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Original research

First-in-human trial of a self-expandable, temporary dilation system for intracranial atherosclerotic disease in patients presenting with acute ischemic stroke

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ABSTRACT

Background Intracranial atherosclerotic disease (ICAD) significantly contributes to ischemic stroke, especially among Asian populations. Large vessel occlusion (LVO) due to underlying ICAD accounts for 15–35% of acute ischemic stroke cases requiring endovascular therapy. However, the successful recanalization rate of ICAD-related LVO remains lower. The TG dilator is a self-expandable device, temporarily dilating ICAD-related blocked blood vessels.

Objective To demonstrate TG dilator safety and efficacy for ICAD-related acute ischemic stroke.

Methods This was a single-arm, open-label, non-randomized, prospective, multicenter, and investigator-initiated trial that involved patients undergoing TG dilator application for acute ischemic stroke caused by ICAD-related LVO or severe stenosis.

Results We enrolled 10 patients in this trial between November 2022 and April 2023. The median (IQR) age was 68 (59.3–75.3) years. Before using the dilator, seven patients received stent retriever treatment. All 10 patients were prescribed a loading dose of aspirin with prasugrel. The median application time was 10 (10–12) min. At the end of the procedure, we achieved significant recanalization immediately in all patients. The stenosis/occlusion decreased from 100% (100–100) to 68% (56.3–75.3). No patient experienced recurrent ischemic stroke or reocclusion within 90 days. We achieved a modified Rankin scale score of 0–2 in 8 patients by day 90. We detected no cases of intracranial hemorrhage, equipment failure, distal embolism, vasospasm, dissection, or perforation requiring intervention.

Conclusions Acute revascularization using the TG dilator on patients with ICAD-related LVO or severe stenosis did not cause any significant adverse event, and consistently improved blood flow at 90 days.

INTRODUCTION

Intracranial atherosclerotic disease (ICAD) significantly contributes to ischemic stroke, especially in Asian populations.¹ In the United States, ICAD accounts for 8–10% cases of ischemic stroke, although this number could rise to 30–50% in Asian people.² ICAD-related large vessel occlusion (LVO) accounts for 15–35% cases of acute ischemic stroke requiring endovascular therapy.^{3,4} However,

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Intracranial atherosclerosis-related acute large vessel occlusion treatment is challenging with conventional endovascular approaches, a new approach should thus be developed.

WHAT THIS STUDY ADDS

⇒ Using a newly developed TG dilator, successful reperfusion was achieved in all patients without causing any significant adverse events. None of the patients experienced recurrent ischemic stroke or reocclusion during the 90 days following the intervention.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ TG dilator could improve clinical outcomes for patients experiencing large vessel occlusion due to intracranial atherosclerosis.

a lower successful recanalization rate, longer groin puncture-to-recanalization time, and poorer outcomes characterize ICAD-related LVO compared with embolic LVO.^{5–7} Therefore, endovascular therapy could be challenging for ICAD-related LVOs.

The TG dilator (T.G. Medical, Tokyo, Japan) is a self-expandable and non-detachable medical device composed of nitinol, temporarily dilating ICAD-related blocked blood vessels. It can be delivered to the target site via a compatible microcatheter with an inner diameter of 0.021–0.027". Its unique dual-layer structure provides it with high conformability to curved vessels and adequate pressure on stenotic vessels. In this study, we aimed at demonstrating TG dilator safety and efficacy for ICAD-related acute ischemic stroke.

MATERIALS AND METHODS

Study design, patient selection, and data collection

The Certified Review Board approved the clinical trial. This was a single-arm, open-label, non-randomized, prospective, multicenter, and investigator-initiated trial.

Patient enrollment

This trial included patients with acute ischemic stroke within 24 hours of their last known normal time, aged 18–85 years with ICAD-related LVO or severe stenosis in the internal carotid artery/M1 or M2 segment of the middle cerebral artery/vertebral artery/basilar artery, and a pre-stroke modified Rankin Scale (mRS) score of 0–2. ICAD-related LVO or severe stenosis was diagnosed through a combination of clinical findings, neuroradiographic images (including angiography), and previous medical history. The TG dilator was used in patients who had not responded to conventional mechanical thrombectomy or in those for whom thrombectomy was medically deemed ineffective. Non-responsiveness was determined by either a complete lack of reopening or subsequent reocclusion following transient reperfusion.

Each participating operator had training on the specification of the device and a hands-on session using a phantom provided by the manufacturer before enrolling a patient. During the study period, all patients with acute ischemic stroke with ICAD-related LVO or severe stenosis were considered for enrollment unless a non-participating operator did the procedure. Futile thrombectomy itself did not justify using the TG dilator without any angiographic evidence of underlying ICAD. We excluded patients with nickel or titanium allergies and less than 90 days of expected follow-up, and those already involved in other trials or medically judged unsuitable to participate. After having explained trial participation risks, benefits, and alternatives, we obtained written consent from all participants. Enrollment would be terminated if there were safety issues with the device or if it lost its scientific validity.

TG dilator structure

The TG dilator structure is shown in [figure 1](#). When the microcatheter is pulled proximally and unsheaths the dilator, the stent part self-expands to dilate the atherosclerotic lesion, and blood flow can be restored. The TG dilator displays radiopaque markers at both ends of the stent, enabling operation under fluoroscopic guidance. The dilator provides its highest radial force immediately on deployment from the microcatheter. The fully deployed TG dilator exhibited a performance equivalent to that of the Gateway PTA balloon (Stryker, Kalamazoo, Michigan, USA) when inflated to 2 atmospheres of pressure. This force reduces rapidly on full expansion. The dilators have three different sizes: two 20 mm and one 15 mm long versions with a diameter of 3 or 4 and 2 mm, respectively.

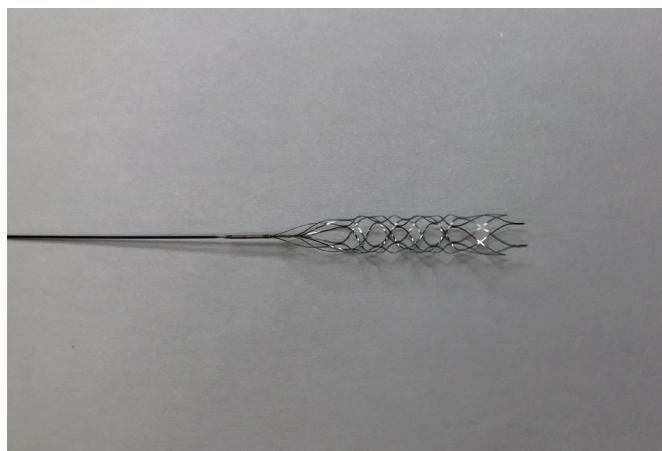


Figure 1 TG dilator structure.

Treatment protocol

Once use of the TG dilator was determined, the patients were pretreated with a loading dose of antiplatelet medications in accordance with the local protocol at each enrolling site. Aspirin and prasugrel were administered orally, and additional ozagrel sodium was administered intravenously if the antiplatelet effects were insufficient. Once we passed the guidewire and microcatheter through the ICAD, we removed the guidewire. Next, we inserted the TG dilator (selected according to the reference vessel size) into the microcatheter and deployed it by retracting the microcatheter while holding the wire in place. We usually waited 5–20 min for the effect of the antiplatelet medication to ensure proper dilation before advancing the microcatheter over the dilator to recapture the device. Finally, we removed both the microcatheter and dilator. If no significant reperfusion could be achieved with the second application of the dilator, alternative treatments were permitted.

Endpoints

The primary efficacy endpoint was immediate successful reperfusion without additional treatment, defined as modified Thrombolysis In Cerebral Infarction (mTICI) 2b or higher.⁸ We did not consider the degree of residual stenosis as a goal. The primary safety endpoint was any symptomatic intracranial hemorrhage, causing worsened National Institutes of Health Stroke Scale (NIHSS) scores⁹ beyond 4, as well as any adverse events attributable to the study device, such as dissection, perforation, and distal embolism, at 24±12 hours of the treatment.

The secondary endpoint involved additional treatments such as stenting, severe strokes with worsening NIHSS score ≥4, or neurological death attributable to the device or treatment within 7 days, recurrent ischemic strokes or reocclusion of the treated vessel within 7 or 90 days, and mRS score at 90 days. Embolic strokes, beyond the occluded vessel territory, which were not obvious at the first brain images were defined as ischemic strokes related to the device.

Data collection

We collected clinical data, including age, sex, pre-stroke mRS score,¹⁰ NIHSS scores on admission, smoking status, previous history of coronary artery disease, aortic disease, chronic renal failure, and peripheral artery disease, vascular risk factors such as hypertension, diabetes mellitus, and dyslipidemia, antiplatelet medication use during the procedure, additional treatment devices for ICAD, and potential intravenous alteplase combination with the treatment. We used diffusion-weighted images in MRI or non-contrast CT to determine the Alberta Stroke Program Early CT Score (ASPECTS) just before the intervention.^{11–13} We collected information about the dilator, including its size and lot number, deployment time, the microcatheters and microguidewires used for its delivery, and any defects that might have occurred. We also noted the time of deployment and the degree of stenosis, which were graded based on the Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) Trial.¹⁴

Statistical description

Non-categorical data values are presented as the median and the IQR of 25%–75%.

RESULTS

Patient characteristics

We enrolled 10 (four female and six male) patients in this trial between November 2022 and April 2023. During the study

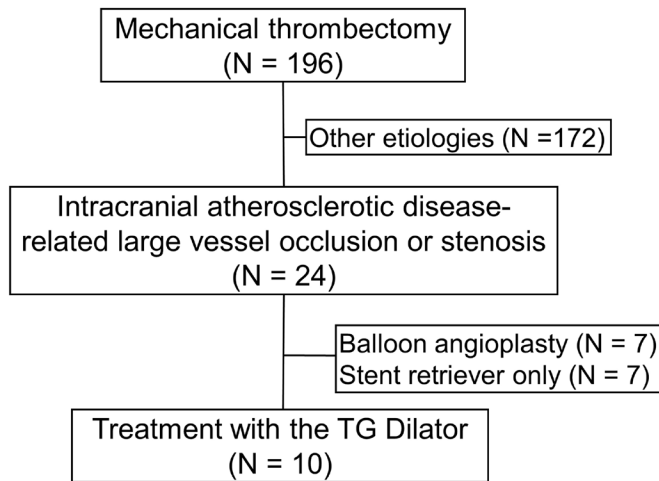


Figure 2 Patient flow chart.

period, we experienced 196 mechanical thrombectomy cases including 24 cases of ICAD-related occlusion or severe stenosis. Of these, seven cases were treated with a stent retriever alone, and no further intervention was necessary due to adequate distal perfusion through the residual ICAD-related stenoses. In the other seven cases, the operators were not trained to use the TG dilator (figure 2). The median (IQR) age was 68 (59.3–75.3) years, ranging between 48 and 79 years. The median NIHSS and ASPECT scores were 13.5 (12–15.5) and 8 (7–9), respectively. ICAD was detected in M1 of the middle cerebral artery in nine patients. Among them, seven and two exhibited occlusions and severe stenosis, respectively. Furthermore, one patient had an occlusion in the basilar artery. No patients had a previous history of coronary artery disease, aortic disease, chronic renal failure, or peripheral artery disease. The baseline mTICI score was 0 for eight occlusion cases and one for two stenosis cases. Table 1 summarizes additional clinical and imaging features.

Table 1 Patient characteristics

| Characteristics | No. (n=10) |
|--|------------------|
| Age | 68 (59.3–75.3) |
| Gender (female) | 4 |
| Onset to door (min) | 400 (261–627) |
| Pre-stroke mRS score | 0 (0–0) |
| NIHSS score | 13.5 (12–15.5) |
| ASPECTS | 8 (7–9) |
| Side (right) | 4 |
| Location | 9 of M1, 1 of BA |
| Smoking status | |
| Current smoker | 6 |
| Ex-smoker | 3 |
| Non-smoker | 1 |
| Hypertension | 10 |
| Diabetes mellitus | 3 |
| Dyslipidemia | 10 |
| Intravenous alteplase | 1 |
| ASPECTS, Alberta Stroke Program Early CT Score; BA, basilar artery; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale. | |

Treatment details

Table 2

Before using the dilator, seven patients received mechanical thrombectomy using a stent retriever. The proximal artery diameter was 2.75 (2.55–2.95) mm. All 10 patients were prescribed a loading dose of aspirin (200 mg) with prasugrel, three and seven of them having received 10 and 20 mg, respectively. The device size was 4×20 and 3×20 mm for seven and three patients, respectively. Microcatheters with an inner diameter of 0.021 inches were used in all 10 cases. The application required 10 (10–12) min. We achieved successful recanalization of mTICI 2b or more immediately after the application in all patients. One patient required a second application of the dilator, which took an additional 37 min, waiting for the dissolution of the attached thrombus with ozagrel sodium infusion, and resulted in a complete recanalization. White thrombi were attached to the dilator in the fifth case. The stenosis/occlusion had decreased from 100% (100–100) to 68% (56.3–75.3), as graded by WASID. The entire procedure time was 37.5 min (56.3–66.5). Dual anti-platelet medications of aspirin and prasugrel were continued for all patients.

Efficacy and safety outcomes

At the end of the procedure, the NIHSS score was 8 (6.5–10). None of the patients experienced recurrent ischemic stroke or reocclusion on MR angiography during the 7–90 day period. At discharge or day 7, the NIHSS score and mRS were both 4 (2–4). Eight and two patients could return home and were transferred to another hospital, respectively. On day 90, the NIHSS and mRS scores were 2 (1.3–2) and 2 (1–2), respectively. An mRS score of 0–2 could be registered in 80% of the patients on day 90.

We detected no cases of intracranial hemorrhage, equipment failure, distal embolism, vasospasm, dissection, or perforation requiring intervention, or any significant adverse events during the procedure or within the 7-day and 90-day periods for any cases.

Case presentation

A patient in their 60s was transferred to the hospital with symptoms of right hemiparesis and aphasia 495 min from the last known well time. The NIHSS score on admission was 16. Head MRI indicated an acute ischemic stroke with ASPECTS of 7 on the diffusion-weighted image. Cerebral angiography revealed severe stenosis on the left M1 of the middle cerebral artery (figure 3A). The patient was given 200 mg of aspirin and 20 mg of prasugrel, followed by a 4×20 mm TG dilator deployment at the ICAD site for 12 min (figure 3B). The stenosis improved from 74% to 37% (figure 3C). The procedure was completed without any sign of reocclusion or vessel damage. The final mTICI score and the total procedure time were 2b and 26 min, respectively. The NIHSS score improved to 10 immediately after the procedure. On day 25, the patient was discharged home with a slight agnosia and NIHSS and mRS scores of 1 and 2, respectively. On day 90, the patient could resume the previous job with an mRS score of 1.

DISCUSSION

In this first-in-human trial, we demonstrated periprocedural safety and 90-day efficacy in all 10 participants using a TG dilator for ICAD-related acute ischemic stroke.

In the ICAD-related LVO, recanalization using a stent retriever proved less successful than in the other LVO group (28.9% vs

Table 2 Efficacy outcomes

| No | Age | NIHSS | Location | Preceding thrombectomy and its device | TG dilator | Application time (min) | Additional treatment | Final mTICI | Pretreatment stenosis (%) | Remaining stenosis (%) | Serious adverse events | mRS score at 90 days |
|----|-----|-------|----------|---------------------------------------|------------|------------------------|--|-------------|---------------------------|------------------------|------------------------|----------------------|
| 1 | 40s | 14 | L-M1 | Trevo NXT | 4×20 | 10 | None | 2b | 100 | 53 | None | 1 |
| 2 | 70s | 8 | R-M1 | Trevo NXT | 4×20 | 10 | None | 3 | 100 | 31 | None | 1 |
| 3 | 60s | 16 | L-M1S | None | 4×20 | 12 | None | 2b | 74 | 37 | None | 1 |
| 4 | 60s | 16 | L-M1S | None | 3×20 | 10 | None | 3 | 80 | 68 | None | 3 |
| 5 | 50s | 8 | R-M1 | Trevo NXT | 4×20 | 10 | None | 3 | 100 | 77 | None | 2 |
| 6 | 70s | 12 | R-M1 | Trevo NXT | 4×20 | 12 | None | 3 | 100 | 78 | None | 3 |
| 7 | 70s | 12 | R-M1 | Trevo NXT | 4×20 | 10 | None | 3 | 100 | 68 | None | 2 |
| 8 | 50s | 14 | L-M1 | Trevo NXT | 3×20 | 15 | None | 3 | 100 | 66 | None | 2 |
| 9 | 70s | 27 | BA | None | 3×20 | 10 | None | 3 | 100 | 70 | None | 2 |
| 10 | 60s | 13 | L-M1 | Trevo NXT | 4×20 | 21 | Another application of the dilator for 37 min. | 2c | 100 | 77 | None | 1 |

BA, basilar artery; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale.

93.5%).⁵ If mechanical thrombectomy is unsuccessful, additional rescue therapy is necessary for ICAD-related LVOs.^{15–18} Various techniques have been advocated for ICAD treatment.¹⁶ Balloon angioplasty, rescue stenting, and stent retriever angioplasty are frequently selected options.

Balloon angioplasty is often performed with an undersized balloon, slowly inflated to avoid blood vessel damage.^{17, 18} Balloon angioplasty alone could be a safe and effective option for treating ICAD, eliminating the need for dual-antiplatelet therapy during the immediate postprocedural period when the risk of intracranial hemorrhage could be higher.^{17, 18} However, it is important to note that balloon angioplasty might result in higher rates of immediate lesion recoil, delayed restenosis, and iatrogenic dissections compared with cases performed in conjunction with stenting.¹⁹ In certain cases, stenting could be necessary as well as dual antiplatelet medications. It is also worth mentioning that longer inflation time could worsen the distal brain ischemia due to flow stagnation during the procedure.

Rescue stenting following an unsuccessful mechanical thrombectomy could reportedly improve recanalization rates, reduce residual dissection-related stenosis, and lead to better outcomes than remaining a reperfusion failure.^{15, 20, 21} However, rescue stenting is not recommended for patients with intracranial hemorrhage, a large core infarct, or extensive parenchymal contrast staining.²² On deployment, the stent applies a constant and strong radial force to the atherosclerotic plaque, potentially pushing atheroma into the origins of adjacent perforator arteries and causing local small-vessel occlusion.²³ In addition, even patients with a higher hemorrhagic risk require antithrombotic therapy.

Stent retriever angioplasty is aimed at performing mild angioplasty by the prolonged deployment of a mechanical

thrombectomy stent retriever to the occluded site. The stent retriever is left in place for a short period prior to partially retracting it into the microcatheter and retrieving to prevent vessel damage.²⁴ This technique could expand the ICAD while avoiding stent insertion or impeding blood flow. However, stent retriever angioplasty remains less effective than balloon angioplasty or rescue stenting due to the relatively low radial force of the stent retriever.

The TG dilator provides its highest radial force immediately after deployment from the microcatheter. This force decreases rapidly on full expansion, thereby reducing the risk of adverse events such as iatrogenic dissections or vessel rupture. The TG dilator allows prolonged dilatation of the lesion to prevent lesion recoil without blocking blood flow. In addition, nothing remains in the patient following the treatment as the device is temporary. Therefore, the TG dilator potentially overcomes the limitations of balloon angioplasty, rescue stenting, and stent retriever angioplasty.

The TG dilator might obviate the need for antithrombotic medications as it is a temporary device that leaves nothing after the treatment. However, all 10 patients received dual antiplatelet medication in a dose lower than the loading dose immediately before the procedure, which was continued for 90 days. Ensuring that the treated ICAD arteries remain open and functional for a significant period is crucial for improvement of clinical outcome. Previous studies indicated a higher reocclusion possibility on endovascular therapy in patients with anterior ICAD-related LVO.^{25–27} Such possibilities are due to unstable ruptured plaques in the stenotic segment as well as aggravated endothelial damage and thrombectomy-related platelet aggregation.²⁸ Our study demonstrated that the patency after the TG dilator with antiplatelet medications could be sustained for 90 days with no procedural severe adverse events.

Our study has several limitations. First, the generalizability of our results is limited due to the initial experience with a small case series. Second, this trial included only Japanese patients. Third, diagnosing ICAD-related LVO or severe stenosis depended on the discretion of the physicians. Fourth, owing to the relatively high level of the remaining stenosis of 68% following the procedure, further evaluation of the extended patency maintenance beyond the initial 90-day period would be recommended. Finally, owing to the unavailability of glycoprotein IIb/IIIa inhibitor in Japan, we had to resort to dual antiplatelet medications for acute and chronic antithrombotic therapy. The necessity and appropriate prescriptions of antithrombotic therapy thus remain



Figure 3 Representative cases. (A) Preprocedural angiographic image of the left middle cerebral artery. (B) Radiographic image of the TG dilator. (C) Postprocedural angiographic image 10 min after the deployment.

undetermined as all participants received dual antiplatelet medication for 90 days. Future studies would thus be required to further determine device safety and efficacy.

CONCLUSION

Acute revascularization using the TG dilator in patients with ICAD-related LVO or severe stenosis did not cause any significant adverse events, and it consistently improved blood flow by day 90. Although further studies are needed to confirm dilator efficacy and safety, this device could potentially be used in future clinical settings.

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Contributors TO substantially contributed to the analysis and interpretation of data and drafted the work and substantively revised it. ST and NS conceived the idea of the study. HY, RF, and HI contributed to the interpretation of the results, drafted the original manuscript. AI, SYo, and CS supervised the conduct of this study. MT, KT, SYa, and KA contributed to the data acquisition and interpretation. All authors reviewed the manuscript draft and revised it critically on intellectual content. All authors approved the final version of the manuscript to be published. NS is the overall guarantor of the study.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by National Cerebral and Cardiovascular Center Hospital certified review board, CRB5210001. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. Not applicable.

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