ORIGINAL ARTICLE

Complication Rates for Percutaneous Lower Extremity Arterial Antegrade Access

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Hypothesis: The antegrade access (AA) for percutaneous arterial interventions is associated with a higher complication rate than is the retrograde access (RA).

Design: Retrospective case review.

Setting: A statewide consortium for peripheral vascular interventions consisting of 13 Michigan hospitals collecting data on their endovascular procedures.

Patients: Demographic and procedure data on all patients receiving a percutaneous peripheral arterial intervention were entered prospectively by a full-time clinical nurse specialist in each hospital site.

Main Outcome Measures: We evaluated vascular complications as a composite of retroperitoneal hematoma, pseudoaneurysm, hematoma requiring blood transfusion, arteriovenous fistula, acute thrombosis, or the need for surgical repair of the access site.

Results: In a 2-year period, we collected 6343 cases, of which 5918 had complete data regarding arterial access; of these, 745 (12.6%) were performed via an AA. There were fewer women and smokers ($P<.001$) in the AA group but more diabetic patients ($P<.001$). The indications for intervention were more frequently rest pain ($P<.001$) and limb salvage ($P<.001$) in the AA group. Multivariate regression analysis showed that the odds of complications were significantly higher with a larger sheath (95% confidence interval, 1.53-4.06; $P<.001$). Also, the incidence of blood transfusion and subsequent amputation was significantly higher in the AA group ($P<.001$).

Conclusion: Endovascular procedures performed via an AA are more likely to result in perioperative complications and therefore should be used cautiously.

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PERCUTANEOUS VASCULAR INTERventions (PVIs) to treat patients with peripheral arterial disease are on the rise. From 1976 to 1996, there was a 7-fold increase in the number of PVIs.[1] In a recent review, the number of PVIs increased by 40% from 1996 to 2003.[1] National in-patient samples have shown that, despite a relatively stable number of patients treated for peripheral arterial disease, the proportion of patients receiving a leg bypass is decreasing while the rate of PVI is increasing.[2] The Bypass vs Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial demonstrated that the adoption of an "endovascular first" approach is reasonable for patients with peripheral arterial disease. The trial found that the endovascular and surgical approaches were equally effective, although the surgical approach was more costly.[3]

In addition to the burden of atherosclerotic disease, the complexity of the procedure being performed influences the complication rate after percutaneous endovascular interventions. In general, the likelihood of a complication is low with simple diagnostic angiography and increases with more complex PVI. Complications at the access site include bleeding, blood transfusion requirement, dissection, thrombosis, distal embolization, pseudoaneurysm formation, and infection. Systemic complications include myocardial ischemia, contrast-induced nephropathy, contrast allergy, and stroke. The purpose of this study was to report the incidence and type of complications associated with the antegrade access (AA) in patients subjected to a PVI.

METHODS

Details of the construct, data collection, and data quality assurance for the University of Michigan Peripheral Vascular Disease Quality Improvement Initiative, now known as the Blue Cross Blue Shield of Michigan Cardiovascular Consortium Peripheral Vascular Intervention Quality Improvement Initiative (BMC2 PVI), have been described previously.[4] In brief, the BMC2 PVI registry is a prospective multicenter registry of patients undergoing PVI as part of a regional collaborative effort to assess and improve quality of care and outcomes and overcome the barriers of traditional market and academic competition. The registry collects data on patients undergoing arterial PVI for claudication, critical limb ischemia, or uncontrolled

Table 1. Baseline Clinical Characteristics[a]

Characteristic	Patient Group AA (n=745)	Patient Group RA (n=5173)	*P* Value
Age, mean (SD), y	69.89 (11.49)	68.22 (11.52)	<.001
Female sex	271 (36.4)	2330 (45.0)	<.001
Current smoker	165 (22.1)	1644 (31.8)	<.001
Obese[b]	253 (34.0)	1792 (34.6)	.70
CAD	524 (70.3)	3510 (67.9)	.20
Diabetes mellitus	387 (51.9)	2296 (44.4)	<.001
Hyperlipidemia	674 (90.5)	4750 (91.8)	.20
CHF	634 (85.1)	4427 (85.6)	.70
COPD	169 (22.7)	1044 (20.2)	.10
CVD/TIA	243 (32.6)	1605 (31.0)	.30

Abbreviations: AA, antegrade access; CAD, coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; RA, retrograde access; TIA, transient ischemic attack.

[a] Unless otherwise indicated, data are expressed as number (percentage) of patients.

[b] Indicates body mass index (calculated as weight in kilograms divided by height in meters squared) greater than 30.

hypertension at 13 participating Michigan hospitals. Endovascular carotid interventions and aortic endografts are not included in the registry because clinical variables for follow-up significantly differ in these patients. A data form is compiled for each procedure. Data quality and the inclusion of consecutive procedures are ensured by ad hoc queries, random medical record review, and a series of diagnostic routines included in the database. The data form consists of demographic, clinical, and procedural variables; baseline and adjunctive pharmacotherapies; and in-hospital outcome data. A list of standard definitions using the American College of Cardiology Task Force on Clinical Data Standards has been used as a reference.[5]

All data undergo a 3-step validation process, including manual review for completeness and face validity, review of rejected data forms during the import process, and review of forms that fail diagnostic inquiries. In addition, a random sample of data forms is checked for face validity. All sites are audited twice yearly by a full-time nurse investigator from the coordinating center. In addition to auditing cases in which an adverse event was recorded, a random 5% sample of cases is audited for accuracy. The variables on the original data form are compared with each patient's hospital medical record, and all hard outcomes (death, myocardial infarction, stroke, amputation, and transfusion) are audited for accuracy.

The study cohort consisted of 6343 patients undergoing PVI from January 1, 2007, through December 31, 2008. Patients underwent PVI via a retrograde access (RA) or an AA. Information on access type was not available in 425 cases, leaving 5918 patients available for this analysis.

Vascular complications were defined as a composite of retroperitoneal hematoma, pseudoaneurysm, hematoma requiring transfusion or associated with a decrease in hemoglobin level of at least 3 g/dL (to convert to grams per liter, multiply by 10), arteriovenous fistula demonstrated by arteriography or ultrasonography, acute thrombosis, or the need for surgical repair of the access site.

Vascular complications were counted on a per-patient basis, and many patients met the definition for vascular access complication according to more than 1 criterion. Most of the procedures were performed percutaneously, and cutdown procedures were rare (<1% of cases). The procedures were performed, in order of frequency, by interventional cardiologists, radiologists, and vascular surgeons; however, the specialty of the operator was not routinely recorded in the database.

Table 2. Presenting Symptoms and Indications

Clinical Indication	Patient Group, No. (%) AA (n=745)	Patient Group, No. (%) RA (n=5173)	*P* Value
Asymptomatic	12 (1.6)	143 (2.8)	.06
Claudication	568 (76.2)	3918 (75.7)	.30
Rest pain	320 (43.0)	1348 (26.1)	<.001
Limb salvage	180 (24.2)	676 (13.1)	<.001
Hybrid vascular surgery	43 (5.8)	155 (3.0)	<.001

Abbreviations: AA, antegrade access; RA, retrograde access.

Statistical analysis was performed using SAS statistical software, version 8.2 (SAS Institute, Inc, Cary, North Carolina). Descriptive statistics were used to report baseline patient characteristics. All tests used $P < .05$ as the critical value of statistical significance. We used the χ^2 test and Fisher exact test to analyze categorical variables and to evaluate the event rates within access groups. Continuous variables were analyzed using the paired *t* test and Wilcoxon rank sum test as needed. Multivariate logistic regression models were used to investigate independent predictors of vascular access site complications.

RESULTS

The demographic characteristics of the 5918 patients enrolled into our study are provided in **Table 1**. There were fewer women ($P < .001$) and fewer smokers ($P < .001$) in the AA group. There were significantly more patients with diabetes mellitus in the AA group ($P < .001$). There were no other differences between groups in terms of common cardiovascular comorbidities. A total of 5173 patients (87.4%) underwent assessment via the RA and 745 (12.6%), via the AA.

The most common indication for intervention in both groups was severe lower extremity claudication (**Table 2**). More patients presented with ischemic rest pain or limb salvage in the AA group ($P < .001$). The site of intervention (**Table 3**) in the AA group was the femoropopliteal segment in 569 patients (76.4%) and below the knee in 305 patients (40.9%). In the RA group, the above-knee femoropopliteal segment was treated in 53.8% of the patients; a segment below the knee was treated in 17.3% of patients. Procedures involving the infrainguinal arterial segments were more common in the AA group. These differences were statistically significant ($P < .001$).

The median procedure time in the AA group was 80 minutes; in the RA group, 75 minutes. Although the median procedure time was not statistically different, the number of cases exceeding the median procedure time was significantly higher in the AA group (54.0%) compared with the RA group (49.8%) ($P = .03$).

Data regarding the type of intervention performed is presented in **Table 4**. There was no difference in the distribution of sheath sizes used between the 2 groups. Manual pressure for access site hemostasis was used equally in the 2 groups. Only the Perclose vascular closure device (Perclose, Inc, Menlo Park, California) was used more frequently in the AA group (13.2% vs 7.2%). The AngioSeal (St Jude Medical, Inc, St Paul, Minnesota) and VasoSeal (Datascope Corp, Mahwah, New Jer-

Table 3. Anatomic Site of Percutaneous Interventions

Location	Patient Group, No. (%) AA (n=745)	RA (n=5173)	*P* Value
Iliac	0	1755 (33.9)	<.001
Femoropopliteal segment	569 (76.4)	2781 (53.8)	<.001
Below the knee	305 (40.9)	897 (17.3)	<.001

Abbreviations: AA, antegrade access; RA, retrograde access.

Table 4. Types of Percutaneous Interventions

Device Used	Patient Group, No. (%) AA (n=745)	RA (n=5173)	*P* Value
Angioplasty only	580 (77.9)	4181 (80.8)	.06
Stent	266 (35.7)	2892 (55.9)	<.001
IVUS	11 (1.5)	166 (3.2)	.009
Lysis	17 (2.3)	56 (1.1)	.006
Laser	81 (10.9)	505 (9.8)	.34
Cryoballoon	28 (3.8)	165 (3.2)	.40

Abbreviations: AA, antegrade access; IVUS, intravascular ultrasonography; RA, retrograde access.

sey) devices were included in the analysis, and neither group favored one more than the other.

The periprocedural complications are listed in **Table 5**. The incidence of vascular access complications, transfusions, and subsequent amputation were significantly higher in the AA group. Multivariate predictors of vascular access site complications (**Table 6**) included female sex, being older than 70 years, larger sheath sizes, and AA.

COMMENT

This was an observational study reporting the complication rates associated with PVI in a consortium of hospitals in a single state. To our knowledge, this is the first study to directly compare complication rates between the antegrade and the retrograde femoral approaches. This large, multicenter, multispecialty registry was developed as part of a statewide quality improvement initiative aiming to ameliorate the processes of care in patients with peripheral vascular disease.

The database for this study is prospective, all inclusive, but nonrandomized. The procedures were performed by interventional radiologists, cardiologists, and vascular surgeons. The complication rates among the different specialties were not part of this analysis. However, the purpose of this study was to test the hypothesis that the AA, a technically more challenging approach, is associated with a higher rate of complications when compared with the more common RA. The data were collected prospectively and inclusive. Data collection was performed by certified clinical nurse reviewers who were specifically trained for the task. Unbiased observers performed the statistical analysis (K.M.). Therefore, these data represent contemporary results in a broad representative sample.

Table 5. Periprocedural Complications

Complication	Patient Group, No. (%) AA (n=745)	RA (n=5173)	*P* Value
Death	4 (0.5)	38 (0.7)	.50
Myocardial infarction	6 (0.8)	32 (0.6)	.50
TIA/stroke	2 (0.3)	13 (0.3)	.90
Transfusion	86 (11.5)	292 (5.6)	<.001
Vascular access	44 (5.9)	165 (3.2)	<.001
Amputation	40 (5.4)	71 (1.4)	<.001
ARF requiring HD	3 (0.4)	15 (0.3)	.60

Abbreviations: AA, antegrade access; ARF, acute renal failure; HD, hemodialysis; RA, retrograde access; TIA, transient ischemic attack.

Table 6. Multivariate Regression Analysis for Determining Predictors for Vascular Access Complications

Characteristic	OR (95% CI)	*P* Value
Female sex	2.10 (1.57-2.93)	<.001
Age >70 y	1.50 (1.08-2.01)	.01
Hypertension	1.50 (0.70-3.00)	.20
CAD	0.89 (0.50-1.30)	.50
Hyperlipidemia	0.90 (0.58-1.40)	.60
Diabetes mellitus	1.10 (0.80-1.50)	.40
Prior aspirin use	1.15 (0.76-1.74)	.40
Prior clopidogrel bisulfate use	1.27 (0.90-1.74)	.10
Sheath		
5F	1.70 (0.99-3.03)	.051
6F	1.60 (1.00-2.60)	.047
7F	2.49 (1.53-4.06)	<.001
8F	3.70 (2.09-6.54)	<.001
9F	7.70 (1.60-37.10)	.01
10F	10.40 (1.09-100.30)	.04
Closure device		
Perclose[a]	0.90 (0.50-1.60)	.80
AngioSeal[b]	0.60 (0.30-1.10)	.10
Antegrade access	1.80 (1.20-2.60)	.001

Abbreviations: CAD, coronary artery disease; CI, confidence interval; OR, odds ratio.
[a] Available from Perclose, Inc, Menlo Park, California.
[b] Available from Datascope Corp, Mahwah, New Jersey.

Of the 6343 patients who underwent percutaneous arterial interventions during the study period, 5918 had complete data related to arterial access and were included in the final analysis. The coordinating centers strive to collect missing and incomplete variables by periodic queries.

Previous reviews have documented that the complication rates after PVI vary according to many factors, including sheath size, anticoagulation, severity of underlying disease, and use of thrombolytics.[4] Brachial and axillary access is also associated with a higher rate of complications compared with femoral access.[6] This study is the first large series comparing the rate of complications after antegrade and retrograde femoral access.

In our present study, there were more patients in the AA group with critical limb ischemia including rest pain as well as those requiring limb salvage operations. As expected, there were more patients who had below-the-knee disease in the AA group, and the AA may be more feasible for below-the-knee intervention. Many of the am-

putations in this registry were planned before the PVI; the PVI is often performed before amputation in an attempt to limit the extent of the amputation or improve healing after the amputation. These data suggest that the AA group had more severe and/or advanced symptomatic arterial disease.

Danetz et al[7] reported the following complication rates after aortoiliac and femoropopliteal angioplasty in the literature: bleeding, 3.4%; embolization, 2.3%; stroke, 0.55%; false aneurysm, 0.5%; renal failure and myocardial infarction, 0.2% each; and arteriovenous fistula, 0.1%. Emergency surgical exploration was required in 2.0% of cases and amputation, in 0.2%; death occurred in 0.2%. In that registry, the mortality rate and stroke rates were similar. The greater rate of blood transfusion and subsequent amputation and the higher rate of local access site complications indicate that caution should be exercised when considering AA.

In many cases, RA may not be possible for anatomic or technical reasons, such as vessel occlusion or calcification. In diabetic patients who present predominately with infrapopliteal occlusive disease, reaching the target may not be possible from a contralateral approach, leaving the AA as the only option. Furthermore, in some cases, catheter and wire manipulation is more easily accomplished using the AA.

Perhaps not surprisingly, our multivariate regression analysis revealed that more local access complications were observed with larger-diameter sheaths. The decision to use a larger sheath is driven mainly by the choice of treatment modality. As lower-profile devices are developed, the requisite sheath size will decrease. We did not see any difference among the percutaneous closure devices. We evaluated only closure devices currently approved for use with AA.

In conclusion, we found that the AA is associated with a higher rate of local access site complications and increased transfusions and subsequent amputations. There was no difference between AA and RA in terms of overall mortality, myocardial infarction, or stroke. Access site complications were independently associated with female sex, being older than 70 years, and larger-diameter sheaths. As a broader armamentarium of peripheral vascular devices becomes available, the need for routine AA may diminish. This information will be helpful when deciding how best to provide percutaneous access for lower extremity interventions.

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