Embolic Balloon Capture Angioplasty

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Acute limb ischemia (ALI) of the peripheral arteries carries very high mortality and morbidity rates.[1,2] Etiology can be broadly divided into thrombotic (from underlying atherosclerotic disease) or embolic. Patients at high risk for embolism are those with atrial fibrillation or cardiomyopathy contributing to a cardiac source of emboli and those with aortic aneurysm or extensive atherosclerotic plaque in the aorta. Patients with hypercoagulable, congenital disorders and other acquired procoagulant states, such as heparin-induced thrombocytopenia, are also prone to arterial thrombosis. Surgical cutdown and embolectomy have been the standard of care for decades in the management of such cases.

Recent advances in endovascular interventions have enabled percutaneous management of acute limb ischemia. However, endovascular approaches often require concomitant use of thrombolytics and thus increase the risk for bleeding and complications.[3] This article describes two cases of ALI in patients with aortoiliac disease who were treated percutaneously with the Proteus device (Angioslide, Inc., Minneapolis, MN), a unique balloon that can infold upon deflation and safely capture lesion debris, preventing embolization and restoring blood flow.

CASE 1

A 52-year-old man with a history of lung cancer presented with sudden onset of left leg pain and was diagnosed with ALI. The patient was noted to have occlusive thrombus in the left external iliac artery (EIA) extending into the left common femoral artery. The patient underwent open surgical thrombectomy from the left common femoral approach. One week later, the patient was noted to have recurrence of left leg ALI. Meanwhile, he continued to deteriorate medically and, at that time, was considered to be a very high surgical risk; endovascular intervention as a salvage attempt was offered.

Angiography of the left leg was performed with a right common femoral puncture and crossover technique, which revealed occlusion of the distal left common iliac artery (CIA) and the EIA (Figure 1). The left common femoral artery was reconstituted via collaterals. A 6-F crossover sheath was placed in the proximal left CIA. The left CIA occlusion was crossed using a hydrophilic guidewire, which was exchanged for a 0.035-inch support guidewire. In view of fresh thrombus in the CIA, a 6- X 60-mm Proteus balloon was used twice for angioplasty and thrombus retrieval (Figure 2). There was minimal residual thrombus after this (Figure 3). An 8- X 100-mm and an 8- X 40-mm self-expanding nitinol stent were deployed across the left CIA extending into the left EIA. A completion angiogram showed a widely patent left CIA, EIA, and distal runoff (Figure 4). The patient was discharged home on postoperative day 2 with triphasic Doppler signals at the ankle and a palpable (2+) left femoral pulse.

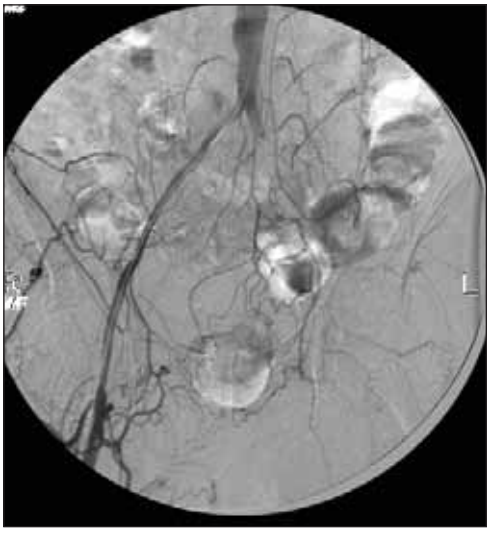

Figure 1. Initial angiogram shows the occlusion of the left CIA and left EIA extending into the left proximal common femoral artery.

Figure 2. Left CIA and EIA balloon angioplasty with thrombus retrieval using the Proteus catheter.

Figure 3. Minimal residual thrombus in the left CIA and EIA.

Figure 4. Poststenting completion angiogram showing a patent left iliac system.

CASE 2

A 39-year-old man with a history of hypertension, diabetes mellitus, hypercholesterolemia, tobacco use, coronary artery disease, and peripheral arterial disease presented to the hospital complaining of lifestyle-limiting claudication (Fontaine IIb) with left hip and calf pain for 6 months. He had a history of left EIA stenting about 2 years previously. The left ankle-brachial index was noted to be 0.62, and duplex ultrasound revealed occlusion of the left CIA with a patent stent in the EIA.

The patient underwent bilateral aortoiliac angiography and left lower extremity angiography via right common femoral artery access. The angiogram showed the left CIA to be totally occluded (Figure 5) with reconstitution of the left EIA via collaterals. The remainder of the left lower extremity runoff via the superficial femoral artery, popliteal artery, and tibioperoneal vessels was unremarkable (Figure 6).

Left common femoral artery access was obtained using fluoroscopic guidance, and bilateral 8-F sheaths were placed. The patient received intravenous heparin for anticoagulation, and the left CIA occlusion was crossed (Figure 7) with a 0.035-inch straight stiff hydrophilic guidewire and a 5-F multipurpose catheter. In view of the significant risk of distal embolization with a recently occluded artery, the decision was made to use embolic capture with the Proteus balloon. A 5- X 60-mm followed by a 6- X 60-mm Proteus balloon was used for balloon inflation across the left CIA (Figure 8). Capture of 3-mm visible debris in the infolded balloon was noted (Figure 9). Due to suboptimal results of plain old balloon angioplasty (Figure 10), a kissing bilateral stent technique was performed to treat the left CIA and to prevent plaque shift of the right CIA. A completion angiogram showed patent bilateral iliofemoral systems with a patent distal runoff (Figure 11). The ankle-brachial index improved to 0.90 in left leg, and the patient was discharged home on postoperative day 3.

DISCUSSION

Percutaneous management of thrombus is a tedious and difficult task and often requires the use of adjuvant thrombolytic therapy. In these challenging cases, use of

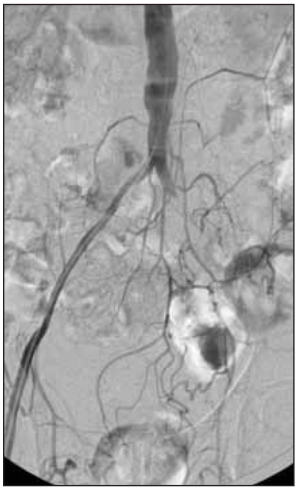

Figure 5. Occlusion of the left CIA and left EIA extending into the proximal common femoral artery.

Figure 6. Distal left leg runoff.

Figure 7. Successful crossing of the left iliac artery with a straight stiff wire.

Figure 8. Proteus balloon angioplasty.

Figure 9. Infolding of the distal half of the balloon.

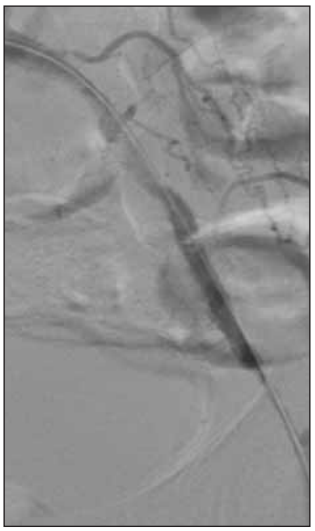

Figure 10. Angiogram obtained after Proteus balloon PTA.

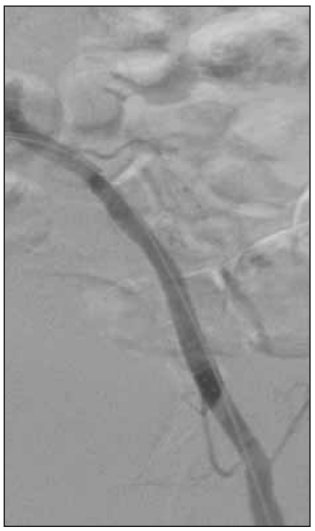

Figure 11. Final angiogram poststenting with a self-expanding stent.

the Proteus balloon resulted in moderate thrombus removal and rapid restoration of flow without the need for thrombolytic therapy or other mechanical thrombectomy devices. The Proteus device has received US Food and Drug Administration clearance for peripheral transluminal angioplasty (PTA) and for capture and containment of embolic material during angioplasty of the iliac, femoral, popliteal, tibial, peroneal, and profunda femoris arteries.

The Proteus device allows the operator to perform angioplasty while concomitantly capturing debris that could otherwise potentially embolize during the procedure. Initially, the device functions as a normal angioplasty balloon: the balloon is semicompliant and is inflated to a nominal pressure of 8 atm. After angioplasty, the balloon is deflated to 2 atm. At this point, while arterial flow is arrested, the balloon is infolded upon itself. This mechanism essentially "sucks" potential embolic debris into the balloon as it is rolled into itself. Finally, the balloon is deflated (creating additional negative pressure), the embolic debris is captured, and the balloon is retrieved through the sheath.

CONCLUSION

Use of the Proteus device in patients with arterial thrombosis can be beneficial by rapidly restoring arterial perfusion while preventing distal embolization of thrombotic debris from the site of the occlusion. In some cases, the use of thrombolytic therapy with its associated cost and risk can be avoided. The Proteus balloon catheter has the same physical and behavioral characteristics as a standard angioplasty balloon with the added feature of debris capture and removal. Larger studies will need to be conducted to better define the device's efficacy for patients with both acute and chronic lower limb ischemia. ■

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