries regarding the emergency use of coronary artery stents or self-expanding stents for acute cerebral infarction (MCA stenosis or occlusion). Recently, Roth et al²⁰ reported that withdrawal of an unfolded, fully recoverable, intracranial stent yielded very promising angiographic and clinical results. In particular, numerous reports have described elective stent placement for MCA stenosis.^{10,18} In those reports from other countries, self-expanding stents were used in all but 1 report. However, we used balloon-expandable stents. With regard to time until stent placement, Zaidate et al¹⁹ reported a mean time until recanalization of 315 minutes in 9 cases of acute cerebral infarction (6 of which involved MCA infarction) when self-expanding stents were used. Brekenfeld et al⁷ reported a mean time until revascularization of 368.7 minutes in 12 acute cases, of which stents were placed for MCA occlusion in 4 cases. Levy et al¹³ reported stent placement in 19 cases of intracranial vascular occlusion. They classified time until stent placement by improvement in NIHSS score after 24 hours, and reported that the time until angiography was needed in the group with improvement of ≥ 4 in NIHSS was 216 \pm 123 minutes, and that in the group without improvement of ≥ 4 in NIHSS was 624 ± 918 minutes. The time was significantly shorter in the improved group. The mean time until recanalization in our 3 patients was 339 minutes, about the same as in previous reports. No relationship was seen between the time until recanalization in the 3 patients and functional prognosis.

Patency rates after stent placement were reported by Brekenfeld et al^7 as a postoperative median TIMI score of 2.5 in 4 patients and by Levy et al^{13} as a TIMI score of 2 to 3 in all 9 patients who underwent stent placement for MCA occlusion. Postoperative TIMI score in our 3 patients was 2 in 2 patients and 3 in 1 patient, similar to the results in other countries.

With regard to perioperative complications, Zaidate et al¹⁹ reported basal ganglia bleeding in 1 of 9 patients and Brekenfeld et al⁷ reported no treatment complications. Jiang et al¹¹ saw complications in 4 of 40 patients (acute occlusion in 1 patient and subarachnoid hemorrhage in 3 patients). In 2005, Lee et al¹² reported 17 cases of intracranial stent placement in the acute period using a balloon-expandable stent in the MCA. After stent placement, stent reocclusion was seen in 9 patients (56.3%) and vessel rupture in 2 patients (12.5%), 1 of whom had subarachnoid hemorrhage and died. In 9 cases of in-stent thrombosis in the acute phase, the in-stent thrombosis had disappeared by angiography performed in the chronic phase and recanalization was obtained. They reported that the existence of in-stent thrombosis in the acute phase does not necessarily reflect the technical success rate in the chronic phase. Our 3 patients experienced no perioperative complications.

With respect to prognosis, Zaidate et al¹⁹ compared mRS and NIHSS scores during hospitalization, and over a mean observation period of 12.5 months, identified improvements in median mRS score from 4 to 2.5 and median NIHSS score from 17 to 6. Brekenfeld et al⁷ reported a median NIHSS score of 15.5 at the time of onset and median mRS score of 3.5 after 3 months. Jiang et al¹¹ reported no adverse neurologic findings with the exception of 1 case with preoperative findings, but there were no cases of repeated transient ischemic attack (TIA) or cerebral infarction over a median observation period of 10 months. Confirmational angiography was conducted for 8 vessels in 7 patients, with restenosis seen in only 1

case. In the report by Levy et al,¹³ improvement of NIHSS score by ≥ 4 was seen in 7 of 14 patients with TIMI score of 2 to 3. However, no improvement of NIHSS score by ≥ 4 was obtained in all 4 patients without TIMI scores of 2 to 3. In a survey of outcomes, Lee et al¹² found that of 17 patients, outcomes were excellent in 10, good in 3, fail in 3, and death in 1, with positive results of good or better in 13 of 17 patients (76.4%). In our patients, mRS score after 90 days was 0 in 1 patient, 3 in 1 patient, and 4 in 1 patient, but a comparison with patients showing no recanalization after t-PA therapy is needed to determine whether this is superior or not. Among cases in our hospital in which only t-PA therapy was provided for MCA obstruction, mRS score after 90 days in 8 cases where revascularization was not obtained was 2 in 1 patient and 5 to 6 in 7 patients. These cases were obviously more serious than the 3 patients in whom stents were placed. While limitations exist in the small number of patients overall and the fact that this was not a randomized control trial, the group with revascularization from stent placement seemed to achieve fairly good functional prognosis. In J-ACT II,² revascularization at 6 and 25 hours after t-PA administration for MCA obstruction are taken as independent predictors of clinical outcome.

No reports have given MRI DWI-ASPECTS scores at the time of hospitalization in cases of stent placement in intracranial arteries. When determining indications for stent placement in cases of acute MCA obstruction, referring to the size of cerebral infarction on admission by DWI is important, but none of our 3 cases showed any differences in MRI DWI-ASPECTS scores at the time of arrival. In fact, case 3, in which the final functional outcome was good, showed the largest high-intensity area on MRI-DWI at the time of hospitalization. In addition, no relationship was seen between NIHSS score at the time of arrival and functional outcome after stent placement. However, the patient with good outcome was somewhat younger than the other patients (61 years old). The reason for the difference in final functional outcome, despite the lack of difference between the 3 patients in time until revascularization with stent placement, may have been that the degree of ischemia from time of arrival until placement of the stent was serious in the patient with poor outcome, and the infarction had become irreversible.

In Japan, 2 cases of emergency balloon-expandable stent placement in the MCA for acute cerebral infarction have been described. In these 2 cases, stents were placed for the purpose of rescue during elective PTA for MCA stenosis. Emergency balloon-expandable stents were placed by Yamamoto et al²² because of dissection and by Tenjin et al²¹ because acute infarction occurred during PTA, but the clinical backgrounds differed from those in our patients.

The high incidence of restenosis during long-term observation is a problem in intracranial stent placement.¹⁰ In the Stenting of Symptomatic Atherosclerotic Lesions

MCA RECIRCULATION WITH STENT AFTER IV t-PA

in the Vertebral or Intracranial Arteries (SSYLVIA) study,⁵ the decision was made to administer 100 mg of aspirin alone from postoperative week 4, while the Wingspan study²³ used 300 to 325 mg of aspirin for life. The guidelines in Japan for endovascular treatment in the brain²⁴ recommend that when angioplasty or stent placement is performed for intracranial arterial stenosis, anticoagulant therapy be performed from the time of operation and that antithrombotic therapy be continued postoperatively, but no specific drugs are indicated. Recently in Japan, cilostazol has been reported to be effective after carotid artery stent placement.²⁵ Among the present patients, we used cilostazol in 2 patients and clopidogrel in 1 patient after intracranial stent placement, but the patient who received clopidogrel had tachycardia with cilostazol. As of the time of this writing, no restenosis has been identified at the stent, but observation of the future course is needed.

Currently, especially in Japan, IV t-PA therapy is widely used, and cases with combination endovascular treatment are also increasing. Emergency stent placement is successful in some patients, such as those we have reported here, and may represent a very effective measure in some cases. Patients who require emergency stent placement are predicted to increase in the coming years, and establishment of proper patient selection criteria for stent placement and accumulation of treatment results are awaited.

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