Infection: A Perilous Complication of a Closure Device

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ABSTRACT: The ability to achieve earlier hemostasis and comfort with percutaneous vascular closure devices (VCD) without major complications has contributed to the increase of their use. The use of VCD has been associated with different complications including access-site/femoral artery infection. We describe herein an illustrative case of a 47-year-old female patient with abnormal nuclear stress test, who developed a suture-based VCD-related infection following diagnostic coronary angiography. The patient was empirically treated with broad-spectrum antibiotics, early wound exploration, and debridement. Infection associated with percutaneous VCD placement is uncommon, but it is an extremely serious complication. Early aggressive medical and surgical interventions are required to resolve this condition.

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H emostasis obtained by manual compression after femoral artery catheterization results in consistently low rates of major complications. Several devices have been developed to aid in the closure of the femoral arteriotomy. The most commonly used devices are collagen-based plug devices like Angio-Seal (St. Jude Medical) and Vasoseal (Datascope Corporation), which was retired by manufacturer due to adverse events; polyglycolic acid based plug devices like Mynx Ace (AccessClosure, Inc.) and Exoseal (Cordis Corporation); clip closure devices like Starclose (Abbott Vascular); and percutaneous suture closure devices like Perclose (Abbott Vascular). The ability to achieve earlier hemostasis with percutaneous vascular closure devices (VCDs) and the resultant increases in patient comfort, shorter time to ambulation, and decreased demand on personnel for applying manual compression have contributed to the increasing use of these devices.

The use of VCDs has been associated with different noninfectious and infectious complications including hematoma, groin bleeding, pseudoaneurysm, arteriovenous fistula formation, retroperitoneal bleeding, limb ischemia, access-site infection, femoral artery infection, and septic emboli. Overall, a complication rate of up to 2% has been reported. Infectious complication rates range from 0.0% to 5.1% and are associated with severe morbidity (requiring multiple surgical debridement, prolonged hospitalization, and antibiotics) and mortality. We describe an illustrative case of suture-based VCD-related infection following diagnostic coronary angiography.
CASE REPORT

A 47-year-old female with hypertension as well as diet-controlled diabetes and dyslipidemia was evaluated in the cardiology clinic for complaints of dyspnea on exertion and reduced exercise tolerance. An exercise nuclear study revealed moderate sized, reversible anterior and inferior defects with evidence of transient ischemic dilation. Echocardiography showed normal left ventricular wall motion and ejection fraction with mild concentric left ventricular hypertrophy. In view of the high-risk findings on the nuclear study, the patient was referred for coronary angiography.

Cardiac catheterization was performed using right femoral arterial access, revealing angiographically normal coronary arteries, normal ejection fraction and elevated left ventricular end-diastolic pressure of 26 mmHg. Femoral angiography revealed a 6 mm sized common femoral artery with the sheath entry side well above its bifurcation (Figure 1).

The femoral access site was closed using a Perclose closure device (Abbott Vascular) under aseptic precautions (including change of gloves by the operator and repeat sterilization of the site with betadine). Prophylactic antibiotic (Cefazolin) was administered as a part of the catheterization laboratory protocol (a precaution taken especially because the patient had diabetes). The patient was discharged home in a stable condition on the same evening.

The patient returned to the emergency department 3 days later with complaints of groin pain. She denied fever, chills, or groin discharge. She was afebrile and demonstrated localized tenderness in the right groin. The overlying skin appeared normal without any open wound or discharge. There were no palpable masses, lymphadenopathy, or hematoma, and femoral, popliteal, and pedal pulses were normal. The white
blood cell count was normal and a femoral ultrasound showed no hematoma, abscess, or pseudoaneurysm. The patient was discharged home and a follow-up was arranged in 2 days.

She returned to the emergency department 3 days later with fever, chills, severe right groin pain radiating down the right leg, blistering skin, and redness in the right groin. She was febrile to 101.5 F and demonstrated severe tenderness and swelling over the right infrainguinal area extending down to mid thigh. The overlying skin was warm, erythematous, and blistered with purulent, hemorrhagic drainage from the arterial puncture site (Figure 2). The right femoral pulse was detected on Doppler only and all distal pulses were diminished. White blood cell count was elevated to 13,300 and glucose was 290 mg/dL. Bedside ultrasound showed a possible hematoma, 1.1 cm x 1.8 cm in size and no free fluid, pseudoaneurysm, or arteriovenous fistula was detected. Vascular surgery and infectious diseases specialists were consulted to assist with the management.

The patient was empirically started on vancomycin, and...
clindamycin, and piperacillin-tazobactam after multiple sets of blood cultures were obtained. Computed tomography (CT) of the pelvis, hip, and upper and lower extremities showed extensive cellulites and fasciitis over right thigh with evidence of air in the subcutaneous tissue. In view of persistent fever (103°F), leukocytosis, leg pain, and the CT scan findings, the patient was taken to the operating room the next day for wound exploration and debridement of the right groin.

Operative findings included the infected suture (Figure 3A), a large seropurulent hematoma and large patches of necrotic tissue and inflammation (Figure 3B, C, and D). She underwent extensive wound debridement followed by ligation of femoral artery, profunda femoris, and superficial femoral arteries. After adequate wound sterilization, an obturator bypass was performed using a PTFE graft anastomosed from the iliac artery to popliteal artery and the graft wound was closed.

Blood cultures from the initial draw were positive for methicillin-sensitive Staphylococcus aureus (MSSA). Wound and arterial cultures grew MSSA and group B streptococci as well. Fever and leukocytosis persisted despite 7 days of antibiotics and overall improvement in the appearance of the wound. All subsequent blood cultures remained negative and antibiotics were switched to nafcillin, gentamycin, and rifampicin. Transesophageal echocardiography was normal. In view of persistent leg pain, fever, leukocytosis, and leg edema, a repeat CT of the thigh and leg was obtained which showed a hematoma over common femoral vessels, a collection of fluid in the medial thigh with air in the subcutaneous tissues (Figure 4), and evidence of deep venous thrombosis in the superficial femoral vein which was confirmed by venous Doppler. Anticoagulation was started with intravenous heparin.

On the following day, the hemoglobin dropped by 3gm/dL, with increasing swelling and pain in the right leg and thigh with limited range of motion. Re-exploration of the groin wound was performed and revealed no active bleeding and large healthy granulation tissue seen. An inferior vena cava filter was placed prophylactically via the left groin in view of concerns about continuing anticoagulation.
The patient was discharged home after 2 weeks of intensive inpatient rehabilitation. She continues to have an open wound over right groin with healthy granulation tissue. An outpatient plastic surgery follow-up has been arranged for delayed skin grafting.

**DISCUSSION**

Despite advancement of radial access, the femoral arterial access remains the main way to access the vascular circulation for coronary angiography and percutaneous coronary intervention (PCI) in the United States. In the past, hemostasis of the access site was achieved by manual compression, but since the 1990s, hemostasis has been also achieved by use of VCDs. Angio-Seal and the Perclose devices remain among the most popular VCDs. These devices have the potential to reduce the time to hemostasis, facilitate early patient mobilization, decrease hospital length of stay, and improve patient comfort.1-4

Although many closure devices are currently in use, with comparable clinical results between each other and with manual compression, the rates of complication are slightly different. Previous studies have found the predisposing factors for VCD infection complications are age between 40 to 79 years old, diabetes mellitus, and obesity,6,7 all of which were present in our patient. The usual presentation includes the presence of symptoms and signs of pain, skin erythema, fever, swelling, and purulent drainage at the access site, usually about 1 week after the procedure, which was also noted in our patient. The most common organism involved is Staphylococcus aureus in 75% of the infections. The infection rate of closure devices is about 0.3% of the total complications associated with closure devices.6-8

Hematoma formation at the puncture site and the presence of foreign material in the intravascular space and arterial wall likely serve as a nidus for a subsequent infection.6 In our patient, it is impossible to state with certainty whether the infection process started from an infected VCD or from an associated infected hematoma. Aseptic conditions were maintained, the puncture site was cleaned again, and the operator put on new sterile gloves before placing the VCD. This procedure follows the Society of Cardiovascular Angiography and Interventions (SCAI) revised guidelines for infection control in the cardiac catheterization laboratory from 2006.9 Also, there were no problems accessing the femoral artery to suggest presence of hematoma, and the final femoral artery angiogram did not show anatomical contraindication for use of the VCD. Whether the closure device had functioned properly or it created a small hematoma due to misfiring or malpositioning is still unknown.

At this moment, antimicrobial drug prophylaxis is not routinely recommended for procedures performed in the cardiac catheterization laboratory. Antibiotic prophylaxis should be considered for immunocompromised patients, any patients with probable or definite wound contamination during the procedure, and diabetic patients undergoing VCD placement.6,9

Prompt aggressive treatment with intravascular antibiotics and early surgical debridement and repair are essential to prevent mortality in infection complications of VCDs. Femoral endarteritis complicating percutaneous suture closure is a challenging new problem for vascular surgeons and can result in catastrophic complications. Customary techniques that use saphenous vein patch or interposition grafting are not
adequate in all circumstances. Successful outcomes require operative exploration in patients with suspected infection. Removal of the percutaneous suture closure device and debridement to the normal arterial wall is recommended in all patients with suspected femoral endarteritis, based on positive intraoperative Gram stains or abnormal appearance of the adjacent femoral artery. Early success with an autologous saphenous interposition is reported. Consensus on the best surgical approach for treatment of vascular infection is controversial, as bypassing the infected area appears obvious, but sometimes difficulties with extra-anatomic bypass can make in situ reconstruction more preferable. It is reasonable to bypass the infected area if the tract of bypass is not through the area of necrosis, fasciitis, infection, or active inflammation. To perform an extra-anatomical obturator bypass for resuming extremity perfusion using healthy (iliac) to healthy (popliteal) arteries seems a safe choice. A study of obturator bypass for the treatment of contemporary groin infection has shown up to 80% graft patency free of infection at 60 months. Synthetic grafts instead of contralateral greater saphenous vein as a conduit can be considered, even though eliminating harvest time can be important when the patient is sick and septic and the bypass is not straightforward.

**CONCLUSION**

Infection associated with percutaneous VCD placement is uncommon but is an extremely serious complication. It is important to be vigilant in the postprocedure follow-up period, when a patient with VCD use returns with groin-related complaints, especially if the patient has risk factors like diabetes mellitus. Morbidity is high, and early aggressive medical and surgical interventions are required to achieve cure.

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**REFERENCES**


