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Controversies in Cardiology

Simplified swift and safe vascular closure device deployment without a local arteriogram: Single center experience in 2074 consecutive patients☆

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ABSTRACT

Objective: Vascular closure devices (VCDs), such as the Angio-Seal, a three-component hemostatic plug, have greatly facilitated the routine clinical practice in the catheterization laboratory. The manufacturer recommends a local angiogram before Angio-Seal deployment. However, from the outset, we employed a simplified routine of deploying this VCD, i.e. without use of local angiography.

Methods: The Angio-Seal was employed without a preceding femoral arteriogram over 8 years in 2074 consecutive patients, 72% presenting with acute coronary syndromes and subjected to coronary angiography ($n = 1032$) or PCI $n = 1042$) via a transfemoral approach with use of heparin and dual antiplatelet therapy.

Results: Deployment of the VCD was successful in 99.4%. Complete hemostasis was obtained in 98% of cases. In 14 patients, Angio-Seal deployment failed. Mean time for placement of Angio-Seal was <1 min, to-hemostasis 1 min, and to-mobilization 3 h. Only 3 (0.15%) patients had a major complication with vessel occlusion that required emergent vascular surgery with a successful outcome. Two patients developed a local pseudoaneurysm treated with ultrasonography-guided compression. Six small and 4 large inguinal hematomas (one requiring blood transfusion) and 5 cases of retroperitoneal bleeding (one requiring blood transfusion) were recorded.

Conclusion: Deployment of Angio-Seal without use of local angiography was efficacious and safe, characterized by a high success rate of deployment and hemostasis with few correctable complications in a large patient cohort undergoing transfemoral catheterization for PCI and non-PCI procedures under anticoagulation and antiplatelet drug therapy. VCD reduced the time-to-hemostasis and time-to-mobilization and minimized the incidence of complications.

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Abbreviations: ACS, acute coronary syndrome(s); DM, diabetes mellitus; PCI, percutaneous coronary intervention; VCD, vascular closure device.

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1. Introduction

Vascular closure devices (VCDs) have an increasingly important role in the catheterization laboratory during coronary angiography and percutaneous coronary interventions (PCI), as an alternative to manual or mechanical compression.[1–3] Of course, nowadays, VCDs have a great competitor of growing importance, i.e. the radial access.[4] Nevertheless, their use offers expedience, safety, patient convenience and early ambulation, and reduced hospital resources and costs. Ample experience has been obtained in our laboratory with routine use of such a device, Angio-Seal™ (St. Jude Medical, St. Paul, MN, USA), for femoral artery puncture site closure and hemostasis. Angio-Seal consists of three resorbable components, a polymer anchor, the collagen plug, and a suture, which are introduced with the aid of a delivery system and seal the arterial puncture site. The manufacturer recommends that before considering Angio-Seal use, a femoral angiogram of the site is indicated. However, a local angiogram increases the amount of radiation exposure, particularly important for the groin area exposure in younger patients, as well as the load of intravascularly administered contrast with its attendant consequences, especially in older diabetic patients or patients with renal insufficiency. From the outset, we employed a simplified routine for the deployment of the VCD, i.e. without use of local angiography and herein report the results of this approach in a large cohort of patients undergoing transfemoral catheterization.

2. Patients and methods

2.1. Patients

Over the last 8 years, the Angio-Seal VCD was employed in 2074 consecutive patients who were submitted to catheterization by our team of 3 operators via a transfemoral approach in order to perform coronary angiography, renal percutaneous angioplasty, aortography, or PCI. Patients ($n = 90$) were excluded when transfemoral access was considered problematic or impossible due to peripheral vascular disease, requiring a transradial approach or deemed as best suited for manual compression rather than use of a VCD; also patients catheterized during periods when the VCD was not available for use in our catheterization laboratory due to a limited supply from the manufacturer were not included in this series. Possible complications and risks, as well the benefits of each procedure were all made explicit to the patient and the patient's family, and informed written consent was obtained from the patient before the procedure.

2.2. Vascular access

Vascular access was routinely obtained via puncture of the right femoral artery and occasionally via the left femoral artery in cases where vascular access problem was anticipated or encountered from the right femoral artery or when repeat access was required within a short period after puncture of the right femoral artery.

Selection of the entry site was guided most commonly by a combination of external anatomical landmarks. Usually, the artery was entered 2–3 cm below the midpoint of the inguinal skin crease or at the midpoint between the anterior superior iliac spine and pubic tubercle, guided by palpation of the maximal arterial pulse. One operator mostly used the fluoroscopy-guided technique using visualization of the femoral head in a posterior-anterior projection with the skin puncture done at a point between the lower border and the mid portion of the head of femur.

After adequate local anesthesia with subcutaneous xylocaine, arterial access was obtained with use of an 18-gauge needle and a modified Seldinger technique with an attempt to limit the stick to the anterior arterial wall and avoid posterior wall puncture. A 6 French femoral sheath was routinely used except when a demanding PCI procedure was planned, in which case a 7 French sheath was employed. After arterial access was secured, 2500 U of intravenous unfractionated heparin was given.

2.3. Percutaneous coronary intervention

All patients submitted to PCI received a bolus of 7000 units of heparin after obtaining vascular access for elective procedures or right after completion of coronary angiography for ad hoc PCI procedures. Additional heparin (2000 units/h) was administered for procedures lasting longer than 1 h if the activated clotting time (ACT) could not be monitored or if ACT was measured, heparin was given in doses needed to maintain the ACT >300 s throughout the procedure. A variety of coronary stents were implanted, including bare metal stents, endothelial progenitor cell capture stents, micro net mesh covered stents, and drug-eluting stents.

For pre-planned procedures an attempt was made to use pretreatment with at least a pre-procedural 3-day regimen of aspirin (325 mg daily) and clopidogrel (75 mg daily); for patients not having been on aspirin or clopidogrel before the procedure, a loading dose of 500 mg and 300–600 mg of each medication, respectively, was given the day of the procedure. For patients with angiographically demonstrated intracoronary thrombi, particularly those with acute ST-elevation myocardial infarction, or other high-risk patients, e.g. diabetic patients receiving multiple stents, glycoprotein IIb/IIIa inhibitors were used, including eptifibatide or tirofiban.

2.4. Vascular closure device

When the procedure was completed, reversal of the effect of heparin was not performed. A guidewire was introduced via the sheath into the artery and then the sheath was removed immediately without checking the ACT, while maintaining pressure above the access site to ensure continued hemostasis. Subsequently, the VCD was deployed over the guidewire.

The Angio-Seal vascular closure device delivery system comprises the Angio-Seal device, an insertion sheath, an arteriotomy locator, and a guidewire. The Angio-Seal device is composed of an absorbable collagen sponge and a specially designed absorbable polymer anchor that are connected by an absorbable self-tightening suture (Fig. 1). The device seals and interposes the arteriotomy between the anchor located