



Thrombectomy for Small-Artery Occlusions with the Small-Diameter Stent Retriever, Tron Fx 2 mm × 15 mm: A Case Series

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Objective: The safety and efficacy of thrombectomy for small-artery occlusions is still controversial. In April 2019, Tron Fx, a stent retriever with an expansion diameter of 2 mm, became reimbursed by health insurance in Japan. We report on cases of thrombectomy for small-artery occlusions performed using this device in seven patients.

Methods: The subjects were seven patients who underwent thrombectomy between July 2019 and June 2020 using Tron Fx with 2 mm in diameter. We analyzed clinical results including recanalization and complications.

Results: The mean age of the seven patients was 80.1 years, and the subjects included six men. The sites of occlusion were the middle cerebral artery M2 (n = 4), M4 (n = 1), anterior cerebral artery A2 (n = 1), and A3 (n = 1). One of the seven patients had an M2 occlusion that was formed during coil embolization for a ruptured cerebral aneurysm. In five cases, four cases were of primary occlusion and one case was of emboli into a new territory, treating with only Tron Fx 2 mm resulted in thrombolysis in cerebral infarction (TICI) 2b–3 in four cases. There was one case of grade 0, which was M4 occlusion. Finally, TICI 2b–3 were achieved in six of seven cases. No symptomatic intracranial hemorrhage occurred. Symptoms improved in five of six patients, excluding a vascular occlusion that occurred during surgery.

Conclusion: Tron Fx with 2 mm diameter can be used safely for small-artery occlusion. The introduction of Tron Fx with 2 mm diameter may contribute to expand indications for thrombectomy for small-artery occlusions.

Keywords ▶ acute ischemia, thrombectomy, small artery occlusion, stent retriever, Tron Fx

Introduction

Thrombectomy for acute-phase cerebral infarction due to internal carotid artery occlusion and middle cerebral artery M1 occlusion has been established as an effective treatment method. However, the efficacy and safety of thrombectomy for small-artery occlusions including middle cerebral artery M2 occlusions remain unclear.^{1–3} On the other hand, there are several recent papers that suggest efficacy of M2 occlusions.^{4–7} In thrombectomy for small-artery occlusions,

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Received: July 28, 2020; Accepted: September 11, 2020

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hemorrhagic complications by a stent retriever have been reported,^{8,9} and the application cannot be easily decided in many cases. Treating physicians must take care about technical difficulties for accessing small-caliber vessels.⁴ Seners et al. reported that complete recanalization was achieved by intravenous (IV) tissue plasminogen activator (tPA) treatment in 38% of patients with M2 and M3 occlusions,¹⁰ and thrombectomy was not always performed in anticipation of the effectiveness of IV tPA treatment. In Japan, two sizes of Tron Fx (Terumo, Tokyo, Japan), one with an expansion diameter of 2 mm and a labeled length of 15 mm and another with an expansion diameter of 4 mm and a labeled length of 20 mm, were introduced in April 2019, and the use of Tron Fx with an expansion diameter of 2 mm is expected to lead to the expansion of indications for thrombectomy of small-artery occlusions. Here, we report on cases of thrombectomy with Tron Fx 2 mm × 15 mm in seven patients at our hospital.

Materials and Methods

The subjects were seven patients who underwent thrombectomy with Tron Fx 2 mm × 15 mm between July 2019

and June 2020 at our hospital. In patients in whom a hemorrhagic lesion was not observed on head CT scan on admission and cerebral infarction due to major artery occlusion was suspected from the symptoms, or those who were diagnosed with cerebral infarction due to major artery occlusion by head MRI/MRA on admission, and in whom the salvageable penumbra was expected to be present by recanalization of the occluded vessel, cerebral angiography was performed on the premise that thrombectomy was performed. In those for whom IV tPA was not contraindicated, IV tPA treatment was combined as principle.

We used the National Institutes of Health Stroke Scale (NIHSS) for neurological assessment before and after treatment and modified Rankin Scale (mRS) before onset and after treatment. For the assessment of imaging before treatment, we used the Alberta Stroke Program Early CT Score (ASPECTS)/ASPECTS-Diffusion-Weighted Imaging (DWI) by CT/MRI. Recanalization was assessed using the thrombolysis in cerebral infarction (TICI) grading system. Intracranial hemorrhage after treatment was assessed according to the criteria for the Safe Implementation of Thrombolysis in Stroke-Monitoring Study, and cases in which the NIHSS score worsened by 4 or more due to intracranial hemorrhage were defined as symptomatic intracranial hemorrhage.¹¹⁾

We obtained written consent from patients or their family before performing cerebral angiography and thrombectomy.

Results

Summary of the subjects is shown in **Tables 1** and **2**. The seven subjects included six men and one woman. The mean age was 80.1 years (range, 69–89 years). The sites of occlusion were middle cerebral artery M2 (n = 4), M4 (n = 1), anterior cerebral artery (ACA) A2 (n = 1), and A3 (n = 1). There was one case in which thrombectomy was performed for middle cerebral artery M2 occlusion due to the thrombus forming during coil embolization for a ruptured cerebral aneurysm. In the remaining six patients, the mean NIHSS score before treatment was 19.5 (8–26). One patient was preoperatively assessed with ASPECTS, for which the score was 9, and five patients were preoperatively assessed with ASPECTS-DWI, for which the score was 8.8 (6–11). The affected sides were right (n = 1) and left (n = 5). Cerebral infarction occurred outside the hospital in all six patients. Of these six patients, five had atrial fibrillation, whereas in one patient, no transient atrial fibrillation or atrial fibrillation was captured during hospitalization. IV

Table 1 Summary of clinical data for patients treated with Tron Fx 2 mm

Case no.	Side/Location	ASPECTS	tPA	TICI	NIHSS at onset	NIHSS after MT	P2R (min)	O2R (min)	Non SIHA/SIHA	Combined device before Tron Fx 2 mm	Additional device after Tron Fx 2 mm	mRS at discharge (mRS before onset)
1*	Right/M2	NA	No	3	NA	NA	NA	NA	No/No	No	No	1 (1)
2**	Left/M4	CT 9	Yes	0	25	19	NA	NA	No/No	No	No	3 (0)
3	Left/A2	DWI 6	No	2b	21	15	99	253	HI 2/No	Tron Fx 4 mm/ Solitaire***	No	4 (3)
4	Left/A3	DWI 9	Yes	3	22	19	35	165	No/No	No	No	4 (3)
5	Right/M2	DWI 9	No	3	8	3	50	NA	No/No	Sofia	No	1 (0)
6	Left/M2	DWI 9	Yes	3	15	11	47	172	No/No	No	Trevo	1 (1)
7	Left/M2	DWI 11	Yes	3	26	0	24	123	No/No	No	No	0 (0)

*M2 occlusion during coil embolization for ruptured cerebral aneurysm.

**Probable more proximal occlusion at onset.

***Primary left M1 occlusion was treated by Tron Fx 4 mm x 30 mm/Solitaire 4, mm x 40 mm. ENT of left A2 was treated by Tron Fx 2 mm x 15 mm.

A: anterior cerebral artery; ASPECTS: Alberta Stroke Program Early CT Score; DWI: Diffusion-Weighted Imaging; ENT: embolization to new territory; M: middle cerebral artery; min: minimum; mRS: modified Rankin Scale; MT: mechanical thrombectomy; NA: not available; NIHSS: National Institutes of Health Stroke Scale; O2R: onset to recanalization; P2R: puncture to recanalization; SIHA: symptomatic intracerebral hemorrhage; TICI: thrombolysis in cerebral infarction; tPA: tissue plasminogen activator

Table 2 Outcome and complication of cases

Used devices	Number of cases	TICI 2b + 3 (TICI 3)	Non SIHA (SIHA)
Tron Fx 2 mm only	4	3 (3)	0 (0)
Combined device before Tron Fx 2 mm			
Tron Fx 4 mm/Solitaire*	1	1 (0)	1 (0)
Sofia	1	1 (1)	0 (0)
Additional device after Tron 2 mm			
Trevo	1	1 (1)	0 (0)
Overall	7	6 (5)	1 (0)

SIHA: symptomatic intracerebral hemorrhage; TICI: thrombolysis in cerebral infarction

tPA treatment was performed in four of six patients. The reason for not performing IV tPA treatment in the remaining two patients was that the time of the onset was unknown ($n = 1$) or that the patient was not a contraindicated case, but an aged case (89 years) ($n = 1$). Tron Fx 2 mm \times 15 mm was used in all seven cases, including the one case in which a thrombus was formed during coil embolization, and in four of these cases, Tron Fx 2 mm \times 15 mm was used alone. In three cases in which other devices were concomitantly used, an aspiration catheter, SOFIA FLOW Plus (Terumo) ($n = 1$), and other stent retrievers ($n = 2$) were used. In Case 3, initial M1 occlusion was recanalized with Tron Fx 4 mm \times 30 mm and Solitaire (Medtronic, Minneapolis, MN, USA) 4 mm \times 40 mm and resulted embolization of new territory, A2 occlusion. This lesion was treated with Tron Fx 2 mm \times 15 mm. In Case 6, Trevo (Stryker, Kalamazoo, MI, USA) 3 mm \times 20 mm was used. The recanalization grades were TICI 3 ($n = 5$), 2b ($n = 1$), and 0 ($n = 1$). In cases with TICI 0, which was M4 occlusion, there was no MRA image before treatment and A4 occlusion was also revealed with angiography, which presumed to be a more proximal occlusion at onset. We were concerned about hemorrhagic complications caused by repeated thrombectomy due to the distal site and small vessel diameter; therefore, the stent was expanded only once for M4 occlusion and retrieved, and at the time when recanalization was not achieved, we terminated the treatment in anticipation of the effectiveness of tPA. In five cases, excluding the cases with TICI 0 and onset during embolization, the mean puncture to recanalization time was 51 minutes (24–99 minutes). In four cases in which the time of the onset was evident, the mean onset to recanalization time was 178 minutes (123–253 minutes). Postoperative asymptomatic intracranial hemorrhage was observed in one patient (14%), who had petechial hemorrhage in the infarct HI 2 with no mass effect. There was no symptomatic intracranial hemorrhage. An analysis of the mRS

before onset and that after treatment showed no change in three patients, worsening by one grade in three patients, and worsening by three grades in one patient.

Case 6: an 82-year-old man

History of present illness

Aphasia and paralysis of the right side occurred after lunch, and the patient was transported to our emergency outpatient unit by ambulance. At the first examination, the NIHSS score was 15. MRI DWI showed hyperintensities in the left insular cortex and part of the left temporal lobe, and the ASPECTS-DWI score was 9. MRA showed an occlusion of the middle branch of the left middle cerebral artery at the site immediately after it branched off, and we decided to perform thrombectomy combined with IV tPA treatment.

Endovascular surgery

IV tPA was started and an 8 Fr introducer sheath was placed in the right femoral artery under local anesthesia. 8 Fr Optimo (Tokai Medical Products, Aichi, Japan) was advanced into the left internal carotid artery. DSA showed an occlusion of the left M2 middle trunk (**Fig. 1A**). A combination of Marksman (Medtronic) and Chikai 14 (Asahi Intecc, Aichi, Japan) led to the occlusion site, and we confirmed that the tip of Marksman had passed beyond the occlusion site (**Fig. 1B**). Since the occlusion site was M2, which is a small-diameter vessel, we decided to use Tron Fx 2 mm \times 15 mm. Tron Fx was advanced from Marksman and expanded at the occlusion site (**Fig. 1C**). Imaging after expansion showed that the distal side of Tron Fx remained occluded (**Fig. 1D**). Balloon of Optimo was inflated to retrieve Tron Fx with manual aspiration. Imaging after retrieval showed no successful recanalization; therefore, Tron Fx may have been expanded at a site slightly proximal to the thrombus. Judging that Tron Fx 2 mm \times 15 mm was not long enough to cover the entire thrombus, we decided to use Trevo ProVue 3 mm \times 20 mm

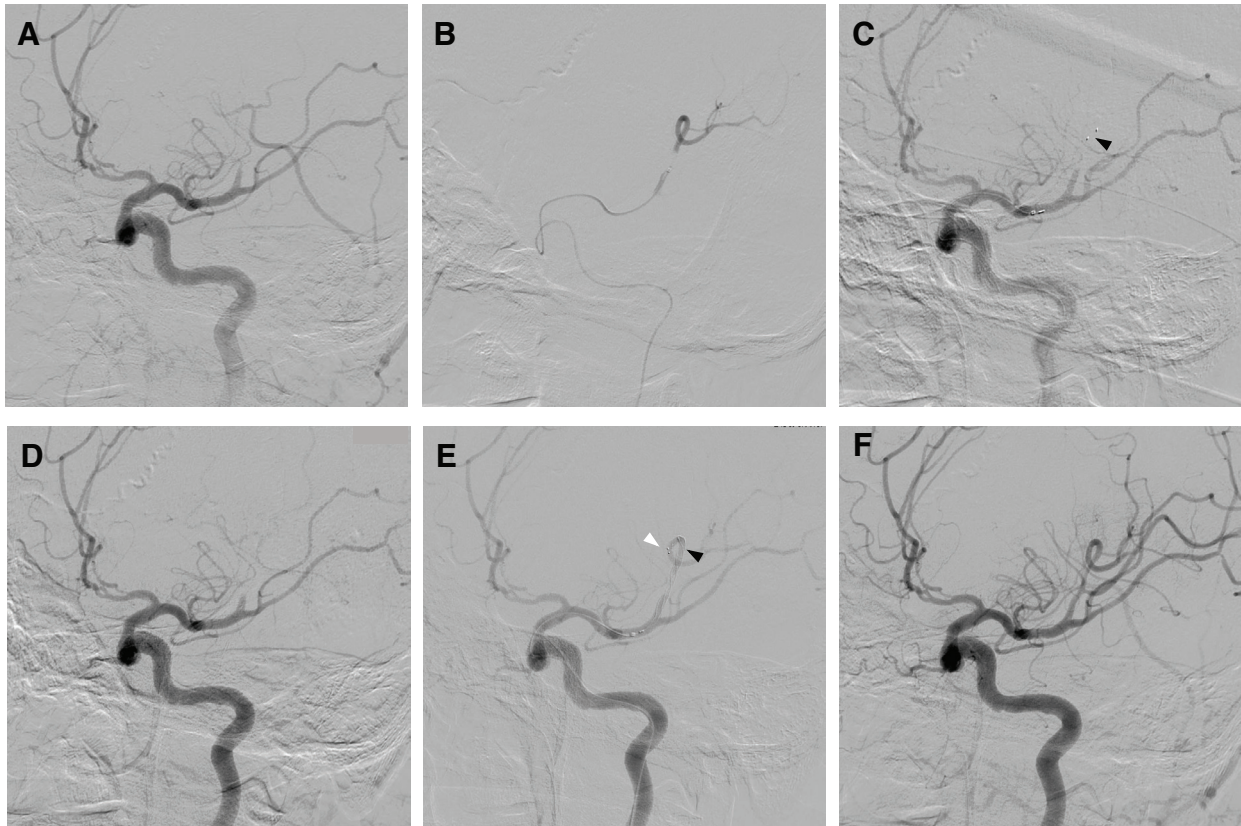


Fig. 1 Case 6: an 82-year-old man who developed a left M2 occlusion. (A) Cerebral angiography shows an occlusion of the left M2. (B) Marksman microcatheter was advanced to the occluded site and contrast injection from Marksman confirmed that it passed beyond the occlusion site. (C) Tron Fx 2 mm × 15 mm stent retriever was expanded. The black arrowhead indicates the tip of Tron Fx. (D)

Imaging after Tron Fx was retrieved shows that the middle trunk remained occluded. (E) Trevo stent retriever was expanded from a more distal side. The white arrowhead indicates the tip of Trevo. The black arrowhead indicates the previous site of the tip of Tron Fx. (F) Cerebral angiography after Trevo was retrieved confirms TICI 3 recanalization. TICI: thrombolysis in cerebral infarction

instead as this has a larger stent diameter, but a longer stent length. After expanding Trevo ProVue at the occlusion site (**Fig. 1E**), it was retrieved and TICI 3 recanalization was achieved (**Fig. 1F**).

Course after treatment

After surgery, the patient's symptoms gradually improved. A Holter monitor during hospitalization showed paroxysmal atrial fibrillation, and oral administration of warfarin was started on day 4 after onset. The patient underwent rehabilitation and was discharged on day 34 with no clear neurological deficits.

Case 7: a 77-year-old man

History of present illness

The patient had a history of atrial fibrillation and had been orally taking rivaroxaban 15 mg. He collapsed at home and was transported to our hospital by ambulance. On admission, he had impaired consciousness, aphasia, and paralysis of the right side. The NIHSS score was 26.

MRI did not show clear intracranial hemorrhage or cerebral infarction, The ASPECTS-DWI score was 11. Left middle cerebral artery M2 occlusion was suspected by MRA. We decided to perform IV tPA treatment and thrombectomy.

Endovascular surgery

IV tPA was started, and a 9 Fr sheath introducer was placed in the right femoral artery under local anesthesia. 9 Fr Optimo was advanced into the left internal carotid artery, and DSA was performed. There was a thrombus at the site where the M2 posterior trunk of the left middle cerebral artery branched, and one branch was completely occluded and the other branch was partially occluded (**Fig. 2A**). We decided to use Tron Fx 2 mm × 15 mm and led a combination of Excelsior SL-10 (Stryker) and Chikai 14 to the completely occluded branch. After the occlusion site was confirmed by imaging from the microcatheter (**Fig. 2B**) as well as the guiding catheter, Tron Fx 2 mm × 15 mm was expanded at the occlusion site (**Fig. 2C and 2D**). Initial

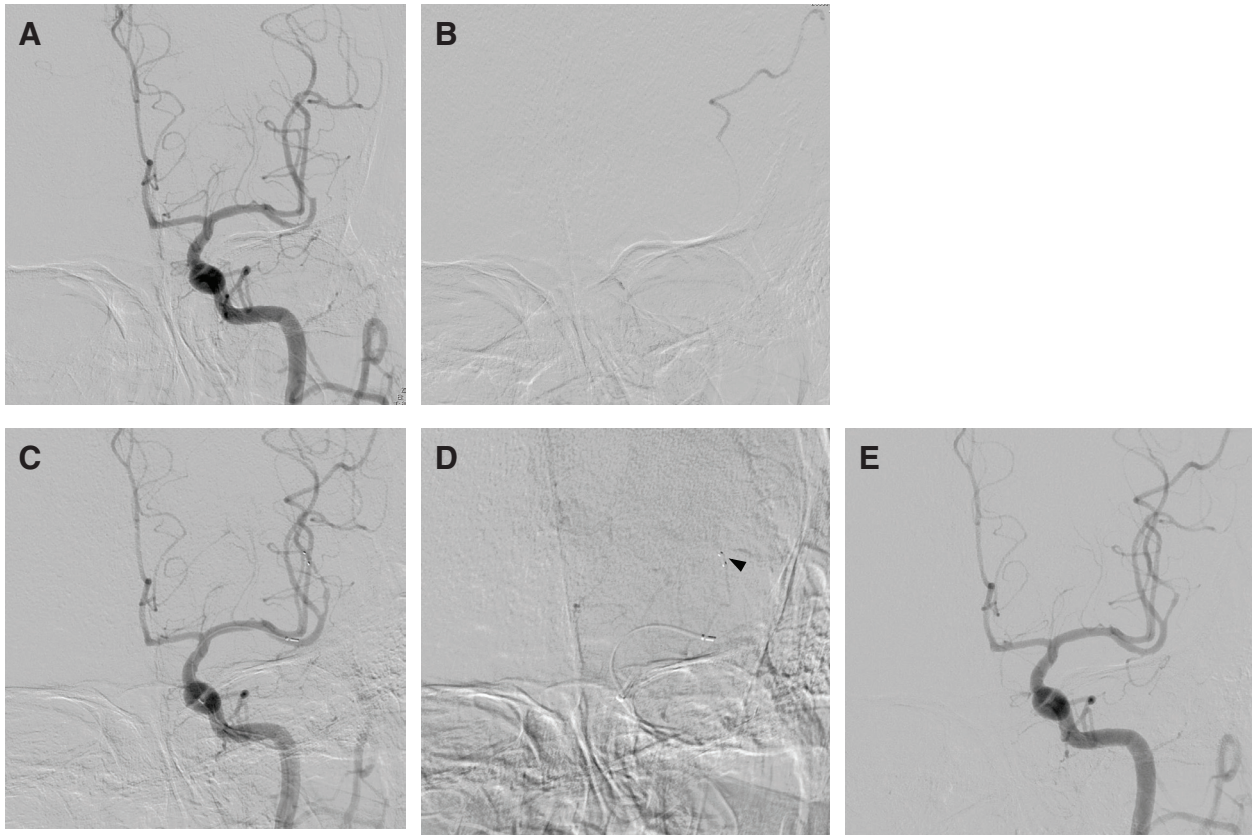


Fig. 2 Case 7: a 77-year-old man who developed a left M2 occlusion. (A) Cerebral angiography shows a thrombus at the site where the left M2 posterior trunk branched and one of the two branches was completely occluded. (B) Confirmation that the tip of SL-10 microcatheter passed

beyond the occlusion site. (C) Tron Fx 2 mm × 15 mm stent retriever was expanded at the occlusion site. (D) The black arrowhead indicates the tip of Tron Fx. (E) Cerebral angiography after Tron Fx was retrieved confirms TIC1 3 recanalization. TIC1: thrombolysis in cerebral infarction

flow restoration was achieved, and the balloon of Optimo was subsequently expanded and Tron Fx was retrieved while manually aspirating the blood from Optimo with a syringe. TIC1 3 was achieved at the end of the surgery (**Fig. 2E**).

Course after treatment

The symptoms tended to improve after the surgery, and a head CT scan did not show intracranial hemorrhage. There were no clear neurological deficits on the next day after the surgery, and his NIHSS score decreased to 0.

Discussion

In 2015, five randomized trials showed the superiority of thrombectomy to medical treatment as treatment for acute-phase cerebral infarction caused by anterior circulation artery occlusion, whereas a meta-analysis of these randomized trials, the HERMES study, that adjusted common odds ratio for treatment effect of thrombectomy was not significant for patients with M2 occlusion.¹⁾ However, M2 occlusions were included only in two of the five trials, and most of

them were misclassified as M1 occlusion at enrolment and then judged as M2 occlusion by the core lab. Sarraj et al. divided 522 patients with M2 occlusions at 10 institutions in the US into a thrombectomy group and a medical treatment group to assess the outcomes at 90 days and symptomatic intracranial hemorrhage.⁴⁾ They reported that the rates of patients with an mRS of 0–2 were 68.2% in the thrombectomy group and 35.4% in the medical treatment group; thus, the thrombectomy group achieved favorable outcomes. The rates of symptomatic intracranial hemorrhage were 5.6% in the thrombectomy group and 2.1% in the medical treatment group, which showed no significant difference between the groups. There are many other studies that suggest the effectiveness of thrombectomy for M2 occlusions.^{4–7,12–14)} Sweid et al. showed that thrombectomy for a distal lesion group including M2 occlusion is as effective as that for a proximal group.⁵⁾ Meta-analysis by Wang et al. showed that 3-month outcome of thrombectomy for M2 is better than that for M1 or best medical treatment without increasing risk of symptomatic intracerebral hemorrhage (sICH).⁷⁾ Meta-analysis of data from HERMES Collaboration

showed maximal treatment effect for M2 proximal occlusions.⁶⁾ Multicenter retrospective cohort study by Sarraj et al. comparing endovascular therapy (EVT) and medical treatment for M2 occlusion revealed that younger age, lower NIHSS score, and lower ASPECTS were factors associated with better outcomes.⁴⁾ However, patients with a higher NIHSS score tend to have severe disabilities without successful treatment. In our study, the NIHSS score of cases was relatively high (8–26, average 19.5) and that of ASPECTS was also high (ASPECTS: 8, ASPECTS-DWI: 6–11). The clinical result was favorable without sICH. On the contrary, a study reports that since the M2 vessel frequently bends in running and most of the branches are small, the risk of complications is high and detailed imaging assessment is needed.¹⁵⁾ According to an investigation with cadavers by Umansky et al., the outer M2 diameter was 1.4–2.3 mm.¹⁶⁾ Rai et al. investigated the diameter of anterior circulation vessels by three-dimensional computed tomography angiography (3D CTA) and reported an M2 vessel diameter of 2.4 ± 0.4 mm.¹⁷⁾ The mechanical thrombectomy (MT) device designed for distal and smaller vessels might improve clinical outcomes.⁶⁾ Stent devices for small-artery occlusions have conventionally been usable overseas, and Kurre et al. reported their 76 cases of thrombectomy for small-artery occlusions with pREset LITE (Phenox, Bochum, Germany).¹⁸⁾ The radial force of pREset LITE is low, and it can be used for vessel diameters of at least 1.5 mm. In their study, TICI 2b and higher recanalization were achieved at 70%, and there were no symptomatic complications caused by thrombectomy. They concluded that stent retrievers with a low radial force that are suitable for small-diameter vessels may allow increasing number of occluded vessels subjected to treatment. In Japan, stent retrievers with a small diameter such as pREset LITE was not available, and the minimum diameter of usable stent retrievers was 3 mm. In such a situation, with the aim of reducing invasion into small-diameter vessels as much as possible, Imahori et al. introduced a half-Trevo technique in their report of the use of Trevo,¹⁹⁾ and Uyama et al. reported penumbra-assisted half-stent thrombectomy for M2 occlusions.²⁰⁾ In April 2019, Tron Fx, a stent retriever with a small stent diameter of 2 mm, was approved in Japan, which presumably led to an increase in conducting thrombectomy for acute-phase cerebral infarction due to small-artery occlusions. To the best of our knowledge, there was no report of cases in which Tron Fx 2 mm \times 15 mm was used. In the present study, although the number of the cases is small, we reported our cases treated at our hospital. In six of seven (85.7%) cases, favorable (TICI 2b or 3)

recanalization was achieved, and symptoms improved in five of six (83.3%) cases excluding the case of the onset during coil embolization. As four of seven cases were treated combined with IV tPA therapy, the effect of tPA therapy must be also taken account. There was no appearance of symptomatic intracranial hemorrhage. Less invasion into occluded small-diameter vessels due to the small stent diameter (2 mm) may have decreased an occurrence of symptomatic intracranial hemorrhage. In addition, both sizes of Tron Fx, 2 mm \times 15 mm and 4 mm \times 20 mm can be used for microcatheters with an internal diameter of 0.0165 inches to 0.027 inches. Therefore, even if the occlusion site is distant and with tortuous access route, the use of a microcatheter that has a smaller outside diameter of the tip and is more highly capable of reaching a distant site than is Marksman, such as Headway 17 (MicroVention, Tustin, CA, USA) and Excelsior SL-10, may allow reaching the occlusion site. In the present study, we used 1.7 Fr microcatheter in five of seven cases including Case 7, which enabled reaching distant occlusion sites such as A3 and M4. MT for ACA distal occlusion is also challenging for navigating a microcatheter. Haruyama et al. suggested usefulness of a smaller caliber 2.3 Fr microcatheter for safe procedure.²¹⁾ Tron Fx can be introduced through a much smaller 1.7 Fr microcatheter, which has a possibility to lead safer thrombectomy procedure. However, since the stent length of Tron Fx 2 mm \times 15 mm is short (15 mm), in cases with longer thrombus, such as Case 6, the stent may be unable to fully retrieve the thrombus. In Case 6, the distal side of the thrombus may not have been fully covered when Tron Fx was expanded; thus, when Tron Fx 2 mm \times 15 mm is used, positioning and accurate expansion of the stent are more essential compared to other stent retrievers.

Conclusion

We reported the cases of thrombectomy for small-artery occlusions performed using Tron Fx 2 mm \times 15 mm at our hospital. Thrombectomy using Tron Fx 2 mm \times 15 mm may be safe and may contribute to expand its indication for small arteries. Standard treatment for small arteries needs to be established by further studies involving more cases including randomized controlled trials with the best medical treatment.

Disclosure Statement

Yasushi Ito has received rewards such as lecture fees from Medtronic Japan Co., Ltd. and Century Medical, Inc. The other authors have no conflict of interest.

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