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Access Site Complications Following Peripheral Vascular Interventions: Incidence, Predictors and Outcomes

Daniel Ortiz, MD[1], **Arshad Jahangir, MD**[2], **Maharaj Singh, PhD**[1], **Suhail Allaqaband, MD**[1], **Tanvir K. Bajwa, MD**[1], and **Mark W. Mewissen, MD**[3]

[1]Aurora Cardiovascular Services, Aurora Sinai/Aurora St. Luke's Medical Centers, University of Wisconsin School of Medicine and Public Health

[2]Center for Integrative Research on Cardiovascular Aging, Aurora University of Wisconsin Medical Group

[3]Vascular Center at Aurora St Luke's Medical Center, Milwaukee, WI

Abstract

Background—Access site hematomas and pseudoaneurysms are the most frequent complications of peripheral vascular intervention (PVI); however, their incidence and risk factors remain unclear.

Methods and Results—We retrospectively analyzed data from the multicenter Vascular Quality Initiative® on 22,226 patients who underwent 27,048 PVI from August 2007 to May 2013. Primary endpoints included incidence and predictors of access site complications (ASC), length of postprocedural hospitalization, discharge status, and 30-day and 1-year mortality. ASC complicated 936 procedures (3.5%). Of these, 74.4% were minor complications, 9.7% were moderate requiring transfusion, 5.4% were moderate requiring thrombin injection, and 10.5% were severe requiring surgery. Predictors of ASC were age >75 years, female gender, white race, no prior PVI, nonfemoral arterial access site, >6-Fr sheath size, thrombolytics, arterial dissection, fluoroscopy time >30 minutes, nonuse of vascular closure device, bedridden preoperative ambulatory status, and urgent indication. Mean hospitalization was longer after procedures complicated by ASC (1.2 ± 1.6 days vs. 1.9 ± 1.9 days; range 0-7 days; p=0.002). Severity of ASC correlated with higher rates of discharge to rehabilitation/nursing facilities compared to home discharge. Patients with severe ASC had higher 30-day mortality (6.1% vs. 1.4%; p<0.001), and those with moderate ASC requiring transfusion had elevated 1-year mortality (12.1%, vs. 5.7%; p<0.001).

Conclusions—Several factors independently predict access site complication following peripheral vascular intervention. Appropriate use of antithrombotic therapies and vascular closure device in patients at increased risk of ASC may improve post-PVI outcomes.

Correspondence to Mark W. Mewissen, MD The Vascular Center at Aurora St Luke's Medical Center 2801 W. Kinnickinnic River Parkway, #540 Milwaukee, WI 53215 Tel. +1 414 385 2429 Fax: +1 414 385 2461 publishing11@aurora.org.

Disclosures

None.

Keywords

peripheral vascular intervention; pseudoaneurysm; hematoma; mortality

Approximately 8.5 million Americans over the age of 40 have peripheral artery disease, a disease that increases morbidity and mortality.[1] Recent advances in peripheral vascular intervention (PVI) have improved safety and vessel patency, increasing the popularity of percutaneous endovascular treatment modalities for peripheral artery disease over traditional open surgical approaches associated with higher morbidity.[2] Since 1995 there has been a tenfold growth in rate of PVI and a simultaneous decrease in surgical vascular interventions.[3] Access site complications (ASC), including hematoma associated with and without pseudoaneurysm, is the most frequent PVI complication, occuring in 1.0% to 11% of procedures.[4-8] Proposed risk factors of this complication include female gender, advanced age, prior anemia, prior heart failure, low creatinine clearance, rest pain, heparin use and nonuse of a closure device.[9] Due to incomplete analysis, inconsistent bleeding definitions and small study populations of patients undergoing PVI, ASC predictors and outcomes are not fully elucidated in the literature. Accordingly, this study evaluated the incidence, predictors and outcomes of periprocedural access site complications in an unselected real-world patient population who underwent PVI.

Methods

Study Population

This retrospective study analyzed data on 22,226 patients who underwent 27,048 PVI procedures from August 2007 to May 2013 in more than 130 centers participating in the Society for Vascular Surgery's Vascular Quality Initiative® (VQI). A description of the VQI has been previously published.[10] Complications are site determined, and based on examination of the medical record documentation. Basic automated validation occurs when data field are empty or when a data is outside preset parameters. Further validation occurs by comparing data entered into the VQI database with billing information. There is no external validation done on the data entered into VQI at this time. The Aurora Health Care IRB prospectively approved this study of unidentified data.

Definitions

ASC is defined by the VQI as the presence of a hematoma at the procedural puncture site associated with or without pseudoaneurysm, prior to discharge and classified as one of four types: minor with no therapy employed, moderate necessitating blood transfusion, moderate necessitating thrombin injection, or major for which an operation was performed. Procedural urgency was considered emergent if the patient was treated within hours of presentation, urgent if treatment was expected in the same hospital stay, and elective if it was scheduled on an outpatient basis. Distal embolization was defined as any vascular embolization occurring after PVI and prior to discharge related to either the endovascular procedure or the access site closure. Similarly, access site occlusion refers to access site stenosis or occlusion after PVI and prior to discharge.

Follow-Up

Immediate and in-hospital events were collected by personnel or providers involved in each patient's care at each center participating in the VQI, or via retrospective chart review by designated data entry personnel. Patient mortality rates at 30 days and 1 year were determined by hospital chart review, inclusion in the Social Security Death Index or ascertained in long-term follow-up. The database was searched for all PVI and includes multiple procedures performed on single individuals.

Statistical Methods

Continuous variables are presented as mean ± standard deviation. Chi-square and Fisher's exact tests were used for analysis of categorical variables when appropriate, and the Student's t-test was used for the analysis of continuous variables. Unequal- variance for t test was used to compare length of hospitalization. A multivariable logistic regression analysis was performed to determine the predictors of ASC. For patients with multiple procedures, only data from the first PVI was included in the modeling. Variables significant at the univariate probability level of < 0.05 were entered into the model. These variables included gender, age, race, body mass index, diabetes, dialysis dependence, preoperative ambulatory status, urgency, arterial access site, vascular closure device, access site sheath size used, fluoroscopy time, the use of heparin or bivalirudin, pharmacologic thrombolysis and prior history of PVI. The model was adjusted to account for patients who were not candidates for closure devices (non-femoral vascular access and 4 F sheaths). The presence of ASC, arterial dissection and arterial perforation in addition to the variables utilized in the aforementioned model were entered in a separate model to identify predictors of 30-day and 1-year mortality. Flouroscopy time was included in the survival analysis as a marker of disease severity while vascular closure device and access sheath size used were excluded as they similarly reflect the extent of vascular disease. For all analysis, alpha level ≤ 0.05 was considered significant. All statistical analysis was done using SAS Version 9.2 (SAS Institute Inc., Cary, NC).

Results

Baseline Demographics

Patient demographics are described in Table 1. ASC occurred in 936 (3.5%) PVI procedures, of which 696 (74.4%) were minor, 91 (9.7%) were moderate necessitating transfusion, 51 (5.5%) were moderate necessitating thrombin injection, and 98 (10.5%) were major necessitating operation. Patients with ASC were older and more likely to be white, nondiabetic and have no prior PVI. Female patients had a higher incidence of ASC compared to males (4.28 vs. 2.87; $p<0.001$). Those on peritoneal dialysis or hemodialysis had lower rates of ASC than other patients (2.51% vs. 3.52; $p=0.02$).

Procedural Characteristics

Procedures complicated by ASC more often had an indication of claudication, and urgent procedures had higher rates of ASC (6.9%) compared to emergent (3.7%) and elective (3.3%) procedures (Table 2). ASC occurred less frequently in unilateral femoral artery

access compared to bilateral femoral artery access sites (3.1% vs. 4.7%; p<0.001), and ASC occurred in 7.9% of procedures in which an arm was used for arterial access. ASC was more frequent in procedures wherein the largest sheath size used was 7-8 Fr compared with those in which 4-6 Fr was used (4.5% vs. 3.2%; p<0.001). Rates of ASC were higher in procedures with fluoroscopy time > 30 minutes compared with those of less duration (4.7% vs. 2.9%; p<0.001). ASC was less frequent in PVI with concomitant common femoral artery endarterectomy than those without (3.6% vs. 2.3%; p=0.003) and in procedures which included pharmacologic thrombolysis (7.5% vs 3.8%; p<0.001). ASC was more common in procedures complicated by arterial perforation (9.4% vs. 3.4%; p<0.001) or arterial dissection (5.1% vs. 3.2%; p<0.001). The use of access guidance, type of pathology and number of arteries treated and technical outcome did not influence ASC.

Antithrombotic Medications and Vascular Closure Devices

ASC occurred less frequently in procedures in which bivalirudin antithrombotic therapy was used compared with heparin therapy (3.1% vs. 4.2%; p=0.041). Rates of distal embolization were similar between bivalirudin and heparin use (Table 3), whereas access site occlusions were less frequent in procedures in which bivalirudin was used (0.5% vs. 1.2%; p=0.020). ASC were less frequent in heparinized patients who received vascular closure devices compared with those who did not (2.5% vs. 4.2%; p<0.001) and in patients who received bivalirudin and vascular closure device compared with those who did not (1.5% vs. 2.5%; p=0.008). Closure devices were associated with low rates of all ASC types while only the minor ASC rate was lower in patients who received bivalirudin (Table 4).

Predictors of Access Site Complication

Multivariable analysis of baseline and procedural factors showed that predictors of ASC were age > 75 years, female gender, white race, no prior PVI, nonfemoral artery access site, sheath size greater than 6 Fr, pharmacologic thrombolysis fluoroscopy time > 30 minutes, and nonuse of vascular closure device (Figure 1). The most powerful indicators of ASC were bedridden preoperative ambulatory status (odds ratio 2.40, 95% confidence interval (CI) 1.39 - 4.14), and thrombolytic use (odds ratio 2.00, 95% CI 1.48 - 2.70).

Patient Outcomes

Average hospitalization was longer after procedures complicated by ASC than those that were not (1.9 ± 1.9 days vs. 1.2 ± 1.6 days; range 0-7 days; p=0.002). ASC severity correlated with higher rates of discharge to rehabilitation and nursing homes in patients who were living at home prior to admission (Figure 2).

Patients with severe ASC had a fourfold increase in 30-day mortality rate compared with the rest of the population (6.1% vs. 1.4%; OR 4.33; CI 2.07-10.92; p<0.001). At 1 year, the highest mortality rate was observed in patients with ASC requiring transfusion (12.1% vs. 5.7%; p=0.001). Multivariable analysis of baseline and procedural characteristics revealed that ASC (both overall and when analyzed by severity) was not an independent predictor of 30-day or 1-year mortality. Baseline, clinical and procedural characteristics that predicted 30-day and 1-year mortality are summarized in Figures 3 and 4.

Discussion

In our study of 27,048 PVI procedures (in 22,226 patients) derived from the VQI database, we observed a relatively low rate of ASC (3.5%) and found that only 0.9% of PVI are complicated by ASC requiring treatment (thrombin injection, blood transfusion or operation). In comparison, access site complication occurred in 7.0% and 8.9% of patients in prior PVI studies.[5,6] The small sample sizes and difference in access site bleeding definitions used in the previous studies may account for the difference in complication rates.

Several baseline, clinical and procedural characteristics independently predicted ASC. Some of these easily identifiable factors may be useful in evaluating the patient risk of developing ASC to guide the use of more beneficial antithrombotic therapy, vascular closure device and the use of smaller access site sheaths. These predictors have not been studied or identified previously in post-PVI populations. A valid comparison between the predictors of ASC complicating PVI to those complicating percutaneous coronary intervention (PCI) is difficult due to differences in registry definitions,[11-13] however, the distinct patient characteristics intrinsic to peripheral artery disease and coronary artery disease, the procedural differences between PVI and PCI, including the use of pharmacologic thrombolysis, and the similarities in antithrombotic therapies, endovascular approaches and patient comorbidities warrant an assessment.[13] Older age, female gender, peripheral artery disease, use of heparin instead of bivalirudin, no prior PCI antithrombotic therapy and prolonged procedure duration are predictors of post-PCI bleeding that are comparable to predictors identified in our study.[14-22] Also similar to PCI, higher rates of access site complication occurred in patients with a body mass index of < 18.5; however, low BMI is not an independent predictor of ASC in PCI on multivariable analysis.[23]

Other predictors of post-PCI bleeding not shared in our analysis of PVI procedures include impaired creatinine clearance, hypertension and heart failure.[15,16] Furthermore, several PCI studies identified diabetes as an independent predictor of bleeding, whereas our study found ASC was less frequent in diabetics. Other predictors unique to the acute coronary syndrome population undergoing PCI include presence of ST-elevation myocardial infarction, cardiogenic shock and intra-aortic balloon pump, and could contribute to the higher rate of ASC (and possibly other bleeding complications) in PCI procedures.[12,19,24]

In the VQI dataset, 4.2% of PVI procedures in which heparin was used were complicated by ASC compared with 3.1%, 2.4% and 1.5% of procedures in which bivalirudin, heparin plus a vascular closure device, and bivalirudin plus a vascular closure device were utilized, respectively. The rate of thrombotic complications was similar between heparin and bivalirudin. Additionally, use of heparin over bivalirudin (odds ratio 1.40, 95% CI 1.03-1.91) and nonuse of vascular closure device (odds ratio 1.74, 95% CI 1.49-2.02) were predictors of ASC. These observations concur with results from prior PVI studies,[5,9] the ACUITY trial[16] and an observational study based on the National Cardiovascular Data Registry®.[25] This shows that despite distinct populations, pathologies, procedures and bleeding definitions, bivalirudin is associated with reduced risk of bleeding complications compared to heparin while having the same efficacy in reducing thrombotic events. Finally, the reduction of specific types of ASC by vascular closure devices and bivalirudin mirrors

the PCI literature.[26,27] The trends of bivalirudin use were beyond the scope of this study and therefore associations between bivalirudin and ASC may be due to selection bias. The ENDOvascular interventions with angioMAX (ENDOMAX) trial may clarify the intrinsic risk of hemorrhagic complication difference between heparin and bivalirudin.[28]

We found that average postprocedure hospitalization was longer after PVI complicated by ASC and that the presence and severity of hematoma were related to higher rates of discharge to rehabilitation and nursing homes. This has not been previously reported. A nearly twofold increase in 1-year mortality in patients whose ASC required blood transfusion compared to all other patients was found. Vavalle et al. also reported an increase in 1-year mortality rate in post-PCI hematoma requiring transfusion (including non-access site hematomas), which they determined to be an independent predictor of 30-day and 1-year mortality.[14] Our data reveal that ASC necessitating blood transfusion was not an independent predictor of 30-day or 1-year mortality. This suggests that although ASC requiring blood transfusion is causally related to poor outcomes in some patients, it may only be an indicator of patients at higher risk for poor outcomes.[29] This hypothesis is further supported by the predictors found to predict both ASC and mortality. We observed that patients with severe hematomas had a fourfold increase in 30-day mortality rate compared to the rest of the study population, which mirrors the PCI literature that has repeatedly found higher mortality rates in patients with major bleeding complications at 30 days, 6 months, and 1 year.[15-19] Explanations of the association between bleeding complications and mortality in PCI patients that may apply to severe ASC post-PVI include: the discontinuation of antithrombotic therapy, which may result in adverse cardiac outcomes; bleeding in the presence of other comorbidities precipitating decompensated heart failure; and blood transfusion complications leading to increased mortality.[15] Finally, complications related to the surgical management of severe ASC and prolonged hospitalization may explain the increased 30-day mortality in this group.

Study Limitations

Strengths of the current study include its large sample size, the amount of data collected for each procedure and its unselected real-world population. However, certain limitations must be considered when interpreting the results. First, the current study only addressed hematomas at the arterial access site associated with and without pseudoaneurysm and no other ASC, including pseudoaneurysm without hematomas, retroperitoneal bleeding or other bleeding from other site. Institutional variability may result in underreporting of post-PVI ASC and as the analyzed data was de-identified, clustering of patients within hospitals was not done. In addition, other procedure-related bleeding complications are not adjudicated by the VQI. Furthermore, the retrospective nature of the study conveys inherent limitations, and the multivariable analysis performed may not have accounted for all relevant variables. Another limitation is that no analysis was performed to identify factors that may have influenced the administration of bivalirudin and placement of vascular closure devices, or variables that led to the treatment of ASC with thrombin injections, blood transfusions or surgeries. In addition, hematomas were more frequent in patients with arterial access in the arm, however the VQI does not specify which specific upper extremity artery was accessed. Since only newer extra-long equipment provides the means to treat above-the-knee lesions

by a transradial approach, we postulate that many of those procedures involved brachial access.[30] The PCI literature has demonstrated that transbrachial access is associated with a higher rate of puncture site complication, and that transradial access is safer than the femoral approach.[31,32] Future studies are necessary to determine if there is a similar difference in PVI. Lastly, it was not possible to explore the relationship between bleeding and dosage, timing and duration of antithrombotic agents. This may be an important factor, as a recent analysis of post-PCI bleeding determined that maximum in-laboratory activated clotting time was the second most important predictor of bleeding in that population.[33] Future studies are necessary to elucidate these questions.

Conclusions

The results of this study suggest that access site hematoma requiring transfusion or operation had a significant, independent, negative impact on mortality in patients undergoing peripheral vascular intervention. ASC complications also were associated with prolonged hospitalization and more adverse discharge status. Several patient and procedural variables independently predict ASC, including treatment with heparin rather than bivalirudin and the nonuse of a vascular closure device. Risk assessment for the potential development of ASC with knowledge of these findings could facilitate the appropriate selection of antithrombotic therapy and the use of closure devices to improve post-PVI outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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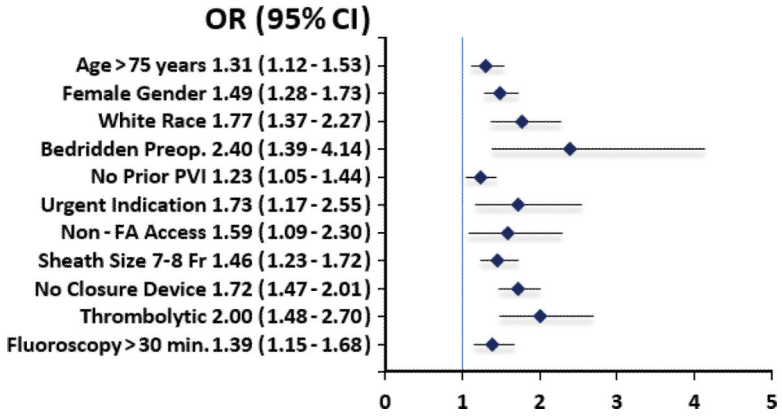

Figure 1.

Predictors of access site complication. CI indicates confidence interval; FA, femoral artery; OR, odds ratio; PVI, peripheral vascular intervention.

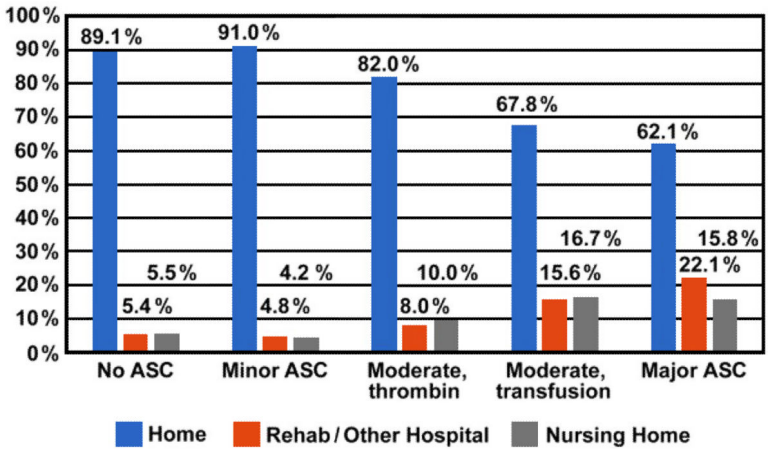

Figure 2.
Discharge status by type of access site complication (ASC).

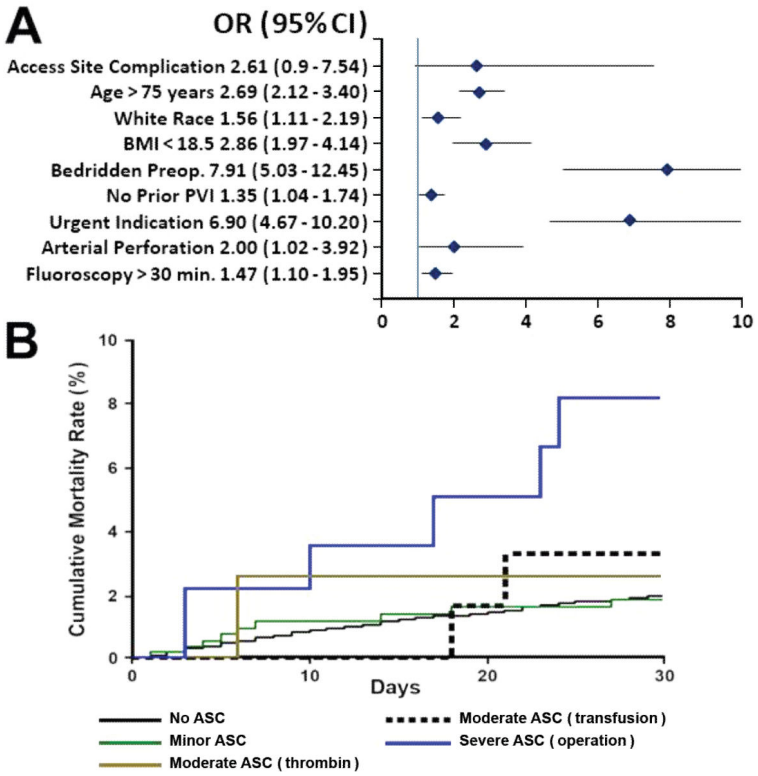

Figure 3.

A, Predictors of 30-day mortality. **B**, Kaplan-Meier curves for 30-day mortality by type of access site complication (ASC). BMI indicates body mass index; CI, confidence interval; OR, odds ratio.

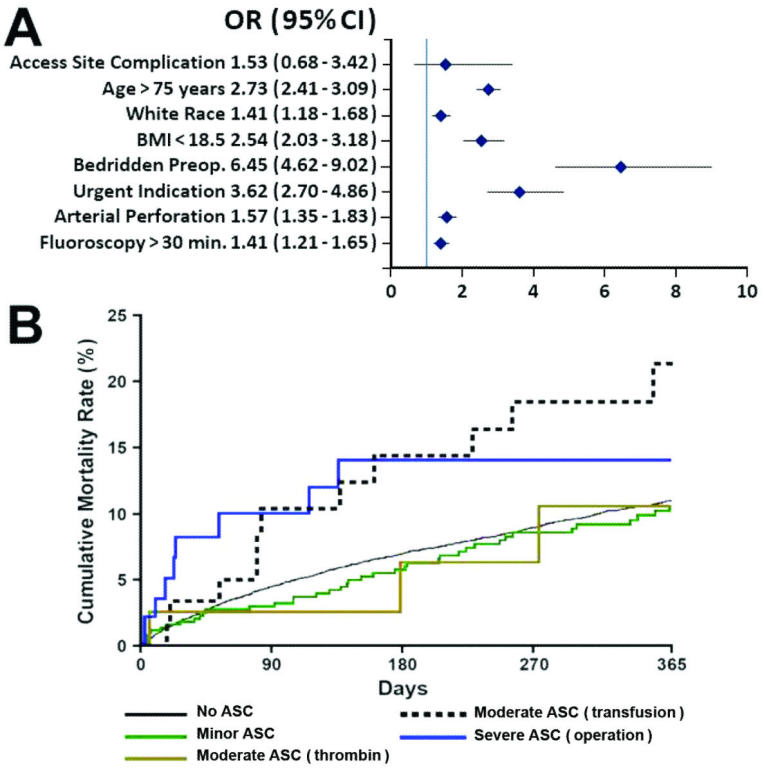

Figure 4.

A, Predictors of 1-year mortality. **B**, Kaplan-Meier curves for 1-year mortality by type of access site complication (ASC). BMI indicates body mass index; CI, confidence interval; DM, diabetes mellitus; FA, femoral artery; OR, odds ratio.

Table 1

Patient Demographic and Clinical Characteristics at Time of Procedure

	No Access Site Complication (n=26,112)	Access Site Complication (n=936)	*P* Value
Age (mean ± SD)	67.81 ± 11.35	69.68 ± 11.37	<0.0001
≤ 65 years, %	38.7	33.0	
65-75 years, %	31.9	31.4	
≥ 75 years, %	29.4	35.6	
Gender			<0.0001
Male, %	58.5	48.2	
Female, %	41.5	51.8	
Race			<0.0001
White, %	83.8	88.7	
Black, %	13.0	8.3	
Other, %	3.3	3.0	
Body mass index			0.0014
< 18.5, %	4.1	5.8	
18.5-24.9, %	29.6	30.7	
25-29.9, %	34.1	36.4	
> 30.0, %	32.2	27.0	
Smoking status			0.17
No smoking, %	20.2	21.9	
Prior, %	40.7	41.9	
Current, %	39.2	36.3	
History of hypertension, %	87.3	87.2	0.94
Diabetic, %	48.6	42.7	<0.001
Chronic obstructive pulmonary disease, %	23.8	25.9	0.15
Coronary artery disease			0.64
None/Asymptomatic, %	68.0	68.7	
Stable angina, %	10.2	10.7	
Prior myocardial infarction or unstable angina, %	21.8	20.6	
Peritoneal dialysis or hemodialysis, %	7.0	5.0	0.043
Congestive heart failure			0.65
None/Asymptomatic, %	93	93.1	
Mild, %	5.1	4.6	
Moderate, %	0.9	1.3	
Severe, %	1.0	1.0	
Preoperative ambulatory status			0.001
Ambulatory, %	79.5	79.1	
Ambulatory with assistance, %	14.8	14.8	
Wheelchair bound, %	5.1	4.3	
Bedridden, %	0.7	1.8	
Prior subinguinal bypass, %	17.5	18.3	0.53

	No Access Site Complication (n=26,112)	Access Site Complication (n=936)	*P* Value
Prior peripheral vascular intervention, %	40.2	36.8	0.038
Prior major or minor lower extremity amputation, %	4.7	3.3	0.16
Prior percutaneous coronary intervention, %	23.0	21.6	0.43
Prior coronary artery bypass graft, %	22.0	20.9	0.58
Preoperative anticoagulants, %			0.86
None, %	16.8	16.6	
Aspirin, %	72.6	72.4	
P2Y12 antagonists, %	7.4	8.1	
Chronic anticoagulation, %	3.1	2.9	

SD indicates standard deviation.

Table 2

Procedural Characteristics

	No Access Site Complication (n=26,112)	Access Site Complication (n=936)	*P* Value
Indication			0.042
Asymptomatic, %	3.4	2.0	
Claudication, %	46.7	51.4	
Rest pain, %	12.4	13.6	
Tissue loss, %	28.1	23.1	
Acute ischemia, %	9.4	10.0	
Urgency			<0.001
Elective, %	83.5	80.3	
Urgent, %	14.6	15.8	
Emergent, %	1.9	4.0	
Type of pathology			0.081
None, %	3.0	2.1	
Occlusive, %	95.2	95.8	
Aneurysmal, %	1.6	2.2	
Both, %	0.2	0.0	
Access guidance			0.09
None, %	27.1	25.6	
Ultrasound, %	33.0	31.1	
Fluoroscopy, %	32.9	36.9	
Cut-down, %	7.0	6.3	
Access site			<0.001
Unilateral femoral artery, %	82.9	74.8	
Bilateral femoral artery, %	14.5	20.0	
Arm, %	1.5	3.7	
Graft, %	0.5	0.6	
Popliteal artery, %	0.3	0.1	
Other, %	0.3	0.8	
Number of arteries treated, mean (range)	1.67 (1 to 6)	1.73 (1 to 6)	0.052
Concomitant CFA endarterectomy, %	7.5	4.9	0.003
Best technical outcome			0.97
Successful, %	95.8	95.8	
Stenosis ≥ 30% or 10-mm gradient, %	1.8	1.7	
Technical failure, %	2.4	2.5	
Pharmacological Thrombolysis	3.8	7.5	<0.001
Largest sheath size			0.003
4 Fr, %	3.6	1.9	
5 Fr, %	16.0	13.2	
6 Fr, %	58.9	56.8	
7 Fr, %	19.3	25.6	

	No Access Site Complication (n=26,112)	Access Site Complication (n=936)	*P* Value
8 Fr, %	2.1	2.5	
Fluoroscopy time			<0.001
< 10 minutes, %	29.3	24.5	
10-30 minutes, %	55.2	54.4	
> 30 minutes, %	15.5	21.1	
Arterial perforation			<0.001
None, %	99.0	97.2	
Iliac artery, %	0.2	1.2	
Femoral or popliteal artery, %	0.5	1.3	
Tibial artery, %	0.2	0.3	
Arterial dissection			<0.001
None, %	94.9	92.1	
Iliac artery, %	1.0	2.3	
Femoral or popliteal artery, %	3.6	5.0	
Tibial artery, %	0.5	0.6	
Postprocedural LOS, mean days ± SD (range)	1.2 ± 1.6 (0-7)	1.9 ± 1.9 (0-7)	0.002

CFA indicates common femoral artery; LOS, length of stay; SD, standard deviation.

Table 3

Procedural Complications by Antithrombotic and Bleeding Avoidance Strategy

	Heparin	Bivalirudin	Heparin + VCD	Bivalirudin + VCD
Access Site Complication, %	4.41	3.23*	2.54*	1.47**
Distal embolization, %	1.87	1.17	1.85	2.83***
Access site occlusion, %	1.22	0.51*	0.99	0.73

VCD indicates vascular closure device.

* Lower rate than in heparin group ($p<0.05$).

** Lower rate of access site complication than all other groups ($p<0.05$).

*** Higher rate than in heparin group ($p<0.05$).

Table 4

Complication Rates by Closure Device use and Antithrombotic Agent

	Closure Device				Antithrombotic Agent			
	No	**Yes**	**OR (95% CI)**	**p**	**Heparin**	**Bivalirudin**	**OR (95% CI)**	**P**
Minor, %	3.15	1.90	1.69(1.44-1.98)	<0.001	2.68	1.78	1.53(1.07-2.17)	0.019
Mod, Transfusion, %	0.45	0.22	2.10(1.34-3.30)	0.001	0.33	0.38	0.89(0.41-1.92)	0.76
Mod, Thrombin, %	0.25	0.12	2.13(1.17-3.89)	0.014	0.21	0.11	1.96(0.48-8.06)	0.35
Severe, Surgery, %	0.47	0.25	1.92(1.25-2.94)	0.003	0.38	0.22	1.77(0.65-4.84)	0.26

Mod indicates moderate ASH. OR, odds ratio