

Femoral Artery Closure Devices-Challenges of Infection

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Abstract

Cardiac catheterization is the gold standard method for determining coronary artery disease and providing percutaneous intervention. Access is obtained by advancing catheters via sheaths mostly in femoral and radial arteries. For hemostasis, manual compression at the access site may cause patient discomfort including severe pain. Femoral artery closure devices were introduced as an alternative to compression. Although bleeding and vascular complication rates with these devices are similar to manual compression, infection is a more serious complication of closure devices. We present a rare case of infection, which turned into complex pseudo aneurysm and discuss treatment and plan for avoiding future device-associated infections.

Keywords: Femoral artery closure devices; Cardiac catheterization; Infection; Pseudo-aneurysm

Introduction

Cardiac catheterization is the gold standard method for examining coronary anatomy, determining coronary artery disease, and providing percutaneous intervention. Access to the heart is conducted by advancing catheters via sheaths, mostly in femoral or radial artery, though brachial artery was once widely used. The femoral artery is preferred because of its larger diameter, but radial artery is gaining importance. Catheters range in size from 4 Fr to 10 Fr in diameter. Which size to use depends on the vascular and cardiac anatomy, the need for adequate opacification of the coronary arteries and cardiac chambers, how much the catheter must be manipulated, and the desire to limit vascular injury and complications [1]

Vascular complications

Cardiac catheterization and/or percutaneous coronary intervention can cause complications; both vascular access complications and complications from closure of the arteriotomy puncture/incision site. Complications such as bleeding, thrombotic complications, and vascular trauma occur in 1% to 9% of cases [2]. Procedural factors that influence risk include sheath size greater than 8F, exces-

sive use of anticoagulants, and site of entry below the common femoral artery [3]. Patient-specific factors include age, female sex, obesity, hypertension, bleeding diathesis, peripheral vascular disease, and anticoagulation regimen [4-6]. Additional complications can arise from closure of the arteriotomy incision. After removal of the catheter, hemostasis is traditionally achieved by manual compression. Manual compression may cause severe pain and for some patients, deep vein thrombosis due to femoral vein compression and stasis, and prolonged bed rest [7]. Vascular access complications remain the leading source of morbidity, cost, and legal ramifications [7]. In 1994, Femoral Artery Closure Devices (FACD) were introduced as an alternative to compression. Their purpose was to reduce time to hemostasis and ambulation. Different modalities of closure including suture-mediated, extravascular clip, and collagen plug must be deployed through a specialized carrier device. The devices can close puncture sites up to 10F. Bleeding and vascular complication rates with FACDs were similar to those that characterize manual compression (1.3% for FACDs vs 1.4% for manual compression) [8]. The Angio-Seal vascular closure device, which was used in our patient, creates a mechanical seal by sandwiching the arteriotomy between a bioabsorbable anchor and collagen sponge, which dissolves within 60 to 90 days. Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation or edema.

Case report

We present a 76-year-old male with history of coronary artery disease status post coronary artery bypass graft surgery (single left internal mammary artery bypass to the left anterior descending artery) in 2009, hypertension, and diabetes mellitus type II, who presented to the Emergency Department (ED) with left shoulder pain that radiated to his left jaw and down his left arm, very similar in character which led to his bypass surgery. His cardiac enzymes were normal and his electrocardiogram was negative for ischemia. Myocardial perfusion scan demonstrated severe and extensive defect in the basal and mid inferior, inferolateral, and inferoseptal area compatible with old infarction and mild peri-infarct ischemia. As this perfusion defect was different than that expected for his prior CAD, he was brought to the cardiac catheterization laboratory for further evaluation. Using electrical clippers for removing hair and chlorhexidine for skin sterilization, the right groin was prepped. Using appropriate sterile techniques, cardiac catheterization was performed using a modified Seldinger technique through a 5 Fr sheath introduced into the right common femoral artery. Angiographic results did not reveal any significant stenosis in the native coronary arteries or in the bypass graft. Immediately after the angiogram, entry site at the common femoral artery and absence of significant atherosclerosis were documented by limited femoral angiography, and a 6 Fr Angio-Seal device was deployed using recommended techniques. After deployment, there was no evidence of an expanding hematoma or oozing. 4 days after discharge, the patient returned to the ED with right groin pain, swelling, and fever. Vital signs were: Temp 100.7 F, heart rate 76 beats/min, and blood pressure 120/70mmHg. The right groin was tender and erythematous. A non-flocculent mobile 3x3 cm mass was palpated. White Blood Cell (WBC) count was 15,000 cells/dl and ultrasound revealed no pseudoaneurysm or fistula but a 2.1 x 1.4 x 1 cm heterogeneous area around the right common femoral artery. He was started on vancomycin 1gm IV every 12 hours per the Infectious Disease (ID) recommendation. After 3 days, blood cultures were negative x2, patient defervesced, and WBC count was stable (15,600 cells/dl). He was discharged home on PO clindamycin as per ID's recommendation and scheduled for outpatient follow up. 5 days later, the patient returned to the ED with increasing pain and serosanguinous discharge from the right groin area. Repeat ultrasound showed evidence of 2 x 2 x 1.4 cm pseudoaneurysm with surrounding edema concerning for infection.

Vascular surgery was consulted and the patient went for exploration of the right common femoral artery with debridement of the infected subcutaneous tissue and lymph nodes, debridement of the distal anterior wall of the common femoral artery with right greater saphenous vein patch angioplasty of the defect in the right common femoral artery, and right sartorius flap coverage of the common femoral artery repair. Femoral artery culture / operation room swab culture results returned positive for MRSA (Methicillin-resistant *Staphylococcus aureus*) sensitive to vancomycin. He was restarted on vancomycin 1.5 gm IV bid. Over the next few days, WBC count improved from 17,200 to 12,400 cells/dl and was discharged on vancomycin for 4 weeks with a wound vac.

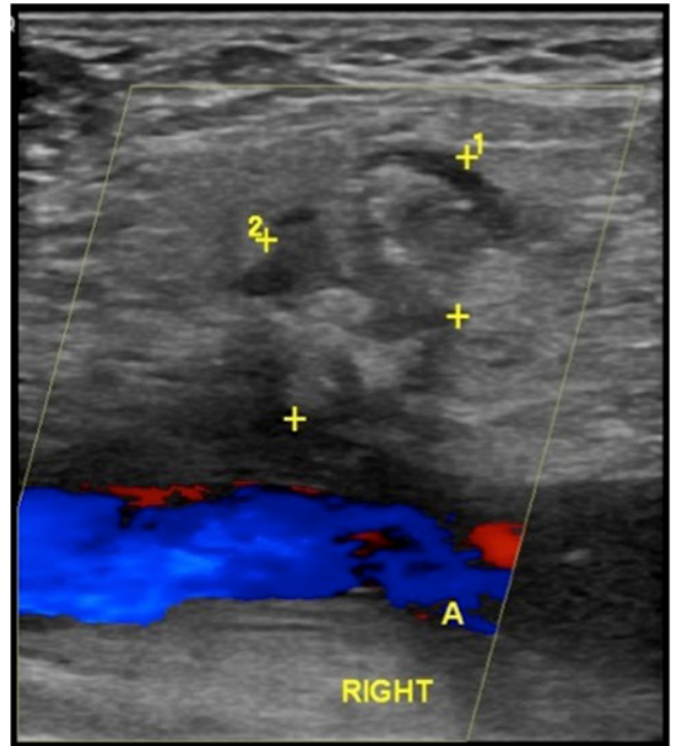


Figure 1: Ultrasound displaying a 2.1 x 1.4 x 1 cm heterogeneous area in the right common femoral artery demarcated by "+"

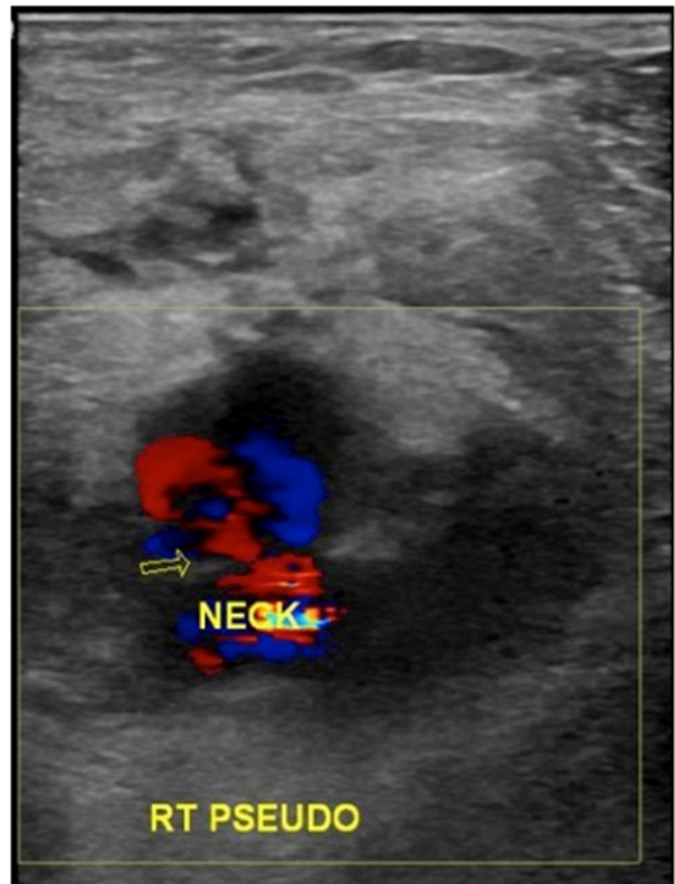


Figure 2: Repeat ultrasound displaying a pseudoaneurysm with the classic "neck" appearance depicted by the arrow.

Discussion

Bleeding and vascular complication rates with FACDs are similar to those that characterize manual compression (1.3% for VCDs vs 1.4% for manual compression) [8]. However, infection is a more common complication with use of FACDs. Bacteremia after PCI is reported in 18% immediately after procedure and 12% after 12hrs, although no sequel noted [9]. In a study of over 4000 patients with PCI, 0.64% had bacterial infection and 0.24% had septic complications [10]. The reported incidence of all catheter related infections was <1%; however, most of these were retrospective studies with a 5-10 day delay which most likely under-estimated the incidence of infectious complications [11].

Hematoma at the puncture site and presence of foreign material in the intravascular space and arterial wall serve as a nidus for infection, resulting in localized endarteritis, which is a risk factor for subsequent development of mycotic pseudoaneurysm. The median incubation period from FACD insertion to clinical presentation with access-site infection is 8 days [12]. 75% of these infections are from *Staphylococcus aureus* (82% MSSA and 18% MRSA), followed by gram negative rods (13%), coagulase negative *Staphylococcus* (5%) and others.

Brachial artery access, contamination of the sterile field by the patient or operator, indwelling sheaths connected to a pressurized heparin solution, repeat puncture of the ipsilateral femoral artery and leaving indwelling femoral artery sheaths for several days after the procedure have been associated with an increased incidence of infection [13-15].

Recent congestive heart failure was an independent predictor of postprocedural bacteremia [16]. Patient-related characteristics that predispose to an increased chance of infection include diabetes, obesity, advanced age, immuno-suppression and emergency patients, including shaving hair in holding area using a safety razor, use of betadine scrub and point of access site in procedure room.

Preventive strategy

Use of scrupulous sterile techniques including use of mask, cap and gown, electrical clippers for removal of hair, avoidance of endovascular graft access where possible, avoidance of femoral artery access ipsilateral to a prosthetic hip, avoidance of reused or sterilized catheters, contralateral puncture of the femoral artery for repeat procedures, particularly if a closure device has been recently used, should be performed, and the use of indwelling catheters after the procedure minimized wherever possible [11]. The 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol formulation is preferred over betadine; it penetrates the first five layers of the stratum corneum, where 80% of skin-dwelling microorganisms reside. It should be allowed to air dry. ChlorPrep skin antiseptic meets the CDC's Guidelines for the Prevention of Intravascular Catheter-related Infections, published in 2002. The Guidelines state: "for cutaneous antiseptics a 2% chlorhexidine preparation is preferred" [17].

Treatment

If infection is suspected, it is recommended to collect at least two sets of blood cultures before antibiotics and doppler ultrasonography to evaluate for mycotic pseudoaneurysm. Empirical broad-spectrum antibiotics that should include coverage for MRSA (i.e., vancomycin) should be initiated soon with intravenous antibiotics for 2 to 4 weeks against identified organism. Duration of antibiotics may be extended up to 6 weeks for complicated cases (i.e., septic arthritis, endocarditis). Surgical debridement should be considered for all patients [18].

At our facility, starting January 1, 2012, in addition to the above sterile techniques, prior to deploying FACD, physicians and nurses have to prepare the groin region involving the intravascular sheath with a ChlorPrep applicator and use a different pair of gloves during deployment of FACD. So far, we have not encountered any complication of infection.

Conclusion

As mentioned above, the risk of infection from FACDs is extremely low, yet infection can still transpire. By instituting this new cutaneous antiseptic measure, hopefully we can further reduce this low incidence or even eliminate infection as a potential complication.

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