

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. (J Am Coll Cardiol 2014;63:2525–30) © 2014 by the American College of Cardiology Foundation

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 (PVI). 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 $\leq 30\%$ 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	Men	p Value*
	n = 5,105 (41.2%)	n = 7,274 (58.8%)	
Age, yrs			
Mean \pm SD	70.0 \pm 11.9	67.2 \pm 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 \pm SD	1.23 \pm 1.4	1.43 \pm 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 \pm 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/m². [‡]Obese is defined as a BMI ≥ 30 kg/m². [§]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.

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