Ultrasound-Assisted Angio-Seal VIP Closure of Antegrade Femoral Access Following Lower Extremity Endovascular Interventions

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Abstract

OBJECTIVE: The aim of this study was to present results of ultrasound assisted Angio-Seal VIP closure of antegrade access after peripheral arterial procedures. In addition, the technique of closure is illustrated. **METHODS:** This study is a single center, retrospective analysis of all consecutive patients who had an ultrasound assisted Angio-Seal VIP closure of an antegrade access between January 2019 and 2021 performed by a single operator. The primary endpoint was procedural success, which was defined as accurate deployment of the Angio-Seal VIP with complete acute hemostasis. Secondary endpoints were major complications (major adverse limb events, death, any complication requiring acute intervention) and minor complications (any complication not within the major criteria). **RESULTS:** One hundred eighty-seven procedures with an ultrasound-assisted Angio-Seal VIP closure were identified. Accurate deployment of the Angio-Seal VIP with complete acute hemostasis was achieved in 186 closures, resulting in a procedural success rate of 99.5%. There was one major (0.5%) and one minor complication (0.5%). Both were cases with pseudoaneurysm formation of which one case required transfusion with 2 packed cells. The pseudoaneurysms were successfully treated with percutaneous thrombin injection. **CONCLUSION:** This study shows that ultrasound-assisted Angio-Seal VIP closure of antegrade femoral access is safe and effective. The findings in this study could lower the threshold for antegrade access in the treatment of complex infra-inguinal peripheral arterial disease.

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In the early days of endovascular treatment of peripheral arterial disease (PAD) hemostasis at the end of the procedure was achieved by manual compression of the puncture site, pressure bandage and bed rest. This has been proven to be associated with bleeding complications, prolonged hospital stay, patient discomfort, and higher costs.[1] Vascular closure devices (VCDs) have been developed to overcome these problems. Studies have shown a reduced time to hemostasis, early ambulation, hospital discharge, and lower costs, without an increased risk of mortality or infection compared to manual compression.[2,3] However, in case of antegrade access for ipsilateral treatment, the implementation of VCDs is technically more complex and associated with higher complication rates compared to retrograde access.[4-7] The Angio-Seal VIP (Terumo Interventional Systems) seems to be a robust and safe device for closure after antegrade access.[8] However, insufficient hemostasis, vascular occlusion and device embolization and kinking or dislocation of the Angio-Seal VIP sheath have all been described.[6,9,10] To prevent these complications, ultrasound (US)-assisted Angio-Seal VIP closure could be an option, but to the best of our knowlegde data on this technique are not available. This study investigates the results of US-assisted Angio-Seal VIP closure of antegrade femoral access. In addition, the closure technique is described step-by-step supported with illustrations.

Methods

Study design. This was a single-center, retrospective observational study. The study did not fall under the Medical Research Involving Human Subjects Act as accorded by the Medical

Research Ethics Committees United and was approved by the local research department of the hospital. Patient informed consent was waived. Study data were extracted from electronic patient records.

Study population. The study population consisted of all consecutive patients who had US-assisted antegrade femoral access closure with an Angio-Seal VIP, between January 2019 and January 2021 performed by a single operator. Antegrade femoral access included ipsilateral common femoral artery (CFA) and proximal superficial femoral artery (SFA) access regardless of the extent of calcium or diameter of the vessel. Lower extremity procedures for acute and chronic peripheral arterial disease were both included. Patients who had an antegrade and retrograde access in the same vessel segment during the same procedure or a recent access closure other than with an Angio-Seal VIP were excluded from analysis.

Study data and endpoints. Patient demographics, procedural information, and information about the endpoints were collected. The primary endpoint was technical success which was defined as deployment of the Angio-Seal VIP with complete acute hemostasis. Other endpoints were Angio-Seal VIP related major complications defined as *major adverse limb event* (*MALE*, defined as above the ankle amputation or major reintervention), *death* or any *complication requiring (acute) intervention* (flow limiting dissection, thrombosis, embolization of plaque or the Angio-Seal VIP itself and major bleeding[11]). Hemostasis and vessel patency were assessed directly after closure by the operator with Duplex Ultrasound (DUS). *Bleeding complications* were classified as minor or major according to the Bleeding Academic Research Consortium criteria (BARC).[12] *Minor complications* were also noted and defined as any complication not within the major criteria. Before hospital discharge, a physical examination, including inspection of the punctured groin, was performed. If an access site complication was suspected, a DUS was performed. Patients were routinely followed-up in the outpatient clinic by a vascular surgeon or interventional radiologist 6-8 weeks after the intervention.

Statistical analysis. Baseline characteristics and procedural information are presented as descriptive outcomes. Continuous variables are expressed as mean along with the standard deviation. Categorical variables are expressed as number (%).

Ultrasound-assisted Angio-Seal VIP closure technique. It is recommended to perform access under US guidance to ensure puncture of the CFA or proximal SFA at the twelve o'clock position. Ultrasound also helps to target the best vessel segment for the puncture avoiding calcified plaques and punctures considered to be too proximal. Furthermore, in obese patients the proximal SFA can be targeted for puncture to avoid steep CFA access and thus potential complications. Because the proximal SFA is of a smaller caliber compared to the CFA and can have significant plaque burden, US assessment of the proximal SFA prior to access is also recommended.

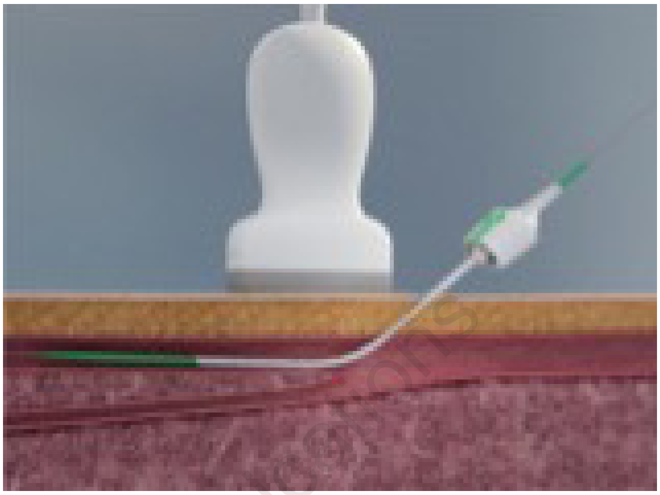

FIGURE 1. Deep introduction of the Angio-Seal VIP sheath. With ultrasound, the Angio-Seal VIP sheath is easily visualized in the superficial femoral artery.

Before exchanging the introduction sheath for the Angio-Seal VIP sheath, US evaluation of the access site needs to be performed to confirm visibility of the artery and sheath. Occasionally, visibility might be insufficient due to per-procedural hematoma formation. If this is the case, standard deployment of the Angio-Seal VIP or manual compression is recommended.

The first step of US-assisted closure involves a deeper introduction of the delivery sheath than is prescribed in the instructions for use (IFU) **(Figure 1)**. We typically use a short high supportive 0.035″ guidewire for sheath introduction as well as for the introduction of the Angio-Seal VIP delivery sheath. This prevents kinking of the wire especially in hostile groins after previous

FIGURE 2. The wire and dilator are removed keeping the sheath in a deep position.

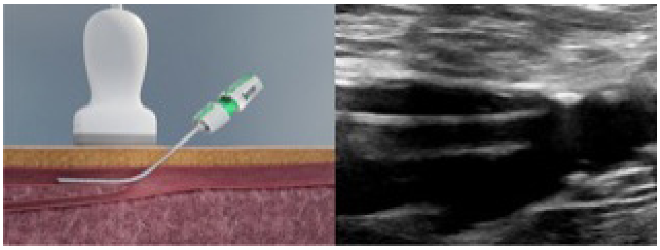

FIGURE 3. The carrier is introduced until the lips are aligned with the holes in the footplate. Care is taken not to lock the carrier because this will prematurely deploy the anchor.

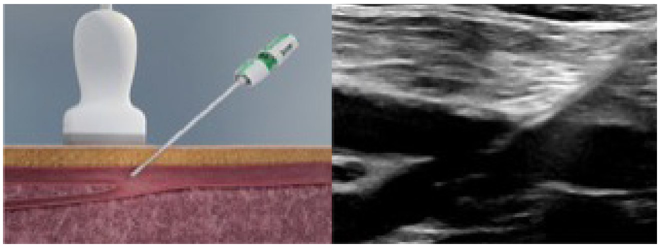

FIGURE 4. The sheath with the carrier is pulled back until the tip of the sheath is in the common femoral artery, close to the puncture site.

surgery. After pulsatile flow is observed the sheath is advanced for an additional 5-10 cm. This will prevent dislocation of the delivery sheath when removing the guidwire in steeper punctures and it also facilitates visualization of the sheath because of the horizontal orientation in the SFA. In addition, in case of kinking of the sheath it offers the operator enough length to use the push and pull technique to deliver the Angio-Seal VIP. With this technique, the carrier is pushed forward while the sheath is pulled back. If the kinking is not resolved, Angio-Seal VIP closure is contraindicated.

In the second step, the dilator and wire are removed **(Figure 2)**. The carrier is introduced with the lips aligned with the holes in the hub and touching it but NOT fully advanced and locked **(Figure 3)**.

The third step is to pull the sheath back with the carrier fixed under US guidance until the tip of the sheath is 1-1.5 cm from the access point **(Figure 4)**. With US, the anchor is visible while it is still in the sheath and can be seen at the tip where the indentation is. Next, pull the sheath back while advancing the carrier until it is locked **(Figure 5)**. Ideally, this should deploy the anchor while keeping it in the same position within the artery lumen.

The fourth and last step under US assistance is to pull the anchor against the anterior vessel wall **(Figure 6)**. If the anchor should catch a plaque, the whole system can be advanced, rotated, and pulled back again.

The final steps are without US assistance and are identical to the standard deployment. The carrier is locked, the whole system is pulled back and the plug is compressed on the vessel wall.

After closure a target DUS is performed to confirm complete

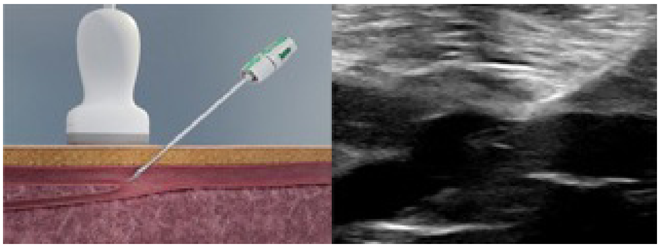

FIGURE 5. The anchor is deployed by advancing the carrier and simultenously pulling back the sheath. Ideally, this maneuver should deploy the anchor close to the puncture site.

FIGURE 6. The anchor is pulled against the anterior vessel wall under ultrasound guidance. Once this is confirmed, closure is performed as is with standard Angio-Seal VIP closure.

hemostasis and CFA-SFA patency. After six and seven French closures patients are ordered bedrest for two hours of which an hour supine. After an eight French closure, bedrest is four hours, of which two hours are in supine position.

Results

Patient demographics. During the study period, 187 procedures were identified in which US-assisted closure with an Angio-Seal VIP was performed by the same operator. Patient demographics are shown in **Table I**.

Procedural success. Procedural success was 99.5%. In one procedure, the Angio-Seal VIP deployment failed. The anchor was delivered in the artery lumen as confirmed by US but did not catch the anterior vessel wall. The Angio-Seal VIP was subsequently placed in the subcutaneous tissue. Manual compression and a pressure bandage were applied. There were no further complications.

Secondary endpoints. In total, two complications occurred that both involved pseudoaneurysm formation. One patient developed pseudoaneurysm with a hematoma in the groin and upper leg a few hours after ambulation. Because there was a hemoglobin drop of 1 mmol/L this patient received 2 units of packed cells and percutaneous embolization of the pseudoaneurysm with thrombin. This case was considered a major complication type 3a according to the BARC criteria. A second patient developed a pseudoaneurysm that was successfully treated with a thrombin

Table I. Patient and procedural characteristics of the 187 procedures with Angio-Seal VIP.

Characteristic	N (%)
Age, mean	75
Male gender	144 (77)
Ischemic heart disease	107 (57)
Diabetes mellitus	134 (72)
Hyperlipidemia	89 (48)
Hypertension	169 (90)
Renal failure (eGFR <30 ml/ min/1.73m2)	24 (13)
Dialysis dependent renal failure	9 (5)
Current/former smoker	127 (68) (n=174, 13 unknown)
Obesity: BMI > 30	31 (17) (n=181, 6 unknown)
Rutherford Becker classification	
0	2 (1)
1-3	22 (12)
4	17 (9)
5-6	146 (78)
Treated limb:	
left	87 (47)
right	100 (53)
Access vessel	
Proximal SFA	14 (7)
CFA	173 (93)
Sheath size	(n=182, 5 unknown)
4 Fr	4 (2)
5 Fr	2 (1)
6 Fr	165 (91)
7 Fr	4 (2)
8 Fr	7 (4)
Angio-Seal VIP size	
6 Fr	179 (96)
8 Fr	8 (4)

BMI = body mass index; CFA = common femoral artery; eGFR = estimated glomerular filtration rate; SFA = superficial femoral artery.

injection only. No transfusion was required. This complication was therefore classified as a minor complication (BARC type 2). No MALE or deaths occurred that could be attributed or related to the Angio-Seal VIP placement.

Discussion

With the aging population and rising incidence of diabetes, operators are facing more and more complex below the knee and ankle arterial occlusive disease. Treatment is challenging because of the presence of extensive calcifications and high rate of chronic total occlusions. The preferred approach in these cases would be antegrade because this ensures optimal control over wires and catheters while offering high pushability and the best chance of crossing and treating lesions. Despite these clear benefits, an antegrade approach is still avoided by many operators, which is very likely because of the higher complexity of artery access and closure. To ensure successful and uneventful antegrade sheath introduction, US-guided puncture is recommended when performing access procedures. It helps in puncturing at the 12 o'clock position and avoiding plaques, which is important for safe sheath introduction, but even more important in preventing access closure failure.

In today's endovascular practice, VCDs are used in the majority of cases, because they significantly reduce patient discomfort, time to hemostatis and time to ambulation without the risk of major complications.[13] However, closure of antegrade accesses with VCDs is not routinely practiced because of the perceived higher risk of complications. A recent pooled analysis of various VCDs demonstrated a higher overall complication rate, with a trend towards significance, for antegrade compared to retrograde use (4%-7% versus 1%-3%).[4] No sub-analysis of the Angio-Seal VIP or comparison between devices was possible.

In a single center retrospective analysis of almost 1900 antegrade Angio-Seal VIP closures in CLTI patients, it was demonstrated that antegrade access closure was safe, with a technical success rate of 97.9%, a major complication rate of 1.1% and an overall complication rate of 2.5%.[14] Despite these results, antegrade closure with the Angio-Seal VIP is still perceived by many as a high-risk procedure. The need of the anchor to cross proximal SFA plaques, the risk of it catching the profunda femoral artery ostium, while not having control over the anchor, could contribute to this perception. The results of our study show that US-assisted Angio-Seal VIP closure of CFA and SFA puncture sites is safe with a high technical success rate (99.5%) and low major (0.5%) and minor (0.5%) complication rates. The technique provides both tactile and visual feedback and thereby offers the operator control over anchor deployment. Moreover, because the anchor is deployed close to the access site, the risk of damaging the vessel wall is minimized. Also, if the anchor should catch a plaque, this can be noted on ultrasound and corrected. To free the anchor, the whole system is advanced and rotated 90-180 degrees under US guidance and subsequently pulled back until the puncture site is reached. After rotating the anchor back to its initial deployment position, it is pulled against the anterior vessel wall and the closure is performed.

The limitations of the current study are the retrospective design, as well as the fact that all procedures were performed by a single operator. We believe that it was important to prove the safety of the technique when performed by a single experienced operator, before implementing it more broadly and teaching it to others. Therefore, the results do not reflect real-life practice, but they do show what results can be achieved if the technique described in this manuscript is applied. Another limitation is that all closures were performed with the use of a high supportive 0.035″ wire which was also used for access and sheath delivery and does not come with the Angio-Seal VIP kit. A high supportive wire will not kink outside the artery lumen and facilitate easy Angio-Seal VIP sheath placement even in scarred hostile groins and steep punctures.

In conclusion, ultrasound-assisted Angio-Seal VIP closure in antegrade lower extremity procedures is safe and effective, even in SFA access and obese patients. Hopefully, the results of this study will lower the threshold for antegrade access so that more operators can benefit of the clear advantages of antegrade access in treating distal femoro-popliteal, below-the-knee, and below-the-ankle disease.

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