



# The Effect of Clinical Care Location on Clinical Outcomes After Peripheral Vascular Intervention in Medicare Beneficiaries

Ryan S. Turley, MD,<sup>a</sup> Xiaojuan Mi, PhD,<sup>b</sup> Laura G. Qualls, MS,<sup>b,c</sup> Sreekanth Vemulapalli, MD,<sup>b,c</sup>  
Eric D. Peterson, MD, MPH,<sup>b,c</sup> Manesh R. Patel, MD,<sup>b,c</sup> Lesley H. Curtis, PhD,<sup>b,c</sup> W. Schuyler Jones, MD,<sup>b,c</sup>

## ABSTRACT

**OBJECTIVES** Modifications in reimbursement rates by Medicare in 2008 have led to peripheral vascular interventions (PVI) being performed more commonly in outpatient and office-based clinics. The objective of this study was to determine the effects of this shift in clinical care setting on clinical outcomes after PVI.

**BACKGROUND** Modifications in reimbursement have led to peripheral vascular intervention (PVI) being more commonly performed in outpatient hospital settings and office-based clinics.

**METHODS** Using a 100% national sample of Medicare beneficiaries from 2010 to 2012, we examined 30-day and 1-year rates of all-cause mortality, major lower extremity amputation, repeat revascularization, and all-cause hospitalization by clinical care location of index PVI.

**RESULTS** A total of 218,858 Medicare beneficiaries underwent an index PVI between 2010 and 2012. Index PVIs performed in inpatient settings were associated with higher 1-year rates of all-cause mortality (23.6% vs. 10.4% and 11.7%;  $p < 0.001$ ), major lower extremity amputation (10.1% vs. 3.7% and 3.5%;  $p < 0.001$ ), and all-cause repeat hospitalization (63.3% vs. 48.5% and 48.0%;  $p < 0.001$ ), but lower rates of repeat revascularization (25.1% vs. 26.9% vs. 38.6%;  $p < 0.001$ ) when compared with outpatient hospital settings and office-based clinics, respectively. After adjustment for potential confounders, patients treated in office-based clinics remained more likely than patients in inpatient hospital settings to require repeat revascularization within 1 year across all specialties. There was also a statistically significant interaction effect between location of index revascularization and geographic region on the occurrence of all-cause hospitalization, repeat revascularization, and lower extremity amputation.

**CONCLUSIONS** Index PVI performed in office-based settings was associated with a higher hazard of repeat revascularization when compared with other settings. Differences in clinical outcomes across treatment settings and geographic regions suggest that inconsistent application of PVI may exist and highlights the need for studies to determine optimal delivery of PVI in clinical practice. (J Am Coll Cardiol Intv 2017;10:1161-71) © 2017 by the American College of Cardiology Foundation.

From the <sup>a</sup>Department of Surgery, Duke University School of Medicine, Durham, North Carolina; <sup>b</sup>Duke Clinical Research Institute, Duke University School of Medicine, Durham, North Carolina; and the <sup>c</sup>Department of Medicine, Duke University School of Medicine, Durham, North Carolina. This project was funded by American Heart Association Clinical and Mentored Population Science Research Grant #14CRP18630003 awarded to Dr. Jones. The content of this manuscript is solely the responsibility of the authors and does not necessarily represent the official views of the American Heart Association. Dr. Vemulapalli has received research grants from the American College of Cardiology, the Agency for Healthcare Research and Quality, and Abbott Vascular; and has served as a consultant for Premiere, Inc. and Novella. Dr. Peterson has received research grants from the American College of Cardiology, the American Heart Association, Eli Lilly and Company, Janssen Pharmaceutical Products, and the Society of Thoracic Surgeons; and served as a consultant or advisory board member for AstraZeneca, Bayer AG, Boehringer Ingelheim, Janssen Pharmaceutical Products, Merck & Co, and Sanofi. Dr. Patel has received research grants from AstraZeneca, Johnson & Johnson, and Pluristem; and has served as a consultant for Baxter, Bayer, Genzyme, and Ortho-McNeil-Janssen. Dr. Curtis has received research grants from Novartis, GlaxoSmithKline, Boston Scientific, and Abbott; and served as a consultant/advisory board member for Amgen. Dr. Jones has received research grants from AstraZeneca, Bristol-Myers Squibb, the Doris Duke Charitable Foundation, and the Patient-Centered Outcomes Research Institute; and has served as a consultant for the American College of Radiology and Daiichi Sankyo.

Manuscript received November 28, 2016; revised manuscript received March 13, 2017, accepted March 23, 2017.

## ABBREVIATIONS AND ACRONYMS

**CCW** = Chronic Condition Data Warehouse

**CMS** = Centers for Medicare & Medicaid Services

**COPD** = chronic obstructive pulmonary disease

**CPT** = Current Procedural Terminology

**ICD-9-CM** = International Classification of Diseases-9th Revision-Clinical Modification

**PAD** = peripheral artery disease

**PVI** = peripheral vascular intervention

**TIA** = transient ischemic attack

Treatment for peripheral artery disease (PAD) has evolved over the past decades such that endovascular revascularization has surpassed surgical bypass as the primary mode of revascularization in the United States (1,2). With this evolution in preferred approach, outpatient and office-based angiography and intervention centers have become more commonplace, and endovascular techniques (previously limited to standard angioplasty) have diversified to include stents, angioplasty with drug-coated balloons, and atherectomy (1-3).

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In 2008, seeking to encourage greater efficiency and lower overall costs, the U.S.

Centers for Medicare & Medicaid Services (CMS) modified reimbursement rates for peripheral vascular intervention (PVI) (4). As a result, a significant proportion of PVIs shifted to ambulatory settings, with approximately 70% now occurring in outpatient hospital settings and office-based clinics. This trend has led to concerns about the appropriateness and potential overuse of PVI in these settings (5). With overlapping indications and a lack of clear evidence supporting one technique over another, marked variation in the use of atherectomy, stenting, and angioplasty has been observed across clinical care settings, especially for procedures performed in outpatient settings and office-based clinics (2). Specifically, the number of atherectomy procedures performed in outpatient hospital and office-based clinic settings has increased more rapidly than angioplasty and stenting, despite a lack of clear evidence supporting the efficacy of atherectomy (2).

Whether differences in procedure type and clinical care settings are associated with cardiovascular and limb-specific outcomes remains unclear. The objective of this study was to describe patient outcomes after PVI based on clinical care location and to assess associations between clinical care location and outcomes.

## METHODS

**DATA SOURCES.** We accessed data from CMS for a 100% national sample of Medicare fee-for-service beneficiaries. The data included inpatient, outpatient, and carrier standard analytic files, Chronic Condition Data Warehouse (CCW) summary files, and the corresponding beneficiary summary files from

2010 to 2012. The inpatient files contain institutional claims for facility costs covered under Medicare Part A and beneficiary, physician, and hospital identifiers, admission and discharge dates, and diagnosis and procedure codes. The outpatient files contain claims from outpatient facility providers. The carrier files contain noninstitutional provider claims for services covered under Medicare Part B, including International Classification of Diseases-9th Revision-Clinical Modification (ICD-9-CM) diagnosis codes, physician specialty, place of service, Current Procedural Terminology (CPT) codes, and dates of service. The CCW summary files provide flags for 21 chronic conditions based on diagnoses in Part A and Part B claims from 1999 forward. Beneficiary summary files include patient demographic characteristics, birth and death dates, and information about program eligibility and enrollment.

**STUDY POPULATION.** From the carrier files, we identified Medicare beneficiaries 65 years and older who had a diagnosis of PAD and a peripheral revascularization procedure on the same claim between January 1, 2010, and December 31, 2012. We defined PAD using ICD-9-CM diagnosis code 250.7, 440.0, 440.2X, 440.3X, 440.4, 440.9, 443.9, 444.0, 444.2X, 444.8X, 445.02, 447.1, or 707.1X in the primary diagnosis field. Using the previous published methods (2,6), we defined PAD indications using ICD-9-CM diagnosis codes as follows: claudication (440.21), critical limb ischemia (440.22, 440.23, or 440.24), PAD not otherwise specified (440.20), and other (440.29). We defined peripheral revascularization procedures using CPT codes 35492, 35493, 35495, 37205 to 37208, 35450, 35470, 35473, 35474, 37220 to 37235, 35563, 35565, 35556, 35558, 35566, 35571, 35646, 35661, 35656, 35666, 35351, 35355, 35302, 35371, 35303, or 35304 to 35306.

We limited the study population to patients enrolled in fee-for-service Medicare at the time of the index revascularization procedure. If multiple PVI procedures existed for a patient, we selected the first for analysis.

**OUTCOMES.** The outcomes of interest were all-cause mortality, all-cause hospitalization, hospitalization for myocardial infarction or stroke, repeat revascularization, and major lower extremity amputation at 30 days and 1 year after the index PVI. We determined all-cause mortality based on death dates in the Medicare denominator files. We determined all-cause hospitalization on the basis of the earliest admission date after the index PVI claim. Hospitalization for myocardial infarction or stroke was a composite outcome, which we defined as the earliest of a primary diagnosis of

myocardial infarction (ICD-9-CM diagnosis code 410.x1) or a diagnosis of stroke (ICD-9-CM diagnosis code 433 or 434) in any position on an inpatient claim. We calculated time to hospitalization as the number of days from the index date to the subsequent admission date, excluding hospitalizations for rehabilitation (diagnosis related group 462 or ICD-9-CM diagnosis code of V57.xx) was not counted as a hospitalization. From the carrier files, we defined repeat revascularization using the same CPT codes as used for inclusion, and major lower extremity amputation using CPT codes 27590 to 27592, 27598, 27880 to 27882, 27884, 27886, 27888-27889, 28820, 28825, 28800, 28805, or 28810. We calculated time to event as the number of days from the index date to the subsequent service date.

**STUDY VARIABLES.** The variables of interest included patient demographic and clinical characteristics. Patient demographic characteristics included age, sex, race, and U.S. geographic region, which we derived from the Medicare denominator files. Comorbid conditions from the CCW files included prior myocardial infarction, cancer, chronic obstructive pulmonary disease (COPD), chronic kidney disease, diabetes mellitus, dementia, heart failure, hypertension, ischemic heart disease, and stroke or transient ischemic attack (TIA). Clinical setting, as defined by the place of care location on the physician claim, included inpatient facility, outpatient facility, or office-based clinic. Based on physician specialty codes, we categorized provider specialty (i.e., the operator specialty of the index PVI) as surgery (i.e., vascular, cardiovascular, and general), cardiology, radiology, and other. U.S. geographic regions were defined by states as follows: Northeast (ME, NH, VT, MA, RI, CT, PA, NY, NJ), South (DE, MD, WV, VA, KY, TN, NC, SC, GA, AL, MS, AR, LA, OK, TX), Midwest (ND, SD, MN, WI, IL, IN, OH, MI, NE, KS), and West (MT, WY, CO, NM, ID, UT, AZ, NV, WA, OR, CA, AK, HI).

We categorized PVI in 3 ways: 1) angioplasty alone, using the CPT code for percutaneous transluminal angioplasty and no CPT code for atherectomy or stent implantation; 2) atherectomy, using the CPT code for atherectomy with or without a code for angioplasty or stent; and 3) stent implantation, using the CPT code for stent implantation with or without a code for angioplasty and without a code for atherectomy. We defined the baseline PAD indication for the index PVI as claudication (ICD-9-CM diagnosis code 440.21), critical limb ischemia (ICD-9-CM diagnosis code 440.22 or 440.23), PAD not otherwise specified (ICD-9-CM diagnosis code 443.9), or other.

**STATISTICAL ANALYSIS.** We describe patient and clinical characteristics of the study population by clinical setting, using frequencies with percentages for categorical variables and medians with interquartile ranges for continuous variables. To test for differences between groups, we used chi-square tests for categorical variables and Kruskal-Wallis tests for continuous variables.

We summarize observed outcomes by clinical setting groups. For mortality at 30 days and 1 year, we calculated cumulative incidence based on Kaplan-Meier estimates and evaluated differences between groups using log-rank tests. For all other outcomes, we calculated incidence based on estimates of the cumulative incidence function, which accounts for the competing risk of mortality, and evaluated differences between groups using Gray tests. We generated plots showing the cumulative incidence of mortality and all other outcomes over the 1-year follow-up period.

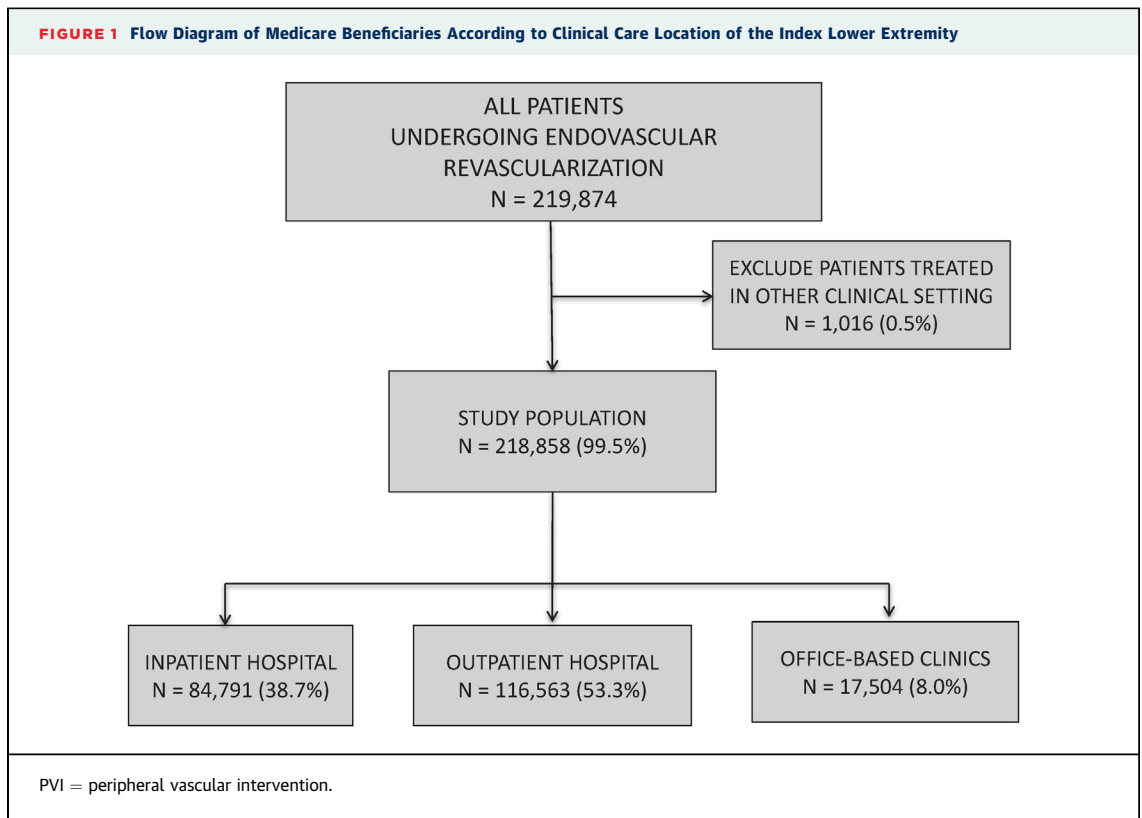
We used Cox proportional hazard models to estimate the unadjusted and adjusted associations between the study variables and 1-year outcomes. In the unadjusted model, each variable was the only predictor except for clinical setting and physician specialty. In the adjusted model, variables included age, sex, race, U.S. geographic region, comorbid conditions (i.e., prior myocardial infarction, cancer, COPD, chronic kidney disease, diabetes mellitus, dementia, heart failure, hypertension, ischemic heart disease, and stroke or TIA), clinical setting, provider specialty, type of index PVI, PAD indication, and an interaction between physician specialty and clinical care setting. Because the interaction term was statistically significant, we compared outcomes between clinical settings at each level of physician specialty, outcomes between physician specialties at each level of clinical setting, and outcomes between clinical setting and geographic region. Due to the multiple comparisons, we report 99% confidence intervals, using  $\alpha = 0.01$  to establish the statistical significance of tests. All tests were 2-sided.

The institutional review board of the Duke University Health System approved the study.

We used SAS version 9.42 (SAS Institute, Cary, North Carolina) for all analyses.

## RESULTS

**STUDY POPULATION.** In a 100% national sample of Medicare fee-for-service beneficiaries, 218,858 patients underwent lower extremity PVI between 2010 and 2012 (Figure 1). Of these, 38.7% were treated in



inpatient hospital settings, 53.3% in outpatient hospital settings, and 8.0% in office-based clinic settings. **Table 1** shows the baseline characteristics of the study population by the clinical care location of the index PVI. Patients treated in inpatient hospital settings were older and were more likely to have comorbid conditions, including recent myocardial infarction, cancer, COPD, renal disease, diabetes mellitus, and heart failure, compared with patients treated in outpatient settings or office-based clinics. Patients who underwent the index PVI in outpatient settings (45.1%) or office-based clinics (43.3%) were more frequently treated for intermittent claudication, compared with those undergoing PVI in inpatient settings (26.2%;  $p < 0.001$ ).

Atherectomy was performed nearly twice as often in office-based clinic settings (41.2%), compared with inpatient (20.7%) and outpatient hospital settings (22.8%;  $p < 0.001$ ).

**INCIDENCE OF OUTCOMES.** **Table 2** and **Figure 2** show the cumulative incidence rates of all-cause mortality, all-cause hospitalization, myocardial infarction or stroke, repeat revascularization, and major lower extremity amputation. The cumulative incidence of all-cause mortality, all-cause hospitalization, myocardial infarction or stroke, and major

lower extremity amputation were highest in inpatient hospital settings at both 30 days and 1 year. However, patients undergoing PVI in office-based clinics had higher cumulative incidence of repeat revascularization (14.2% at 30 days and 38.6% at 1 year), compared with those treated in inpatient hospital settings (9.0% at 30 days and 25.1% at 1 year) or outpatient hospital settings (8.2% at 30 days and 26.9% at 1 year).

**ADJUSTED ANALYSES.** After adjustment for clinical variables and inclusion of an interaction term between clinical care location and physician specialty, multiple factors remained significantly associated with a higher hazard of all-cause mortality, including increasing age, male sex, white race, prior myocardial infarction, cancer, COPD, renal disease, diabetes, dementia, heart failure, history of stroke or TIA, and critical limb ischemia (**Table 3**). The interaction effect between clinical care location and physician specialty was statistically significant ( $p < 0.001$ ) for all-cause mortality. Therefore, we incorporated these variables as interaction terms with the adjusted results shown in **Table 3**. Index PVI in inpatient hospital settings was associated with a greater hazard of all-cause mortality, a finding that remained statistically significant after adjustment for other demographic and clinical characteristics.

**TABLE 1 Characteristics of the Study Population by Clinical Setting (N = 218,858)**

	Clinical Setting			p Value
	Inpatient (n = 84,791)	Outpatient (n = 116,563)	Office (n = 17,504)	
Age, yrs	76.0 (70.0–82.0)	75.0 (69.0–81.0)	75.0 (70.0–81.0)	<0.001
Age group, yrs				<0.001
65–69	19,040 (22.5)	29,948 (25.7)	4,162 (23.8)	
70–74	18,379 (21.7)	27,764 (23.8)	4,161 (23.8)	
75–79	17,272 (20.4)	24,541 (21.1)	3,641 (20.8)	
≥80	30,100 (35.5)	34,310 (29.4)	5,540 (31.6)	
Men	43,979 (51.9)	61,833 (53.0)	9,358 (53.5)	<0.001
Race				<0.001
Black	11,588 (13.7)	12,967 (11.1)	3,163 (18.1)	
White	68,427 (80.7)	99,349 (85.2)	13,169 (75.2)	
Other	4,776 (5.6)	4,247 (3.6)	1,172 (6.7)	
Comorbid conditions*				
Cancer†	11,332 (13.4)	13,663 (11.7)	2,001 (11.4)	<0.001
Chronic obstructive pulmonary disease	33,249 (39.2)	36,490 (31.3)	4,842 (27.7)	<0.001
Renal disease	48,947 (57.7)	47,151 (40.5)	8,412 (48.1)	<0.001
Diabetes mellitus	51,718 (61.0)	60,615 (52.0)	9,912 (56.6)	<0.001
Dementia	18,939 (22.3)	14,691 (12.6)	2,693 (15.4)	<0.001
Heart failure	45,807 (54.0)	43,236 (37.1)	7,299 (41.7)	<0.001
Hypertension	81,400 (96.0)	107,801 (92.5)	15,967 (91.2)	<0.001
Ischemic heart disease	69,967 (82.5)	89,451 (76.7)	13,543 (77.4)	<0.001
Prior myocardial infarction	5,924 (7.0)	4,244 (3.6)	604 (3.5)	<0.001
Stroke or transient ischemic attack	11,608 (13.7)	10,666 (9.2)	1,841 (10.5)	<0.001
U.S. geographic region				<0.001
Midwest	21,940 (25.9)	32,189 (27.6)	1,172 (6.7)	
Northeast	16,020 (18.9)	14,968 (12.8)	2,156 (12.3)	
South	34,939 (41.2)	54,356 (46.6)	11,611 (66.3)	
West	11,892 (14.0)	15,050 (12.9)	2,565 (14.7)	
Peripheral artery disease indication				<0.001
Claudication	22,244 (26.2)	52,581 (45.1)	7,584 (43.3)	
Critical limb ischemia	21,645 (25.5)	22,667 (19.4)	3,313 (18.9)	
Not otherwise specified	12,441 (14.7)	18,106 (15.5)	2,705 (15.5)	
Other	28,461 (33.6)	23,209 (19.9)	3,902 (22.3)	
Physician specialty				<0.001
Cardiology	27,811 (32.8)	46,835 (40.2)	5,804 (33.2)	
Radiology	10,933 (12.9)	14,661 (12.6)	2,210 (12.6)	
Surgery	41,150 (48.5)	48,941 (42.0)	7,752 (44.3)	
Other	4,897 (5.8)	6,126 (5.3)	1,738 (9.9)	
Type of index intervention				<0.001
Angioplasty	23,640 (27.9)	29,234 (25.1)	3,487 (19.9)	
Atherectomy	17,582 (20.7)	26,617 (22.8)	7,206 (41.2)	
Stenting	43,569 (51.4)	60,712 (52.1)	6,811 (38.9)	

Values are median (interquartile range) or n (%). \*From Chronic Conditions Data Warehouse flags. †Cancer includes colorectal, endometrial, breast, lung, and prostate cancers.

**PREDICTORS OF OUTCOMES.** Table 4 summarizes the factors associated with repeat revascularization after index PVI. In the adjusted analysis, younger age, race other than white, COPD, renal disease, diabetes, hypertension, ischemic heart disease, and critical limb ischemia were associated with higher hazards of repeat revascularization. Furthermore, stenting and angioplasty procedures were associated with lower hazards of repeat revascularization when

compared with atherectomy. The interaction effect between clinical care location and physician specialty was also statistically significant for repeat revascularization (p < 0.001). We included these variables in the model as interaction terms (Table 4). After adjustment, the hazard of repeat revascularization was significantly higher in office-based clinic settings, compared with inpatient hospital settings across all physician specialties (hazard ratios 1.40 for

**TABLE 2 Cumulative Incidence of All-Cause Mortality, All-Cause Hospitalization, Myocardial Infarction or Stroke, Repeat Revascularization, and Major Lower Extremity Amputation**

Event and Time From Procedure to Event	Clinical Setting No. (Rate*)			p Value
	Inpatient (n = 84,791)	Outpatient (n = 116,563)	Office (n = 17,504)	
All-cause mortality				
30 days	4,460 (5.3)	1,059 (0.9)	194 (1.1)	<0.001
1 yr	17,815 (23.6)	10,314 (10.4)	1,573 (11.7)	<0.001
All-cause hospitalization				
30 days	19,980 (24.0)	15,099 (13.1)	2,118 (12.4)	<0.001
1 yr	49,311 (63.3)	50,405 (48.5)	6,979 (48.0)	<0.001
Myocardial infarction or stroke				
30 days	1,466 (1.8)	1,568 (1.4)	221 (1.3)	<0.001
1 yr	7,189 (9.7)	8,513 (8.5)	1,111 (8.0)	<0.001
Repeat revascularization				
30 days	7,536 (9.0)	9,446 (8.2)	2,410 (14.2)	<0.001
1 yr	19,419 (25.1)	28,314 (26.9)	5,948 (38.6)	<0.001
Major lower extremity amputation				
30 days	4,172 (5.0)	1,233 (1.1)	149 (0.9)	<0.001
1 yr	7,992 (10.1)	3,910 (3.7)	507 (3.5)	<0.001

\*Cumulative incidence per 100 patients at risk.

surgeons, 1.53 for radiologists, and 1.85 for cardiologists).

Factors associated with major lower extremity amputation and all-cause hospitalization after index PVI are summarized in [Online Tables 1 and 2](#), respectively. A separate series of sensitivity analyses were performed to examine the interaction effect between clinical care location of index PVI and geographic region. These results are summarized in [Online Tables 3 to 5](#).

The primary causes of hospitalization are shown in [Online Table 6](#). PAD was the primary cause of repeat hospitalization and accounted for 27.5% of all repeat hospitalizations.

## DISCUSSION

In response to reports attributing greater overall costs of PVI when performed in inpatient settings, CMS established bundled payments for PVI performed in outpatient hospital settings and office-based clinics. The establishment of ambulatory payment classifications has been associated with a greater proportion of PVI being performed in outpatient hospital settings and office-based clinics, where procedure choices and prescription practices differ from those in inpatient hospital settings (2,7).

**MAIN FINDINGS.** Due to changes in reimbursement for PVI and the resulting variations in how and where PVI occurs in the United States (1,8), we examined clinical outcomes after PVI and report 3 main findings.

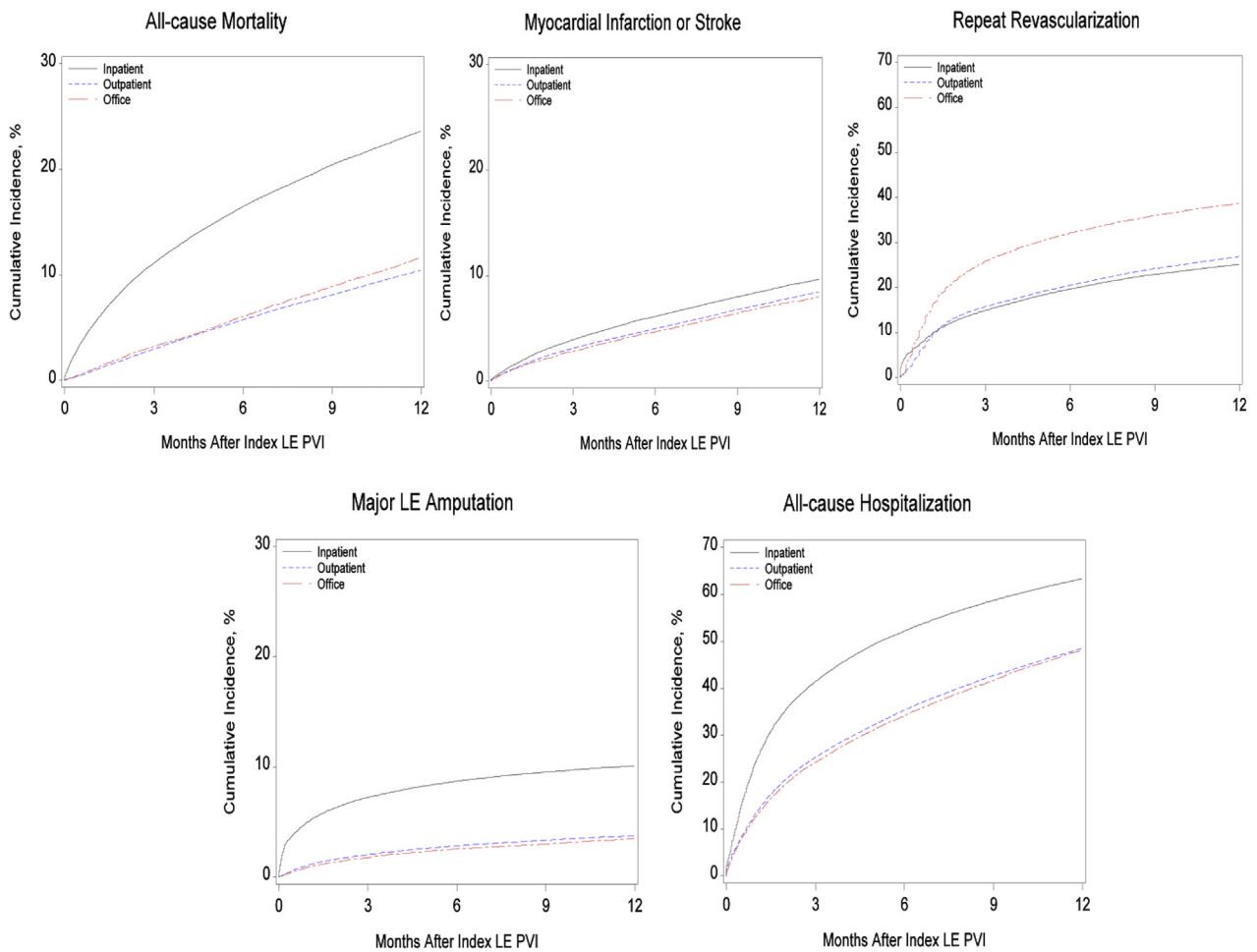
First, patients who underwent an index PVI between 2010 and 2012 had cumulative incidence rates of all-cause mortality of 15.7%, major lower extremity amputation of 6.2%, and all-cause hospitalization of 54.2% at 1 year. Second, patients treated in office-based clinics underwent atherectomy nearly twice as often as patients treated in inpatient and outpatient hospital settings and were significantly more likely to undergo repeat revascularization within 30 days and 1 year. Third, compared with outpatient hospital settings and office-based clinic settings, index PVI in inpatient settings was significantly associated with greater all-cause mortality, all-cause hospitalization, and major lower extremity amputation at 1 year. The cumulative findings likely reflect a greater burden of concomitant comorbidity in patients undergoing index PVI in inpatient hospital settings; however, the greater use of more expensive devices and more frequent repeat revascularization in office-based clinics bring to light the need for more research into why these patterns exist and whether more efficient and effective health care practices can be defined for patients with PAD.

## MAIN FINDINGS IN CONTEXT OF CURRENT KNOWLEDGE.

The rates of all-cause mortality, major lower extremity amputation, and all-cause hospitalization observed in this study highlight a pressing need for improved clinical care for Medicare beneficiaries with PAD. All-cause mortality of 15.7% at 1 year exceeds the mortality rate associated with myocardial infarction, and a major lower extremity amputation rate of 6.2% after index PVI is unacceptably high, especially considering that many patients in the United States still undergo major lower extremity amputation (without angiography and/or PVI) for the treatment of critical limb ischemia (9). An all-cause hospitalization rate of 54.2% suggests that patients who undergo PVI constitute a group with multiple comorbid conditions that may directly impact clinical outcomes yet be amenable to further risk factor modification and treatment optimization. These findings contribute to the relatively scant published data on process improvement for patients undergoing PVI. They also serve as a reminder that multiple evidence gaps exist in the care of patients with PAD, including whether all patients with critical limb ischemia should undergo attempted PVI before major lower extremity amputation, optimal use of cardioprotective medications after PVI, and appropriate use of PVI based on symptom severity, anatomic burden of disease, and lesion morphology (6-12).

**EXPLANATION OF MAIN FINDINGS.** Although multiple factors contributed to the high rates of all-cause

**FIGURE 2** Kaplan-Meier Plots



Kaplan-Meier plots are shown of the incidence of all-cause mortality, all-cause hospitalization, myocardial infarction or stroke, lower extremity (LE) amputation, and repeat revascularization after the index LE peripheral vascular intervention (PVI).

mortality, major lower extremity amputation, and all-cause hospitalization after index PVI, clinical care location, physician specialty, and geographic region were significantly associated with clinical outcomes. For example, patients who underwent PVI in inpatient settings had a greater burden of serious comorbid conditions and were at significantly higher risk for each outcome. By contrast, patients who underwent PVI in office-based clinics had a lower comorbidity burden, underwent a significantly higher number of initial atherectomy procedures, and underwent more frequent repeat revascularization attempts.

Although we cannot prove causality, we suspect that unmeasured factors (such as facility and physician reimbursement) may drive differences in treatment strategies seen among clinical care locations.

The resultant long-term effects on patient outcomes and health care costs resulting from the heterogeneous treatment strategies provided among clinical care location and across geographic regions remain uncertain and need to be further examined. Previous studies have shown that higher intensity vascular care (including re-intervention after PVI) is associated with lower amputation rates (9,13). Thus, it is possible that the higher re-intervention rate seen in the office-based setting as compared to the inpatient setting may be driving their lower rates of major amputation. Challenging this hypothesis, however, are the similar amputation rates seen among patients treated in the outpatient and office-based settings despite lower re-intervention rates for patients treated initially in the outpatient setting.

**TABLE 3 Factors Associated With All-Cause Mortality After Lower Extremity Peripheral Vascular Intervention**

	Unadjusted		Adjusted	
	HR (99% CI)	p Value	HR (99% CI)	p Value
Location (outpatient vs. inpatient)				
Outpatient vs. inpatient for surgeon	0.41 (0.40-0.43)	<0.001	0.61 (0.59-0.64)	<0.001
Outpatient vs. inpatient for radiologist	0.37 (0.34-0.40)	<0.001	0.60 (0.55-0.65)	<0.001
Outpatient vs. inpatient for cardiologist	0.38 (0.36-0.40)	<0.001	0.59 (0.55-0.62)	<0.001
Location (office vs. inpatient)				
Office vs. inpatient for surgeon	0.41 (0.37-0.45)	<0.001	0.60 (0.54-0.66)	<0.001
Office vs. inpatient for radiologist	0.46 (0.39-0.54)	<0.001	0.59 (0.50-0.69)	<0.001
Office vs. inpatient for cardiologist	0.33 (0.29-0.38)	<0.001	0.49 (0.42-0.56)	<0.001
Type of index intervention				
Angioplasty	1.41 (1.35-1.47)	<0.001	1.13 (1.08-1.18)	<0.001
Atherectomy	1.00 [Reference]		1.00 [Reference]	
Stenting	1.02 (0.98-1.06)	0.26	1.03 (0.99-1.07)	0.09
Peripheral artery disease indication				
Claudication	1.00 [Reference]		1.00 [Reference]	
Critical limb ischemia	3.32 (3.18-3.46)	<0.001	1.82 (1.73-1.90)	<0.001
Not otherwise specified	1.76 (1.67-1.86)	<0.001	1.38 (1.31-1.46)	<0.001
Others	3.17 (3.03-3.30)	<0.001	1.82 (1.74-1.91)	<0.001
Age group, yrs				
65-69	1.00 [Reference]		1.00 [Reference]	
70-74	1.19 (1.13-1.25)	<0.0001	1.09 (1.03-1.15)	<0.001
75-79	1.54 (1.46-1.62)	<0.0001	1.28 (1.21-1.35)	<0.001
≥80	2.71 (2.59-2.83)	<0.0001	1.84 (1.76-1.93)	<0.001
Male	1.00 (0.97-1.03)	0.93	1.08 (1.05-1.12)	<0.001
Race				
Black	1.14 (1.09-1.19)	<0.001	0.88 (0.84-0.92)	<0.001
White	1.00 [Reference]		1.00 [Reference]	
Other	1.13 (1.06-1.21)	<0.001	0.88 (0.82-0.95)	<0.001
Comorbid conditions*				
Cancer†	1.46 (1.40-1.52)	<0.001	1.27 (1.22-1.33)	<0.001
Chronic obstructive pulmonary disease	1.70 (1.65-1.75)	<0.001	1.30 (1.26-1.34)	<0.001
Diabetes mellitus	1.60 (1.55-1.65)	<0.001	1.05 (1.01-1.08)	<0.001
Dementia	3.30 (3.20-3.41)	<0.001	1.76 (1.70-1.83)	<0.001
Heart failure	4.11 (3.97-4.26)	<0.001	2.30 (2.21-2.39)	<0.001
Hypertension	1.46 (1.36-1.57)	<0.001	0.64 (0.60-0.70)	<0.001
Ischemic heart disease	1.66 (1.59-1.73)	<0.001	0.94 (0.90-0.99)	0.001
Prior myocardial infarction	2.79 (2.66-2.93)	<0.001	1.61 (1.54-1.70)	<0.001
Renal disease	3.57 (3.44-3.69)	<0.001	2.08 (2.00-2.16)	<0.001
Stroke or transient ischemic attack	2.02 (1.95-2.10)	<0.001	1.30 (1.24-1.35)	<0.001

\*In the adjusted model, all variables listed in the table and interactions between location and physician specialty were included. The interaction effect was statistically significant ( $p < 0.001$ ). Locations were compared at each level of physician specialty. †Cancer includes colorectal, endometrial, breast, lung, and prostate cancers.  
CI = confidence interval; HR = hazard ratio.

Furthermore, the proposed cost savings to Medicare for office-based PVI may be compromised with greater use of the more expensive atherectomy and higher numbers of repeat revascularization.

The trends in PVI use and variation in clinical outcomes signal that implementation of appropriate use criteria for PVI should be considered, especially in office-based clinics where patients with fewer comorbid conditions underwent more expensive procedures and more frequent repeat revascularization. These results serve as a call to action for the vascular

community (including the major professional societies for cardiology, vascular surgery, and radiology) to develop systems to more closely examine current practices, develop a firm evidence base, and ultimately improve clinical outcomes. Appropriate use criteria and clinical guidelines for PVI need to be better delineated based on patient factors, disease severity, lesion location, and indications for procedures. To inform the development of these guidelines, collaboration within the vascular community as a whole to design and conduct prospective clinical



**TABLE 4 Factors Associated With Repeat Revascularization After Lower Extremity Peripheral Vascular Intervention**

	Unadjusted		Adjusted	
	HR (99% CI)	p Value	HR (99% CI)	p Value
Location (outpatient vs. inpatient)				
Outpatient vs. inpatient for surgeon	0.94 (0.90-0.97)	<0.001	0.97 (0.94-1.01)	0.05
Outpatient vs. inpatient for radiologist	0.85 (0.79-0.91)	<0.001	0.91 (0.84-0.98)	<0.001
Outpatient vs. inpatient for cardiologist	1.00 (0.97-1.04)	0.84	1.04 (1.00-1.08)	0.01
Outpatient vs. inpatient for other	1.11 (1.00-1.22)	0.009	1.12 (1.02-1.24)	0.003
Location (office vs. inpatient)				
Office vs. inpatient for surgeon	1.49 (1.40-1.58)	<0.001	1.40 (1.32-1.49)	<0.001
Office vs. inpatient for radiologist	1.57 (1.40-1.75)	<0.001	1.53 (1.37-1.72)	<0.001
Office vs. inpatient for cardiologist	1.85 (1.74-1.96)	<0.001	1.79 (1.68-1.90)	<0.001
Type of index intervention				
Angioplasty	0.68 (0.66-0.70)	<0.001	0.74 (0.71-0.76)	<0.001
Atherectomy	1.00 [Reference]		1.00 [Reference]	
Stenting	0.53 (0.52-0.55)	<0.001	0.58 (0.57-0.60)	<0.001
Peripheral artery disease indication				
Claudication	1.00 [Reference]		1.00 [Reference]	
Critical limb ischemia	1.04 (1.01-1.07)	<0.001	1.09 (1.05-1.12)	<0.001
Not otherwise specified	0.96 (0.92-0.99)	<0.001	0.91 (0.88-0.94)	<0.001
Others	0.91 (0.88-0.93)	<0.001	1.01 (0.98-1.04)	0.53
Age group, yrs				
65-69	1.00 [Reference]		1.00 [Reference]	
70-74	0.97 (0.94-1.00)	0.01	0.95 (0.92-0.98)	<0.001
75-79	0.96 (0.93-1.00)	0.004	0.93 (0.90-0.97)	<0.001
≥ 80	0.96 (0.94-0.99)	0.002	0.93 (0.90-0.96)	<0.001
Male	1.04 (1.02-1.07)	<0.001	1.01 (0.99-1.04)	0.12
Race				
Black	1.16 (1.13-1.20)	<0.001	1.08 (1.04-1.11)	<0.001
White	1.00 [Reference]		1.00 [Reference]	
Other	1.16 (1.11-1.22)	<0.001	1.06 (1.01-1.12)	0.002
Comorbid conditions*				
Cancer†	0.98 (0.95-1.01)	0.13	1.00 (0.96-1.03)	0.84
Chronic obstructive pulmonary disease	1.02 (0.99-1.04)	0.05	1.04 (1.01-1.06)	<0.001
Diabetes mellitus	1.21 (1.18-1.23)	<0.001	1.10 (1.07-1.12)	<0.001
Dementia	1.00 (0.97-1.03)	0.70	0.94 (0.91-0.97)	<0.001
Heart failure	1.13 (1.10-1.15)	<0.001	1.01 (0.99-1.04)	0.22
Hypertension	1.46 (1.39-1.54)	<0.001	1.28 (1.21-1.35)	<0.001
Ischemic heart disease	1.26 (1.22-1.30)	<0.001	1.10 (1.06-1.13)	<0.001
Prior myocardial infarction	1.07 (1.02-1.13)	<0.001	1.01 (0.96-1.06)	0.69
Renal disease	1.16 (1.14-1.19)	<0.001	1.09 (1.06-1.11)	<0.001
Stroke or transient ischemic attack	1.06 (1.03-1.10)	<0.001	1.02 (0.99-1.06)	0.11

\*In the adjusted model, all variables listed in the table and interactions between location and physician specialty were included. The interaction effect was statistically significant (p < 0.001). Locations were compared at each level of physician specialty. †Cancer includes colorectal, endometrial, breast, lung, and prostate cancers. Abbreviations as in Table 3.

trials is needed to provide a scientific foundation for treatment choices for PAD.

**THE PATH FORWARD.** Our findings emphasize the need to understand best practices after PVI that would extend across all clinical care settings, physician specialties, and geographic regions. Identifying providers or health care systems with lower rates of all-cause mortality, major lower extremity amputation, and all-cause hospitalization in age- and risk-adjusted populations would be the first step to

model and incorporate these best practices into appropriate use criteria and health policy decision making. On the national level, PVI data are currently entered into multiple registries based on provider specialty (e.g., the American College of Cardiology’s PVI Registry, the Society for Vascular Surgery’s Vascular Quality Initiative, and the Society of Interventional Radiology’s registry), making best practice data gleaned from these sources less generalizable across specialties. The emergence of more sophisticated electronic health records systems may facilitate

quality improvement programs, sometimes termed “learning health systems,” across hospitals and health care systems to more accurately measure quality and outcomes in real time. These programs could determine the impact of currently unmeasured factors in administrative datasets, such as anatomy or burden of disease, more specific intervention details (e.g., balloon type, stent length, atherectomy type), and more specific clinical information (such as degree of ischemia or location of tissue loss), as well as access to care and disparities in care. Until major changes are implemented to monitor and measure vascular care, inconsistent application of treatments (including medications, PVI, and major lower extremity amputation) will continue to occur, and patients will continue to experience high rates of all-cause mortality, major lower extremity amputation, repeat revascularization, and all-cause hospitalization.

**STUDY LIMITATIONS.** First, symptoms and the severity of PAD are not accurately captured in Medicare claims data. Second, disease characteristics that influence choice of intervention, including disease complexity, percent stenosis, anatomic location, extent of calcification, and length of disease, cannot be gleaned from Medicare data. Third, we included only patients who were 65 years and older and enrolled in fee-for-service Medicare, which may not be generalizable to other populations. Fourth, we were unable to determine whether the need for repeat revascularization was truly related to treatment failure as opposed to staged treatment strategies or incomplete index procedures. Fifth, even though we adjusted for known confounders, it is possible that an unmeasured treatment bias exists that cannot be fully captured using administrative CMS data. Furthermore, despite a predilection to perform PVI on high-risk patients in inpatient settings, we were unable to determine whether these patients were more or less likely to receive optimal medical therapy (e.g., smoking cessation counseling, blood pressure control, tight glucose control) that may improve post-procedural clinical outcomes. Finally, the use of ambiguous claims codes on the primary diagnosis line for index PVI made the indication for PVI unclear for 40% of patients in the study, limiting our ability to draw conclusions about associations between the indication for PVI and clinical outcomes. Although the study only used CMS data between 2010 and 2012, this time frame provides an accurate assessment of the overall effects of the 2008 CMS reimbursement policy changes after a 2-year adjustment period.

## CONCLUSIONS

In this large, contemporary cohort of Medicare beneficiaries, we observed large variability in clinical outcomes after PVI that was significantly associated with the clinical care setting, the physician specialty, and the geographic region of the index PVI. Outcomes were consistently worse in patients treated in inpatient hospital settings, calling into question whether opportunity existed to treat these patients differently. Furthermore, we observed associations between index PVI in office-based clinics, the use of treatment modalities with higher reimbursement (namely atherectomy), and the subsequent need for repeat revascularization.

These findings support the need for better measures of quality and appropriateness to ensure consistent and proper PVI procedures in all settings.

**ACKNOWLEDGMENT** Damon M. Seils, MA, Duke University, provided editorial assistance and prepared the manuscript for submission. Mr. Seils did not receive compensation for his assistance apart from his employment at the institution where the study was conducted.

**ADDRESS FOR CORRESPONDENCE:** Dr. W. Schuyler Jones, Duke University Medical Center, Box 3330, Durham, North Carolina 27710. E-mail: [schuyler.jones@duke.edu](mailto:schuyler.jones@duke.edu).

## PERSPECTIVES

**WHAT IS KNOWN?** The current study reports the contemporary rates of clinical outcomes (i.e., death, myocardial infarction, stroke, repeat hospitalization, and repeat revascularization) following PVI.

**WHAT IS NEW?** With changes in reimbursement by the CMS have come shifts in the clinical care location of PVI and variation in clinical outcomes after PVI. Specifically, the clinical care location, physician specialty, and geographic region of the index PVI were all statistically significantly associated with differences in rates of death, myocardial infarction, stroke, repeat hospitalization, and repeat revascularization.

**WHAT IS NEXT?** More evidence and better measures of quality and appropriateness are needed to ensure consistent application of PVI to our patients with PAD across the United States.

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**KEY WORDS** amputation, angioplasty, death, Medicare, peripheral artery disease

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**APPENDIX** For supplemental tables, please see the online version of this article.