Novel use of a stent retriever as a distal filler protection device for prevention of secondary embolization

Shohei Iijima, Yukihiro Imaoka, Satoshi Iihoshi, Shinya Kohyama
Department of Endovascular Neurosurgery, Saitama Medical University International Medical Center, Japan

Distal embolus due to mechanical thrombectomy is a frequent complication and directly results in a poor prognosis. Therefore, it is important to decrease distal embolus as much as possible in mechanical thrombectomy. EmboTrap III may be useful as a filter to prevent distal embolus in patients with a large volume of thrombus. Here, we report the results of one suggestive case and we also provide experimental data from a vessel model. The patient was a 78-year-old female who was admitted to hospital as an emergency case with chief complaints including dysarthria and left hemiplegia, including facial paralysis. She was diagnosed as large vessel occlusion-acute ischemic stroke with right tandem lesions by workup and underwent mechanical thrombectomy. A large volume of secondary thrombus due to flow stasis was assumed based around the occlusion site, and worsening of neurological symptoms was a concern due to distal embolus caused by recanalization of the cervical internal carotid artery. The SEIMLESS technique was performed under distal protection using EmboTrap III. There was no distal embolus or deterioration of neurological symptoms, and a good prognosis was achieved. This outcome suggests that PTA under distal protection using EmboTrap III may be useful for prevention of distal embolus.

Keywords Embolic Protection Devices, EmboTrap III, Percutaneous transluminal angioplasty, Thrombectomy

INTRODUCTION

EmboTrap III has a dual-layer structure consisting of an outer cage and an inner channel, which differs from conventional stent retrievers (SRs). The outer cage consists of independent segments and the inner channel has a stent-type structure that allows secure capture of a thrombus between the inner channel and outer cage. Furthermore, the closed basket at the tail of stent to reduce missing thrombus is specific structure. The ARISE II study confirmed the efficacy and safety of EmboTrap III. In mechanical thrombectomy (MT) for combination of intracranial and extra-
Stent retriever for distal protection

cranial major artery occlusions, called tandem lesions (TLs), the thrombus volume is likely to be high, which may result in embolization in a distal territory (EDT) and embolization in a new territory (ENT). The SEIMLESS technique described by Sultan-Qurraie et al. may be the effective procedure for preventing EDT and ENT in TLs. This technique uses a conventional SR that is deployed at intracranial occlusion site and whose delivery wire was used by PTA balloon for cervical internal carotid artery (ICA). We hypothesized that distal embolus can be reduced by using EmboTrap III with the SEIMLESS technique. Here, we report a case study using this method and experimental results in a vessel model.

DESCRIPTION OF CASE

A 73-year-old female patient developed dysarthria and left hemiplegia including facial paralysis and was admitted to our hospital 6 hours after onset. The National Institute of Health Stroke Scale was 8 points. Brain diffusion-weighted Magnetic resonance imaging (MRI) showed high signal intensity areas from the right temporal to parietal lobes, with DWI-ASPECTS of 9 points. Brain Magnetic resonance angiography (MRA) showed occlusion of the right cervical ICA and middle cerebral artery (MCA). Consequently, the patient was diagnosed with right TLs (Fig. 1) and underwent MT.

A 9-Fr sheath (Medikit Co., Ltd., Tokyo, Japan) was inserted into the right femoral artery and a 9F Optimo (Tokai Medical Products Inc., Aichi, Japan) was inserted using 5-Fr JB2 (Medikit Co., Ltd., Tokyo, Japan) to indwell the Optimo in the right common carotid artery (CCA). Right CCA angiography showed that the right ICA was occluded from the origin (Fig. 2). Subsequently, JB2 was carefully crossed over the lesions. It was found that the right MCA was also occluded, which was consistent with the findings of MRA and TLs (Fig. 2). Next, MT was performed; i.e., JB2 was unchanged and then a Phenom 21 microcatheter (Medtronic, MN, USA) and Chikai 14 (Asahi Intecc Co., Ltd., Aichi, Japan) were crossed coaxially and the Phenom was crossed over the occlusion site of the right MCA. EmboTrap III (6.5×45 mm; Cerenovus, Fremont, CA, USA) was deployed to cover the horizontal site of the MCA to anterior cerebral artery (Fig. 3). Using a delivery wire of the EmboTrap, a Sterling

Fig. 1. Brain diffusion-weighted MRI (A) and MRA (B) on arrival. Acute cerebral infarction was found from the right temporal to parietal lobes. MRA showed occlusion in the right internal carotid artery and middle cerebral artery. MRI, magnetic resonance imaging; MRA, magnetic resonance angiography
PTA balloon $3 \times 40$ mm (Boston Scientific, Valencia, CA, USA) was then introduced at the occlusion site of the cervical ICA. After PTA, guiding catheter could be introduced to cervical ICA and EmboTrap was retrieved. Both the stent itself and the closed basket at the tip had captured many thrombi. Final angiography showed recanalization of arteries other than the parietooccipital artery, in which cerebral infarction had already occurred, and a thrombolysis in cerebral infarction (TICI) score of 2b (Fig. 4). Postoperative brain MRI confirmed no new infarction suspected to be due to distal embolus, other than known thrombus lesions.

**Experiment**

To evaluate whether an SR can function as a distal protection device, we produced a silicon vascular model of the human anterior circulation and conducted an experiment. The vessel diameter of the ICA and M1 was 6 and 4 mm, respectively. The thrombus was produced with mixed components of 0% and 30% red blood cells, based on the report of Duffy et al., and sliced into 10 fragments of 0.5-1.5 mm. In this experiment, produced thrombus was assumed to be a secondary thrombus produced by flow stasis due to ICA occlusion or plaque fragments by PTA procedure to ICA occlusion in the case of TLs. The SR was deployed from the center of the
MCA to C2 of the ICA. Then, the 10 thrombus fragments were placed in the cervical ICA, after which the vascular model was connected to a perfusion pump and started at flow rates of 60 mL/s and a pulse of 60 bpm. The number of thrombotic segments captured by each SR was assessed. Three kinds of SRs: Solitaire (6×40 mm; Medtronic, Irvine, CA, USA), Trevo NXT (6×37 mm; Stryker, Kalamazoo, MI, USA) and EmboTrap (6rap, 6.5×40 mm; Medtronic) were assessed as distal protection devices. In a single experiment, 1/10, 0/10 and 9/10 thrombi were captured by Solitaire, Trevo and EmboTrap III, respectively, indicating the superiority of EmboTrap III for prevention of distal embolus (Fig. 5).

DISCUSSION

In this case of TLs, MT under distal protection using EmboTrap III and SEIMLESS technique prevented distal embolus and achieved good recanalization. Additionally, the strong point of this strategy is shortening of puncture to recanalization time at intracranial occlusion site in the case of TLs and cost-effectiveness, comparing with usual filter devices. EDT and ENT during MT inhibit collateral circulation to the penumbra regions and cause new ischemia, resulting in a poor prognosis. The rate of distal embolus with conventional SRs is 22% in total, and 7% are due to ENT. In ADAPT, the rate of distal embolus was 16%, reflecting a complication with a high incidence. Therefore, it is important to use MT to decrease distal embolus as much as possible.

The SEIMLESS technique reported by Sultan-Qurraie et al. is a procedure for TLs, in which a conventional SR is expanded at the distal occlusion site, a monorail PTA balloon is introduced to the proximal occlusion site along with the SR delivery wire, PTA is performed while a balloon guiding catheter (BGC) is deployed, and the SR is set back. This procedure is designed to deploy the SR at the distal site and make the SR function as a distal protection device that captures thrombus scattering at the proximal site for protection against distal embolus, which is expected for TLs with a large volume of thrombus. Anterograde blood flow blockade using a BGC is known to reduce distal embolus, but the extent to which a conventional SR deployed at the distal site functions as a distal protection device is unclear. Sultan-Qurraie et al. did not refer to achievement of distal embolus protection using a conventional SR.
Solitaire has been reported to crush a thrombus during the procedure, which increases the risk of distal embolus,\(^3\) and Solitaire causes ENT at about twice the rate of EmboTrap in the anterior cerebral artery region in MT for the MCA.\(^1\) This is understandable because a conventional SR is likely to become hollow, compared to EmboTrap with a closed basket structure at the tip. Thus, a conventional SR may not sufficiently prevent distal embolus. In addition, a large thrombus of >1000 μm is likely to occur in MCA occlusion, and Chueh et al. found that EmboTrap did not crush such a thrombus and significantly reduced distal embolus due to its closed basket structure at the tip, in comparison with Solitaire in vitro.\(^1\) The effect of expansion of EmboTrap at a distal site as a distal protection device to capture thrombus scattering at the proximal site was not examined in Chueh et al.\(^1\) Our experiment had a limitation because tiny thrombus such as thrombus under 0.5 mm were not assessed.

Given these previous results, EmboTrap III was used in the current case, and as expected, EmboTrap III captured most scattering thrombi. We usually estimate the volume of thrombus based on preoperative T2 (weighted gradient echo images) and intraoperative angiography, and use EmboTrap III as the first-line device. In cases of ICA occlusion with a large volume of thrombus, EmboTrap III is expanded at a distal site again after the first pass and before BGC deflation, resulting in a large volume of thrombus in the closed basket at the tip, as seen in the current case. These results suggest that distal embolus due to residual and secondary thrombi can be reduced. The specific construction consisting of inner-channel and outer-cage may also help to reduce EDT and ENT, suggesting longer size is better. Further studies

---

**Fig. 5.** A blood vessel prosthesis model and pseudo-thrombus were produced and Solitaire (6×40 mm), Trevo NXT (6×37 mm) and EmboTrap (6.5×40 mm) were assessed as distal protection devices. The thrombus was cleaved into 10 fragments, the pump was started at a flow rate of 60 mL/sec and a pulse of 60 bpm, and the number of thrombotic segments captured by the SR was assessed. The numbers of captured thrombi were 1/10 by Solitaire (A), 0/10 by Trevo (B) and 9/10 by EmboTrap III (C, D).
are required, but this new SR procedure using EmboTrap III may be effective for protection against distal embolus.

CONCLUSIONS

MT under distal protection using EmboTrap III may reduce occurrence of distal embolus. In particular, SEIMLESS technique using EmboTrap III is useful for TLs.

ACKNOWLEDGMENT

Data in this article were partially obtained with support of Johnson & Johnson K.K.

Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

REFERENCES