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Impact of Sex on Morbidity and Mortality Rates After Lower Extremity Interventions for Peripheral Arterial Disease

Observations From the Blue Cross Blue Shield of Michigan Cardiovascular Consortium

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Objectives This study sought to examine sex-related differences in outcomes related to peripheral vascular intervention (PVI) procedures.

Background Percutaneous PVI is frequently performed for the treatment of peripheral arterial disease (PAD). However, little is known about sex-related differences related to PVI procedures.

Methods We assessed the impact of sex among 12,379 patients (41% female) who underwent lower extremity (LE)-PVI from 2004 to 2009 at 16 hospitals participating in the Blue Cross Blue Shield of Michigan Cardiovascular Consortium PVI registry. Multivariate propensity-matched analyses were performed to adjust for differences in baseline characteristics, procedural indications, and comorbidities on the basis of sex.

Results Compared with men, women were older and have multilevel disease and critical limb ischemia. In a propensity-matched analysis, female sex was associated with a higher rate of vascular complications, transfusions, and embolism. No differences were observed for in-hospital death, myocardial infarction, or stroke or transient ischemic attack. Technical success was more commonly achieved in women (91.2% vs. 89.1%, $p = 0.014$), but because of a higher complication rate, the overall procedural success rates were similar in men and women (79.7% vs. 81.6%, $p = 0.08$).

Conclusions Women represent a significant proportion of patients undergoing LE-PVI, have a more severe and complex disease process, and are at increased risk for adverse outcomes. Despite higher complications rates, women had similar procedural success compared with men, making PVI an effective treatment strategy among women with LE-PAD.
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Approximately 8 million Americans carry a diagnosis of peripheral arterial disease (PAD) (1–3). Among women undergoing percutaneous coronary interventions (PCIs), several studies have observed higher adjusted complication rates including bleeding and vascular access site complications (4–7). These sex-related differences are potentially related to older age, smaller vessel size, an increased number of comorbidities, or differences in disease severity (8–10). To date, data on sex-related differences for outcomes related to PAD interventions are limited. The Blue Cross Blue

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Abbreviations and Acronyms

ACE = angiotensin-converting enzyme
CLI = critical limb ischemia
LE = lower extremity
MI = myocardial infarction
PAD = peripheral arterial disease
PCI = percutaneous coronary intervention
PVI = peripheral vascular intervention
TIA = transient ischemic attack

Shield of Michigan Cardiovascular Consortium Peripheral Vascular Intervention (BMC2 PVI) registry is a statewide, multihospital, physician-coordinated, quality-improvement initiative focused on all patients undergoing percutaneous peripheral vascular interventions (PVIs). Data from this real-life cohort of patients were utilized to evaluate procedural outcomes by sex.

Methods

The study population consisted of consecutive patients who underwent PVI between January 1, 2004, and December 31, 2009, at 16 hospitals in Michigan. Details regarding BMC2 PVI have been described elsewhere (11). Data were collected on demographic and clinical characteristics of patients undergoing PVI procedures. Approval from institutional review boards was obtained for each center. All patients who underwent lower extremity (LE) PVI, defined as an endovascular intervention performed on an artery in the aortoiliac, femoropopliteal, and below the knee arterial beds, were included in this analysis. Major endpoints for this analysis included in-hospital death, myocardial infarction (MI), stroke or transient ischemic attack (TIA), and in-hospital major adverse cardiovascular events, defined as the composite of death, MI, and stroke/TIA. Intra-procedural endpoints included embolic or thrombotic complications. Post-procedural endpoints included repeat PVI, post-PVI amputation, post-procedural transfusions of red blood cells, and vascular access complications. Procedural variables included technical success, defined as vascular access, deployment of device(s), and ≤30% diameter residual stenosis after revascularization; and procedural success, defined as technical success and freedom from major peri-procedural complications (12). Further details of the registry and the analysis are provided in the Online Appendix.

Statistical analysis. The differences in discrete variables between groups were evaluated by the chi-square test and

Table 1 Baseline Characteristics for PVI Patients

Characteristics	Women n = 5,105 (41.2%)	Men n = 7,274 (58.8%)	p Value*
Age, yrs			
Mean ± SD	70.0 ± 11.9	67.2 ± 11.1	<0.0001
Median (Q1, Q3)	71 (62, 79)	67 (59, 75)	<0.0001
Current smoker	1,411 (27.6)	2,485 (34.2)	<0.0001
Overweight†	1,524 (30.2)	2,749 (38.4)	<0.0001
Obese‡	1,854 (36.7)	2,440 (34.1)	0.003
Medical history			
Coronary artery disease	3,211 (62.9)	5,264 (72.4)	<0.0001
Diabetes	2,436 (47.7)	3,465 (47.6)	0.9
Hypertension	4,690 (91.9)	6,515 (89.6)	<0.0001
Hyperlipidemia	4,254 (83.3)	6,208 (85.3)	0.002
Congestive heart failure	1,017 (19.9)	1,406 (19.3)	0.4
COPD	1,400 (27.4)	2,011 (27.6)	0.8
Stroke/TIA	1,483 (29.0)	2,011 (27.6)	0.8
Renal failure with dialysis	208 (4.1)	325 (4.5)	0.3
Anemia	1,952 (40.0)	2,734 (39.3)	0.4
Anemia	12.4 (11.2, 13.6)	13.5 (12.1, 14.7)	<0.0001
Claudication§	2,911 (57.0)	4,587 (63.1)	<0.0001
Critical limb ischemia‖	2,113 (41.4)	2,555 (35.1)	<0.0001
Pre-procedural creatinine			
Mean ± SD	1.23 ± 1.4	1.43 ± 1.42	<0.0001
Median (Q1, Q3)	1.0 (0.8, 1.2)	1.1 (0.9, 1.4)	0.0001
Pre-procedural eGFR, <60 ml/min/1.73 m^2			
n (%)	2,754 (53.9)	3,161 (43.4)	<0.0001
Median (Q1, Q3)	43.3 (32.9, 51.2)	44.9 (34.3, 53.1)	0.0001

Values are mean ± SD, median (Q1, Q3), or n (%). *The Kruskal-Wallis test was used for determining p values where the median was used as the spread between the groups. †Overweight is defined as a body mass index (BMI) ≤25 to <30 kg/m^2. ‡Obese is defined as a BMI ≥30 kg/m^2. §Claudication is defined as Fontaine stage IIa or IIb or Rutherford category 1, 2, or 3. ‖Critical limb ischemia is defined as rest pain and/or ischemic lesion requiring emergent or urgent procedure when intervention was done in the setting of critical limb ischemia to save limb/tissue or to aid in healing (Fontaine stage III and above or Rutherford category 4 and above).

COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate; PVI = peripheral vascular intervention; TIA = transient ischemic attack.

Fisher exact test, and continuous variables by the Student's *t*-test and Wilcoxon rank sum test. We used propensity matching to compare the adjusted outcome of women and men. The probability or a propensity score of being a woman if all other baseline variables were known was calculated using a nonparsimonious logistic regression model. SAS version 9.3 software (SAS Institute, Cary, North Carolina) was used for all analyses.

Results

A total of 12,379 patients were included in this analysis, of which 41.2% were women (Table 1). Female LE-PVI patients were more likely to be older and to have a history of hypertension compared with male PVI patients. Women were less likely to be overweight or obese, be current smokers, or have a medical history for coronary artery disease or hyperlipidemia compared with men. The indications for LE-PVIs differed between men and women. Men were more likely to have claudication symptoms, whereas women were more likely to present with critical limb ischemia (CLI) as an indication for PVI (Table 1).

Sex-related differences were also observed for LE-PVI location and procedure characteristics (Table 2). Women were more likely to undergo interventions in the femoropopliteal location and were more likely to have multilevel disease, thus requiring multilevel intervention (defined as 2 or more arterial beds; i.e., aortoiliac bed, femoropopliteal bed, below the knee). Mode of intervention also differed on the basis of sex, with more female patients undergoing PVI with balloon only or atherectomy with balloon, whereas more male patients received interventions using stents. Male access site vessels were less likely to be closed using a closure device, whereas female patients were more likely to receive a closure device.

Female patients were less likely to receive several cardiovascular medications before PVI as compared with male patients, including angiotensin-converting enzyme (ACE) inhibitors, and lipid-lowering medications including statins (Table 3). Fewer women received dual antiplatelet therapy. Receipt of any antiplatelet therapy before the procedure was lower among women compared with men. After PVI, rates of receipt of ACE inhibitors and lipid-lowering medications (including statins) continued to be lower for women compared with men.

In unadjusted analysis, no sex-related differences were observed for in-hospital death, MI, stroke/TIA, or amputation (Table 4). Women experienced higher rates of unadjusted post-procedure transfusion, vascular access complications, and repeat PVI compared with male patients. Technical success was achieved less often among men compared with women. Procedural success was observed more often among men compared with women.

In a propensity-matched analysis, 2,346 women were matched to an equal number of men (Table 4). Compared with male patients, women experienced more transfusions,

Table 2 PVI Location, Access Type, Device Usage, and Procedural Success in Women and Men

Procedure Characteristics	Women n = 5,105 (41.2%)	Men n = 7,274 (58.8%)	p Value
Intervention location			
Aortoiliac	1,608 (31.5)	2,310 (31.7)	0.7
Femoropopliteal	3,513 (68.9)	4,828 (66.4)	0.004
Below knee (tibial, peroneal, dorsalis pedis, or tibioperoneal trunk	1,292 (25.3)	1,860 (25.6)	0.7
Multivessel interventions (2 or more arterial bed)	2,661 (52.2)	3,602 (49.5)	0.004
Access type			
Antegrade intervention*	410 (10.5)	624 (11.5)	0.1
Retrograde intervention	3,423 (87.5)	4,660 (85.9)	0.03
Antegrade and retrograde†	79 (2.0)	139 (2.5)	0.08
Device			
Balloon only	1,649 (32.3)	2,165 (29.7)	0.002
Stent	2,081 (40.7)	3,117 (42.8)	0.02
Any atherectomy	1,174 (23.0)	1,551 (21.3)	0.02
IVUS	170 (3.3)	231 (3.2)	0.6
Cutting balloon	150 (2.94)	233 (3.2)	0.4
Cryoballoon	284 (5.56)	377 (5.18)	0.3
Laser	331 (6.48)	526 (7.23)	0.1
Thrombolysis	78 (1.53)	118 (1.62)	0.6
Closure device			
Manual	2,217 (55)	3,209 (57.3)	0.02
Closure device (Perclose, Angio-Seal, or VasoSeal)	1,814 (45.0)	2,391 (42.7)	0.02

Values are n (%). *Antegrade/retrograde information was available only for 9,335 cases of 12,379. †Both antegrade and retrograde access types were used.

IVUS = intravascular ultrasound; PVI = peripheral vascular intervention.

Table 3 Pre- and Post-Procedural (Discharge) Medication Usage Between Sexes

Characteristics	Women n = 5,105 (41.2%)	Men n = 7,274 (58.8%)	p Value
Pre-procedural medication			
ACE inhibitor	2,210 (45.7)	3,538 (51.2)	<0.0001
Beta-blocker	3,077 (62.2)	4,467 (63.3)	0.2
Statin	3,394 (67.7)	5,155 (71.8)	<0.0001
Any lipid lowering*	3,578 (71.3)	5,414 (75.5)	<0.0001
Mono-antiplatelet†	1,839 (36.0)	2,558 (35.2)	0.3
Dual antiplatelet‡	2,326 (45.5)	3,470 (47.7)	0.02
Any antiplatelet§	4,346 (85.1)	6,337 (87.1)	0.001
Coumadin	319 (6.2)	514 (7.1)	0.07
Heparin	325 (6.4)	382 (5.2)	0.008
Discharge medication			
ACE inhibitor	2,338 (48.6)	3,657 (53.2)	<0.0001
Beta-blocker	3,249 (66.0)	4,745 (67.5)	0.09
Statin	3,722 (74.6)	5,504 (77.0)	0.002
Any lipid lowering	3,885 (77.9)	5,738 (80.3)	0.001
Mono-antiplatelet	974 (19.1)	1,201 (16.5)	0.002
Dual antiplatelet	3,557 (69.7)	5,167 (71.0)	0.1
Any antiplatelet	4,812 (94.8)	6,877 (94.9)	0.8
Coumadin	560 (11.0)	883 (12.1)	0.04
Heparin	359 (7.0)	437 (6.0)	0.02

Values are n (%) unless otherwise specified. *Any lipid lowering indicates a choice of any lipid-lowering agents. †Mono antiplatelet indicates a choice of any one antiplatelet agent from aspirin, clopidogrel, ticlopidine, or cilostazol. ‡Dual antiplatelet indicates a choice of any 2 antiplatelet agents from aspirin, clopidogrel, ticlopidine, or cilostazol. §Any antiplatelet indicates a choice of any antiplatelet from aspirin, clopidogrel, ticlopidine, or cilostazol.
ACE = angiotensin-converting enzyme.

vascular complications, and embolic or thrombotic complications. Women were more likely to have technically successful PVIs compared with men. Overall procedural success, which combines technical success with adverse events such as vascular complications or bleeding events, was similar among women and men.

Discussion

In this large cohort of patients undergoing LE-PVI, we observed that women presented with more severe manifestations of PAD and had more complications, but had similar rates of procedural success and were more likely to have

Table 4 Propensity-Matched In-hospital Adverse Events in Female and Male PVI Patients

In-Hospital Outcomes	Matched Data* Women (n = 2,346)	Matched Data* Men (n = 2,346)	Matched Data* p Value	All Data Women (n = 5,105)	All Data Men (n = 7,274)	All Data p Value
Death	9 (0.38)	5 (0.21)	0.3	31 (0.6)	28 (0.4)	0.08
MI	14 (0.6)	7 (0.3)	0.2	32 (0.6)	35 (0.48)	0.3
TIA/stroke	5 (0.2)	5 (0.2)	1.0	11 (0.22)	14 (0.2)	0.8
MACE	22 (0.9)	14 (0.6)	0.2	63 (1.2)	65 (0.9)	0.06
Transfusion	164 (6.99)	89 (3.79)	<0.0001	429 (8.4)	309 (4.2)	<0.0001
Vascular access complications	105 (4.48)	47 (2.00)	<0.0001	248 (4.9)	152 (2.1)	<0.0001
Embolic complications	27 (1.15)	10 (0.43)	0.005	40 (0.8)	24 (0.3)	0.0005
Thrombotic complications	17 (0.72)	21 (0.9)	0.5	52 (1.0)	49 (0.7)	0.04
Amputation	103 (2.0)	134 (1.84)	0.4	47 (2.0)	42 (1.8)	0.6
Lesions not crossed	64 (2.73)	87 (3.71)	0.057	302 (5.9)	587 (8.07)	<0.0001
Technical success	2,140 (91.22)	2,090 (89.09)	0.014	3,993 (86.9)	5,578 (84.5)	0.0004
Procedural success	1,870 (79.7)	1,916 (81.67)	0.08	3,456 (75.2)	5,107 (77.4)	0.008
Length of hospital stay, days						
Mean ± SD	1.92 ± 3.6	1.69 ± 3.19		2.15 ± 3.98	1.76 ± 3.37	
Median (Q1, Q3)	1 (1, 1)	1 (1, 1)	<0.0001	1 (1, 1)	1 (1, 1)	<0.0001

Values are n (%) unless otherwise specified. *Patient characteristic variables that were used for matching are age, estimated glomerular filtration rate, coronary artery disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, chronic obstructive pulmonary disease, anemia, body mass index categories (lean, overweight and obese), claudication, critical limb ischemia, vascular bed location (aortoiliac, femoropopliteal, and below knee), and pre-procedural medication usage (angiotensinogen inhibitors, β-blockers, heparin, low molecular weight heparin, warfarin, diuretic, bivalirudin, eptifibatide/tirofiban, lipid-lowering drug, antiplatelet therapy).
MACE = major adverse cardiovascular event(s); MI = myocardial infarction; PVI = peripheral vascular intervention; TIA = transient ischemic attack.

technical success associated with PVI compared with male patients.

Factors associated with PAD and PVI. As with prior studies (13–15), we observed that women were generally older and less likely to smoke, but more likely to have a prior history of hypertension. We also observed that women more often presented with CLI. Given that men were more likely to be smokers and have elevated lipids, the etiology for women having a more severe presentation of CLI is unclear. Other investigators have suggested that comorbidities including osteoporosis and arthritis may confound traditional assessments of claudication in women (15,16). Furthermore, women may present late with PAD and thus be more likely to present with CLI.

Difference in medications. We observed similar rates of receipt for most cardiac medications with the exception of ACE inhibitors and statin therapy. Receipt of statins on discharge increased from pre-procedure rates for both sexes; however, 23% of men and 25.4% of women were still not receiving statins at the time of discharge. Given that PAD is considered as a coronary artery disease risk equivalent, our findings suggest room for improvement with regard to compliance with current medical therapy guidelines (17,18).

In-hospital post-procedural outcomes. We observed no sex-related differences for in-hospital death, MI, stroke/TIA, or the combined endpoint of these outcomes. We did, however, observe increased vascular complications and post-procedural transfusions among women as compared with men. The findings regarding an increased risk of vascular access complications, bleeding, and transfusions among female patients who undergo PVI procedures are consistent with other studies (13,19). A review of hospital discharge databases from New York, New Jersey, and Florida demonstrated increased risk of bleeding after vascular interventions for PAD for women compared with men. In that study, women also had higher peri-operative mortality rates; however, procedures were not limited to PVIs and thus included open procedures and amputations (13).

We also observed that women were more likely to receive pre-PVI procedure heparin as compared with men. This is likely related to the higher proportion of women who presented with CLI; however, the use of pre-procedural heparin may be a factor in the increased bleeding observed among women (20). The increase in vascular and bleeding complications mirrors what has been observed in sex-specific data on coronary interventions (7,21).

Given the higher rates of PVI-related vascular access complications and transfusions among female patients as compared with male patients, it was surprising to observe no sex-related difference in procedural success, a clinically meaningful measure of technical success and freedom from complications. This paradox was explained by the observed higher rates of technical success for women as compared with men. These data suggest female patients may benefit to a greater degree with an invasive percutaneous strategy for the management of PAD, particularly if complications can be avoided. The data in our study are not from a randomized controlled trial; clearly further research regarding sex-related differences in the technical and procedural success of PVI is warranted.

Study limitations. Several limitations exist for this study. First, the findings represented here are based on observational data that are not adjudicated by a core facility; as such it may be limited by variability in measurement. However, adverse outcomes are audited by the BMC2 PVI coordinating center staff for completeness and accuracy. Second, data were examined using risk-adjustment models and propensity analysis; however, we cannot exclude possible residual confounding by known and/or unknown factors. Third, all patients in our study underwent PVI at hospitals participating in a quality-improvement initiative (22). The findings may or may not apply to other institutions or to patients from other geographically distinct areas.

Conclusions

In this real-world registry, we observed that women had inferior adherence to guideline-recommended medical therapy before the procedure and, although improved, were less likely to receive statins than men post-PVI. Paradoxically, female sex was associated with superior technical success but more procedural complications that resulted in similar rates of procedural success associated with LE-PVI. These data suggest the need for quality-improvement interventions designed to improve medical therapy and enhanced efforts to understand and ameliorate PVI-associated complications, in particular bleeding and vascular complications among women.

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Key Words: peripheral arterial intervention ■ peripheral vascular disease ■ sex.

APPENDIX

For an expanded Methods section and supplemental table, please see the online version of this article.