CLINICAL STUDY

Implementation of the EXOSEAL Vascular Closure Device in the Transpopliteal Arterial Approach

Ömür Ballı, MD, Volkan Çakır, MD, Mehmet Coşkun, MD, Rıdvan Pekçevik, MD, and Serkan Gür, MD

ABSTRACT

Purpose: To investigate the feasibility and safety of the EXOSEAL vascular closure device (VCD) in achieving hemostasis in transpopliteal arterial interventions.

Materials and Methods: Between May 2014 and May 2016, 46 procedures involving transpopliteal arterial access in 28 patients (18 bilateral and 10 unilateral) were analyzed retrospectively. Popliteal arterial puncture was performed under ultrasonographic (US) and fluoroscopic guidance by using a micropuncture access set with a 21-gauge needle. Six-French sheaths were used in 45 procedures, and a 7-F sheath was used in 1 procedure. Hemostasis was achieved with the EXOSEAL VCD. All patients were examined for any access-related complications with US at 6 and 24 hours after the procedure. One week later, all patients were followed up in the outpatient clinic.

Results: In 44 of the 46 procedures, the EXOSEAL VCD was applied successfully. The technical failure rate was 4.4%. An excessively steep angle of the introducer sheath and improper placement of the EXOSEAL plug in the setting of high blood pressure (220/120 mm Hg) were the reasons for the 2 failures. Among the 44 successful procedures, 1 (2.3%) minor 3-cm hematoma was found to be associated with the VCD. In 1 of the 46 procedures, an arteriovenous fistula (2.2%) was observed as a puncture-related complication and treated with a stent graft.

Conclusions: The EXOSEAL VCD can be safely used for hemostasis in interventions that use transpopliteal arterial approaches, with a high technical success rate and a low rate of entry-site complications.

ABBREVIATIONS

AVF = arteriovenous fistula, CFA = common femoral artery, PA = popliteal artery, PV = popliteal vein, SFA = superficial femoral artery, VCD = vascular closure device

Endovascular approaches have been the preferred treatment methods for peripheral vascular diseases in recent years (1–3). The common femoral artery (CFA) is the most common access site for interventional procedures (4). However, in cases in which the contralateral CFA cannot be effectively used, such as a narrow aortic bifurcation angle and iliac tortuosity, or in cases of failed or difficult antegrade superficial femoral artery (SFA) attempts, such as obesity, flush SFA occlusion, and tandem iliofemoral lesions, popliteal artery (PA) access may become the ideal option (5,6).

The most important aspect of PA puncture is the relationship between the PA and the popliteal vein (PV). With a patient in prone position, the artery usually crosses over the vein, creating a potential risk of iatrogenic arteriovenous fistula (AVF) (7). Therefore, imaging guidance, especially with ultrasonography (US), is one of the most important procedural steps in transpopliteal puncture approaches (5,6).

The most common technique used to achieve hemostasis is manual compression, which is considered the gold standard (8). However, hemostasis may not always be possible with manual compression in the PA region because of the deep location of the artery, loose tissue around the PA, and the administration of fibrinolytic agents (5,6,9). The use of vascular closure devices (VCDs) reduces the time to hemostasis, decreases patient pain and discomfort, and provides

From the Department of Interventional Radiology, İzmir Katip Çelebi University Atatürk Training and Research Hospital, İzmir TR 35360, Turkey. Received October 12, 2017; final revision received February 15, 2018; accepted March 22, 2018. Address correspondence to Ö.B.; E-mail: omurballi@gmail.com

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early mobilization, and has been shown to be noninferior to manual compression in terms of vascular access-site complications (8,10–12).

VCDs have been used for hemostasis for approximately the past 30 years and are classified into 2 main categories—active and passive closure devices—based on their mechanism of action. Passive closure devices are compression assist devices. Active closure devices can be categorized into 3 categories: plug-mediated devices (eg, Angio-Seal [St. Jude Medical, Saint Paul, Minnesota], EXOSEAL [Cordis, Miami Lakes, Florida], and Mynx [Cordis]), suture-mediated devices (Perclose ProGlide; Abbott Vascular, Abbott Park, Illinois), and clip-mediated devices (StarClose; Abbott Vascular). Some devices use an intravascular component as an anchor (Angio-Seal) or a temporary endoluminal balloon (Mynx). An intravascular anchor has a theoretical risk of thrombosis or stenosis, especially in vessels with a small diameter (13–15). The EXOSEAL VCD delivers a plug made of a polyglycolic acid material to securely close the arterial puncture site extravascularly. This plug is resorbed within 2–3 months. This device is available in 5-, 6-, and 7-F sizes and uses the original standard vascular sheath, so its use does not require sheath exchange (16).

The purpose of the present study is to assess the feasibility and safety of the EXOSEAL VCD for hemostasis in trans-PA puncture.

MATERIALS AND METHODS

Study Design and Patient Population

This retrospective study was approved by the local ethics committee, and informed consent was obtained from all participants before clinical procedures were performed. Informed consent was waived by the local ethics committee for the use of clinical data for research purposes.

Between May 2014 and May 2016, a total of 28 patients (21 male, 7 female; mean age, 63 y; median age, 64 y; age range, 39–71 y) who underwent 46 procedures that used transpopliteal retrograde approaches (18 bilateral and 10 unilateral) via 6-F or 7-F vascular sheaths with subsequent hemostasis achieved with the EXOSEAL VCD were included. All procedures were performed via the PA in a single session. Fontaine stages were IIb in 19 patients, III in 7 patients, and IV in 2 patients (Table 1). None of the patients had acute limb ischemia, and pharmacologic thrombolysis was not administered. Indications and lesion localizations for transpopliteal approaches are shown in Table 2.

Popliteal Access and VCD Procedures

All procedures were performed by 3 interventional radiologists with overall mean and median experience of 7 and 5 years, respectively (Ö.B., 5 y; V.C., 5 y; M.G., 11 y), and with national board certification approved by the Cardiovascular and Interventional Radiological Society of Europe. All patients were referred to the interventional radiology department for endovascular treatment. Preprocedural assessment was conducted by digital subtraction angiography (DSA) or computed tomographic angiography of the lower extremity (Table 1). Color Doppler US was also performed before and during PA puncture to reduce the risk of AVF. All diagnostic imaging was evaluated for iliofemoral lesions, PA diameter, and the disease-free segment of the PA. If the diameter of the PA was 4 mm or more and the PA did not have a significant stenosis that required an interventional procedure, and if the PA had a minimum 3–4-cm disease-free segment in which to easily and safely introduce a vascular sheath, the PA was considered suitable for puncture.

Table 1. Demographic and Clinical Characteristics of Study Population (N = 28)

Charactistic	Value
Age (y)	
Mean	63
Range	39–81
Limbs treated	41
Punctures	46*
Lesions treated	48
Risk factors/comorbidities	
Diabetes	11 (39)
Hypertension	14 (50)
Smoker (current/former)	15 (54)
Hypercholesterolemia	5 (18)
Coronary artery disease	11 (39)
Cerebrovascular disease	2 (7)
Renal insufficiency	2 (7)
Preoperative fontaine stage	
IIB	19 (68)
III	7 (25)
IV	2 (7)
Preoperative imaging	
CT angiography	20 (71)
DSA	8 (29)
Color Doppler US	28 (100)

Note–Values in parentheses are percentages.
DSA = digital subtraction angiography.
*The reason for the difference between the number of punctures and the number of treated limbs is that the pathologic side had to be angiographically displayed during the procedure.

PA punctures were performed under US guidance by using a micropuncture access set with a 21-gauge needle. A 0.018-inch guide wire was advanced and then exchanged for a 6-F (45 accesses) or 7-F vascular sheath (1 access) under fluoroscopic guidance with the patient in the prone position. Then, 5,000 IU of heparin was administered intravenously shortly after placement of the vascular sheath. After the interventional procedure was completed, the puncture site was closed with the use of an EXOSEAL VCD, which constitutes an off-label use of the device.

The EXOSEAL VCD consists of (*i*) an indicator window containing 2 markers, (*ii*) a bleed-back indicator, (*iii*) a