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Technical Note

Technique for Recanalization of Sheath Introducer Occlusion due to Captured Thrombus during Mechanical Thrombectomy for Acute Ischemic Stroke: A Technical Note

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Objective: Mechanical thrombectomy (MT) is the gold standard treatment for acute ischemic stroke. During these interventions, a thrombus frequently obstructs a guiding catheter. The obstructed guiding catheter should be withdrawn before distal embolism occurs; however, albeit infrequently, the thrombus occludes even a sheath introducer (SI). While conventionally new SI placement is required for continuation of treatment, we propose a viable alternative for recanalization of the occluded SI, termed vacuum-assisted delivery of thrombus (VADT), with a clinical report of our cases. The usefulness of this technique was also evaluated in simulation experiments.

Case Presentations: The VADT procedure is as follows: 1) insert a peel-away sheath, originally attached to a balloon-guiding catheter (BGC), into the SI to continuously open the hemostatic valve; 2) advance the BGC into the peel-away sheath while applying mechanical aspiration; and 3) remove the peel-away sheath/BGC assembly slowly. In a simulation environment using an artificial thrombus, we repeated the VADT procedure five times and reproducibly achieved SI reopening within only 10–20 seconds. From March 2013 to September 2022, 204 patients were treated with MT at our stroke center and SI occlusion occurred in three patients (1.5%). These events occurred exclusively in patients with extracranial internal carotid artery occlusion. All three patients with SI occlusion underwent successfully thrombus extraction in the SI using the VADT on the first try.

Conclusion: The results of clinical experience and simulation experiments strongly support VADT as a reliable option for recanalization of an occluded SI.

Keywords acute ischemic stroke, mechanical thrombectomy, sheath introducer occlusion

Introduction

Mechanical thrombectomy (MT) has become a standard treatment for patients with acute ischemic stroke (AIS) according to the recommended indications.[1] While the indication expansion and increased opportunities for MT are highly predictable, neurosurgeons and neurointerventionists should become proficient at troubleshooting emergencies, such as intraoperative thrombotic and hemorrhagic complications.

Recent advances in MT devices and modern techniques are expected to help improve performance in capturing a giant and firm thrombus; however, they sometimes work negatively in the case of guiding or aspiration catheter occlusion by a large thrombus volume. In addition, even a sheath introducer (SI) may be occluded by a thrombus during MT.[2] This troublesome situation, as shown in **Fig. 1**, occurs principally following withdrawal of the thrombus-occluded guiding catheter. The thrombus may

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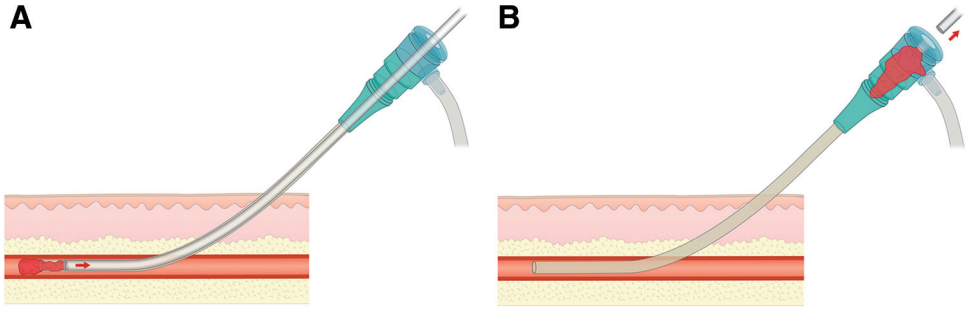

Fig. 1 Schematic illustration of SI occlusion. (**A**) The firm or larger thrombus than the inner lumen of a BGC is difficult to be retrieved, occasionally leading to the BGC occlusion at the distal tip. The occluded BGC should be withdrawn with the trapped thrombus, while continuing aspiration. (**B**) The thrombus likely breaks off from the BGC tip and migrates immediately inside the hemostatic valve of an SI. Thus, reverse blood flow from the SI side port is hampered by the migrated thrombus and SI occlusion occurs. BGC: balloon-guiding catheter; SI: sheath introducer

break off from the guiding catheter tip and become stuck at the hemostatic valve of the SI. Here, the primary concern is that continuation of treatment can result in the crushing of the thrombus trapped in the SI, leading to secondary embolism. Distinct from the occluded catheter, the occluded SI cannot be easily withdrawn and conventionally requires consideration of new SI placement, albeit with accompanying invasiveness and time loss.

Herein, we propose a safe and minimally invasive technique for the recanalization of occluded SI, termed vacuum-assisted delivery of thrombus (VADT), with a clinical report of our cases. The usefulness of the VADT technique was evaluated through a simulation experiment.

Case Presentation

The research within our submission has been approved by the ethics institutional review board of Hanwa Memorial Hospital in August 2022 (Reference No. 2022-07). The VADT procedure is as follows: 1) insert a peel-away sheath, originally attached to the FlowGate² (FG2) Balloon Guide Catheter (Stryker, Kalamazoo, MI, USA), into an SI, and continuously open a hemostatic valve and gently push the peel-away sheath against a thrombus; 2) advance the FG2 into the peel-away sheath while applying vigorous aspiration through the FG2 with the Dominant Flex (Medela AG, Baar, Switzerland); and 3) remove the peel-away sheath/FG2 assembly slowly and maintain the aspiration. The behavior of the captured thrombus during these processes is shown in **Fig. 2**. To verify the usefulness of the VADT technique, we created a simulation model considering SI occlusion during MT. The details of simulation model are provided in the supplementary information and **Supplementary Fig. S1**. (All supplementary files are available online.) We repeated the VADT procedure five times in the same simulation environment and reproducibly achieved successful SI reopening within only 10–20 seconds. These procedures are also shown in **Supplementary Video 1**.

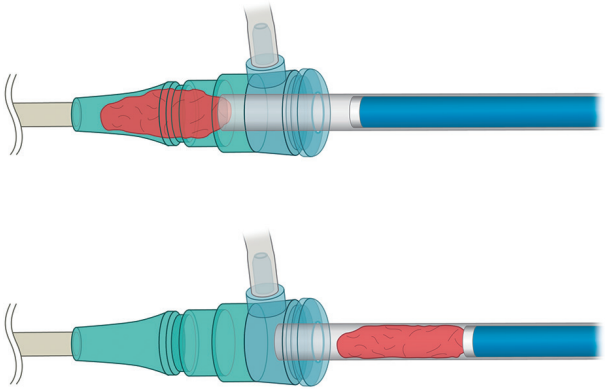

Fig. 2 Process of thrombectomy from SI. The illustration above shows the first step of the VADT. After opening the hemostatic valve continuously by a peel-away sheath, a BGC is advanced into the peel-away sheath while applying mechanical aspiration. The illustration below shows the second step of the VADT. The thrombus was retrieved through the peel-away sheath by contact aspiration via the BGC. BGC: balloon-guiding catheter; SI: sheath introducer; VADT: vacuum-assisted delivery of thrombus

From March 2013 to September 2022, 204 patients (42.6% female; median age, 77.5 years) were treated with MT for AIS at our stroke center. In our clinical experience, SI occlusion occurred in three cases (1.5%) during the MT procedure. The clinical characteristics, treatments, and outcomes of these patients are summarized in **Table 1**. All three patients with SI occlusion underwent successfully thrombus extraction in the SI, using the VADT on the first try. For retrieving the thrombus from the hemostatic valve of the SI, the original "VADT" technique as described above was adopted in Cases 1 and 2. In Case 3,

Table 1 Summary of clinical characteristics, treatment, and outcomes of three patients with SI occlusion

Case	Age/Sex	R/L	Occlusion site	Etiology	Technique	Device (BGC, AC, SR)	mTICI grade	mRS at discharge
1	81/F	L	Ex-ICA	Af	ADAPT SR	FG2 CAT6 EMBOTRAP II 5-33	3	3
2	96/F	R	Ex-ICA	Af	ADAPT SR	FG2 CAT6 Trevo NXT 4-28	2b	5
3	80/F	L	Ex-ICA	Af	ADAPT	9-Fr Branchor CAT6-	2b	3

AC: aspiration catheter; ADAPT: a direct aspiration first pass technique; Af: atrial fibrillation; BGC: balloon-guiding catheter; CAT6: the AXS Catalyst 6; Ex-ICA: extracranial internal carotid artery; F: female; FG2: FlowGate^2; L: left; mRS: modified Rankin Scale; mTICI: modified thrombolysis in cerebral infarction; R: right; SI: sheath introducer; SR: stent retriever

we substituted the AXS Catalyst 6 (CAT6) Distal Access Catheter (Stryker) and its peel-away sheath for the FG2, because a peel-away sheath suited to the balloon-guiding catheter (BGC) was not secured. Here, we report a representative case of AIS requiring the VADT technique.

Illustrative case (Case 1)

An 81-year-old woman who presented suddenly with severe right-sided paralysis was brought to our stroke center; she had a Glasgow Coma Scale score of 6 (E2, V1, and M3) and conjugate eye deviation to the left. MRI of the head showed the left internal carotid artery (ICA) occlusion, and high signal intensity on diffusion-weighted imaging (DWI), equivalent to an Alberta Stroke Program Early Computed Tomography Score (ASPECTS)-DWI of 7. Consequently, we urgently performed MT without intravenous tissue plasminogen activator.

A 9-Fr Super Sheath (Medikit, Tokyo, Japan) was inserted into the right femoral artery, and the FG2 was placed into the left common carotid artery (CCA). Left CCA angiography revealed the left ICA occlusion at the origin (**Fig. 3A** and **3B**). Thrombus aspiration using the CAT6 and Dominant Flex was performed with a direct aspiration first-pass technique (ADAPT).[3] Further left CCA angiography showed the filling defect at the distal segment of the left CCA, suggesting that the thrombus had migrated proximally (**Fig. 3C** and **3D**). Hence, mechanical aspiration at the left CCA was performed again using the FG2. Since the FG2 was subsequently occluded by the thrombus, it was temporarily withdrawn. Here, the side port of the SI became nonfunctional without reversed blood flow and the SI came to be occluded by the thrombus inside the hemostatic valve. The thrombus was successfully retrieved from the hemostatic valve of the SI using the "VADT" technique as described above. After the SI reopened, left CCA angiography showed the left CCA recanalization; however, the left MCA M1 was occluded by distal embolization. The Trevo Trak 21 (Stryker) was advanced to the left MCA M2 inferior trunk, and the EMBOTRAP II 5 mm × 33 mm (Johnson & Johnson, New Brunswick, NJ, USA) was deployed on the left M1 over M2. The migrated thrombus was retrieved, leading to modified thrombolysis in cerebral infarction grade 3 reperfusion at the end of the procedure (**Fig. 3E** and **3F**). Through a sequence of manipulations, a significant amount of thrombus was extracted as shown in **Fig. 4**.

Discussion

SI recanalization was successfully achieved using the VADT technique in all three patients. The adequacy and reproducibility of this technique were confirmed by the simulated experiment. The chief advantage of VADT is that it can be completed with the exclusive use of interventional products used for the MT procedure, leading to rapidity and cost-effectiveness. Additionally, VADT is technically feasible outside the body as a minimally invasive procedure. To the best of our knowledge, no published reports exist on techniques for SI recanalization. Therefore, VADT is expected to be the most effective rescue option for SI occlusion during MT.

Peel-away sheath insertion is a key part of the VADT process that continuously opens the SI hemostatic valve. To be prepared for SI occlusion, keeping an unused peel-away sheath is recommended. Among BGCs, the FG2 has the advantage of having two peel-away sheaths. In contrast, the Branchor and Optimo series (Asahi Intecc, Nagoya, Japan) provides only a single peel-away sheath. Notably, a spare peel-away sheath is easily secured when using FG2 and permits prompt VADT execution. Parenthetically, the aspiration catheters such as the AXS Catalyst (Stryker)

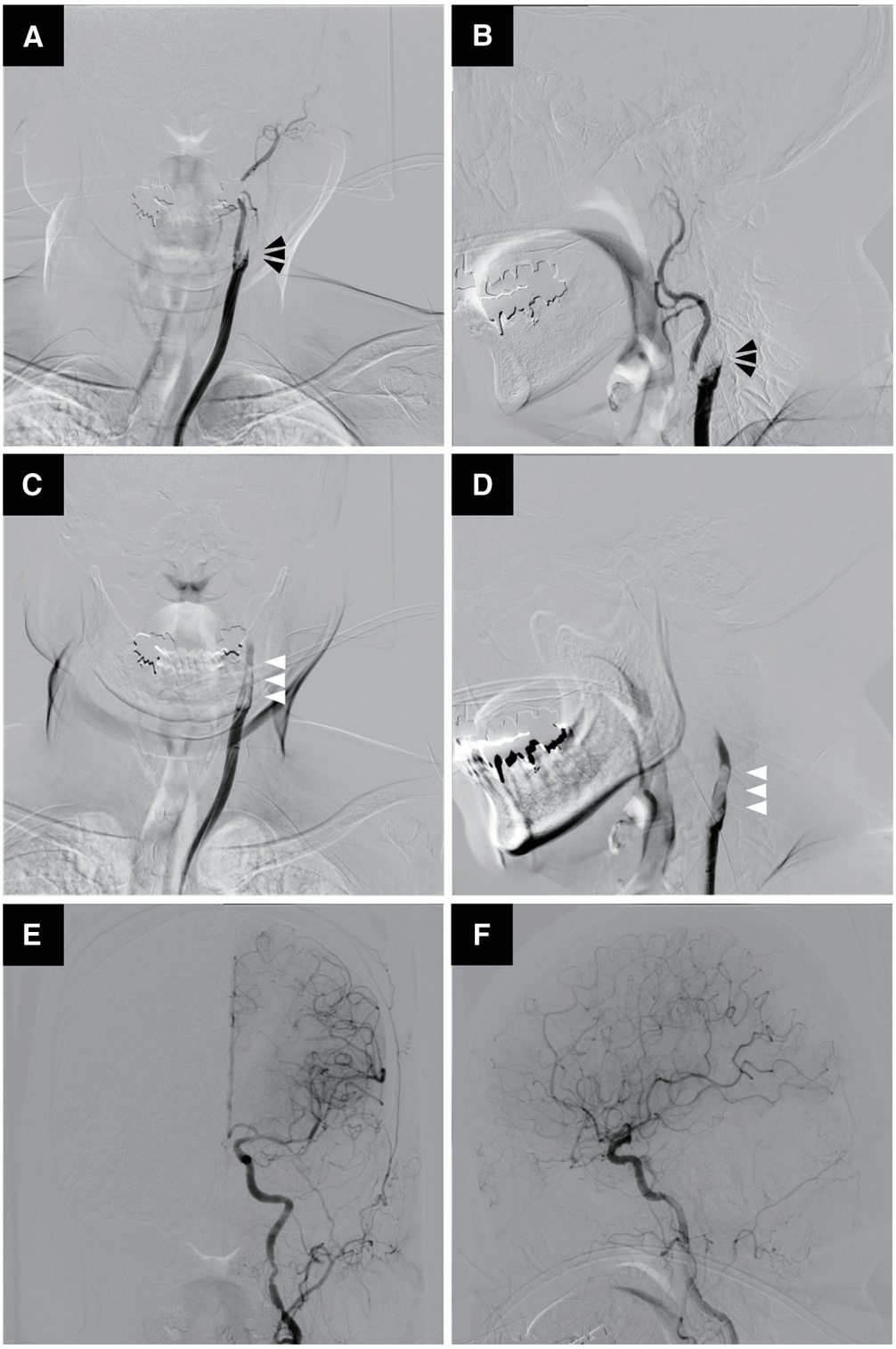

Fig. 3 Angiography obtained during MT (Case 1). (**A** and **B**) Left carotid angiograms of anteroposterior and lateral views demonstrating complete occlusion of the left ICA at its origin. An intraluminal filling defect at the left ICA origin was confirmed (black arrowheads), suggesting the presence of a thrombus. (**C** and **D**) Angiograms after ADAPT indicating proximal migration of the thrombus to the CCA and new-onset external carotid artery occlusion. (**E** and **F**) Final angiograms showing a reperfusion of TICI grade 3. ADAPT: a direct aspiration first-pass technique; CCA: common carotid artery; ICA: internal carotid artery; MT: mechanical thrombectomy; TICI: thrombolysis in cerebral infarction

Fig. 4 Extracted clot (Case 1). A significant amount of thrombus was retrieved post treatment.

and the Penumbra RED series (Penumbra, Alameda, CA, USA) also have two peel-away sheaths, which can be substituted in combination with the aspiration catheters during the VADT. Although thrombus extraction in the SI can be performed regardless of an 8-Fr BGC or a 6-Fr aspiration catheter from our experience, the 8-Fr BGC with a larger inner lumen is speculated to robustly provide more powerful aspiration than the 6-Fr aspiration catheter, which is arguably valuable for SI recanalization.[4)]

In our study, SI occlusion occurred in only 1.5% of MT cases, being a rare event. However, these events occurred exclusively in patients with CCA–extracranial ICA occlusion, indicating a 7.5% incidence in CCA–extracranial ICA occlusion cases. This seems an entirely reasonable result because the trapped thrombus inevitably becomes larger along with the obstructed vessel diameter. During MT for proximal artery occlusion, it should be kept in mind that a giant thrombus may result in SI occlusion.

The early detection of SI occlusion before the VADT procedure is of great significance. If treatment proceeds without detection, the occlusive thrombus in the SI can migrate into distal and/or proximal vessels, causing secondary embolism. Therefore, caution should be exercised in reversed blood flow from the SI side port immediately after withdrawing the obstructed BGC. In addition, the timing of the event when the thrombus falls out of the tip of the BGC can be detected according to the degree of blood backflow into the catheters and should be carefully monitored at the moment when the BGC tip begins to be housed in the SI.

The thrombus captured by a BGC is most likely to break off at the moment of passing through the distal end or hemostatic valve of an SI. Following detection of SI occlusion, manual aspiration with the SI side port presumably migrates the thrombus from the distal end of the SI to the hemostatic valve. As the SI side port is a small-diameter pipe, extracting the thrombus from the side port is usually difficult. In all the cases in this study, the thrombus reached a portion of the hemostatic valve that was grossly recognizable above the hemostatic valve, as indicated in **Supplementary Fig. S1**. VADT shows great promise for the extraction of the thrombus that reaches the hemostatic valve and is expected to be equally effective for the thrombus stuck in the middle of the SI, with deep insertion of the catheter through the peel-away sheath. However, if the thrombus gets stuck at the distal end of the SI, the thrombus is likely larger than the sheath lumen, and VADT may be less helpful in drawing the thrombus into the SI and may rather extrude the thrombus from the SI, leading to secondary embolism. Thus, VADT can be performed safely with an understanding of the obstructed segment of the SI. Echocardiography may be diagnostically useful if a thrombus is presumed to be trapped at the distal end of an SI.

The results of this study strongly support VADT as a reliable option. However, further confirmation of its practicability based on accumulated clinical experience is warranted. If the VADT method fails several times, the operator should switch to a conventional method, such as SI replacement, without getting attached to its prolonged use.

Conclusion

The results of clinical experience and simulation experiments strongly support VADT as a reliable option for recanalization of an occluded SI.

Disclosure Statement

The authors declare that they have no conflicts of interest.

Supplementary Information

Supplementary methods

Simulation experiments

To verify the usefulness of the VADT technique, we set up a simulation model considering SI occlusion during MT, as

shown in **Supplementary Fig. S1**. The SI was perfused retrogradely with saline using a dilator and pressure infusion bag. The reflux pressure was set at 180 mmHg, comparable to the body's blood pressure. We attached a 20-mL syringe to an SI side port and pulled negatively on the syringe plunger until the reverse flow of saline was stopped. An artificial thrombus was overfilled into an 8-Fr SI from its distal end. The SI was completely occluded at the hemostatic valve by the artificial thrombus, recognizable over a hemostatic valve. The reopening of the SI was confirmed by finding reverse saline from the side port. We repeated the VADT procedure five times in the same simulation environment and reproducibly achieved successful SI reopening within only 10–20 seconds. These procedures are also shown in **Supplementary Video 1**.

Supplementary Fig. S1

Simulation model of SI occlusion during MT. (**A**) Panoramic photograph of the simulation experiments. (**B**) An artificial thrombus is seen through a hemostatic valve (black arrowhead). (**C** and **D**) VADT procedure in the simulation model. The artificial thrombus was successfully retrieved from the SI using a peel-away sheath/FG2 assembly. FG2: FlowGate²; MT: mechanical thrombectomy; SI: sheath introducer; VADT: vacuum-assisted delivery of thrombus

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