JACC: CARDIOVASCULAR INTERVENTIONS VOL. 4, NO. 6, 2011

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC. DOI: 10.1016/j.jcin.2011.03.012

Safety of Contemporary Percutaneous Peripheral Arterial Interventions in the Elderly

Insights From the BMC2 PVI (Blue Cross Blue Shield of Michigan Cardiovascular Consortium Peripheral Vascular Intervention) Registry

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Objectives This study sought to evaluate the effect of age on procedure type, periprocedural management, and in-hospital outcomes of patients undergoing lower-extremity (LE) peripheral vascular intervention (PVI).

Background Surgical therapy of peripheral arterial disease is associated with significant morbidity and mortality in the elderly. There are limited data related to the influence of advanced age on the outcome of patients undergoing percutaneous LE PVI.

Methods Clinical presentation, comorbidities, and in-hospital outcomes of patients undergoing LE PVI in a multicenter, multidisciplinary registry were compared between 3 age groups: <70 years, between 70 and 80 years, and ≥80 years (elderly group).

Results In our cohort, 7,769 patients underwent LE PVI. The elderly patients were more likely to be female and to have a greater burden of comorbidities. Procedural success was lower in the elderly group (74.2% for age ≥80 years vs. 78% for age 70 to <80 years and 81.4% in patients age <70 years, respectively; $p < 0.0001$). Unadjusted rates of procedure-related vascular access complications, post-procedure transfusion, contrast-induced nephropathy, amputation, and major adverse cardiac events were higher in elderly patients. After adjustment for baseline covariates, the elderly patients were more likely to experience vascular access complications; however, advanced age was not found to be associated with major adverse cardiac events, transfusion, contrast-induced nephropathy, or amputation.

Conclusions Contemporary PVI can be performed in elderly patients with high procedural and technical success with low rates of periprocedural complications including mortality. These findings may support the notion of using PVI as a preferred revascularization strategy in the treatment of severe peripheral arterial disease in the elderly population. (J Am Coll Cardiol Intv 2011;4:694–701)

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Manuscript received December 6, 2010; revised manuscript received February 23, 2011, accepted March 5, 2011.

Peripheral artery disease (PAD) represents a significant problem in the United States, especially among the elderly population (1–3). According to NHANES (National Health and Nutrition Examination Survey) (1999 to 2000), the prevalence of PAD among individuals >70 years was 14.5%, or nearly 4 million adults, with equal distribution between sexes (2). As the prevalence and severity of PAD is increased with age, so too are the risks associated with surgical revascularization.

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Compared with younger patients, elderly patients who undergo surgical interventions have higher 30-day and 1-year post-operative mortality; lack similar improvement in functional outcomes, health perception, or well-being post-operatively; have delayed return to normal activities; and require increased use of hospital resources (1,4–8).

Peripheral vascular intervention (PVI) offers several theoretical advantages over surgical revascularization for the treatment of PAD. PVIs are associated with lower overall morbidity, can be performed with less anesthesia, have minimal access site trauma, faster recovery times, shorter hospitalizations, lower infection rates, less cardiovascular stress, and present a viable option for patients deemed too high risk for primary surgical management of lower limb PAD (9–15). Although there has been significant growth in PVI rates in the last several years, there is a paucity of literature on the precise relationship between advanced age and PVI outcomes. We examined this relationship between advanced age, defined as age ≥80 years, and outcomes of patients undergoing PVI in a multicenter PVI registry.

Methods

BMC2 PVI registry. The details of the BMC2 PVI (Blue Cross Blue Shield of Michigan Cardiovascular Consortium Peripheral Vascular Intervention) program have been described previously (16). Supported by Blue Cross Blue Shield of Michigan, BMC2 PVI is a prospective, multicenter observational registry designed to collect information on patients undergoing PVI in an effort to evaluate evidence-based disease management and to support collaborative improvement in quality of care and outcomes. The database was initiated in 2001, with multiple individual sites contributing data since 2002. The registry currently collects detailed information on consecutive patients who have undergone PVI for clinical syndromes including claudication, critical limb ischemia, or uncontrolled hypertension. Endovascular carotid interventions and abdominal aortic stent grafts are not included in the registry because clinical parameters for follow-up significantly differ in these patients. A data form is compiled for each patient, including demographic information, past medical history, laboratories pre- and post-PVI, patient history, presenting symptoms, procedural indications, medication details, PVI type, details of procedure, and associated complications if present. Data quality and the inclusion of consecutive procedures are ensured by ad hoc queries, random chart review, and a series of diagnostic routines included in the database (16). A list of standard definitions determined by the American College of Cardiology Data Standards Committee has been used as a reference. Periprocedural and in-hospital data are collected from each individual. The registry has been approved by the institutional review board of each participating hospital.

Data quality control. 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. Additionally, a database manager checks all data forms for completeness, and a random sample of data forms is checked for face validity and clinical consistency. Twice yearly, sites are audited by a nurse monitor from the coordinating center where all cases associated with severe complications and a randomly selected 5% of cases are audited for accuracy. Variables on the original data form are compared with each patient's hospital chart, and all hard outcomes, including any death, stroke, amputation, or transfusion are audited for accuracy. Incorrect data are corrected and reentered in the database.

Abbreviations and Acronyms

CIN = contrast-induced nephropathy

CVD = cerebrovascular disease

MACE = major adverse cardiac event(s)

MI = myocardial infarction

PAD = peripheral artery disease

PVI = peripheral vascular intervention

TIA = transient ischemic attack

Study patients and definitions. From the 10,184 consecutive patients who underwent PVIs between January 2001 and December 2008, 8,052 cases were treated exclusively for lower-extremity PAD. Of these, 283 cases underwent a planned percutaneous intervention combined with open vascular surgery during the same hospital admission and, hence, were discarded from this analysis. The remaining 7,769 cases were divided into 3 age categories: <70 years (n = 4,017), between 70 and 80 years (n = 2,350), and ≥80 years (n = 1,402). All these cases were performed at 18 hospital centers that participate in the registry, and their numbers ranged from 5 to 2,381 cases. Similar variations were observed in adverse outcomes across the consortium.

All patients had confirmed PAD based on 1 or more of the following: abnormal ankle brachial index, noninvasive imaging studies (duplex ultrasound, computed tomographic angiography, or magnetic resonance angiography), or angiography. Periprocedural, periodic follow-up data (death, myocardial infarction [MI], transient ischemic attack [TIA], stroke, limb ischemia requiring urgent surgery, renal failure, dialysis, symptom status, ankle brachial index, Rutherford score, walking distance, medications, risk factor status), along with in-hospital clinical information were collected prospectively by trained abstractors using a standardized data collection form. Lower-extremity PVI patients were categorized to 1 of 3 groups by symptom status of increasing severity for the purpose of analysis: claudication, rest pain, or limb salvage. Those in the rest pain and limb salvage group are acknowledged to have critical limb ischemia. Limb salvage was defined as patients who were undergoing the PVI with the primary purpose of preventing or limiting an amputation and in those with evidence of tissue loss including ischemic ulcer or infection to aid in healing. Contrast-induced nephropathy (CIN) was defined as elevation in serum creatinine ≥0.5 mg/dl after PVI. Major adverse cardiac events (MACE) were defined as death, MI, or stroke/TIA. PVI 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 periprocedural complications (17). Vascular access complications were defined as a composite of retroperitoneal hematoma, pseudoaneurysm, hematoma requiring transfusion or associated with a decrease in hemoglobin ≥3 g/dl, arteriovenous fistula demonstrated by arteriography or ultrasound, acute thrombosis, or need for surgical repair of the access site.

Clinical characteristics, periprocedural, and in-hospital outcomes were compared among patients across the 3 age groups.

Statistical analysis. Univariate association among the 3 levels of age variable with pre-procedural patient characteristics variables (2-level categorical) were determined by chi-square or Fisher exact test. One-way analysis of variance was used to compare the differences among continuous variables within the 3 age categories. Transfusion rates, and individual adverse events, including death, MI, cerebrovascular disease/transient ischemic attack (CVD/TIA), CIN, and vascular access complications were also compared among the 3 age groups (18). Because significant associations between several adverse events and advanced age were revealed by univariate analysis, separate multivariate logistic regression models were developed for transfusion, MACE, CIN, vascular access complication, and amputation as dependent variables. Explanatory variables were chosen for each model by using stepwise forward selection method ($p \leq 0.05$) to arrive at parsimonious models. The models were also forced to include 5 explanatory variables: sex; age category 1 (>70 years); age category 2 (≥70 to <80 years); age category 3 (≥80 years); and age-sex interaction variables. Variables included in the multivariable models were: sociodemographic factors (sex, age, body mass index [lean, overweight, and obese]); historical clinical factors (MI, anemia, diabetes, coronary artery disease, congestive heart failure, CVD/TIA, and creatinine clearance); procedural symptoms/indication (limb salvage, rest pain); pre-procedural medications (unfractionated heparin, low molecular weight heparin, angiotensin-converting enzyme inhibitor, beta-blocker, integrelin, abciximab, statin, warfarin, and antiplatelet usage); procedural variables (procedure duration, heavily calcified vascular bed, vessel location [renal, iliac, femoropopliteal, below-the-knee]; and device usage [stent, balloon, atherectomy, cryoballoon, laser and cutting balloon]; and exceeding contrast dose (exceeding a weight- and creatinine-adjusted maximum contrast dose calculated using the formula: body weight in kilograms × 5 cc/serum creatinine) (18,19). For creatinine clearance, 3.8% of cases had either missing weight or pre-procedural creatinine values. These values were imputed to the median values based on sex. Procedural duration values were missing in 1.3% of cases and imputed to sex-based median values. Variables with imputed values were used for multivariable logistic models only.

All tests used $p < 0.05$ for the critical value of statistical significance. All analyses were performed using SAS statistical software (version 9.2, SAS Institute, Cary, North Carolina).

Results

Consecutive patients undergoing lower-extremity interventions (aorto-iliac, femoropopliteal, and below-the-knee) were prospectively enrolled from 18 hospital sites (Online Appendix) in Michigan state during 2001 through 2008 (n = 7,769). These patients were divided into 3 age groups: <70 years, between 70 and 80 years and those ≥80 years. Baseline demographic and clinical characteristics among the 3 age groups are detailed in Table 1. Elderly patients were more likely to be female and have a normal or lean body mass index (<25 kg/m^2) or be anemic. In addition, patients ≥80 years were more likely to have a history of hypertension, congestive heart failure, or CVD/TIA than were other age groups. Patients in the ≥80-year age group were less likely to be current smokers than patients in other age groups. Elderly patients presented with more severe PAD, including rest pain or the goal of limb salvage therapy (Fig. 1). In addition, the ≥80-years group had higher femoropopliteal, below-knee, and multivessel (2 or more) interventions, whereas younger patients were more likely to undergo PVI for aortoiliac disease (Fig. 2). Technical success as well as procedural success rates were higher in both the younger groups than in the elderly group (Fig. 3). Elderly patients were more likely to undergo balloon angioplasty or atherectomy, whereas younger patients were more likely to receive stents (48.7% in <70-years group vs. 42.8% in 70-to-80-year group or 33.6% in >80-years group) (Table 2). Although retrograde access was more prevalent (83%) than antegrade access (17%) among all patients, our study suggested that younger patients received more retrograde access than elderly patients did (84.5% in <70-year group vs. 81.8% in 70-to-80-year and 80.5% in the ≥80-

Table 1. Baseline Demographic and Clinical Characteristics by Age Group

Characteristics	<70 Yrs (n = 4,017) (51.7%)	≥70 to <80 Yrs (n = 2,350) (30.3%)	≥80 Yrs (n = 1,402) (18.1%)	p Value
Age, yrs	59.2 ± 7.3	74.4 ± 2.9	84.2 ± 3.6	<0.0001
Female	33.7	42.8	50.9	<0.0001
Current smoker	45.3	19.1	7.8	<0.0001
Lean, BMI <25 kg/m^2	26.5	29.7	44.1	<0.0001
Obese, BMI ≥30 kg/m^2	41.2	32.6	19.1	<0.0001
CAD	68.7	71.4	70.4	0.06
Diabetes	48.1	48.0	42.4	0.0006
HTN	87.3	92.8	94.6	<0.0001
Hyperlipidemia	85.0	85.5	78.2	<0.0001
CHF	16.8	21.8	25.7	<0.0001
COPD	27.1	29.0	24.1	0.005
CVD/TIA	23.4	32.5	35.0	<0.0001
Dialysis	4.6	4.2	2.7	0.01
Anemia	30.0	41.4	53.2	<0.0001

Values are mean ± SD or % of N.
BMI = body mass index; CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CVD = cerebrovascular disease; HTN = hypertension; TIA = transient ischemic attack.

year-old groups, p = 0.004). By contrast, elderly patients, who underwent more below-the-knee PVIs, were more likely to undergo more antegrade access than the younger groups were (p = 0.01) (Table 2).

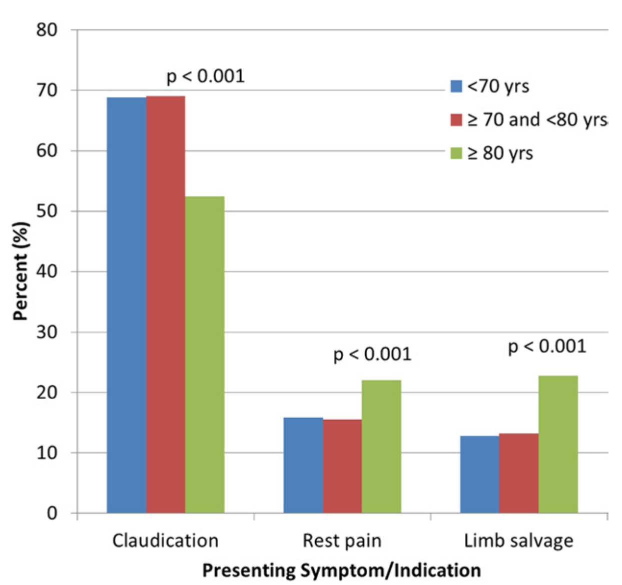

Figure 1. Presenting Symptoms/Indications for Lower Extremity PVI Procedure Stratified by Age Group

The presenting symptoms or indications for peripheral vascular intervention (PVI) procedure are stratified by age group. Rest pain and limb salvage are not mutally exclusive.

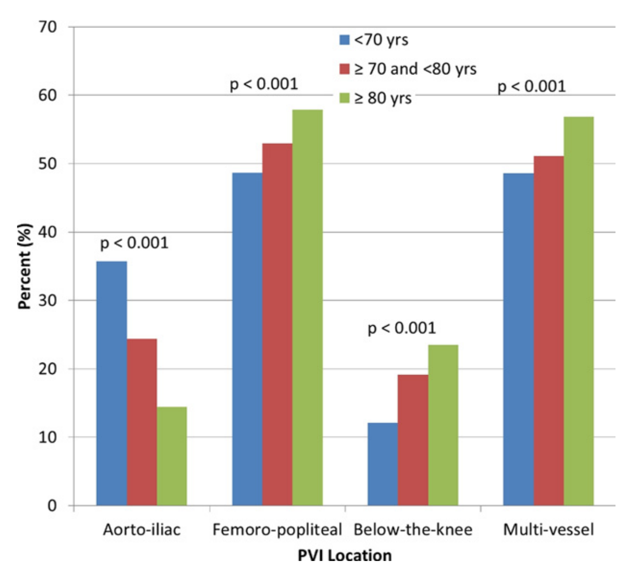

Figure 2. PVI Procedure Locations by Age Group

The arterial bed(s) treated during the peripheral vascular intervention (PVI) procedure are stratified by age group.

Periprocedural medication usage (pre-procedural and at discharge) was lower in the elderly group (Table 3). Patients ≥80 years were less likely to be treated with statins or any other lipid-lowering drugs. Whereas any antiplatelet usage at discharge was high in all the groups, dual antiplatelet was lower in the elderly group (63.4%) than in the younger

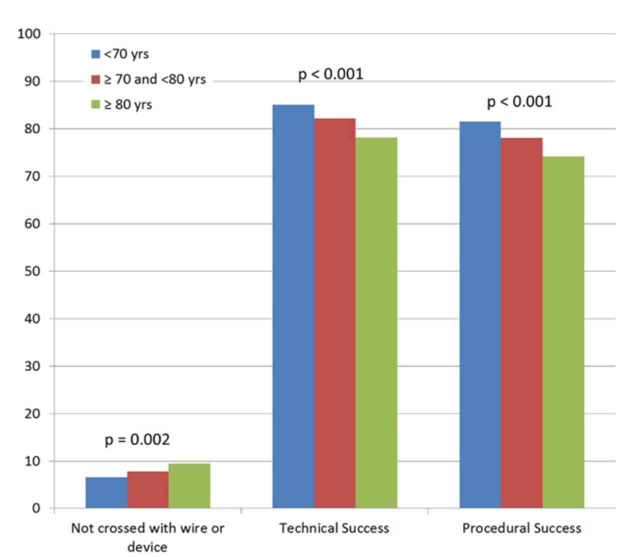

Figure 3. PVI Technical or Procedural Success Differences Between Age Groups

Peripheral vascular intervention (PVI) technical and procedural success stratified by age group.

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Table 2. Procedural Access Type, Devices Used, and Vascular Closure Method

Procedural Information	<70 Yrs	≥70 to <80 Yrs	≥80 Yrs	p Value
Access type*				
Antegrade intervention	15.5	18.8	19.5	0.01
Retrograde intervention	84.5	81.8	80.5	0.004
Device usage				
Balloon only	27.1	31.7	36.2	<0.0001
Stent	48.7	42.8	33.6	<0.0001
Atherectomy (with balloon)	14.1	16.0	18.1	0.001
Atherectomy (with stent)	3.6	3.7	4.3	0.4
Atherectomy only	12.7	14.9	16.0	0.0003
Cryoballoon	5.7	6.3	6.9	0.2
Cutting balloon	3.1	3.9	2.9	0.7
Laser	10.5	11.9	12.6	0.051
Closure device				
Manual	61.9	61.8	60.2	0.5
Closure device	38.1	38.2	39.8	0.5

Values are % of N. *Access type (antegrade/retrograde) information was available only for 4,673 cases.

groups (71% and 69.4%, respectively in <70- and 70-to-80-year groups).

Periprocedural complications were relatively low among all age groups (Fig. 4). Those ≥80 years required more blood transfusions and suffered more vascular access complications. Despite a higher rate of MACE, CIN, and amputation in the ≥80-year group, in-hospital death in all

Table 3. Periprocedural Medication Usage

	<70 Yrs	≥70 to <80 Yrs	≥80 Yrs	p Value
Pre-procedural medication usage				
ACE inhibitor	50.8	45.6	43.2	<0.0001
Beta-blocker	60.4	62.7	60.3	0.1
Statin	69.6	68.5	57.7	<0.0001
Any lipid lowering	74.0	72.3	60.9	<0.0001
Dual antiplatelet	48.2	45.7	39.7	<0.0001
Any antiplatelet	86.2	86.2	82.8	0.004
Warfarin	5.3	7.5	7.1	0.001
Discharge medication usage				
ACE inhibitor	52.9	47.9	44.8	<0.0001
Beta-blocker	64.3	66.1	65.8	0.3
Statin	74.2	74.7	63.7	<0.0001
Any lipid lowering*	78.1	78.6	67.0	<0.0001
Dual antiplatelet†	71.0	69.5	63.4	<0.0001
Any antiplatelet‡	94.2	94.4	93.7	0.6
Warfarin	9.8	13.9	15.1	<0.0001

Values are % of N. *Any lipid lowering is the choice of any lipid lowering agents. †Dual antiplatelet is the choice of any 2 of the following: aspirin, clopidogrel, ticlopidine, or cilostazol. ‡Any antiplatelet is the choice of any 1 or more of the following: aspirin, clopidogrel, ticlopidine, or cilostazol.
ACE = angiotensin-converting enzyme.

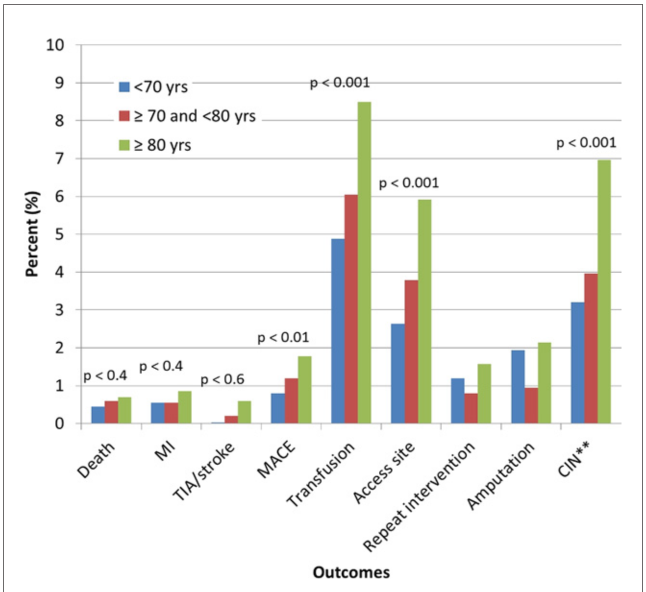

Figure 4. PVI Procedure Complication Differences by Age Group

PVI complications stratified by age group. **Contrast-induced nephropathy (CIN) was defined as an increase in serum creatinine ≥0.5 mg per deciliter after PVI. MACE = major adverse cardiac event(s); MI = myocardial infarction; PVI = peripheral vascular intervention; TIA = transient ischemic attack.

age groups were overall quite low and did not differ significantly. There was no difference in the incidence of MI, the need for repeat intervention, or TIA/stroke among the 3 groups. Univariate analysis showed significantly higher rates of MACE, transfusion, CIN, and amputation in the elderly group; therefore, we used multivariate regression modeling to determine whether advanced age was associated with these outcomes. After multivariate adjustments (Fig. 5), advanced age was found to be a predictor of vascular access complication (odds ratio [OR]: 2.2, 95% confidence interval [CI]: 1.2 to 3.9); by contrast, advanced age did not show any independent correlation with post-PVI transfusion (OR: 1.08, 95% CI: 0.8 to 1.4, p = 0.5), CIN (OR: 0.9, 95% CI: 0.6 to 1.4, p = 0.9), or PVI-related MACE (OR: 1.3, 95% CI: 0.7 to 2.3, p = 0.4), or amputation (OR: 0.7, 95% CI: 0.4 to 1.2, p = 0.2). The C-statistic for models predicting vascular access complication, transfusion, CIN, amputation, and MACE were 0.71, 0.82, 0.79, 0.91, and 0.82, respectively, suggesting adequate model discrimination.

Discussion

In this multicenter, multidisciplinary, prospective registry of patients undergoing PVI, elderly patients, as defined by age ≥80 years, had more pre-existing comorbidities including hypertension, congestive heart failure, and CVD/TIA, as well as more frequent baseline anemia. Although current evidence suggests that the progression

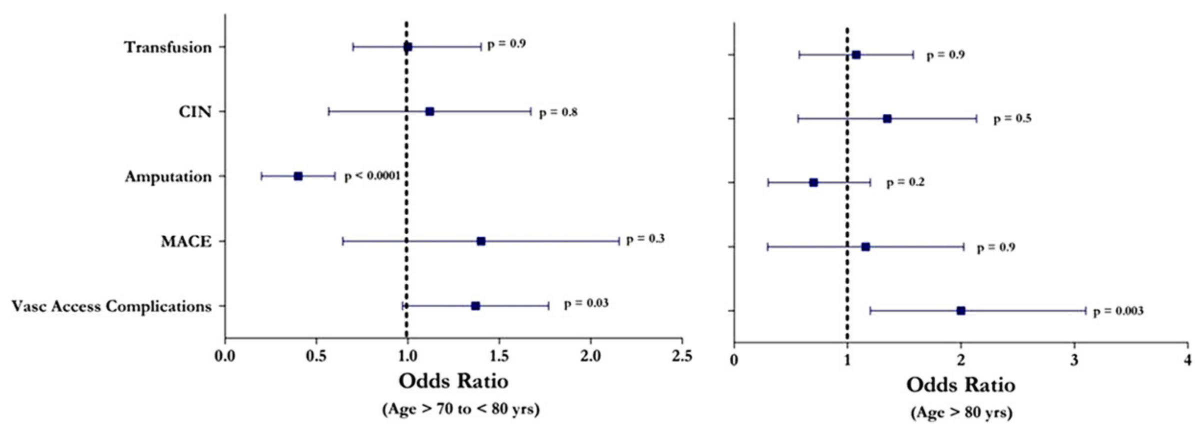

Figure 5. Multivariate Predictions of Complications by Age Group (<70 Years Reference Group)

Adjusted odds ratios with 95% confidence intervals for complications displayed by age group with the age <70 years cohort used as a reference group. Abbreviations as in Figure 4.

of underlying PAD is similar whether patients have symptoms, older patients in this study had more urgent presentations, often presenting with less classic claudication symptoms and instead with more rest pain or with the goal of limb salvage (1). Patients ≥80 years were also more likely to undergo femoropopliteal, below-knee, or multivessel arterial interventions (Table 2). Unadjusted rates of periprocedural complications were relatively low among all groups with a higher percentage of MACE, CIN, transfusion, and vascular complications in the ≥80-year group. However, after multivariate adjustments, these associations were not significant.

PAD is highly prevalent, with a high incidence among those with advanced age (1–3). As the U.S. population continues to gray with the aging of the baby boomer demographic, the treatment of PAD will continue to gain greater significance, both because of its inherent morbidity and because of the close association between PAD and coexisting coronary and cerebrovascular disease (3). The management of patients with severe PAD is often initially focused on appropriate medical therapy and lifestyle changes designed to improve symptoms, decrease the risk of developing limb ischemia, and alter the risk profile for cardiovascular morbidity and mortality. Surgical and endovascular revascularization procedures are typically reserved for patients with severe or lifestyle-limiting symptoms or evidence of end organ ischemia related to their PAD (3). Prognosis of the affected area is often determined by the acuity of ischemia, the extent and location of PAD distribution, and the rapidity of restoration of arterial circulation to the area in question.

As the prevalence and severity of PAD are increased with age, so too are the risks associated with surgical revascularization. When compared with younger patients undergoing surgical revascularization procedures for PAD, elderly patients have been shown to experience greater complication burdens, have higher mortality, experience less satisfaction post-operatively, have less improvement in functional outcomes with delays in returning to normal activities, and increased use of hospital resources (1,4–8,20–23). According to Conte et al. (23) in the 2006 multicenter, randomized PREVENT III (Project or Ex-Vivo vein graft Engineering via Transfection III) trial, mortality in elderly patients undergoing lower-extremity bypass surgery ranged from 2% to 10% with a surgical complication rate of 20% to 50%. Also, in the 2007 prospective cohort study by Brosi et al. (5), 376 consecutive patients presenting with 416 critically ischemic legs from 1999 to 2004, the 30-day and 1-year mortality rate was higher in octogenarians after surgical revascularization when compared to younger (<80 years) patients in the same situation.

Compared to surgical revascularization, the growing popularity of PVI is because of the perception of lower overall morbidity and mortality. In the 2007 prospective study by DeRubertis et al. (24), 1,000 consecutive PVI between 2001 and 2006 were performed for claudication or limb-threatening ischemia. The primary endpoints of the study included patency at 6-month intervals, recurrence of claudication, failure of wound healing, or need for major amputation. PVI for chronic lower-extremity PAD was associated with minimal mortality and 2-year patency rates of 80% when performed in patients with claudication (24). Similar results have been shown with PVI for femoral-popliteal, critical limb ischemia, and infrainguinal disease (25–29). It is also thought that PVI may not preclude or alter subsequent surgeries and may be repeated if necessary (30).

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The effect that advanced age has on PVI procedural success, safety, and complication rates had not been effectively evaluated in multicenter studies until now. One strength of this study is that approximately 30% of patients were ≥70 and <80 years of age and 18% of cases were more than 80 years. This number is the reflection of an aging population. Interestingly, contrary to the higher risks associated with surgical revascularization of PAD in elderly patients, we found that for patients undergoing PVI, advanced age may not be a significant predictor of in-hospital adverse events. Multivariate logistic models adjusted for age and sex did not demonstrate a significant relationship between age ≥70 years and MACE, transfusion, amputation, and CIN, respectively. However, advanced age showed significant association with vascular access complication. Mortality was very low in all age groups, and no statistical difference was seen for MI, the need for repeat intervention, or renal failure requiring dialysis as well.

According to uniform reporting standards in assessing endovascular treatments for chronic ischemia of lower limb arteries (17), technical and procedural success are considered 2 important parameters for successful outcomes in PVI. In this study, both technical and procedural success rates were high in the <70 and 70- to <80-year age groups (85% and 82.1%, respectively, for technical success; and 81.45% and 78%, respectively, for procedural success), whereas ≥80-year-old group showed a lower technical as well as procedural success rates (78.2% and 74.2%, respectively). We also performed 2 subgroup analyses on patients with history of diabetes and chronic renal failure to be able to understand the contribution of age toward different outcomes (Online Tables 1 and 2). Interestingly, the unadjusted pattern of outcomes between the age groups in these 2 subgroups remained the same as they were observed in the analyses that included all patients. However, diabetes and chronic renal failure remained 2 independent predictors of MACE, amputation, and CIN, respectively, by our multivariate analyses.

Study limitations. The results of this study are based upon observational data, and the outcomes were not centrally adjudicated. The use of a large registry, with clinical heterogeneity and reporting variability, opens the possibility for confounding variables and bias. However, our data are based on the largest registry of its type and reflect the outcome of unselected patients undergoing PVI procedures performed by multiple specialists with different training backgrounds and provide a contemporary insight into treatment in this population.

Conclusions

Our data suggest that contemporary PVI can be performed in elderly patients with high procedural and technical success with a very low overall incidence of adverse events and acceptably low mortality rates. These findings support the use of PVI as the preferred method of revascularization in the treatment of severe PAD in the elderly population.

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Key Words: elderly ■ outcomes ■ peripheral artery disease ■ peripheral vascular intervention.

APPENDIX

For a list of participating organizations and supplementary information, please see the online version of this paper.