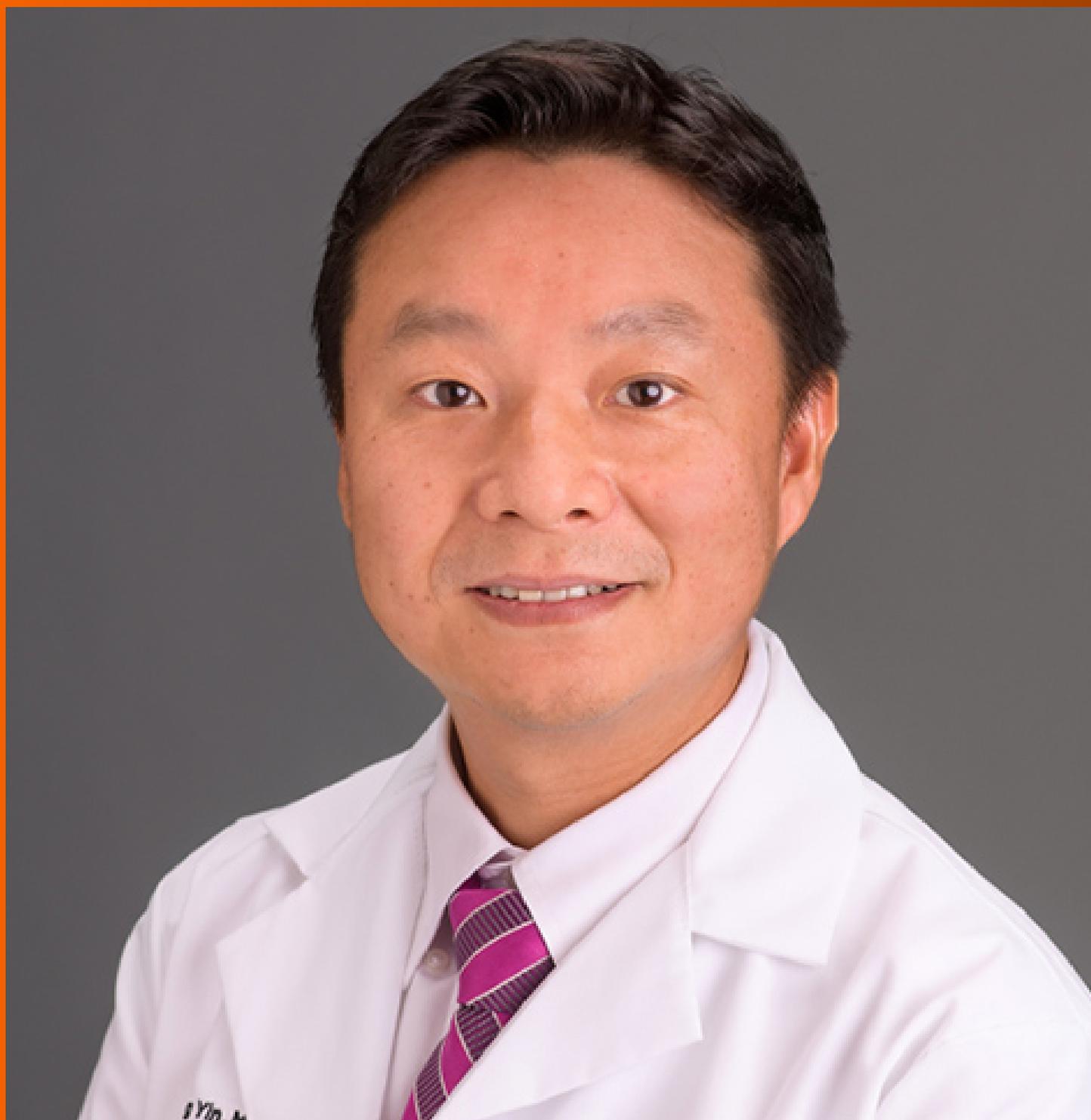


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Flip-over of blood vessel intima caused by vascular closure device: A case report

Li-Xia Sun, Xue-Song Yang, Da-Wei Zhang, Bo Zhao, Lian-Lian Li, Qi Zhang, Qing-Zhi Hao

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Abstract

BACKGROUND

Complications of vascular closure devices mainly include bleeding, vascular injury, and trapped device that cannot be removed percutaneously. However, arterial stenosis or occlusion induced by vascular injury is rare. This article introduces a rare case with severe acute limb ischemia after using the vascular closure device (StarClose).

CASE SUMMARY

A 54-year-old man was admitted because of necrosis of the second toe of the left foot for 2 mo. Ultrasound showed left femoral artery stenosis, and occlusion of the left popliteal, posterior tibial, peroneal, anterior tibial and dorsalis pedis arteries, suggesting arteriosclerosis obliterans of low extremities, gangrene and type 2 diabetes. He underwent an interventional procedure of drug-eluting balloon in the left lower limb *via* antegrade puncture of the left common femoral artery. He developed acute limb ischemia after 1 h, and severe pain, numbness, pale skin, low skin temperature and weakened sensation in the left foot. Injury of the common femoral artery intima was considered. Exploratory surgery showed occlusion at the puncture point accompanied with bulged vascular lumen and flipped vascular intima caused by StarClose. The flipped intima was removed. The limb blood supply was restored and the limb was saved post-surgery. He recovered well at final follow-up.

CONCLUSION

Incorrect use of the vascular closure device was the main cause of severe acute limb ischemia in this case.

Key Words: StarClose vascular closure device; Vascular injury; Complications; Case report

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Core Tip: Clinical reports on the complications of vascular injury caused by vascular closure devices are rare. Here, we report a case of severe acute limb ischemia after using a vascular closure device (StarClose). The case suggests that use of the vascular closure device was the main cause of severe acute limb ischemia in this case. The vascular closure device should be operated carefully.

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INTRODUCTION

Vascular closure devices overcome the limitations of traditional hemostasis methods, achieve rapid hemostasis and shorten the in-bed time after surgery. However, they also have some complications, with the most common being bleeding and the least common stenosis or occlusion caused by vascular injury[1]. At present, clinical reports on the complications of vascular injury caused by vascular closure devices are rare. In this article, one case of severe acute limb ischemia after using vascular closure device (StarClose) is reported.

CASE PRESENTATION

Chief complaints

The patient was a 54-year-old man who was admitted due to cyanotic necrosis and severe pain in the second toe.

History of present illness

The patient had the necrosis of the second toe of the left foot for 2 mo.

History of past illness

The patient had a history of smoking for 30 years and type 2 diabetes for 1 mo.

Physical examination

The pulse of the femoral artery of the left lower limb was weakened, and those of the popliteal, posterior tibial, and dorsal foot arteries were not palpable.

Laboratory examinations

Blood routine examination showed white blood cell count $9.46 \times 10^9/L$, absolute neutrophils $6.43 \times 10^9/L$, absolute monocytes $0.78 \times 10^9/L$, absolute basophils $0.07 \times 10^9/L$, erythrocytes $9.46 \times 10^{12}/L$, hemoglobin 148 g/L, and platelets $299 \times 10^9/L$. Blood biochemical results indicated blood potassium 4.63 mmol/L, alanine aminotransferase 50 U/L, aspartate aminotransferase 22 U/L, total bilirubin 9.2 mol/L, creatinine of 47 mol/L, glomerular filtration rate 120.06 mol/L, homocysteine 11.2 mol/L, glucose 6.48 mmol/L, glycosylated hemoglobin 10.6%, and erythrocyte sedimentation rate 22 mm/h. Blood coagulation test suggested international standardized ratio 1.03, plasma prothrombin time 13.6 s, activated partial thromboplastin time 42.6 s, plasma fibrinogen 5.76 g/L, and thrombin time 16.5 s.

Imaging examinations

Color Doppler ultrasound showed left femoral artery stenosis, and occlusion of the left popliteal, posterior tibial, peroneal, anterior tibial and dorsalis pedis arteries. The diagnosis of arteriosclerosis obliterans of the lower extremity accompanied with gangrene and type 2 diabetes was made. Under local anesthesia, the interventional procedure of drug-eluting balloon in the left lower limb was performed *via* antegrade puncture of the left common femoral artery. The operation went smoothly. However, 1 h after the puncture point was closed by the StarClose vascular closure device, the patient developed manifestations of acute ischemia, including severe pain, numbness, pale skin, low skin

temperature and weakened sensation in the left foot. The pulse of the left common femoral artery disappeared by palpation. Arterial angiography of the left lower extremity showed occlusion of the middle and distal segment of the common femoral artery, but no thrombus was observed (Figure 1).

FINAL DIAGNOSIS

The injury of the common femoral artery intima was considered.

TREATMENT

Exploratory surgery was performed on the left common femoral artery. Occlusion at the puncture point was observed with bulged vascular lumen. There was intima tissue in the vascular lumen. An incision of about 1.5 cm was made at the puncture point. We observed that the intima embedded with the nickel-titanium alloy clip of the StarClose vascular closure device flipped over and blocked the lumen (Figure 2A). The flipped intimal tissue of about 4 cm was removed during the operation (Figure 2B). A jet-like blood flow was observed at the distal end of the common femoral artery incision. The common femoral artery incision was sutured and repaired without using the StarClose vascular closure device.

OUTCOME AND FOLLOW-UP

Arterial angiography showed smooth blood flow in the common and superficial femoral artery. Color Doppler ultrasound of the left lower limb artery showed that the blood flow of the left common iliac, common femoral, popliteal, anterior tibial and peroneal arteries was unobstructed. The patient was given antiplatelet, anticoagulation, anti-infection and microcirculatory improvement drugs after surgery. The patient was discharged after hospitalization for 11 d. During follow-up at 6 mo after surgery, the patient recovered well. The patient is under constant follow-up.

DISCUSSION

For a long time, manual compression of the puncture point was the traditional method of hemostasis after vascular interventional therapy. However, this required no less than 30 min of continuous compression and several or even dozens of hours of immobilization after the operation[2,3]. To overcome the limitations of traditional hemostasis methods, the vascular closure devices have been developed since the 1990s. However, the vascular closure devices have complications during clinical application. Bleeding is the most common one, and the incidence of stenosis or occlusion caused by vascular injury is the lowest[4]. In the present case, the patient had acute limb arterial ischemia after intervention. It is considered that during the placement of StarClose vascular closure device, due to incorrect operation, the nickel-titanium alloy clip of the device clamped the intima of the blood vessel. When it was pulled out violently, the intima of the blood vessel was flipped over, resulting in arterial stenosis and occlusion, and causing ischemic symptoms at the distal end of the limb. Finally, the occluded segment of the intima was removed through femoral artery incision, and the femoral artery was repaired to restore the blood supply of the affected limb. Dzieciuchowicz *et al*[1] also reported a case of acute limb arterial ischemia caused by the incorrect release of the StarClose vascular closure device in a 31-year-old woman. In our case and the case reported by Dzieciuchowicz *et al*[1], surgical incision was used to restore the blood supply of the affected limb. Although some scholars have suggested that the stenosis and occlusive complications should be resolved through endovascular treatment[5,6], surgical incision has to be performed in some cases according to the type and location of the lesion as well as the severity of limb ischemia.

According to previous reports, complications occur in 3%-4% of cases intervened with StarClose vascular closure devices[7-9], with bleeding as the most common complication. The inguinal complications are classified into self-limiting hematoma, hematoma requiring blood transfusion, other/minor (pseudoaneurysm and infection) or other/severe (vascular complications) complications. For example, McTaggar *et al*[10] used StarClose in 281 patients undergoing interventional surgery and found that the incidence of self-limiting hematoma was the highest, and no patients had other/minor complications. Gaba *et al*[11] observed 83 patients with liver tumors using StarClose vascular closure device as interventional treatment and found that only three (3.6%) developed small inguinal hematomas after the operation. The least common complication of the vascular closure device was acute limb ischemia, vascular stenosis or occlusion. Rodriguez *et al*[4] reported that among 603 patients receiving intervention with StarClose vascular closure, only two had this complication, including one case of

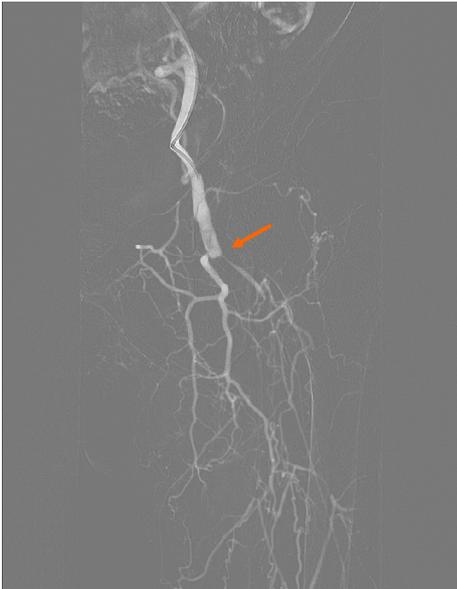


Figure 1 Angiography of the left lower extremity at 1 h after interventional surgery. The orange arrow indicates occlusion of the middle and distal segment of the common femoral artery.

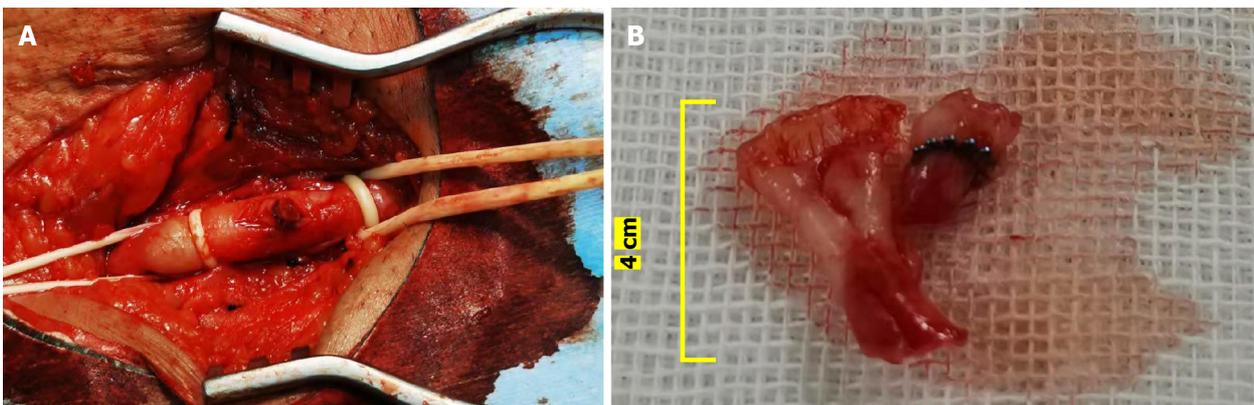


Figure 2 Intima of the common femoral artery at the puncture point was flipped over. A: The intima of the common femoral artery embedded with the nickel–titanium alloy clip of the StarClose vascular closure device was flipped over; B: The flipped intima tissue of about 4 cm was removed during the operation.

common femoral artery occlusion, and another of common femoral artery stenosis. Another common complication[12] is that the nickel–titanium alloy clip of the vascular closure device is compressed or stuck by the scar tissue or normal tissue at the puncture site and cannot be removed percutaneously. The Medical Device Adverse Events database of the US FDA showed that from July 2009 to October 2010, there were 224 cases with complications of stuck StarClose vascular closure device[13]. The surgeon should pull the handle of the closure device linearly[14] and then remove it smoothly. Studies have shown that the release of the vascular closure device under ultrasound guidance can reduce the number of complications[15–17]. In addition, although the vascular closure device has significant advantages in closing large-sized blood vessels, its operation is complicated[18]. Once the operation fails, it will not only fail to stop bleeding, but also cause some delayed complications (such as secondary thrombosis and pseudoaneurysm)[10,19–21]. The complications secondary to StarClose are summarized in Table 1. Therefore, the proficiency of the surgeons handling the vascular closure device should be improved, and the operation should be cautious and standardized, so as to avoid the occurrence of complications.

CONCLUSION

This article reports a rare case of acute limb ischemia after using a vascular closure device. This case suggests that the vascular closure device should be operated carefully and standardized within the scope of the instructions to reduce complications. In addition, strengthening the training and

Table 1 Complications secondary to StarClose

Complications secondary to StarClose	Incidence % (n/N)
Failure to stop bleeding immediately[20]	8.7% (15/171)
Small inguinal hematoma[10]	3.6% (3/83)
Pseudoaneurysm[20]	0.6% (1/156)
Retroperitoneal hematoma[21]	0.43% (461/107710)
Acute limb ischemia[11]	0.33% (2/603)
Self-limiting hematoma[10]	1.4% (4/281)
Hematoma requiring blood transfusion[10]	0.4% (1/281)

supervision of clinicians is also important.

FOOTNOTES

Author contributions: Hao QZ designed the study and collected the fund; Sun LX, Yang XS, Zhang DW, and Zhao B collected the case, analyzed the data; Li LL and Zhang Q searched the literatures; and Sun LX wrote the manuscript.

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