The efficacy and safety of closure of brachial access using the AngioSeal closure device: Experience with 161 interventions in diabetic patients with critical limb ischemia

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Purpose: **This study retrospectively evaluated the efficacy and safety of the 6F Angio-Seal (St. Jude Medical, St. Paul, Minn) as a closure device for transbrachial artery access for endovascular procedures in diabetic patients with critical limb ischemia.**

Methods: **From January 2005 and September 2007, 1887 diabetic patients underwent interventional procedures in the lower limbs at a two diabetic foot centers. Patients presented with rest pain (16%), ulcers (80%), or gangrene (4%). Systemic anticoagulation with sodium heparin (70 IU/kg) was obtained for all patients at the beginning of the endovascular treatment. A total of 249 brachial arteries (238 patients) were evaluated for possible Angio-Seal use after endovascular recanalization of the leg. Color Doppler ultrasound imaging of the artery was obtained before revascularization only in patients with previous Angio-Seal placement in the brachial artery. No further imaging studies were done in the remaining brachial arteries where the Angio-Seal was deployed at the operator's discretion. Impairment or disappearance of the radial pulse or onsets of hand ischemia or hand pain, or impairment of hand function during or at the end of the endovascular revascularization were all regarded as contraindications to Angio-Seal usage. Evidence of a highly calcified plaque of the brachial artery access site at the time of vessel puncture was regarded as an absolute contraindication to the Angio-Seal use. Patients were seen before discharge, at 1, 3, and 8 weeks after the procedure, and at 3-month intervals thereafter. Complications included hemorrhage, pseudoaneurysm, infection, and vessel occlusion.**

Results: **A total of 1947 Angio-Seal collagen plugs were deployed in 1709 diabetic patients (90.5%). The Angio-Seal was used for brachial artery closure in 159 patients (8.4%) in 161 procedures (159 in the left, 2 in the right brachial artery). In 79 patients (4.2%) in 88 procedures (87 in the left and 1 in the right brachial artery), the device was deemed contraindicated due to small vessel size in 73 patients (92.4%) or presence of calcium at the access site in five patients (6.3%). One patient (1.3%) refused the collagen plug closure after revascularization. The non-Angio-Seal group was evaluated for comparison. The success rate for achieving hemostasis in the Angio-Seal group was 96.9%. Five major complications (3.1%) at 30 days consisted of two puncture site hematomas >4 cm, two brachial artery occlusions, and one brachial artery pseudoaneurysm, with three patients requiring open surgery. Minor complications (7.50%) were three puncture site hematomas < 4 cm, three oozing of blood from the access site, and six patients had mild pain in the cubital fossa. No further complications were recorded in the 14-month follow-up (range 1-25 months) of a total of 140 patients.**

Conclusions: **This retrospective study shows that the 6F Angio-Seal is a valuable and safe vascular closure device for transbrachial access in diabetic patients undergoing interventional procedures for critical limb ischemia. (J Vasc Surg 2008;47:782-8.)**

Percutaneous access to the arterial system for endovascular procedures in the lower limbs is usually achieved through the femoral arteries. When femoral access is precluded, the brachial or axillary artery can serve as alternatives.[1,2] The brachial approach is currently regarded as one of the most valuable alternatives to transfemoral arterial puncture.[3] In selected cases, this option can also be more advantageous than the standard approach in terms of accessibility of the artery or when the procedure is conducted in an outpatient setting, or both.[2]

For several years, manual compression was the only method of achieving hemostasis of the punctured artery after diagnostic studies and interventional procedures. Access site complications with this technique have been reported to be ≤6% in most studies and have included bleeding, pseudoaneurysm formation, and vessel occlusion.[4,5] However, the increase in the artery hole diameter because of the sheath, the time delay until the activated clotting time (ACT) allows the physician to withdraw the introducer sheath, and the traditional manual compression involve prolonged arm mobilization and protracted, sometimes painful, local strong pressure as well as decreased patient compliance and satisfaction.

These problems have led to a great deal of interest in alternative methods of achieving hemostasis at the site of

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the femoral artery puncture, particularly in those patients who have received heavy anticoagulation.[6] The earliest reports describing the use of arterial puncture closure devices were published in 1992 and 1993.[7,8] Numerous reports describing the use of closure devices in the femoral artery have been published in last 10 years.[6,9-13] Conversely, few studies on the use of closure devices for the brachial artery access have been published so far; currently, there is evidence of only one study with >50 patients in whom an Angio-Seal (St. Jude Medical, St. Paul, Minn) was inserted for brachial artery closure after diagnostic or therapeutic interventions.[14,15] The purpose of this study was to assess the feasibility and clinical usefulness of Angio-Seal, a combined suture and collagen-based device, after brachial artery retrograde puncture for peripheral arterial interventions in diabetic patients with critical limb ischemia who have received full anticoagulation therapy.

METHODS

This was a retrospective, single-center study conducted between January 2005 and September 2007 at Multimedica Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS), Sesto San Giovanni Milan-Santa Maria Castellanza (VA), Italy, in a cohort of diabetic patients who underwent interventional procedures for critical limb ischemia (CLI). The patients presented with rest pain (16%), ulcers (80%), or gangrene (4%). No patients with claudication were included in this study.

Patients were assessed for the presence of CLI as defined by the Transatlantic InterSociety Consensus (TASC) criteria.[16] Critical limb ischemia was diagnosed if one foot pulse was reduced or absent, if ankle pressure was <70 mm Hg when assessable, and if transcutaneous oxygen tension at the dorsum of the foot was <50 mm Hg. Examination with duplex ultrasound (DUS) imaging and angiography were performed in all patients with these abnormalities. If obstruction >50% of the vessel diameter was present, percutaneous transluminal angioplasty (PTA) was performed as a first-choice revascularization procedure in the same angiographic session.[17]

A total of 249 brachial arteries in 238 patients were evaluated for possible Angio-Seal use after endovascular recanalization of the lower limbs. The brachial access was selected in cases of difficult femoral access due to severe groin fibrosis, local vascular surgery, aortic-iliac bifurcation being too acute, obesity, or an absent femoral pulse. All brachial access procedures were performed at the antecubital fossa. Patient age, sex, demographics, and the use of anticoagulants and antiplatelet agents were recorded.

Procedure. The same team of operators (J. C., T. L.) did all interventional procedures and Angio-Seal deployments. All operators had used the Angio-Seal device at least 150 times in the femoral artery before 2005, and therefore, no learning curve with the device was involved in the present study. Patients received 100 mg of aspirin (Bayer, Leverkusen, Germany) orally 2 hours before the scheduled intervention and continued taking it indefinitely.

All procedures were performed in the angiography suite after informed consent was obtained. After subcutaneous injection of a small amount of lidocaine, brachial artery cannulation was achieved with 21-gauge entry needles using the Seldinger technique. Procedures were not performed in patients who were taking warfarin if their international normalized ratio was >2.0. The size of the vascular sheath used, the type of procedure performed, and the indication for arteriography were noted. Previous diagnostic angiography was done through the brachial approach using a 5F, 25-cm-long introducer sheath (Super Sheath, Boston Scientific, Natick, Mass) in all patients. When indication to iliac, femoral, or popliteal endovascular treatment was made, the 5F sheath was changed for a 6F, 90-cm-long armored introducer sheath (Accuflex, Bipore Inc, Northvale, NJ).

All patients undergoing interventional treatments received 5000 IU of heparin after insertion of the 6F introducer sheath. Additional heparin was administered during the procedure to maintain an ACT >250 seconds. Eptifibatide (Integrilin, Millennium Pharmaceuticals Inc, Cambridge, Mass), an antagonist of platelet glycoprotein IIb-IIIa, was administered in three patients after sudden thrombosis of the lower limb vessels occurring during revascularization.

Sheath removal and device placement was performed immediately after completion of the angioplasty. No Angio-Seal device was implanted in patients in whom the interventional treatment was deemed not possible or contraindicated after angiography from the brachial approach. These patients underwent manual compression of the 5F hole in the artery. Heparin was never reversed at the conclusion of the angiography or endovascular intervention. Periprocedural antibiotics were not used.

In all cases, a 6F, 90-cm-long, armored sheath was used for the interventional procedure. No 5F sheaths were used for interventional procedures performed from the brachial artery in the present study. Color Doppler US imaging of the brachial artery was done before Angio-Seal deployment in the first 15 patients of the study. No imaging studies were done in the remaining brachial arteries where the Angio-Seal was deployed at the operator's discretion; therefore, in almost all patients, the decision to deploy an Angio-Seal in the brachial artery was made on clinical criteria solely. Specifically, impairment or disappearance of the radial pulse, or onsets of hand ischemia, hand pain, or impairment of hand function during or at the end of the procedure were considered contraindications to Angio-Seal use. Indeed, the occurrence of any of these symptoms might indicate the presence of a vessel diameter ≤4 mm at the puncture site.

No difficulty was encountered in placing the collagen of the Angio-Seal in the superficial location of the brachial artery provided it was >1 cm. In fact, a further contraindication to the procedure was the evidence of a superficial brachial artery sited to <1 cm beneath the skin of the antecubital fossa. For this reason, the Angio-Seal was deployed in each case by the same operator who had previ-

Table I. Vascular access closure after endovascular revascularization for critical limb ischemia

Variable	*Total, No. (%)*	*Femoral artery, No (%)*	*Brachial artery, No (%)*	*Brachial and femoral artery, No (%)*	*Bilateral femoral artery, No (%)*
Patients treated for CLI	1887				
Angio-Seal	1709 (90.5)	1480 (78.4)	159 (8.4)	19 (1)	51 (2.7)
Manual compression	178 (9.5)	90 (4.7)	79 (4.2)	5 (0.2)	4 (0.2)
Overall cases performed for CLI	2160				
Angio-seal placement	1947 (90.1)	1715 (79.4)	161 (7.4)	19 (0.9)	52 (2.4)
Manual compression	213 (9.9)	116 (5.4)	88 (4.1)	5 (0.2)	4 (0.2)

CLI, Critical limb ischemia.

ously performed the vessel puncture and who was thus aware of the real depth of the brachial artery. The evidence of a highly calcified plaque of the brachial artery access site at the time of vessel puncture was regarded as the main contraindication to the Angio-Seal use.

Manual compression or Angio-Seal deployment was done immediately after the conclusion of each procedure. After Angio-Seal placement, manual compression was applied for 45 to 60 second to all patients. At the end of Angio-Seal placement or manual compression, the access site was screened for 5 minutes. Then a compression bandage was placed over the puncture site in all patients and they were placed at bedrest for ≥2 hours. No Angio-Seal devices were employed in an outpatient setting. A 6F Angio-Seal device was deployed after the use of a 6F sheath. No 8F Angio-Seal or other types of closure devices were used in the present study.

Follow-up. The radial pulse was monitored immediately after closure device deployment as well as at 15 and 30 minutes and at 2-hour intervals thereafter. Time to removal of the cubital fossa compression bandage was 16 to 24 hours. The day after the percutaneous intervention, all patients underwent clinical follow-up examinations that included a physical examination performed by an interventional radiologist (J. C., T. L.) vascular surgeons (L.S., C.A.) or a diabetologist (M.D.P., F.E., C.G.) and a determination of brachial, radial, and ulnar pulses of the punctured arm. Patients were also examined for access site complications and success of the intervention before discharge from the hospital, at 1, 4, and 12 weeks after the procedure, and at 3-month intervals thereafter. Complications were classified according to severity and recorded as described in Table I. When a hematoma occurred, this was marked using a permanent ink marker and measured to quantify its size.

Study end points and definitions. The primary end point was the combined number of major complications at 30 days after the endovascular treatment. Procedural success was measured as an additional primary end point and was defined a hemostasis achieved with the collagen plug device, followed by compressive bandage for ≥16 hours. Failure to deploy the device, regardless of whether the outcome was final hemostasis or a complication, was defined as the inability to gain access with the device sheath, to engage the artery with the anchor, or to successfully secure the anchor or the collagen plug. The secondary end point was the combined number of minor complications during the first 30 days after the vascular closure procedure.

RESULTS

During the study period, 2160 endovascular procedures were performed, and 1947 Angio-Seal collagen plugs were deployed in 1709 of 1887 diabetic patients (90.5%) treated by endovascular recanalization for CLI. The Angio-Seal was used for brachial artery closure in 159 patients (8.4%) in 161 procedures (159 in the left, 2 in the right brachial artery); whereas in the remaining 79 patients (4.2%), consisting of 88 procedures (87 in the left and 1 in the right brachial artery), the device was contraindicated owing to the onset of hand pain or ischemia or both in 73 patients (92.4%) or the presence of calcium at the access site in five (6.3%). One patient (1.3%) refused to undergo collagen plug closure after revascularization. Two patients underwent repeat 6 F Angio-Seal deployments in the same left brachial artery at 2 and 16 months from the first intervention, respectively. An additional puncture of the femoral artery (4 retrograde, 15 antegrade) was required in the same operative session in 19 patients, all of whom underwent 6F Angio-Seal device deployments at the end of the procedure; therefore, 180 6F Angio-Seal plugs were used in this cohort of patients (Angio-Seal group).

The 79 patients in whom the Angio-Seal plug was not inserted (non-Angio-Seal group) were evaluated for comparison (Table I). The non-Angio-Seal group included 54 women and 25 men with age, comorbidities, and vascular lesions of the lower limbs that were comparable with those of the Angio-Seal group.

The Angio-Seal group included 58 women and 101 men, and their mean age was 75 years (range, 36-97). All patients had diabetes, 54% had hypertension, and 61% had coronary artery disease. Antiplatelet agents were being taken by 79% of patients, and 21% were receiving warfarin or Coumadin (Bristol-Myers Squibb, Princeton, NJ) anticoagulation. The 161 interventions were performed on 22 iliac arteries, 28 common femoral arteries, 71 superficial femoral arteries, 16 profunda arteries, and 24 popliteal arteries. Angioplasty was followed by stenting in 157 patients, and direct stenting was done in two patients. Stent

placement was performed in all patients with hemodynamically significant lesions of the iliac artery as well as in patients who had a residual stenosis >50% after angioplasty of the femoral-popliteal artery.

Primary end points. Five (3.1%) major complications were recorded in the Angio-Seal group: two left brachial artery occlusions (1.25%), one 5-cm pseudoaneurysm (0.65%), and two puncture site hematomas (1.25%) of 4.5 and 5 cm, respectively. One brachial occlusion was caused by a collagen plug displacement within the vessel lumen (with immediate occlusion of the artery as a result), and another was due to a brachial artery intimal dissection; specifically, this was caused by the anchor lifting up an intimal plaque that resulted in vessel thrombosis and ischemic rest pain at 27 days. Both patients were successfully treated by open surgery ≤24 hours of diagnosis. The 5-cm pseudoaneurysm developed after 2 hours from an apparently successful closure procedure. It was due to failure of the anchor to engage the arterial wall as the Angio-Seal delivery system was withdrawn before being properly positioned. The patient underwent successful surgical repair of the lesion the day after the interventional procedure. Finally, the two puncture site hematomas developed despite an initially successful deployment of the device, one at 30 minutes, and one at 3 hours. In both cases, no surgical treatment of the hematoma was needed.

The rate of major complications at 30 days was 3.1%. Of importance was that three of these five major complications occurred during the first 50 cases. Procedural success for obtaining hemostasis was achieved in 156 of the 161 cases (96.9%), because in addition to the three patients who required open surgery, in two patients there was failure to deploy the device. In these instances, antecubital fossa hemostasis was achieved by manual compression.

Four (4.6%) major complications were recorded in the non-Angio-Seal group after manual compression: one brachial artery thrombosis (1.1%) and three puncture site hematomas (3.4%) >4 cm. All complications developed ≤4 hours of the procedure. The brachial thrombosis required immediate surgical repair. One patient with a hematoma received a blood transfusion.

Secondary end points. Minor complications were recorded in 12 patients (7.45%) in the Angio-Seal group: three (1.86%) had oozing of blood from the puncture site at 25, 45, and 150 minutes, respectively, requiring manual compression, and three (2.48%) had hematomas <4 cm. Furthermore, six patients (3.72%) experienced mild pain at the puncture site during the first 24 hours after the procedure. The overall rate of complications in the Angio-Seal group at 30 days was 10.5%.

Eight (6.8%) minor complications were recorded in the non-Angio-Seal group. One arteriovenous fistula (1.1%) developed; two patients (2.3%) had oozing of blood from the puncture site requiring further manual compression at 20 and 60 minutes; and two hematomas (2.3%) <4 cm occurred. Two patients (2.3%) experienced severe pain at the puncture site during the first 12 hours after the procedure requiring the continuous administration of intravenous analgesic drugs. The overall rate of complications in the non-Angio-Seal group at 30 days was 13.7%. No elbow infection was seen in either group at any time. Major and minor complications are reported in Table II.

Table II. Complications after brachial artery puncture observed at 30 days in patients with and without Angio-Seal

Complication	*Angio-Seal group (n = 161), No (%)*	*Non-Angio-Seal group (n = 88), No (%)*
Major complication	5 (3.3)	4 (4.5)
Hematoma >4 cm in diameter or bleeding requiring transfusion	2 (1.3)	3 (3.4)
Pseudoaneurysm	1 (0.7)	0
Vessel occlusion or thrombosis	2 (1.3)	1 (1.1)
Minor complications	12 (7.5)	7 (8.0)
Hematoma <4 cm or bleeding not requiring transfusion	3 (1.9)	2 (2.3)
Oozing of blood	3 (1.9)	2 (2.3)
Arteriovenous fistula	0	1 (1.1)
Pain at the puncture site (up to24 h)	6 (3.7)	2 (2.3)
Overall complications	17 (10.8)	12 (12.5)

All but two patients in the Angio-Seal group were sent home with a normal radial pulse. A mild impairment of the left radial pulse that was noted at discharge in one patient resolved completely after 8 weeks. The impairment in the remaining patient was due to an underlying left subclavian artery stenosis that was successfully treated endovascularly after 6 weeks. No Angio-Seal or manual compression-related complications were seen at the 14-month follow-up (range, 1-25 months).

During this time, 16 patients in the Angio-Seal group died of unrelated causes. An additional three patients were lost to follow up 6, 9, and 11 months after their procedure and were doing well at the time of their last visit. No immediate or late complications were seen in patients in whom the Angio-Seal was used also in the groin. Six patients in the non-Angio-Seal group died of unrelated cause during the follow-up period, whereas two patients were lost to follow-up 10 and 12 months after the procedure. The difference in rates of major and minor complications between the two groups was not statistically different.

DISCUSSION

In cases of severe iliac occlusive disease, the axillary and brachial artery access routes have been used as alternative approaches to the femoral artery.[5,18] The brachial approach is currently regarded as the most useful alternative to transfemoral arterial puncture, and its use, particularly for interventions in the iliac axis, is increasing among endovascular therapists.[3] This option can also be more advantageous in selected cases than the standard approach in terms of accessibility of the artery or when the procedure is conducted in an outpatient setting, or both.[2]

Occlusive peripheral disease in diabetic patients is characterized by distal, multiple obstructions with a higher percentage of occlusions with respect to stenoses.[19] Stenosis or occlusions of the iliac and common femoral axis are not uncommon, however, and may render the femoral approach very challenging. The obesity present in some diabetic patients may not allow the antegrade puncture, whereas other diabetic patients have undergone previous surgery at the groin, which may contraindicate the use of the transfemoral approach. Finally, some patients, particularly elderly ones, show a very angulated aortic bifurcation and thus require a different approach from the femoral one. In all these situations the choice of the brachial artery as vascular access has been proven to be relatively safe and effective.[3] On the other hand, such an approach does not generally facilitate the use of devices larger than 7F.

Manual compression is the accepted method of achieving hemostasis after brachial artery access for diagnostic and interventional procedures. A variety of arterial closure devices have been introduced with the aim of reducing the time to hemostasis, but all are indicated for femoral use only. Closure devices show several advantages compared with manual compression. First, they are especially effective for highly anticoagulated patients and patients on glycoprotein IIb/IIIa inhibitors. Second, closure devices allow early ambulation and provide a high level of patient satisfaction. Finally, their use can dramatically enhance the overall cost-effectiveness and productivity of vascular surgery departments and catheter laboratories, particularly of those that perform several endovascular procedures per day.[9,20]

The disadvantage is the presence of the intravascular suture and anchor, which can act as a nidus for platelet aggregation, the risk of intravascular deployment of the collagen plug with subsequent occlusion of the accessed artery, and risk of distal embolization of the anchor. The latter, emphasizes the need to ensure that the vascular surgeons are aware of the presence of the anchor in patients in whom a further surgical procedure is needed so that the retaining suture is not cut.[21]

The recent growth in the number and design of closure devices has occurred without a consensus about whether these devices should be used routinely or selectively and under what circumstances they should be used.[11] Moreover, a variety of clinical trials and observational studies show conflicting results, with some showing superiority, inferiority, and no difference when vascular closure devices are compared with manual compression.[22,23]

The Angio-Seal device was introduced in Europe in 1994. The original design has undergone several modifications that allow for easier and more consistent deployment. Retrograde closures of the brachial arteries have not yet been approved by the United States Food and Drug Administration. The device consists of a small lozenge-shaped anchor composed of a polylactide and polyglycolide polymer, a collagen plug, and suture contained within a special carrier system.[12] When inserted, the arterial wall and puncture site are "sandwiched" between the anchor (within the vessel lumen) and the plug (on the adventitia) by traction on the suture and by pushing on a small plastic tube that is also threaded over the suture to provide countertraction. The Angio-Seal is an extremely simple device to master, it can be consistently deployed within 45 to 90 seconds, and it is completely bioabsorbable. Vessels previously sealed with this device have been safely re-entered within 1 to 7 days.[24]

With increased usage of these devices, reports of complications have also emerged. Common femoral artery occlusion secondary to the use of the Angio-Seal has been reported.[25] One of the most important complications has been collagen embolization to the lower extremity arteries.[26,27] Particular concern has also been expressed about infections resulting from the placement of these devices.[28,29]

In our experience, the Angio-Seal for brachial artery puncture site closure is a safe technique with an acceptable rate of complications. Although the use of Angio-Seal in the brachial artery in our cohort of diabetic subjects did not decrease the time of arm mobilization compared with manual compression, patient compliance and satisfaction was high owing to the reduced local compression at the site of puncture and a faster return to the ward. The rate of major complications in the present study was as low as 3.1%, with open surgery being required only in 1.90% (3 patients), and compared well with that of manual compression. Of importance was that all but one patient in the Angio-Seal group did very well after discharge. The only patient requiring unintended readmission to the hospital $\leq$30 days of a procedure was the patient with brachial artery dissection that evolved into vessel thrombosis 3 weeks after the intervention.

These results compare well with results from other studies conducted using the Angio-Seal or a different closure device in the femoral artery; however, great care has to be taken in certain patients, particularly young women.[12,13] Indeed, women generally have smaller brachial arteries than men, and young patients are more prone to vessel spasm during and also after vessel catheterization. To avoid Angio-Seal–related complications, the brachial artery inner diameter should be $>$4 mm. For this reason, the brachial artery at the antecubital fossa should be carefully evaluated, whenever possible, by color Doppler US imaging before Angio-Seal deployment. When color Doppler US is not available, clinical evaluation of the hand throughout the procedure is mandatory. Evidence of hand pain or ischemia at any time during the procedure increases the risk of complications after Angio-Seal placement. Manual compression should be preferred in these situations.

Great care should be also taken in patients whose brachial artery is too superficial in location, thus presenting inadequate space for the collagen plug. To overcome this problem, some authors[15] suggest the use of a local anaesthetic solution to be infiltrated both in the skin and subcutaneous tissue surrounding the puncture site before Angio-Seal deployment.[15] According to these authors, a local

tissue infiltration of 5 mL of solution in the region of the entry site may easily result in a tissue bulk of 2 to 2.5 cm^3, which creates enough room for safe anchor placement and collagen sponge deployment. Although manual compression may not be necessary in most patients, we recommend this maneuver for at least 45 to 60 seconds after complete deployment of the device.

In the present series, no color Doppler US imaging of the brachial artery was performed before vessel puncture, which is a main limitation of this study. Indeed, the decision to use the closure device was made solely on clinical criteria, as reported in "Material and Methods." Actually, a pre-evaluation of the brachial artery with color Doppler US imaging is likely to reduce the rate of complications at the site of puncture. In a recent article by Belenky et al,[15] the technical success of Angio-Seal deployment in the brachial artery previously evaluated with color Doppler US was as high as 100%. Moreover, these authors reported no related-device major complications in the short- and mid-term follow-up of 65 patients after Angio-Seal deployment in the brachial artery for diagnostic or therapeutic angiographies.

CONCLUSION

This retrospective study shows that the 6F Angio-Seal is a valuable and safe vascular closure device for transbrachial access in diabetic patients undergoing interventional procedures for CLI. Preintervention color-Doppler US imaging of the brachial artery is not mandatory but may increase the feasibility and safety of the procedure by providing better patient selection. Further studies in larger patient groups and with use of different closure devices are needed to determine the role of closure devices in brachial artery access.

AUTHOR CONTRIBUTIONS

Conception and design: LT, LS
Analysis and interpretation: LT, CG
Data collection: DM, FE
Writing the article: LT
Critical revision of the article: FE, LS, LT
Final approval of the article: CJ, LS, LT
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