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Closure device use for common femoral artery antegrade access is higher risk than retrograde access

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Abstract

Objective: Although the use of closure devices (CD) for femoral artery antegrade access (AA) is not in the instructions for use (IFU) for many devices, AA has been reported to be associated with a lower incidence of access site complications compared to manual compression alone. We hypothesized that CD use for AA would not be associated with a clinically significant increased odds of access site complications compared to CD use for retrograde access (RA).

Methods: This was a retrospective review of the Vascular Quality Initiative from 2010 to 2019 for infrainguinal peripheral vascular interventions with common femoral artery access closed with a CD. Patients who had a cutdown or multiple access sites were excluded. Cases were then stratified into whether access was antegrade or retrograde. Hierarchical multivariable logistic regressions controlling for hospital level variation were used to examine the independent association between AA and access site complications. The primary outcomes were access site hematoma, stenosis, or occlusion as defined in the VQI. The secondary outcome was the development of an access site hematoma requiring an intervention, which was defined as transfusion, thrombin injection, or surgery. Sensitivity analyses after coarsened exact matching were performed to reduce residual bias.

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AUTHOR CONTRIBUTIONS

The study was designed and implemented by J. L. Ramirez and J. C. Iannuzzi. Statistical analyses were conducted by J. L. Ramirez. The manuscript was written by J. L. Ramirez, E. J. T. Smith, and J. C. Iannuzzi with expert contributions and critical revisions by all of the authors, each of whom has approved the final version.

Conflicts of interest: Dr. Peter Schneider is a consultant for Surmodics, Medtronic, Cardiovascular Systems, Inc., Intact Vascular, Cagent, PQ Bypass, and Boston Scientific. The rest of the authors have no conflicts of interest to report.

NOTE TO THE EDITOR

An abstract of this work was presented at the Vascular and Endovascular Surgery Society 45th Annual Winter Meeting in Sun Valley, ID January 21st – 24th, 2020.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.avsg.2021.03.009.

Results: Overall, 72,463 cases were identified and 6,070 (8.4%) had AA. Patients with AA were less likely to be smokers (27.2% vs 33.0%) or obese (31.5% vs 35.6%; all $P<0.05$). Patients with AA were more likely to be on dialysis (12.8% vs 10.1%) and have ultrasound-guided access (76.4% vs 66.2%; $P<0.05$ for all). Compared to RA, patients with AA were more likely to develop any access site hematoma (2.5% vs 1.8%; $P<0.01$) and a hematoma requiring intervention (0.7% vs 0.5%; $P=0.03$), but had no difference in access site stenosis or occlusion (0.3% vs 0.2%; $P=0.21$). On multivariable analyses, AA had increased odds of developing any access site hematoma (OR = 1.46; 95% CI=1.22–1.76) and a hematoma requiring intervention (OR=1.48; 95% CI=1.10–1.98). Sensitivity analyses after coarsened exact matching confirmed these findings.

Conclusion: In this nationally representative sample, the use of CDs for femoral access was associated with an overall low rate of access site complications. However, there was an increased odds of access site hematomas with AA. Patient selection for AA remains important and ultrasound guided access should be the standard of care for this approach.

INTRODUCTION

Endovascular therapy for infrainguinal arterial disease has become ubiquitous, with retrograde access (RA) of the common femoral artery being the standard approach for lower extremity arterial access.[1] Although RA is the most common approach for treatment of lower extremity arterial disease, antegrade access (AA) may increase versatility in how target lesions are approached. AA is particularly well-suited for infrageniculate disease, heavily calcified or occluded aortoiliac lesions, the presence of bilateral iliac stents, previous aorto-bifemoral bypass, and unfavorable aortoiliac anatomy.[2–4]

Despite its advantages, there are technical considerations and individual patient characteristics that can make AA challenging.[3, 5, 6] Although AA has a reported increased risk of access-related complications, the evidence appears to be mixed.[4, 7] Despite this putative increased risk, the incidence of access-related complications remains low overall and may be reduced with the use of closure devices (CD).[8] Although the use of closure devices for AA is not within the instructions for use (IFU) for most devices, it has been associated with a lower incidence of access site complications compared to manual compression alone.[8] However, there is a paucity of data that has directly compared the incidence of access site complications after CD use in AA versus RA.

Increasing the versatility of approaches to lower extremity interventions requires better characterization of outcomes for CD-assisted access. The objective of this study was to compare access site related outcomes between RA and AA after use of a CD. We hypothesized that CD use for AA would not be associated with an increased odds of access site complications compared to RA.

METHODS

This was a retrospective analysis of data collected prospectively in the Society for Vascular Surgery Vascular Quality Initiative (VQI). This study and these data are presented following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.[9] These data were deidentified and did not include any protected health

information, which does not meet criteria for human research and was considered exempt from institutional review board approval by the University of California, San Francisco Institutional Review Board.

Data source and cohort

Prospectively collected data from the VQI infrainguinal peripheral vascular interventions (PVI) database from 2010 to 2019 was queried and retrospectively analyzed. Analyses using the VQI have been previously published and the database is described in the literature.[10] In brief, the VQI is a national vascular surgery quality improvement database that collects patient-level clinical data on commonly performed vascular surgery operations, including in-hospital, mid-term outcomes, and long-term outcomes. Participating hospitals individually enter their data, which is then made available to all participating institutions after submission and approval of a written data request. All variables utilized in this study had a missingness <10%. Variables with missing data were grouped with the referent group (null) for binary variables to create a conservative estimate for all independent variables,

Patients who underwent an infrainguinal PVI with femoral access sealed with a CD were included (Fig. 1). Patients who had a concurrent lower extremity bypass, only manual compression held, a femoral artery cutdown, upper extremity access, or access site other than the femoral artery were excluded. Patients with multiple access sites (i.e., bilateral femoral or femoral and upper extremity) were excluded as well due to the inability to determine the location of the access site complication. Cases were then stratified into whether access was antegrade or retrograde.

Study outcomes and variables

The primary outcomes were access site complications, including the development of an access site hematoma, access site stenosis, or occlusion as defined in the VQI. The secondary outcome was the development of an access site hematoma requiring an intervention, which was defined as transfusion, thrombin injection, or surgery. Access site stenosis was defined as 50% stenosis by duplex based on peak systolic velocity ratio at the lesion compared to adjacent segment ≥2.4. Occlusion was defined using duplex.

Demographic variables examined included age, sex, white race, preoperative ambulatory status (independent or with assistance), Medicare/Medicaid as primary insurer, obesity (body mass index ≥30 kg/m^2), current smoking status, coronary artery disease (CAD), hypertension, diabetes mellitus, congestive heart failure (CHF), chronic obstructive pulmonary disease, or dialysis, and preoperative medications (angiotensin converting enzyme inhibitor, aspirin, statin, $P2Y_{12}$ inhibitors, and anticoagulant [warfarin, direct thrombin inhibitors, or Factor Xa inhibitors]). Prior operative history included history of coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), carotid endarterectomy (CEA), carotid artery stent (CAS), major amputation (below knee or proximal amputation), inflow stent, angioplasty, or bypass, and infrainguinal stent, angioplasty, or bypass. Procedural details that were examined included elective operation, indication for procedure, right-sided access, ultrasound-guided access, largest sheath utilized, amount of contrast, and heparin reversal with protamine.

There were a total of seven unique CDs registered in this cohort: “Perclose” (Abbott, Santa Clara, California), “Starclose” (Abbott, Santa Clara, California), “Mynx” (Cardinal Health, Dublin, Ohio), “Angioseal” (Terumo, Somerset, New Jersey), “Femoral Introducer Sheath & Hemostasis” (Morris Innovative, Bloomington, Indiana), “ExoSeal Vascular Closure System” (Cordis, Santa Clara, California), “TR Band” (Terumo, Somerset, New Jersey), and “Other”. Consistent with the VQI SVS Device Identification Policy, the identities of the individual CDs were blinded, and therefore no analyses of individual CDs were conducted.

Statistical analysis

All statistical analyses were performed using STATA version 15.1 (StataCorp, College Station, Texas). Cases were stratified into whether access was antegrade or retrograde. Summary statistics were reported using mean and standard deviation for continuous variables, along with frequency and percentage for categorical variables. Between group differences were calculated using a X^2 test for categorical variables and a two-tailed Student’s t-test for continuous variables. Hierarchical multivariable logistic regressions controlling for hospital-level variation were used to examine the independent association between AA and access site complications, as described above. Variables returning $P<0.10$ on bivariate analyses progressed to inclusion in the multivariable models. The models were constructed in a stepwise manual method using a $P<0.05$ for retention in the models.

To reduce imbalance and bias associated with observational data, the two groups (AA and RA) were then matched on age, female sex, weight, smoking status, diabetes, CAD, dialysis, prior infrainguinal bypass, preoperative anticoagulant use, largest sheath size, ultrasound guidance, and elective operation using coarsened exact matching (CEM).[11] These variables were selected *a priori* based on clinical relevance. In brief, CEM organizes variables to discrete values using a binning strategy. Each participant is then assigned a bin signature, which is utilized to match between groups. CEM reduces imbalance, model dependence, estimation error, researcher bias, and variance between groups.[11] This reduction in imbalance is denoted by the L_1 statistic; imbalance decreases as the L_1 statistic declines. Sensitivity analyses then assessed the association between AA and the outcomes of interest after CEM.

RESULTS

Overall, 72,463 cases were identified and 6,070 (8.4%) had AA (Table 1). Patients with AA were less likely to be current smokers (27.2% vs 33.0%), obese (31.5% vs 35.6%), ambulatory (74.7% vs 82.2%), or female (33.2% vs 40.1%; all $P<0.05$). Patients with AA were more likely to be on dialysis (12.8% vs 10.1%) and have had a prior major amputation (14.3% vs 11.1%; $P<0.05$ for all) (Table 2). Patients with AA were more likely to have had ultrasound-guided access (76.4% vs 66.2%; $P<0.05$ for all). There was no significant difference between groups for the use of protamine for heparin reversal (16.0% vs 16.6%) or urgency of operation (83.2% vs 83.8%; $P>0.05$ for all).

The overall incidence of any access site hematoma was 1,354 (1.9%), although only 343 (0.5%) required an intervention (i.e., transfusion, thrombin injection, or surgery). On unadjusted analyses, compared to RA, patients with AA were more likely to develop any

access site hematoma (2.5% vs 1.8%; $P<0.01$) or a hematoma requiring intervention (0.7% vs 0.5%; $P=0.03$) and had no significant difference in access site stenosis or occlusion (0.3% vs 0.2%; $P=0.21$) (Table 3).

On multivariable analyses, AA was independently associated with increased odds of developing any access site hematoma (OR=1.46; 95% CI=1.22–1.76; c-statistic=0.65) and of developing a hematoma requiring intervention (OR=1.48; 95% CI=1.10–1.98; c-statistic=0.70) (Table 4 and 5). Similar to the unadjusted analyses, there was no significant association between AA and access site stenosis or occlusion on multivariable analysis (Table 6).

The groups (AA and RA) were then matched on age, female sex, weight, smoking status, diabetes, CAD, dialysis, prior infrainguinal bypass, preoperative anticoagulant use, largest sheath size, ultrasound guidance, and elective operation using CEM. The pre-match imbalance of $L_1=0.37$ decreased to $L_2=0.02$ after matching, which indicated a decreased imbalance between the groups. After CEM, 59,255 total cases were included. In the matched cohort, 5,668 (9.6%) had AA. (Supplemental Table 1 & 2). Sensitivity analyses after CEM confirmed the previous findings where AA was associated with increased odds of any access site hematoma (OR: 1.43, 95% CI=1.17–1.73; c-statistic=0.66) and access site hematoma requiring intervention (OR: 1.47, 95% CI=1.06–2.05; *c*-statistic=0.72) (Table 7). Similarly, there remained no significant association between AA and access site stenosis or occlusion.

DISCUSSION

In this analysis of a nationally representative vascular surgery quality improvement database, the use of CDs for femoral access resulted in an overall low incidence of access site hematoma and stenosis or occlusion. However, the use of a CD for AA was associated with a 0.7% increased absolute risk of access site hematoma and a nearly 50% increased odds of any access site hematoma and hematoma requiring intervention on multivariable analysis when compared to RA. Although the overall incidence of access site stenosis or occlusion after CD use was low (0.2%), there was no significant association with access orientation. These results collectively suggest that CDs may be safely used for femoral RA and AA, although there is generally a higher risk of access site hematoma when used in AA, which should be considered by the operator during preoperative planning.

Patients in this study who had AA were less likely to be obese, which may be due to the technical challenges of obtaining AA in obese patients. Obesity has previously been reported as a risk factor for unsuccessful CD deployment when used in AA, potentially explaining the increased risk of access site hematoma.[12] Patients who had AA were also 10% more likely to have had ultrasound-guided access, which has been reported to be associated with a reduced risk of access site complications in AA and RA access.[13] However, this protective effect may only be true for surgeons who regularly use ultrasound.[14] The lower rate of obesity and higher rate of the use of ultrasound-guided access in patients undergoing AA would suggest that patients selected for AA in this study may be less likely to develop an access site hematoma. However, ultrasound-guided access was notably an independent predictor of decreased odds of access site stenosis or occlusion (OR: 0.68, 95%

CI=0.49–0.95), further confirming the utility of ultrasound when attempting femoral access, regardless of access orientation.

AA for peripheral vascular interventions is an important tool for vascular surgeons. It provides the surgeon with versatility and is particularly useful to treat infrageniculate disease, which may be challenging to treat from RA of the contralateral femoral artery. AA also has an essential role in treating patients with a challenging aortic bifurcation or iliac anatomy (i.e., previous open or endovascular intervention, occlusion, heavy calcification, tortuous aortoiliac anatomy). The use of AA for treatment of lower extremity arterial disease has been reported to have comparable outcomes to RA. In a prospective study of 556 patients undergoing femoropopliteal angioplasty, Cragg *et al.* reported that compared to femoral RA, AA was not significantly associated with a higher rate of access site complications (AA: 3.7% vs RA: 1.1%; P=0.186).[15] The same study reported fewer access site complications in patients treated with CDs, although this was not statistically significant. However, access site complications were broadly defined in the analysis, there was no sub-analysis of more severe access site complications (i.e. requiring thrombin injection or surgical intervention), and there was no multivariable analysis to reduce potential confounding. In an analysis of the VQI, Siracuse *et al.* also reported no difference in access site complications, including hematoma, between femoral RA and AA, although this study did not report on the use of CDs.[7]

There is a paucity of data on how the use of CD in AA compares to CD in RA and conclusions on comparative efficacy are largely based on juxtaposing studies that have examined CD use in RA *or* AA access. Although the use of CDs for AA is considered off-IFU for many devices, there are several reports of their use. A recently published single center, retrospective, case-control study by Barrette *et al.* compared the use of CDs in 401 limbs with RA and 107 limbs with AA.[16] In contrast to the current study, they reported no difference in the incidence of minor access site hematoma (2.0% vs 2.8%, P=0.61). Notably, these reported rates of minor access site hematoma are similar to the rates reported in the current study and their results may represent a type II error. A meta-analysis comparing CD use for antegrade common femoral artery (CFA) and superficial femoral artery (SFA) access by Kennedy *et al.* examined 24 studies that included a total of 4,124 cases using six unique CDs.[17] They reported acceptable rates of access site hematomas for both CFA (3.6%) and SFA (3.6%) AA without any statistically significant difference. A recent analysis of national data from the VQI reported that the use of a CD for AA was associated with decreased odds of developing any access site hematoma (OR: 0.75, 95% CI=0.59–0.95) and a hematoma requiring intervention (OR: 0.56, 95% CI=0.38–0.81) compared to manual compression alone.[8] Notably, access-site complications are generally rare, and many analyses of CD outcomes are likely underpowered to identify differences between individual CDs or are limited by the VQI SVS Device Identification Policy, which requires that the identities of the individual CDs are blinded.

The use of CDs have many reported benefits that were not measured in the current study, including improved patient satisfaction and comfort and reduced time-to-hemostasis and ambulation.[18–20] The data reported in this study suggests that access-site complications after CD use for antegrade or retrograde CFA access are uncommon. Certain patient

characteristics, such as female sex, current dialysis, and the use of a $P2Y_{12}$ inhibitor, were all associated with an increased odds of an access site hematoma requiring intervention. In contrast, elective operation was associated with a decreased odds of an access site hematoma requiring intervention, which may reflect the amount of time or effort that was spent gaining access. Although the incidence of access site hematoma was slightly higher after CD use for AA, the absolute difference compared to RA was small and may not be clinically significant. It is important to consider these differences with patient selection and operative planning, but regardless it may be reasonable to regularly utilize CDs for RA and AA. There are no studies to date describing the learning curve for AA and CD use in AA. Nuances about performing AA and choosing a CD could lead to a volume-outcome relationship with a substantial learning curve, although this is beyond the scope of the current analysis. Future study should evaluate whether a learning curve for CD use in AA exists.

LIMITATIONS

This was a retrospective review of a large prospectively maintained database and has limitations. Although the VQI collects data on the development of access site arteriovenous fistula (AVF) and pseudoaneurysms, these variables were poorly reported with a missing rate of more than 60% and were not included in this analysis. We therefore cannot comment on the association between CD use and the development of access site AVF or pseudoaneurysms. Similarly, the VQI collects data on failed CD deployment attempts starting in 2015 but this variable was poorly reported (<50%) and was not included in this study. Therefore, we cannot accurately determine the rate of CD deployment failure, which may affect perioperative risks of utilizing CDs and incidence of postoperative hematoma. In order to address this limitation in the future, the VQI should consider including a variable defining why a cutdown was done (i.e. as a primary exposure or as a salvage maneuver).

Due to the VQI device identification policy, the specific CDs were unable to be determined and sub-analyses of individual CDs was not performed. It is possible that certain CDs, or that certain forms of CDs (i.e. suture mediated or collagen mediated), may have variable efficacy. Although, due to the low incidence of access site complications, even if CD identities were known there may be insufficient power to detect differences by device type. Further study of these individual devices will be required prior to making formal recommendations about CD use. Access site stenosis or occlusion may be underreported in this study since it may not present acutely or be initially symptomatic and would therefore not be recorded in the VQI. There is also no requirement in the VQI for a completion ultrasound or surveillance imaging to evaluate for access site stenosis or occlusion. Since the VQI does not collect long-term follow-up data on access site complications, all of the data presented in this study represents peri-procedural outcomes and conclusions cannot be made regarding the long-term impact of CDs.

CONCLUSION

In this nationally representative sample, the use of CDs for RA and AA femoral access resulted in an overall low incidence of access site hematoma and stenosis or occlusion. However, compared to RA, CD use for AA was associated with a higher odds of access site

hematoma requiring intervention. Patient selection for AA remains important and ultrasound guided access should be the standard of care for this approach.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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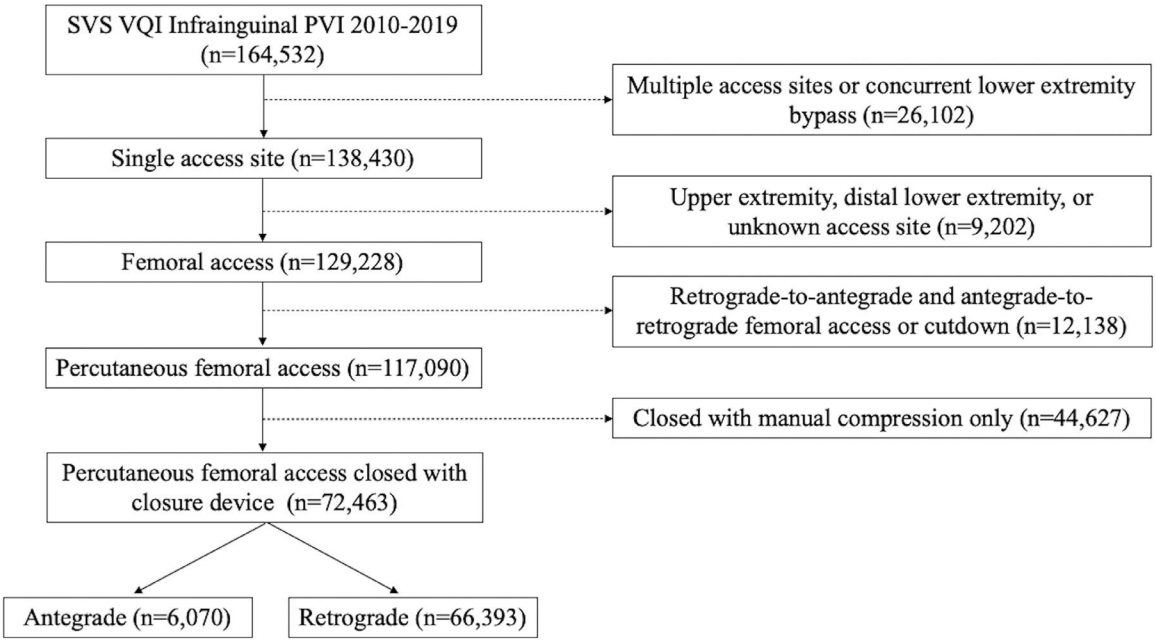

Fig. 1.

Cohort inclusion criteria. SVS = Society for Vascular Surgery; VQI = Vascular Quality Initiative.

Table 1.

Baseline characteristics

Characteristics	Retrograde (*n*=66,393)	Antegrade (*n*=6,070)	*P* Value*
Demographics			
Age (years)			**<0.001**
<60	15,530 (23.4%)	1,275 (21.0%)	**<0.001**
60–69	20,760 (31.3%)	1,657 (27.3%)	
70–79	18,011 (27.1%)	1,746 (28.8%)	
≥80	12,102 (18.2%)	1,392 (22.9%)	
Female Sex	26,641 (40.1%)	2,012 (33.2%)	**<0.001**
White	50,032 (75.4%)	4,541 (74.8%)	0.343
Ambulatory	54,563 (82.2%)	4,537 (74.7%)	**<0.001**
Medicare/Medicaid	38,808 (58.5%)	3,801 (62.6%)	**<0.001**
Comorbidities			
Obese	23,639 (35.6%)	1,910 (31.5%)	**<0.001**
Current Smoker	21,903 (33.0%)	1,651 (27.2%)	**<0.001**
Coronary Artery Disease	20,830 (31.4%)	1,810 (29.8%)	**0.012**
Prior CABG or PCI	22,332 (33.6%)	1,982 (32.7%)	0.122
Prior CEA or CAS	2,104 (3.2%)	190 (3.1%)	0.909
Hypertension	58,484 (88.1%)	5,289 (87.1%)	**0.030**
Diabetes	37,179 (56.0%)	3,460 (57.0%)	0.134
Congestive Heart Failure	13,046 (19.7%)	1,271 (20.9%)	**0.017**
COPD	15,506 (23.4%)	1,342 (22.1%)	**0.028**
Dialysis	6,721 (10.1%)	776 (12.8%)	**<0.001**
Preoperative Medications			
ACE Inhibitor	32,464 (48.9%)	2,763 (45.5%)	**<0.001**
Aspirin	46,892 (70.8%)	4,171 (68.7%)	**0.001**
Anticoagulant	860 (1.3%)	105 (1.7%)	**0.006**
$P2Y_{12}$ Inhibitor	27,988 (42.2%)	2,571 (42.4%)	0.765
Statin	45,798 (69.0%)	4,056 (66.8%)	**0.001**

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Values as n (%). ACE = angiotensin converting enzyme; CABG = coronary artery bypass graft; CAS = carotid artery stent; CEA = carotid endarterectomy, COPD = chronic obstructive pulmonary disease; PCI = percutaneous coronary intervention.

* Calculated using a X^2 test for categorical variables and a Student's t-test for continuous variables.

Table 2.

Procedural details

Characteristics	Retrograde (*n*=66,393)	Antegrade (*n*=6,070)	*P* Value*
Operative History			
Prior Major Amputation	7,361 (11.1%)	870 (14.3%)	<**0.001**
Prior Inflow Stent or Angioplasty			<**0.001**
None	57,800 (87.1%)	5,242 (86.4%)	
Ipsilateral	3,036 (4.6%)	258 (4.3%)	
Contralateral	2,410 (3.6%)	208 (3.4%)	
Bilateral	3,147 (4.7%)	362 (6.0%)	
Prior Inflow Bypass			<**0.001**
None	65,009 (97.9%)	5,781 (95.2%)	
Ipsilateral	537 (0.8%)	84 (1.4%)	
Contralateral	387 (0.6%)	62 (1.0%	
Bilateral	460 (0.7%)	143 (2.4%)	
Prior Infrainguinal Stent or Angioplasty			<**0.001**
None	41,772 (62.9%)	3,760 (62.0%)	
Ipsilateral	10,364 (15.6%)	1,090 (18.0%)	
Contralateral	7,554 (11.4%)	670 (11.0%)	
Bilateral	6,703 (10.1%)	550 (9.1%)	
Prior Infrainguinal Bypass			<**0.001**
None	59,988 (90.4%)	5,429 (89.4%)	
Ipsilateral	2,945 (4.4%)	247 (4.1%)	
Contralateral	2,484 (3.7%)	297 (4.9%)	
Bilateral	976 (1.5%)	97 (1.6%)	
Procedural Details			
Elective	55,614 (83.8%)	5,049 (83.2%)	0.238
Indication			<**0.001**
Occlusive Disease	64,073 (96.5%)	5,495 (90.5%)	
Aneurysm	536 (0.8%)	238 (3.9%)	
Occlusive or Aneurysm	81 (0.1%)	38 (0.6%)	

Characteristics	Retrograde (*n*=66,393)	Antegrade (*n*=6,070)	*P* Value*
None/Unknown	1,703 (2.6%)	299 (4.9%)	
Right-sided Access	34,532 (52.0%)	3,308 (54.5%)	**<0.001**
Ultrasound Guidance	43,916 (66.2%)	4,635 (76.4%)	**<0.001**
Largest Sheath Size (French)	6.0 ± 0.7	6.0 ± 1.0	**<0.001**
Contrast (ml)	90.8 ± 57.6	76.8 ± 51.7	**<0.001**
Protamine	10,992 (16.6%)	974 (16.0%)	0.312

Values as mean ± standard deviation or n (%).

* Calculated using a X^2 test for categorical variables and a Student's t-test for continuous variables.

Table 3.

Access site complications

	Retrograde (*n*=66,393)	Antegrade (*n*=6,070)	*P* Value*
Access Site Complications			
Hematoma			**0.002**
No	65,192 (98.2%)	5,917 (97.5%)	
Minor	898 (1.4%)	113 (1.9%)	
Transfusion	140 (0.2%)	21 (0.4%)	
Thrombin Injection	52 (0.1%)	4 (0.1%)	
Operative Treatment	111 (0.2%)	15 (0.3%)	
Any Hematoma	1,201 (1.8%)	153 (2.5%)	**<0.001**
Hematoma Requiring Intervention	303 (0.5%)	40 (0.7%)	**0.032**
Access Site Stenosis or Occlusion	150 (0.2%)	19 (0.3%)	0.208

Values as n (%).

*Calculated using a X^2 test.

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Table 4.

Multivariable analysis of any access site hematoma

Covariates	OR	95% CI	*P* Value
Antegrade Access	**1.46**	**1.22–1.75**	**<0.001**
Age (years): Ref <60			
60–69	1.06	0.88–1.29	0.534
70–79	1.54	1.29–1.84	**<0.001**
>80	1.68	1.39–2.03	**<0.001**
Female Sex	1.67	1.50–1.87	**<0.001**
Protamine	1.50	1.25–1.81	**<0.001**
White	1.37	1.15–1.64	**0.001**
Prior Infrainguinal Bypass: Ref None			
Ipsilateral	1.36	1.07–1.72	**0.011**
Contralateral	1.20	0.89–1.62	0.235
Bilateral	1.53	1.07–2.18	**0.019**
Prior Inflow Stent or Angioplasty: Ref None			
Ipsilateral	0.92	0.76–1.12	0.419
Contralateral	1.15	0.97–1.37	0.107
Bilateral	0.66	0.50–0.87	**0.003**
Largest Sheath Size	1.07	1.01–1.15	**0.025**
Contrast	1.002	1.001–1.003	**0.004**
Right-sided Access	0.87	0.79–0.97	**0.009**
Coronary Artery Disease	0.85	0.74–0.99	**0.033**
Diabetes	0.71	0.63–0.79	**<0.001**
Elective	0.67	0.58–0.78	**<0.001**

CI = confidence interval; OR = odds ratio.

Table 5.

Multivariable analysis of access site hematoma requiring intervention

Covariates	OR	95% CI	*P* Value
Antegrade Access	**1.48**	**1.10–1.98**	**0.009**
Female Sex	2.28	1.84–2.84	**<0.001**
Prior Infrainguinal Bypass: Ref None			
Ipsilateral	2.25	1.54–3.31	**<0.001**
Contralateral	1.18	0.59–2.36	0.636
Bilateral	1.91	0.98–3.70	0.056
Dialysis	1.64	1.16–2.32	**0.006**
Age (years): Ref <60			
60–69	0.84	0.58–1.21	0.351
70–79	1.42	1.01–1.99	**0.044**
>80	1.48	1.00–2.19	**0.052**
Congestive Heart Failure	1.44	1.11–1.87	**0.006**
White	1.36	1.02–1.81	**0.034**
$P2Y_{12}$ Inhibitor	1.32	1.06–1.64	**0.012**
Right-sided access	0.81	0.67–0.99	**0.044**
Coronary Artery Disease	0.71	0.56–0.90	**0.004**
Diabetes	0.66	0.52–0.84	**0.001**
Elective	0.55	0.42–0.72	**<0.001**

CI = confidence interval; OR = odds ratio.

Table 6.

Multivariable analysis of access site stenosis or occlusion

Covariates	OR	95% CI	*P* Value
Antegrade Access	**1.47**	**0.94–2.31**	0.092
Prior Infrainguinal Bypass: Ref None			
Ipsilateral	1.48	0.79–2.76	0.222
Contralateral	0.52	0.16–1.63	0.261
Bilateral	3.80	1.95–7.41	**<0.001**
Female Sex	1.70	1.22–2.37	**0.002**
Protamine	1.52	1.03–2.23	**0.033**
Prior Inflow Stent or Angioplasty: Ref None			
Ipsilateral	1.30	0.87–1.94	0.203
Contralateral	0.50	0.27–0.91	**0.024**
Bilateral	0.75	0.43–1.32	0.320
Obese	0.70	0.51–0.97	**0.034**
Ultrasound Guidance	0.68	0.49–0.95	**0.022**
Elective	0.48	0.34–0.68	**<0.001**

CI = confidence interval; OR = odds ratio.

Table 7.

Multivariable analysis of access complications after antegrade access with matched data [*]

Complication	OR	95% CI	*P* Value
Any Hematoma [†]	1.43	1.17–1.73	<**0.001**
Hematoma Requiring Intervention [‡]	1.47	1.06–2.05	**0.022**
Stenosis or Occlusion [§]	1.58	0.95–2.61	0.076

[*] Matched on age, female sex, weight, smoking status, diabetes, coronary artery disease, dialysis, prior infrainguinal bypass, preoperative anticoagulant use, largest sheath size, ultrasound guidance, and elective operation.

[†] Adjusted for age, female sex, white race, coronary artery disease, diabetes, prior infrainguinal bypass, prior inflow stent or angioplasty, protamine reversal, largest sheath size, contrast, right-sided access, and elective operation.

[‡] Adjusted for age, female sex, white race, dialysis, congestive heart failure, coronary artery disease, diabetes, preoperative P2Y12 inhibitor use, prior infrainguinal bypass, right-sided access, and elective operation.

[§] Adjusted for female sex, obese, prior infrainguinal bypass, prior inflow stent or angioplasty, protamine reversal, ultrasound guidance, and elective operation.

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