# Access-site complications after peripheral vascular interventions in patients with peripheral arterial disease at Assiut University Hospital

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**Aim**
The aim was to describe the incidence of access-site complications (ASCs) and determine the risk factors leading to them in patients undergoing endovascular interventions for treatment of peripheral arterial disease.

**Materials and methods**
A prospective study was conducted on all patients who underwent endovascular procedures for the treatment of peripheral arterial disease at the Department Vascular Surgery, Assiut University Hospital, between May 2017 and May 2018. Access choice depended on the vessel condition, Duplex ultrasound examination, and surgeon's preference. ASCs were detected using clinical and duplex ultrasound examination. Follow-up of patients was done at 3 and 6 months postoperatively. Univariate and multivariate analyses were used to determine risk factors predicting occurrence of ASCs.

**Results**
Of the 210 patients, ASCs were encountered in 23 (11%) cases. Nine (4.3%) patients presented with thrombosis of the access artery, eight (3.8%) had access-site hematoma, four (1.9%) complained of external bleeding, and two patients (0.95%) presented with femoral artery pseudoaneurysm. Significant risk factors for ASCs were advanced age ($P$=0.027), hypertension ($P$=0.011), increased BMI ($P$=0.015), small vessel diameter ($P$=0.031), and prolonged procedure time ($P$<0.0001). BMI and procedure time were found to be predictors of occurrence of ASCs.

**Conclusion**
Long procedure time and increased BMI were found to be predictive of the occurrence of ASCs. Early detection and management of ASCs provide good outcome after 6-month follow-up.

**Keywords:**
Access-site complications, peripheral arterial diseases, peripheral vascular interventions

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## Introduction

Access-site complications (ASCs) are a major cause of perioperative morbidity and mortality among patients undergoing percutaneous endovascular intervention. They include clinically significant bleeding, hematomas, and pseudoaneurysm (PSA) [1].

The effects of ASCs include not only prolonged hospital stay and patient discomfort but also increased mortality rates even at one year after the procedure. Even with external anatomic or fluoroscopic landmarks to guide the arterial access, the optimal location of femoral puncture is missed in 13% of cases [2].

High punctures may result in retroperitoneal hematomas while, low punctures can lead to PSAs. Some procedural factors that predict higher rates of ASCs are antegrade versus retrograde approach and interventional rather than diagnostic procedures[3] Previous studies have shown that manual compression was significantly associated with ASCs, so duplex ultrasonography is preferred to assess the vascular access site after arterial puncture [4].

## Aim

The aim was to describe the incidence of ASCs and determine the risk factors leading to ASCs in patients undergoing endovascular interventions for peripheral arterial disease (PAD) at the Department of Vascular Surgery in Assiut University Hospital.

## Materials and methods

This prospective descriptive study was conducted between May 2017 and May 2018 on 210 patients, comprising 161 (76.7%) males and 49 (23.3%) females, with a mean age of 62.0 ± 9.5 years, at the Vascular and Endovascular Surgery Department, Assiut University Hospitals. All patients underwent endovascular procedures for the treatment of lower extremity PAD were included.

Patients who underwent endovascular procedures for other indications such as endovascular abdominal aortic repair and embolization were excluded.

History of the current presenting symptoms; relevant medical and surgical history; review of cardiac, pulmonary, renal, hepatic, and hematologic systems; and history of allergies and current medications were obtained. Moreover, the location of prior arterial bypass grafts or stents, risk factors for contrast material reaction, contrast-induced nephropathy, and complications from previous endovascular procedures were identified.

### Physical examination and investigations

Physical examination was performed to select the access artery and to exclude any contraindications for the arterial access such as groin infection, common femoral artery aneurysm, overlying hernia, and fresh incision over the access artery. All arterial pulses and symptoms and signs of PAD were evaluated.

The planned access site was interrogated using a color duplex ultrasound examination (Philips Envisor C and PhilipsHD5; Philips Medical System, The Nederland B.V.) with L 12-3-MHz linear transducer probe to determine access artery size, peak systolic velocity, and presence of calcification and/or proximal or distal arterial diseases.

All patients underwent routine laboratory investigations with the main focus on renal function and coagulation status.

### Procedure

Regarding anesthesia, at the beginning of the procedure, 1 or 2% lidocaine hydrochloride was used for local infiltration anesthesia.

Regarding obtaining a vascular access, in general, arterial access was guided by palpation of the arterial pulse, or under fluoroscopy or duplex guidance. Often times, the operator used a combination of one or more of those methods to determine a proper puncture site. Surgical cut down of access artery was also used in some cases.

The arterial puncture was done using an 18 G needle (or 21 G needle in case of micropuncture access). After visualization of blood jets, a 0.035" short-wire (0.018" short-wire in case of micropuncture) was advanced. At this point, fluoroscopy was performed, and the location of the wire was identified within the intended vessel.

Once the wire was successfully placed in the intended vessel, a vascular sheath could be advanced after a small dermatotomy.

Regarding performing the planned angioplasty procedure, after obtaining a vascular access, the intended angioplasty procedure was performed.

Regarding postprocedural care, in general, a manual compression at the puncture site for 15–20 min was done to achieve hemostasis for smaller bore vascular sheaths up to 6 F. Patients were instructed for immobilization for at least 6 h.

Patients were monitored for arterial access-related complications by physical examination and duplex ultrasonography the next day after the procedure.

ASCs were managed according to the type of complications, time of presentation, patients' symptoms, available resources, and surgeon's preference.

### Statistical analysis

Data entry and analysis was done using SPSS version 20 (SPSS Inc., Chicago, Illinois, USA). Data were presented as mean ± SD. *P* value less than 0.05 was considered statistically significant.

To identify risk factors, univariate and multivariate analysis was conducted using patient demographics (age and sex), comorbidities (smoking, BMI, hypertension, diabetes mellitus, ischemic heart disease, chronic kidney disease, and previous stroke), and angioplasty procedure and access-site characteristics (diameter of access artery, access site location, and access site guidance, calcification at access site and procedure time).

The study was approved and monitored by the Medical Ethics Committee, Assiut Faculty of Medicine (IRB: 17100945).

All patients signed an informed consent form.

## Results

This prospective study included 210 patients, comprising 161 (76.7%) males and 49 (23.3%) females,

with a mean age of 62.0 ± 9.5 years (range: 30–86 years; median: 65 years). Patient characteristics data are listed in Table 1.

Tissue loss was the main indication for the angioplasty procedures (68.1%). The contralateral femoral artery was the most used access site (39.5%).

Other access site characteristics are summarized in Table 2.

Of all the patients included in this study, ASCs were encountered in 23 (11%) patients.

Nine (4.3%) patients were complicated with thrombosis of the access artery leading to acute limb ischemia. All of them were successfully treated with surgical thrombectomy using Fogarty thrombectomy catheters.

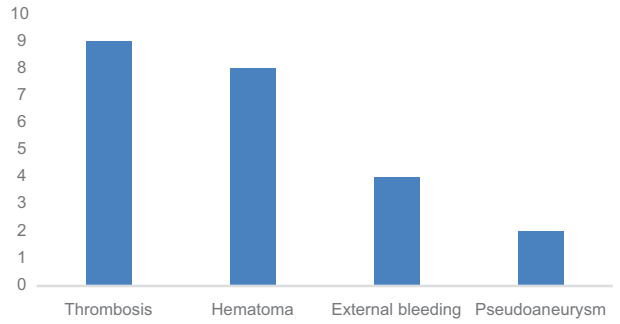
Eight (3.8%) patients had access-site hematoma that was treated conservatively with compression of the access site and follow-up duplex ultrasonography examination.

Four (1.9%) patients complained of external bleeding that was controlled by compression at the access site and stabilization of patients' hemodynamics. However, one patient died owing to irreversible hemorrhagic shock.

Two (0.95%) patients presented with femoral artery pseudoaneurysm. One was treated with duplex-guided compression therapy, whereas the other needed surgical intervention and suture repair of the puncture site (Fig. 1).

Univariate analysis of demographics, procedure, and access-site data demonstrated that advanced age ($P$ = 0.27), hypertension ($P$ = 0.011), increased BMI ($P$ = 0.015), small vessel diameter ($P$ = 0.031), and prolonged procedure time ($P$ < 0.0001) were the significant predictors of ASCs (Tables 3, 4) However, analysis of these data using a multivariate logistic regression model revealed that increased BMI ($P$ = 0.011) and prolonged procedure time ($P$ = 0.004) are the only significant independent predictors of ASCs.

**Figure 1**




Access-site complication rate stratified by the complication type.

**Table 1 Demographic data**

| Variables | *n* (%) |
|---|---|
| Age (years) | |
| Mean±SD | 62.0±9.5 |
| Range | 30-86 |
| Median | 65 |
| Male sex | 161 (77) |
| Diabetes | 158 (75.2) |
| Hypertension | 109 (51.9) |
| IHD | 65 (31) |
| CKD (60>eGFR >15) | 14 (6.7) |
| BMI (kg/m$^2$) | |
| Mean±SD | 23.3±3.3 |
| Range | 18-32 |
| Median | 24 |
| Current smoking | 113 (53.8) |
| Previous stroke/TIAs | 28 (13.3) |

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate (ml/min/1.73 m$^2$); IHD, ischemic heart disease; TIAs, transient ischemic attacks.

**Table 2 Angioplasty procedure and access-site characteristics**

| Variables | *n* (%) |
|---|---|
| Indication of angioplasty (Rutherford classification)[5] | |
| Category 3 | 24 (11.4) |
| Category 4 | 43 (20.5) |
| Category 5 | 80 (38.1) |
| Category 6 | 63 (30) |
| Access site | |
| Ipsilateral femoral | 70 (33.3) |
| Contralateral femoral | 83 (39.5) |
| Brachial | 47 (22.4) |
| Anterior tibial | 4 (1.9) |
| Posterior tibial | 6 (2.9) |
| Access vessel diameter (mm) | |
| Mean±SD | 6.9±1.7 |
| Range | 3-9.8 |
| Median | 7.5 |
| Access site guidance | |
| Palpation | 58 (27.6) |
| Fluoroscopy guided | 109 (51.9) |
| Duplex guided | 18 (8.6) |
| Open access | 25 (11.9) |
| Previous use of the same access site | 34 (16.2) |
| Calcification at access site | 82 (39) |
| Arterial lesion proximal to access site | 33 (15.7) |
| Arterial lesion distal to access site | 118 (56.2) |
| Procedure time (min) | |
| Mean±SD | 77.9±35.3 |
| Range | 30-300 |
| Median | 65 |

**Table 3 Univariate analysis of possible predictors of access-site complications**

| Variables | Access-site complications | | *P* |
|---|---|---|---|
| | Yes | No | |
| Age | NA | NA | **0.027** |
| Male sex | 15 | 146 | 0.174 |
| Diabetes | 19 | 139 | 0.389 |
| Hypertension | 18 | 91 | **0.011** |
| IHD | 8 | 57 | 0.674 |
| CKD (60>eGFR >15) | 2 | 12 | 0.681 |
| BMI | NA | NA | **0.015** |
| Current smoking | 9 | 104 | 0.140 |
| Previous stroke/TIAs | 4 | 24 | 0.546 |
| Rutherford classification | | | |
| Category 3 | 6 | 18 | |
| Category 4 | 3 | 40 | 0.073 |
| Category 5 | 8 | 72 | |
| Category 6 | 6 | 57 | |
| Access site | | | |
| Ipsilateral femoral artery | 5 | 65 | |
| Contralateral femoral artery | 8 | 75 | |
| Brachial artery | 9 | 38 | 0.312 |
| Anterior tibial artery | 1 | 3 | |
| Posterior tibial artery | 0 | 6 | |
| Access vessel diameter | NA | NA | **0.031** |
| Access-site guidance | | | |
| None | 5 | 53 | |
| Fluoroscopy guided | 13 | 96 | 0.668 |
| Duplex guided | 1 | 17 | |
| Open access | 4 | 21 | |
| Previous use of the same access site | 5 | 29 | 0.447 |
| Calcification at access site | 12 | 70 | 0.176 |
| Arterial lesion proximal to access site | 3 | 30 | 0.710 |
| Arterial lesion distal to access site | 10 | 108 | 0.197 |
| Procedure time | NA | NA | **<0.0001** |

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate (ml/min/1.73 $m^2$); IHD, ischemic heart disease; TIA, transient ischemic attack. Significance of bold value for access site complications

**Table 4 Multivariate analysis of possible predictors of access-site complications**

| Variables | *P* |
|---|---|
| Age | 0.318 |
| Male sex | 0.831 |
| Diabetes | 0.820 |
| Hypertension | 0.070 |
| IHD | 0.669 |
| CKD (60>eGFR >15) | 0.345 |
| BMI | **0.011** |
| Current smoking | 0.605 |
| Previous stroke/TIAs | 0.644 |
| Rutherford classification | 0.296 |
| Access site | 0.736 |
| Access vessel diameter | 0.200 |
| Access-site guidance | 0.548 |
| Previous use of the same access site | 0.558 |
| Calcification at access site | 0.356 |
| Arterial lesion proximal to access site | 0.756 |
| Arterial lesion distal to access site | 0.258 |
| Procedure time | **0.004** |

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate (ml/min/1.73 $m^2$); IHD, ischemic heart disease; TIA, transient ischemic attack.

## Discussion

Recent advances in peripheral vascular intervention (PVI) have improved safety and vessel patency, and consequently increased the popularity of percutaneous endovascular treatment modalities for peripheral artery disease over the traditional open surgical approaches that can be associated with higher morbidity rates [6].

Since 1995, there has been a 10-fold growth in the rate of PVI and a simultaneous decrease in surgical vascular interventions [7].

The data on the incidence of and risk factors for ASCs among patients undergoing lower extremity revascularization are relatively sparse, relative to patients undergoing percutaneous coronary intervention [1].

We studied 210 patients (77% of patients were males) with PAD, with a mean age of 62.0 ± 9.5 years.

The overall rate of ASCs was 11%. In similar studies, Hackl *et al.* [8], Siracuse *et al.* [9], and Bakshi *et al.*[10] reported complication rates of 11.5, 11.7, and 14%, respectively. In other studies, ASCs including hematoma (with or without pseudoaneurysm) were the most frequent PVI complication, occurring in 1–11% of procedures [11].

On the contrary, Ortiz *et al.* [12], Lo *et al.* [13], and Mehta *et al.*[14] reported complication rates of 3.5, 5.4, and 2.4%, respectively.

In this study, hypertension was a significant predictor for ASCs ($P$ = 0.011). This comes in accordance with Gerald *et al.* [8], who identified a high blood pressure more than 200 mmHg as a strong predictor for the development of puncture-site complications.

Advanced age was a significant predictor for ASCs ($P$ = 0.027). Moreover, Ortiz *et al.*[12] and Jeffrey *et al.*[15] reported that age more than 60 and 80 years, respectively, were significant risk factors for ASCs.

Moreover, patients with increased BMI were at a higher risk for ASCs ($P$ = 0.015). In contrast Ortiz *et al.*[12] reported higher rates of ASCs in patients with a BMI of less than 18.5.

In this study, the type of access-site guidance was not a predictor of ASCs. However, Kalish *et al.*[16] and Lo *et al.*[1] concluded that using duplex ultrasound was protective against ASCs. Moreover, Kret *et al.*[17] identified that ASCs were less frequent after arterial cut

down (4.1%) compared with duplex-guided (11.8%) or fluoroscopy-guided access (7.3%).

Prolonged procedure time was associated with a higher risk of ASCs ($P < 0.0001$). This comes in line with Ortiz and colleagues who reported that prolonged time more than 30 min was a predictor for ASCs.

In contrast to the finding reported by Lo *et al.* [1], IHD was not a predictor of ASCs in the present study.

In this study, diabetes was not found to be a significant risk factor for ASC, in contrast to the findings reported by Darling *et al.*[18] and Ortiz *et al.* [19], who concluded that diabetes was a predictor for ASCs during and after PVI.

In our study, the type of access was not a significant predictor for ASCs which contradicts the finding reported by Siracuse *et al.* [9]. Antegrade ipsilateral access is safe and is not associated with increased ASCs. This approach remains a viable alternative to traditional retrograde contralateral access when it is more feasible [20].

All pedal access sites were patent by duplex ultrasound examination; retrograde trans pedal access was found nonsignificant for ASCs development. This is in line with Patel *et al.* [21], Stern *et al.* [22], and Bazan *et al.* [23].

Moreover, we encountered that the size of access artery was a predictor of ASCs with small vessel diameters less than 6 mm ($P = 0.031$).

In this study, we found cerebrovascular stroke, previous access of the same site, and location of arterial lesion in relation to access site to be non-significant for ASCs development.

Renal impairment was not significant for ASC in the present study, although Kret *et al.*[17] have found a higher rate of ASCs in patients with renal failure.

In our study, calcification of access artery was not significant for ASCs, in contrast to Stone *et al.*[24] who found calcification of access artery to be a predictor for ASCs.

In our study, eight (3.8%) patients were complicated by access site hematoma, keeping with corresponding rates reported by Siracuse *et al.*[9] (2.7%) and Komshian *et al.*[25] (3.1%).

Our 1.9% (four of patients) rate of access site hemorrhage compares favorably with the 5.6% rate reported by Madden *et al.* [26].

In this study, we identified two (0.96%) patients complicated with PSA which comes in agreement with rates reported by Mehta *et al.*[14] (0.6%) and Siracuse *et al.*[9] (1.3%). Higher rate were also reported by Stone *et al.*[24] (2.3%) and Kassem *et al.*[27] (3.42%). Very high rates reaching up to 32% for postpercutaneous intervention were also reported by Masterson *et al.* [28], during femoral artery screening with duplex ultrasound.

Nine (4.3%) of patients in the present study were complicated with thrombosis of the access artery, with similar corresponding rates reported by Madden *et al.*[26] (4.6%). Considerably lower rates for access artery thrombosis (0.6%) were also reported by Mehta *et al.* [14].

## Conclusion

ASCs occur after peripheral vascular interventions in patients with PAD. Individual risk level for ASCs in patients undergoing peripheral vascular intervention may be predicted.

Of all the patients included in this study, ASCs were encountered in 23 (11%) patients; nine (4.3%) patients presented with thrombosis of the access artery, eight (3.8%) patients had access site hematoma, four (1.9%) patients complained of external bleeding, and two (0.95%) patients presented with femoral artery pseudoaneurysm.

Early detection, proper management, and meticulous follow-up of ASCs provide better outcome after peripheral vascular interventions in patients with PAD.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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