CASE REPORT

Nitinol clip distal migration and resultant popliteo-tibial artery occlusion complicating access closure by the StarClose SE vascular closure system

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SUMMARY

Lower extremity ischemia following deployment of a vascular closure device for access site closure after a transfemoral endovascular procedure rarely occurs. A 68-year-old woman diagnosed with subarachnoid hemorrhage due to a ruptured anterior communicating aneurysm was treated by endovascular coil embolization. The StarClose SE device was deployed for right femoral arteriotomy closure. After 2 days, critical ischemia occurred on her right lower leg due to total occlusion of the popliteo-tibial artery. Emergent surgical embolectomy was performed and the nitinol clip of the StarClose device was captured in the lumen of the tibioperoneal trunk. Although StarClose is an extravascular closure system, intravascular deployment, distal migration, and resultant critical limb ischemia can occur.

The clip applicator was connected to the StarClose exchange sheath, and the intravascular flexible locator wings were deployed. The device was then withdrawn until resistance was felt, which confirmed the engagement of the anterior arterial wall and an appropriate deployment location for the clip. The clip delivery tube was then advanced to the access site while stabilizing the device at the angle of the tissue tract. The body of the device was then raised to a 60° angle and pushed down gently on top of the artery to seat the clip delivery tube on top of the access site. The clip was then deployed while maintaining downward pressure. Immediate hemostasis was not achieved after device

BACKGROUND

Vascular closure devices (VCDs) have been introduced and developed since the mid-1990s to improve patient and physician's comfort, and reduce time to hemostasis and ambulation after endovascular procedure. StarClose SE (Abbott Vascular) is a nitinol clip based VCD that closes the arteriotomy site extravascularly, not leaving any component in the vessel lumen.

Here, we report a case of intravascular misplacement and distal migration of the nitinol clip, which subsequently caused critical limb ischemia.

CASE PRESENTATION

A 68-year-old woman was admitted because of loss of consciousness. She was diagnosed as having diffuse subarachnoid and intracerebral hemorrhage due to a ruptured anterior communicating artery aneurysm. Endovascular coil embolization was performed via right common femoral artery access using a 6 F femoral sheath. Femoral angiography was performed after sheath insertion to confirm the appropriateness of the access site. The puncture was performed at the superficial femoral artery (SFA) due to high bifurcation of the femoral artery. The diameter of the SFA was larger than 5 mm and therefore sufficient for the use of the StarClose SE device (figure 1).

The StarClose SE device was deployed for arteriotomy closure according to the manufacturer's instructions. The sheath site was prepared by blunt dissection to allow better apposition of the device to the arteriotomy site. The procedural introducer sheath was exchanged for the sheath of the device.

Figure 1 DSA of the right femoral artery. The diameter of the femoral artery was 5.3 mm.

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removal, so consequently manual compression was applied for 20 min and then hemostasis was achieved.

Two days after the procedure, the patient's right lower extremity below the knee became cold and pale with decreased pulsation of the right dorsalis pedis artery. Femoral CT angiography visualized long segmental total occlusion from the right popliteal artery involving distal arteries (posterior tibial and peroneal artery), and significant stenosis at the right proximal SFA and popliteal artery (figure 2).

TREATMENT

Emergent surgical embolectomy was conducted on the right femoral and tibial arteries. After incision of the tibioperoneal trunk, the disc shaped metallic clip was found at the proximal one-third of the tibioperoneal trunk (figure 3). The clip was successfully removed.

OUTCOME AND FOLLOW-UP

After embolectomy, pulsation and blood flow of the right leg were fully recovered without any sequelae.

DISCUSSION

The StarClose SE is an active approximator, which physically closes an arteriotomy site extravascularly using a 4 mm disc shaped nitinol clip, which is deployed on the anterior arterial wall. The main advantage of this device is that it does not require implantation into the vascular lumen, which theoretically reduces the risk of distal thromboembolism associated with the use of collagen based VCDs.¹

Several studies have confirmed that the StarClose is both safe and effective, and successful deployment has been reported in more than 95% of cases with immediate hemostasis.^{2 3} Rates of major and minor complications have been reported to be 0–1.9% and 2.2–8%, respectively.^{2 4} The rate of lower limb ischemia after use of the StarClose was 2.4% in a previous study.⁵ Jaff *et al*¹ used ultrasound to evaluate post-deployment complications of the StarClose and confirmed reliable extravascular placement of the clip without evidence of vessel injury. Furthermore, the StarClose has been reported to have favorable effectiveness and safety compared with other VCDs and manual compression.³ In addition, our learning curve for the device may be sufficient because it has been performed in more than 500 cases over

Figure 3 The StarClose nitinol clip retrieved from the lumen of the tibioperoneal trunk.

approximately 5 years, and we have experienced a few, mainly device failures, without major complications.

The important drawback of this device is the rate of device failure, which was found to be 11% in a preliminary CLIP trial.⁶ In subsequent studies, the deployment failure rate decreased to 3.1–6.1%.⁴ The relative frequency of failure to achieve hemostasis among the complications was 36.5% in the US Food and Drug Administration Manufacturer and User Facility Device Experience database.⁷

Two cases of nitinol clip intravascular misplacement have been previously reported.^{8 9} However, the problem occurred at the level of the SFA in those cases. To our knowledge, distal migration of the nitinol clip causing occlusion of the distal artery has not been previously reported. Although the diameters of the distal SFA and popliteal artery in our case were in the range of 4–5 mm by CT angiography, the 4 mm nitinol clip migrated a considerable distance and was stuck in the tibioperoneal trunk, causing stenosis of the SFA and occlusion of the tibial artery.

Intravascular misplacement of the clip seems to have happened as the clip delivery tube was inadequately pushed into the vessel, overcoming the resistance of the vessel wall and surrounding tissue while the locator wings were not withdrawn properly to attach to the inner surface of the vessel wall. If the delivery tube penetrates the vessel wall, excessive resistance while advancing the delivery tube should be felt, and the patient might complain of severe groin pain, but the operator experienced only normal tactile feedback from the device and this patient could not complain of pain because she was under general anesthesia.

Although StarClose SE is a second generation clip based VCD that was developed to improve patient safety and clinical confidence, it could not totally prevent incorrect deployment of the clip and it is impossible to retrieve an incorrectly deployed clip.

To decrease incorrect deployment of the clip and vascular complications, ultrasound guided VCD deployment may be helpful.¹⁰ Lucatelli *et al*¹⁰ reported that the technical success rate significantly increased and the complication rate significantly decreased under ultrasound guidance, and the authors mentioned that through the use of ultrasound they were able to prevent two cases of incorrect deployment of the StarClose, which was stuck in the lumen rather than in the anterior arterial wall.

Figure 2 Femoral CT angiography. (A) Stenosis of the right proximal superficial femoral artery. (B) Total occlusion from the right popliteal artery. The diameter of the popliteal artery above the occlusion was about 4.8 mm.

Learning points

- ▶ The StarClose clip can be misplaced intravascularly and migrate distally to the tibial artery.
- ▶ Intravascular misplacement of clip may cause critical lower extremity ischemia.
- ▶ Careful attention is needed while deploying vascular closure devices, including the StarClose device.

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