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Use of a Vascular Closure Device (AngioSeal) in Endovascular Interventions Performed Through the Popliteal Artery Due to Iliofemoral Artery Occlusion

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Abstract

Objectives: We aimed to evaluate the results of the use of AngioSeal in endovascular interventions performed through the popliteal artery access as a consequence of occlusive disease in the iliofemoral artery.

Materials and Methods: This case series was conducted at Ordu University Training and Research Hospital between June 1, 2020 and August 31, 2020. All endovascular interventions that were performed via popliteal artery puncture followed by AngioSeal application during the relevant dates were included in the study.

Results: 77.3% of the 22 cases were male, the mean age was 66.64±12.73 (minimum-maximum: 40-89), and 59.1% of the patients were smokers. Endovascular treatment indications were resting pain (in 54.5%) and claudication (in 45.5%). No major complications developed after the procedures, but a single case with minor complication (hematoma <3 cm) was recorded. Procedural success was achieved in 90.9% of patients. There were two unsuccessful cases, one was a 75-year-old male and the other was a 65-year-old female. Both were non-smokers and had diagnoses of hypertension and coronary

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artery disease. While the target lesion location was mid + proximal superficial femoral artery (SFA) in the female patient, it was SFA + iliac artery in the male patient.

Conclusion: When AngioSeal is used to provide hemostasis after popliteal artery puncture in endovascular interventions, success rate and patient comfort are highly satisfactory. In addition, the incidence of complications after the procedure is quite low.

Keywords: Vascular closure device, hemostasis, ambulation, peripheral arterial disease

Introduction

Peripheral artery disease can be defined as the atherosclerotic or thrombotic disease of arteries other than the coronary artery and aorta[1]. Lower extremity artery disease is characterized by the involvement of the iliac and/or distal arteries. It may present with different clinical manifestations, including asymptomatic presentation, intermittent claudication, resting pain, acute leg ischemia and chronic leg-threatening ischemia. Lower extremity arterial disease is closely associated with increased cardiovascular events, including patients without symptoms[1,2]. Treatment of peripheral arterial disease consists of preventive measures and exercise, and also interventional and surgical treatment. Today, with the advances in devices and the increase in operator experience, endovascular interventions (depending on the localization of the lesion, its length and the surgical risk of the patient) have gained an important place in the treatment of symptomatic peripheral arterial disease[3].

Complications such as bleeding, hematoma, pseudoaneurysm, and vascular occlusion may occur after endovascular treatment, resulting in increased treatment costs, hospital stay, and workload. Some of these complications are directly related to the treatment and some of them are related to the arterial access site[4,5]. After interventional vascular procedures, hemostasis has traditionally been achieved by manual compression (MC). Recently, vascular closure devices (VCD) for hemostasis have gained popularity after endovascular procedures[6,7]. Compared to MC, patients receiving VCD have reduced hemostasis time and pain, without increased risk of complications, thereby shortening time until ambulation[6,7]. Different systems for vascular access site closure have been developed, including suture closure systems (Perclose Abbott, Super Stitch Sutura), clip application systems (StarClose 6F Abbott, Angiolink Medtronic), and plugging systems (AngioSeal Saint Jude, Vasoseal Datascope)[8].

In cases where the common femoral artery or the superficial femoral artery (SFA) cannot be used effectively (in the presence of non-palpable artery, severe calcification, graft prostheses, high femoral bifurcation, previous operation scar or obesity), the popliteal artery (PA) can be preferred as an access site for endovascular treatment[9]. PA access has limitations such as requiring prone position and ultrasonographic guidance[10]. There are very few studies that have published the results of VCD use in PA-access interventions, but the authors have mostly reported successful results[11-14]. To our knowledge, there is no comprehensive study reporting the results of AngioSeal use in endovascular interventions with PA access. In this study, we aimed to evaluate the results of AngioSeal use in endovascular interventions performed through the PA access due to the presence of occlusive disease in the iliofemoral artery.

Materials and Methods

This case series study was conducted at Ordu University Training and Research Hospital between June 1, 2020 and August 31, 2020. Ethical approval was obtained from the Ordu Universty Clinical Ethics Committee (no: 2021/183).

Patients

All endovascular interventions performed via popliteal artery puncture followed by AngioSeal use during the relevant dates were evaluated for eligibility to the study.

Exclusion Criteria

- History of bleeding or platelet disorder.
- Undergoing diagnostic procedures,
- Having pre-existing systemic or cutaneous infection,
- Having abnormal international normalized ratio (INR) or platelet count before the procedure,
- Presence of scar tissue at the access site.

Vascular interventions were performed in 124 cases at the relevant dates, and 22 of these cases met the inclusion criteria.

Variables

The parameters examined were as follows:

- Patient characteristics (age, gender, smoking status, comorbid diseases),
- Features of the procedure (target lesion location, indication, percentage of vascular occlusion, endpoint, complication, time to ambulation)

Procedure

Computed tomography angiography was performed in all patients before endovascular treatment. The PA access site was selected according to the lesion location and type. Following successful puncture, an 0.018-inch guidewire was advanced through the needle and manipulated into the SFA. Angioplasty procedures were carried out in a standard fashion. PA punctures were performed under ultrasound guidance by using a micro-puncture access set with a 21-gauge needle. After advancing a 0.018-inch guidewire, it was exchanged for a 6-F vascular sheath (in 45 accesses) or a 7-F vascular sheath (in 2 accesses) under fluoroscopic guidance on the patient in the prone position (Figure 1a).

After arteriography was performed and the lesion site was observed, 5000 IU/mL heparin was administered just before the intervention. After the completion of the procedure, the puncture site was closed with the use of an AngioSeal VCD (6-Fr), which constitutes an off-label use of the device. Closure was performed as follows: a guidewire, provided with the standard Angioseal set, was passed through the 6-Fr arterial sheath. Manual pressure was applied to the puncture site as the vascular sheath was removed over the wire. A 6-Fr sheath, again provided with the standard AngioSeal set, was passed over the guidewire and positioned in the artery. The anchor was set in position (by deploying the device through the sheath) and was pulled back to seal the puncture by tamping the arterial plug against the arterial wall.

The external view of the VCD application procedure is shown in Figure 1b and Figure 1c. Hemostasis usually occurs within 2-3 minutes (Figure 1d). Afterward, the patients were placed in the supine position and taken to a recovery room with standard dressing (without sandbag). Four hours of bed rest was recommended. Achieving hemostasis was accepted as procedural success. Doppler ultrasonography was performed within 4-6 hours in all patients to check the distal flow. Patients were advised to use acetylsalicylic acid (100 mg) and clopidogrel (75 mg) daily after discharge. The popliteal intervention site was examined in the outpatient clinic at the 1st week and 1st month after the intervention for the assessment of complications such as hematoma, arteriovenous fistula, or pseudoaneurysm.

Statistical Analysis

All analyses were performed on SPSS version 21.0 (SPSS Inc., Chicago, IL, USA). For the normality check, the Shapiro-Wilk test was used. Data were given as mean ± standard deviation or median [minimum-maximum (min-max)] for continuous variables according to the normality of distribution, and as frequency (percentage) for categorical variables.

Results

Among the 22 patients included in the study, 77.3% were male and the mean age was 66.64±12.73 (min-max):

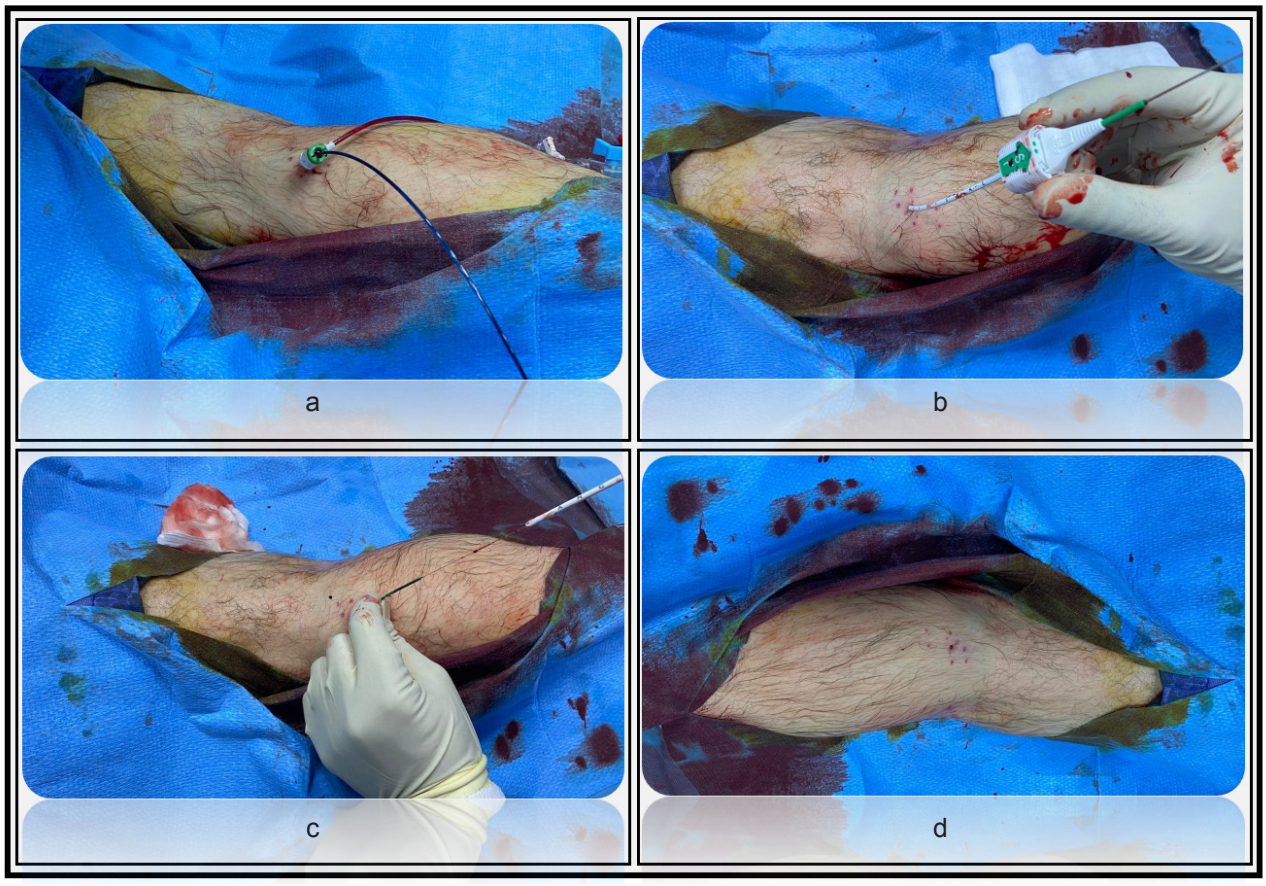

Figure 1. a) Popliteal intervention to the patient in the prone position.
b and c) AngioSeal application procedure.
The same type of Angioseal was applied to all patients. The arteriotomy was closed in all patients immediately after the operation in the interventional radiology department. A guidewire that came with the standard Angioseal package was routed through the 6-Fr arterial sheath. The vascular sheath was withdrawn over the wire, and manual pressure was applied to the puncture site. A 6-Fr sheath from the Angioseal package was passed over the guidewire and placed in the artery. After the device was deployed through the sheath, the anchor was placed. Finally, the anchor was retracted, and the puncture was closed by pressing the arterial plug toward the arterial wall.
d) Ensuring hemostasis without hematoma after the procedure

40-89 years. 59.1% of the patients were smokers. The most common comorbidities were hypertension (77.3%), diabetes mellitus (45.5%), coronary artery disease (31.8%), and hyperlipidemia (27.3%). The indications for endovascular treatment were resting pain (in 54.5%) and claudication (in 45.5%). No major complications (major hematoma, AV fistula, pseudoaneurysm, or acute lower extremity ischemia) developed after the procedures, and only one (n=1) minor complication was recorded –a case of hematoma which was <3 cm in size. The median (min-max) ambulation time of the cases was 3 (3-8) hours. Unilateral intervention was performed in all cases, except for one patient who underwent bilateral intervention.

Procedural success was identified in 90.9% of patients (in one case, the AngioSeal could not be placed completely, and in the other case, the procedure failed due to high blood pressure; 180/140 mmHg). Regarding these two cases in which the operation failed, one was a 75-year-old male and one was a 65-year-old female. The latter was the patient who had suffered from a minor hematoma.

In these two patients, hemostasis was achieved with MC after the procedure (MC durations were 15 min and 20 min, respectively). Both cases were non-smokers and had diagnoses of hypertension and coronary artery disease. While the target lesion location was mid + proximal SFA in the female patient, it was SFA + iliac artery in the male patient. The summary of patient characteristics is shown in Table 1.

Table 1. Summary of the patients' characteristics

Age (year)	**66.64±12.73**
Gender	
Male	17 (77.3%)
Female	5 (22.7%)
Smoking	
Yes	9 (40.9%)
No	13 (59.1%)
Additional disease	
Hypertension	17 (77.3%)
Diabetes mellitus	10 (45.5%)
Coronary artery disease	7 (31.8%)
Hyperlipidemia	6 (27.3%)
Chronic kidney disease	3 (13.6%)
Target lesion location	
Distal SFA	6 (27.3%)
Proximal SFA	4 (18.2%)
Mid-SFA	2 (9.1%)
Mid + proximal SFA	5 (22.7%)
SFA + Iliac artery	5 (22.7%)
Indication	
Rest pain	12 (54.5%)
Claudication	10 (45.5%)
Vascular occlusion (%)	100 (70-100)
Endpoint	
Success	20 (90.9%)
Failure	2 (9.1%)
Complication	
No	21 (95.5%)
Hematoma	1 (4.5%)
Time to ambulation (h)	3 (3-8)

SFA: Superficial femoral artery
Data are given as mean ± standard deviation or median (minimum-maximum) for continuous variables according to the normality of distribution, and as frequency (percentage) for categorical variables

Discussion

With the widespread use of endovascular interventions for treatment, different techniques have been developed and alternative options have been produced for many procedures. Some of the key differences between these options are the puncture site, the decision to use a VCD, the specific type of VCD to be used and other factors. In this study, the results of endovascular treatment interventions using PA access and AngioSeal device were evaluated in patients who had required PA access due to iliofemoral occlusive diseases. It was determined that the procedure was successful in approximately nine out of 10 cases, and there was only a single case who developed a minor complication.

The number of studies published concerning the results of endovascular treatment via PA access is very limited. As far as we know, there is no comprehensive study that has described the results of AngioSeal use in such patients. In a previous study, the authors reported that the procedures were successful and no complications developed in three cases in which they used AngioSeal after endovascular treatment via PA access[11]. The results of the use of different VCDs in interventions from popliteal puncture have also been published. In a case series of 13 cases, it was reported that the treatment was successful in all cases, and acute thrombosis developed due to incorrect intravascular deployment of the device in one of the three cases in which the ExoSeal VCD was used[12]. In another study investigating ExoSeal use with PA approach, the authors reported that they were successful in 44 of the 46 cases. Complications were present in two cases: the first was a minor hematoma (<3 cm) originating from VCD, while the other was AV fistula development[13]. A different study reported 100% success in 28 cases in which a clip device was used in endovascular treatments performed through PA access; however, the authors found that a major complication (PA occlusion) had developed in one case, and minor hematoma (<5 cm) had developed in three cases[14]. One comparative study assessing the results of using common femoral artery access and PA access for

femoropopliteal artery occlusive disease (without VCD) found that there was no significant difference between the two access sites in terms of complications, but a lower success rate was reported in PA access[15]. The lower success rate via PA access may be important when comparing treatments and the utility of VCD application from these access sites. However, the majority of the literature appears to show that interventions with PA access yield successful results and are reliable in terms of complication development[16-18]. Consistent with this evidence, in our study, it was determined that 91% of the interventions using AngioSeal were successful. We think that AngioSeal may be a preferable option if there are no contraindications for endovascular intervention via PA puncture.

In order to achieve adequate hemostasis after endovascular interventions, patients must lie in bed for a long time. This period is prolonged especially when MC and sandbags are applied, often decreasing patient comfort and increasing length of stay in the hospital, as well as causing unnecessary workload for staff[6,19-22]. The use of VCDs in endovascular interventions is very valuable in this respect, and they may benefit both healthcare providers and patients. Although this study did not include a comparative group with a different application, based on our clinical experience and the results of available studies, we believe that the time to ambulation (median: 3 hours) determined in our study was relatively short. When studies on this subject are examined, a decrease in time to ambulation has been reported after VCD use, which supports our opinion[19]. That said, currently there is no comprehensive study that has published the results of AngioSeal application after PA access. However, it has been shown in many extensive studies that the use of VCD on other access sites reduces time to ambulation by approximately 50%[6,20-22]. Thus, based on prior results and our findings, it appears that the use of AngioSeal in endovascular interventions with PA access has ideal results in terms of time to ambulation.

An indicator of success in endovascular interventions is procedure-related complications. As the risk of complications decreases, the preferability of the procedure increases. In our study, complications that developed after the intervention were recorded for this purpose. Accordingly, no major complications developed after endovascular interventions performed through the PA access site. Minor hematoma (<3 cm) was detected in only one case. In almost all of the comprehensive systematic reviews and meta-analyses, it has been shown that the most common complication after the use of AngioSeal is hematoma. In addition, it was underlined that major complications related to the AngioSeal device did not develop and that only some minor complications may be observed with the use of AngioSeal[7,22-26]. There is no agreement between published studies regarding complication frequency with VCD or MC applications after endovascular intervention. In various studies investigating complications, different outcomes have been reported; some have found VCD to be superior[22,27,28], others have found no difference[6,20,29,30], while a couple of studies have reported MC to be superior[31,32]. However, as mentioned before, there are no comprehensive reports of complications pertaining to endovascular interventions performed through PA access using AngioSeal. On the other hand, relatively low frequency of minor complications has been reported in PA-access procedures performed with other VCD devices[12-14]. In the light of our study and previous studies, interventions with PA access using AngioSeal were thought to be safe in terms of complications. In addition, low frequency of major complications was noted in studies in which only the results of MC application were published[18,33-35]. However, since there was no control group in our study, we cannot directly suggest superiority concerning this matter.

Study Limitations

The retrospective and single-center design of this study are important limitations. The relatively low number of cases evaluated in the study and the short follow-up period may have prevented the occurrence of rare complications. In studies with more participants, rare complications and related conditions may be observed. Since case groups

receiving different approaches (other VCD device or MC) were not included in our study, specific comments cannot be made for the comparison of AngioSeal with other methods of closure. Although there is no consensus on this subject, it has been shown in various studies that the development of complications after endovascular interventions may be related to patient-related characteristics, body weight, comorbidities, sheath size, some procedural features, and the experience of the clinician[32,36-41]. Since there was no control group in our study, the effect of these parameters on the results could not be examined.

Conclusion

To the best of our knowledge, this is the first study to report the clinical features of cases for which AngioSeal was used to provide hemostasis after the use of PA access for endovascular intervention (due to the presence of occlusive disease in the iliofemoral artery). No major complications occurred with the use of AngioSeal. Also, considering our clinical experience and the results of other studies, time to ambulation was shortened. In cases in which the use of SFA access is not possible, it may be preferable to utilize PA access with AngioSeal closure as demonstrated by successful results in terms of procedural success, complications, and patient comfort. In future studies, optimal intervention(s) can be determined by comparing different VCD devices and MC in patients undergoing endovascular intervention with PA access.

Ethics

Ethics Committee Approval: This case series study was conducted at Ordu University Training and Research Hospital between June 1, 2020 and August 31, 2020. Ethical approval was obtained from the Ordu Universty Clinical Ethics Committee (no: 2021/183).

Informed Consent: Informed consent was taken from all the patients.

Peer-review: Externally peer-reviewed.

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