



Mechanical Failure of an Angio-Seal Requiring Surgical Extraction

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Abstract

We describe a unique case of an Angio-Seal™ (St. Jude Medical, St. Paul, MN) device mechanical malfunction with failure of the locking system and subsequent failure of retraction of the device from inside the artery. The patient underwent femoral artery exploration with surgical extraction of the Angio-Seal™ device and surgical repair of the common femoral artery.

Introduction

Vascular closure devices (VCD) have been increasingly used for vascular closure and hemostasis after percutaneous endovascular therapies. Angio-Seal™ (St. Jude Medical, St. Paul, MN) is one of the most commonly used VCD, which is a bio-absorbable, sheath-delivered device that deposits a small collagen plug into the puncture channel to seal the puncture defect mechanically. However, Angio-Seal™ deployment can be associated with various, and sometimes life threatening, complications.

Case Presentation

A 65-year-old man presented to the hospital after a ventricular fibrillation cardiac arrest. He had a significant past medical history of peripheral vascular disease (PVD) for which he underwent right iliofemoral-tibial-peroneal trunk bypass twice, renal artery stenosis with renal stenting, and abdominal aortic aneurysm treated with open repair with tube graft. His BMI was 25 kg/m². On presentation, he underwent cardiac catheterization via the right radial approach which showed a heavily calcified 95% stenosis in the right coronary artery (RCA). Crossing this critical lesion with a 2 mm Trek balloon was failed and resulted in dissection proximal to the stenosis. The dissection was stented and the patient was scheduled for another cardiac catheterization. Repeat cardiac catheterization was done via the left femoral artery approach. The artery was accessed using an ultrasound guided micro-puncture needle with placement of a 10 cm 6 French femoral Terumo® Pinnacle sheath. Because of the significant tortuosity of the femoral and iliac arteries and the lack of support, the sheath was exchanged to a 35 cm 6 French femoral sheath. After multiple attempts to cross the lesion in the RCA with no success, the procedure was aborted. At the end of the procedure, left iliac arteriography showed appropriate access of the common femoral artery above the bifurcation into superficial and profunda femoral arteries.

A 6F VIP Angio-Seal™ was chosen as a closure device for femoral artery access site. The insertion sheath and the arteriotomy locator were advanced over a long guide wire into the femoral artery by standard technique with no difficulty. A good pulsatile flow exiting the arteriotomy locator port was obtained. The locator was removed and the compaction tube was advanced through the insertion sheath until the click, which indicates the protrusion of the foot plates out of the sheath, was heard. The compaction tube was pulled back, but the second click, which indicates locking of the tube into the sheath, was not obtainable despite multiple attempts. Gentle pulling on the whole Angio-Seal™ system was associated with resistance. Forceful pulling was avoided to avoid shearing of the artery. We realized the mechanical failure of the device, which was then left in place and hemostasis was achieved via manual compression. The patient remained hemodynamically stable with no symptoms throughout this event, although he had mild mottling of the left leg and decrease of the dorsalis pedis pulsation. Emergent vascular surgeries consult recommended exploration of the left femoral artery and surgical extraction of the device. The device was extracted and there were no signs of fracture or missing pieces of it (Figure 1). The common femoral artery was repaired with a bovine pericardial patch. Following revascularization, there was normalization of the leg color with regaining of the dorsalis pedis pulsations. The patient was discharged home the next day. On a follow up after a week, he continued to be asymptomatic with intact distal pulsations.

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Figure 1: The 6F VIP Angio-Seal™ device after surgical extraction from inside the artery.

Analysis of the malfunctioned device by St. Jude Medical Company revealed failure of with subsequent failure of deployment of the collagen plug and the sandwich mechanism.

Discussion

Studies have shown that VCD may reduce hemostasis time and facilitate early ambulation, potentially decreasing hospital length of stay and improving patient satisfaction [1]. Although VCD usage is relatively safe, various complications may occur. These include pseudo-aneurysm formation, arterio-venous fistula, failure to deploy the collagen plug with failure to obtain hemostasis, retroperitoneal bleeding, access site hematoma, arterial stenosis, occlusion or peripheral vascular embolization leading to lower limb ischemia, and infection [2-6]. We add to these complications a mechanical failure of the locking system of the device with inability to retrieve the device from inside the artery.

Several large meta-analyses and registries have yielded conflicting data regarding superiority of VCD over manual compression in terms of complications. A larger meta-analysis that included 30 studies involving 37,066 patients concluded that the risk of complications depended upon the specific device used and whether the procedure was a diagnostic catheterization or a percutaneous coronary intervention (PCI) [7]. In the overall analysis, there was a significant increase in risk with VCD (odds ratio (OR) 1.34, 95% CI 1.01-1.79). In 2010, a meta-analysis involved 31 prospective, randomized studies including 7,528 patients who were randomized to VCD or manual/mechanical compression, showed similar results in the study groups in terms of groin hematoma, bleeding, pseudoaneurysm, and blood transfusion. Lower limb ischemia and other arterial ischemic complications as well as need of surgery for vascular complications were somewhat more frequent with VCD [1]. In the Danish Registry Study, risk factors of vascular complications following coronary angiogram and PCI included left sided femoral access, PAD, female sex and BMI < 18.5 kg/m² [6].

Multiple endovascular approaches to treat limb ischemia caused by VCD have been described, but most authors recommend direct surgical cut down retrieval of the device and definitive arterial repair [8]. Although these procedures can be limb sparing, it can be associated with additional significant morbidity. Complications may include bleeding, infection, or compartment syndrome [9].

Conclusion

We highlight a previously unreported complication of an Angio-Seal™ VCD. Although our patient was at risk for vascular

complications given his extensive vascular disease and the left sided femoral access, his complication was a result of an Angio-Seal™ mechanical malfunction. We believe that our case should raise suggestions for possible modifications of the device that may limit or eliminate the potential for this happening again. We also reported one of the appropriate surgical approaches to treat this complication to minimize the harmful consequences to the patient.

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