

# Peripheral Arterial Testing Before Lower Extremity Amputation Among Medicare Beneficiaries, 2000 to 2010

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**Background**—Despite mild reductions in rates of lower extremity amputation over the past decade, few data exist on the use of arterial testing in patients before amputation.

**Methods and Results**—Using Medicare claims from 2000 through 2010, we examined rates of preamputation arterial testing between 0 to 12 and 0 to 24 months before amputation. We used multivariable, modified Poisson regression models to identify patient and clinical predictors of preamputation arterial testing. The main outcome measures were rates of preamputation arterial testing. Among 17463 patients undergoing nontraumatic amputation, 68.4% underwent some type of arterial testing. Of these patients, 47.5% underwent ankle-brachial index measurement, 38.7% duplex ultrasound, 31.1% invasive angiography, 6.7% computed tomographic angiography, and 5.6% magnetic resonance angiography. Temporal analysis revealed an increase in testing from 65.7% in 2002 to 69.2% in 2010 ( $P<0.001$ ). The use of preamputation arterial testing varied significantly by location of amputation and was lowest for foot amputation (62.5%), followed by above-knee amputation (69.0%) and below-knee amputation (76.7%;  $P<0.001$ ). After multivariable adjustment, older age, male sex, black race, renal disease, diabetes mellitus, known peripheral arterial disease, evaluation by a vascular specialist, and living in the East North Central region were associated with greater rates of preamputation arterial testing.

**Conclusions**—Rates of evaluation for peripheral arterial disease before amputation were low, and testing varied by patient, provider, and regional characteristics. (*Circ Cardiovasc Qual Outcomes*. 2014;7:142-150.)

**Key Words:** amputation ■ ankle-brachial index ■ diagnostic techniques, cardiovascular ■ peripheral arterial disease

Lower extremity peripheral artery disease (PAD) affects ≈8 million people in the United States and, in its most severe form, can require lower extremity amputation.<sup>1,2</sup> Lower extremity amputation is associated with significant morbidity, mortality, and healthcare costs.<sup>3,4</sup> During the past decade, improved detection, screening, and treatment strategies for PAD have been associated with a declining rate of lower extremity amputation among patients with the disease.<sup>5,6</sup> The possibility of improved revascularization options for patients facing lower extremity amputation is limited inherently to patients for whom the diagnosis of PAD has been considered and the arterial anatomy has been assessed. As a result, current guidelines suggest that at-risk patients should be screened with arterial testing for the diagnosis of PAD.<sup>1</sup>

Although previous studies have examined the intensity of vascular care before amputation, these studies were limited to patients with known PAD and did not address lower extremity arterial testing.<sup>7</sup> Consequently, we sought to characterize the frequency and change over time in arterial testing for the identification and anatomic characterization of PAD in older patients undergoing nontraumatic lower extremity amputation.

## Methods

### Data Sources

We obtained data for a nationally representative 5% cohort of Medicare beneficiaries from 2000 through 2010 from the Centers for Medicare and Medicaid Services. The inpatient files contain institutional claims for facility costs covered under Medicare Part A, and the outpatient files contain claims from institutional outpatient providers (eg, ambulatory surgery centers, hospital outpatient departments). The carrier files contain noninstitutional provider claims for services covered under Medicare Part B. The denominator files contain beneficiary demographic data and information about program eligibility and enrollment. We restricted the analysis to fee-for-service Medicare beneficiaries living in the United States.

### Study Population

We searched carrier claims submitted between January 1, 2002, and December 31, 2010, to identify patients who underwent any lower extremity amputation (see Table I in the Data Supplement for procedure codes). To ensure that these amputations were not a result of trauma, we omitted data for patients who had a concurrent diagnosis of traumatic amputation on the carrier claim. For patients with multiple claims for lower extremity amputation, we defined the earliest as the index procedure and required that no amputation was performed in the 12 months before the index procedure. To assess comorbid

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## WHAT IS KNOWN

- Improvements in detection, screening, and treatment strategies for peripheral arterial disease have been associated with a declining rate of lower extremity amputation.
- The possibility of improved revascularization in patients facing lower extremity amputation is limited to patients for whom a diagnosis of peripheral arterial disease has been considered and the arterial anatomy has been assessed. Thus, guidelines suggest that at-risk patients should be screened with arterial testing for a diagnosis of peripheral arterial disease.

## WHAT THE STUDY ADDS

- Many patients, both with and without known peripheral arterial disease, underwent lower extremity amputation without arterial testing in the year before amputation.
- Consistent with underrecognition and undertreatment of peripheral arterial disease in women, women were less likely to receive preamputation arterial testing.
- Younger patients and patients living in rural areas also were less likely to receive preamputation arterial testing.

conditions and previous procedures, we required continuous enrollment in fee-for-service Medicare for 24 months before the index procedure. Because Medicare beneficiaries <65 years of age often have chronic illnesses that predispose them to PAD, and because current guidelines suggest that patients >50 years of age with risk factors are at risk for PAD, this analysis includes beneficiaries of all ages.<sup>8</sup>

## Preamputation Arterial Testing

We searched carrier claims for Current Procedural Terminology codes for ankle-brachial index (ABI) measurement, lower extremity arterial duplex ultrasound, lower extremity computed tomographic angiography, lower extremity magnetic resonance angiography, and lower extremity angiography performed on the day of amputation or in the previous 12 months to identify receipt of arterial testing before nontraumatic lower extremity amputation (Table in the Data Supplement). In a sensitivity analysis, we extended the preamputation testing ascertainment period to 0 to 24 months before the index procedure date.

## Predictors of Preamputation Arterial Testing

Patient demographic characteristics included age, sex, race, and state and zip code of residence. We used the self-reported race categories black and white and combined all other categories as other. On the basis of state of residence, we grouped beneficiaries into 9 US census regions. We derived a rural indicator variable from rural-urban commuting area scores based on zip code of residence.<sup>9,10</sup> For comorbid conditions, we used previously validated coding algorithms to search inpatient, outpatient, and carrier claims in the 12 to 24 months before the index procedure for evidence of cancer, cerebrovascular disease, chronic obstructive pulmonary disease, heart failure, ischemic heart disease, dementia, diabetes mellitus, hypertension, and renal disease.<sup>11,12</sup> We defined PAD on the basis of any diagnosis code or procedure code for revascularization.<sup>7,13</sup> We also searched carrier claims for outpatient evaluation and management visits with a vascular specialist, excluding service in an inpatient hospital or emergency

department (Table in the Data Supplement). We identified vascular specialists using the Health Care Financing Administration specialty code on the carrier claim, including cardiologists, peripheral vascular disease specialists, vascular surgeons, and interventional radiologists (Table in the Data Supplement).

## Statistical Analysis

We present categorical variables as frequencies with percentages and continuous variables as mean with SDs. We tested for differences in patient characteristics and use of preamputation imaging by location (foot, below the knee, or above the knee) using  $\chi^2$  tests for categorical variables and Kruskal-Wallis tests for the continuous age variable, which had a nonnormal distribution. Similarly, we tested for differences in the use of preamputation imaging between patients with or without a diagnosis of PAD in the 12 to 24 months before amputation and between patients <65 and  $\geq 65$  years of age. We plotted the yearly rates of preamputation arterial testing stratified by amputation location, and we tested for temporal trends using the Cochran-Mantel-Haenszel test for nonzero correlation. We examined factors associated with receipt of preamputation arterial testing using univariate and multivariable, modified Poisson regression models.<sup>14</sup> In the multivariable models, we adjusted for covariates including age at amputation, sex, race, US census region, rural location, comorbid conditions in the previous year, outpatient evaluation and management visit with a vascular specialist in the previous year, and year of the index procedure.

The 2-sided significance level was 0.05. We used SAS version 9.2 for all analyses. The institutional review board of the Duke University Health System approved the study.

## Results

Overall, we identified 17 463 patients who underwent nontraumatic lower extremity amputation between 2002 and 2010. These amputations included 7343 (42%) foot amputations, 4804 (27.5%) below-knee amputations, and 5316 (30.4%) above-knee amputations. Table 1 shows the demographic and clinical characteristics of the cohort.

Among patients who underwent nontraumatic lower extremity amputation, the mean age was 73.8 years, 49.1% were women, and 71.8% were white. In the 12 to 24 months before amputation, 54.1% of patients had PAD, 47% had ischemic heart disease, 35.4% had heart failure, 62.8% had diabetes mellitus, and 27.7% had renal disease. About one third of patients were seen by a vascular specialist and 26.6% were seen by a cardiologist.

Preamputation arterial testing was performed in 68.4% of all patients undergoing nontraumatic lower extremity amputation between 2002 and 2010. The median time from arterial testing to amputation was 14 days (interquartile range, 4–50). Rates were significantly different among patients undergoing foot (62.5%), below-knee (76.7%), and above-knee (62.5%) amputations ( $P < 0.001$ ; Table 2). The rate of preamputation ABI measurement was 47.5% overall and was significantly different between the groups (46.1%, 52.9%, and 44.5%;  $P < 0.001$ ). Extending the period of ascertainment for preamputation arterial testing from 0 to 12 months to 0 to 24 months before amputation did not change the relative frequencies of arterial testing. The use of preamputation arterial testing among patients  $\geq 65$  years of age was higher than among those <65 years of age (69.2% versus 65.1%;  $P < 0.001$ ; Table 3). The median time from arterial testing to amputation was 14 days (interquartile range, 4–57) among patients <65 years of age and 14 days (interquartile range, 4–49) among patients  $\geq 65$  years of age.

**Table 1. Baseline Characteristics of the Study Population by Location of Amputation**

Characteristic	All Patients (N=17 463)	Foot (n=7343)	Below Knee (n=4804)	Above Knee (n=5316)	P Value*
Age, mean (SD), y	73.8 (12.0)	73.1 (11.9)	71.5 (12.4)	76.8 (11.3)	<0.001
Age group, n (%)					<0.001
<50	772 (4.4)	356 (4.8)	286 (6.0)	130 (2.4)	
50–54	569 (3.3)	251 (3.4)	210 (4.4)	108 (2.0)	
55–59	854 (4.9)	376 (5.1)	313 (6.5)	165 (3.1)	
60–64	1108 (6.3)	460 (6.3)	365 (7.6)	283 (5.3)	
65–69	2131 (12.2)	946 (12.9)	669 (13.9)	516 (9.7)	
70–74	2880 (16.5)	1286 (17.5)	818 (17.0)	776 (14.6)	
75–79	3095 (17.7)	1328 (18.1)	819 (17.0)	948 (17.8)	
80–84	2871 (16.4)	1181 (16.1)	659 (13.7)	1031 (19.4)	
85–89	2003 (11.5)	778 (10.6)	443 (9.2)	782 (14.7)	
≥90	1180 (6.8)	381 (5.2)	222 (4.6)	577 (10.9)	
Women, n (%)	8570 (49.1)	3539 (48.2)	2118 (44.1)	2913 (54.8)	<0.001
Race, no. (%)					<0.001
Black	3993 (22.9)	1128 (15.4)	1227 (25.5)	1638 (30.8)	
White	12 535 (71.8)	5835 (79.5)	3289 (68.5)	3411 (64.2)	
Other	935 (5.4)	380 (5.2)	288 (6.0)	267 (5.0)	
Comorbid conditions, n (%)					
Cancer	1887 (10.8)	827 (11.3)	512 (10.7)	548 (10.3)	0.22
Cerebrovascular disease	5033 (28.8)	1790 (24.4)	1317 (27.4)	1926 (36.2)	<0.001
Chronic obstructive pulmonary disease	4920 (28.2)	1999 (27.2)	1335 (27.8)	1586 (29.8)	0.004
Congestive heart failure	6184 (35.4)	2391 (32.6)	1819 (37.9)	1974 (37.1)	<0.001
Ischemic heart disease	8249 (47.2)	3349 (45.6)	2390 (49.8)	2510 (47.2)	<0.001
Dementia	1397 (8.0)	360 (4.9)	262 (5.5)	775 (14.6)	<0.001
Diabetes mellitus	10 971 (62.8)	4746 (64.6)	3308 (68.9)	2917 (54.9)	<0.001
Hypertension	13 933 (79.8)	5841 (79.5)	3852 (80.2)	4240 (79.8)	0.69
Peripheral arterial disease					
ICD-9-CM or revascularization	9447 (54.1)	3807 (51.8)	2732 (56.9)	2908 (54.7)	<0.001
ICD-9-CM only	9412 (53.9)	3796 (51.7)	2718 (56.6)	2898 (54.5)	<0.001
Revascularization only	924 (5.3)	283 (3.9)	324 (6.7)	317 (6.0)	<0.001
Peripheral vascular disease	7706 (44.1)	2966 (40.4)	2230 (46.4)	2510 (47.2)	<0.001
Renal disease	4832 (27.7)	1906 (26.0)	1673 (34.8)	1253 (23.6)	<0.001
US Census region, n (%)					<0.001
Northeast					
New England	763 (4.4)	380 (5.2)	193 (4.0)	190 (3.6)	
Middle Atlantic	2310 (13.2)	1027 (14.0)	574 (11.9)	709 (13.3)	
South					
South Atlantic	4070 (23.3)	1489 (20.3)	1162 (24.2)	1419 (26.7)	
East South Central	1581 (9.1)	544 (7.4)	410 (8.5)	627 (11.8)	
West South Central	2389 (13.7)	917 (12.5)	674 (14.0)	798 (15.0)	
Midwest					
East North Central	2971 (17.0)	1347 (18.3)	825 (17.2)	799 (15.0)	
West North Central	1221 (7.0)	628 (8.6)	302 (6.3)	291 (5.5)	
West					
Mountain	684 (3.9)	356 (4.8)	213 (4.4)	115 (2.2)	
Pacific	1474 (8.4)	655 (8.9)	451 (9.4)	368 (6.9)	

(Continued)

Table 1. Continued

Characteristic	All Patients (N=17 463)	Foot (n=7343)	Below Knee (n=4804)	Above Knee (n=5316)	PValue*
Rural location, n (%)	5092 (29.2)	2065 (28.1)	1392 (29.0)	1635 (30.8)	0.005
Outpatient evaluation and management visit, n (%)	5477 (31.4)	2437 (33.2)	1627 (33.9)	1413 (26.6)	<0.001
Cardiologist	4649 (26.6)	2138 (29.1)	1382 (28.8)	1129 (21.2)	<0.001
Interventional radiologist	20 (0.1)	...†	...†	...†	0.90
Peripheral vascular disease specialist	69 (0.4)	26 (0.4)	21 (0.4)	22 (0.4)	0.75
Vascular surgeon	1421 (8.1)	549 (7.5)	437 (9.1)	435 (8.2)	0.006
Year of index amputation, n (%)					<0.001
2002	2323 (13.3)	824 (11.2)	693 (14.4)	806 (15.2)	
2003	2217 (12.7)	848 (11.5)	658 (13.7)	711 (13.4)	
2004	2130 (12.2)	836 (11.4)	633 (13.2)	661 (12.4)	
2005	2042 (11.7)	812 (11.1)	582 (12.1)	648 (12.2)	
2006	1789 (10.2)	752 (10.2)	493 (10.3)	544 (10.2)	
2007	1713 (9.8)	746 (10.2)	436 (9.1)	531 (10.0)	
2008	1765 (10.1)	833 (11.3)	437 (9.1)	495 (9.3)	
2009	1776 (10.2)	826 (11.2)	437 (9.1)	513 (9.7)	
2010	1708 (9.8)	866 (11.8)	435 (9.1)	407 (7.7)	

ICD-9-CM indicates International Classification of Diseases, Ninth Revision, Clinical Modification.

\*We tested for differences by location (foot, below the knee, or above the knee) using  $\chi^2$  tests for categorical variables and Kruskal-Wallis tests for continuous variables.

†Data not shown for cells with <11 observations.

To assess changing practice patterns, we examined the frequency of preamputation arterial testing over time (Figure 1). Although there was a significant increase in arterial testing overall during the study period (65.7% in 2002 versus 69.2% in 2010;  $P<0.001$ ), rates remained <80% for both above-knee and below-knee amputations. Preamputation arterial testing in foot amputations remained consistent during the study period at  $\approx 62\%$ . Specifically, there was a statistically significant increase in the rate of preamputation ABI measurement (43.8%–49%), duplex ultrasound (25.4%–37.5%), and computed tomographic angiography (0.4%–12.9%). There was no statistically significant change in invasive angiography (39.3%–39.1%), and there was a significant decrease in preamputation magnetic resonance angiography (3.1%–1.9%; Figure 2).

Table 4 summarizes the frequency of preamputation arterial testing by previous PAD diagnosis in patients undergoing

lower extremity amputation. Any arterial testing (73.7% versus 62.1%;  $P<0.001$ ) and ABI measurement (52.8% versus 41.2%) were more frequent in patients with known PAD. Among patients with known PAD, anatomic arterial testing, defined as duplex ultrasound, computed tomographic angiography, magnetic resonance angiography, or invasive angiography, occurred in 34.8%, 6.8%, 6.3%, and 42.1%, respectively. Extending the ascertainment period for arterial testing to 2 years before amputation did not change the frequency of testing substantially in patients without PAD (62.1% versus 62.5%).

Table 5 shows the results of the Poisson models created to identify clinical predictors of preamputation arterial testing. After multivariable adjustment, younger age, female sex, dementia, Mountain region, and rural location were associated with lower likelihoods of undergoing preamputation arterial testing. Black race, renal disease, diabetes mellitus,

Table 2. Use of Arterial Testing Before Amputation by Location of Amputation

Test	Location of Amputation, n (%)				PValue*
	All Patients (N=17 463)	Foot (n=7343)	Below Knee (n=4804)	Above Knee (n=5316)	
Any arterial testing	11 945 (68.4)	4589 (62.5)	3686 (76.7)	3670 (69.0)	<0.001
Ankle-brachial index	8293 (47.5)	3386 (46.1)	2542 (52.9)	2365 (44.5)	<0.001
Duplex ultrasound	5426 (31.1)	1959 (26.7)	1675 (34.9)	1792 (33.7)	<0.001
Computed tomographic angiography	1169 (6.7)	406 (5.5)	364 (7.6)	399 (7.5)	<0.001
Magnetic resonance angiography	974 (5.6)	391 (5.3)	342 (7.1)	241 (4.5)	<0.001
Invasive angiography	6750 (38.7)	2500 (34.0)	2362 (49.2)	1888 (35.5)	<0.001
Any arterial testing in the previous 2 y	12512 (71.6)	4853 (66.1)	3820 (79.5)	3839 (72.2)	<0.001

\*We tested for differences in patient characteristics by location (foot, below the knee, or above the knee) using  $\chi^2$  tests.



**Table 3. Use of Arterial Testing Before Amputation by Age**

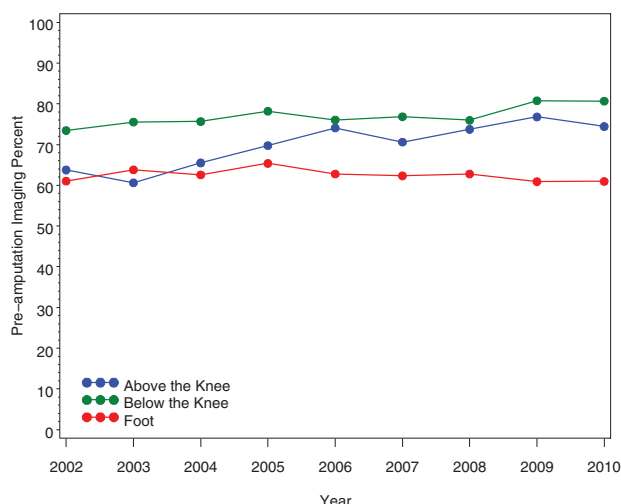
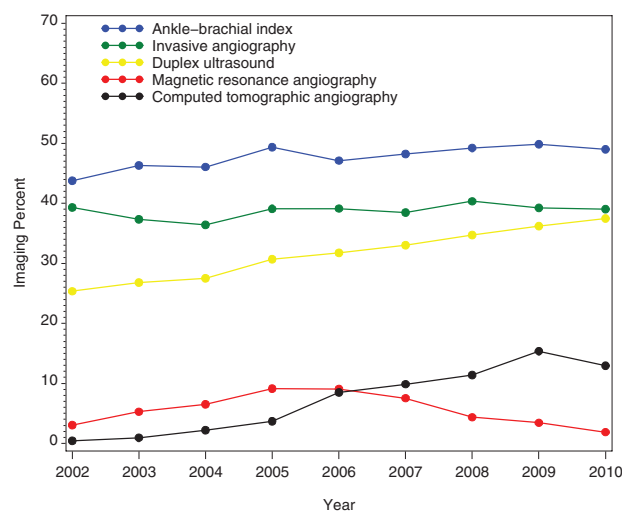
Test	Age, n (%)		P Value
	<65 y (n=3303)	≥65 y (n=14 160)	
Any arterial testing	2151 (65.1)	9794 (69.2)	<0.001
Ankle-brachial index	1486 (45.0)	6807 (48.1)	0.001
Duplex ultrasound	950 (28.8)	4476 (31.6)	0.001
Computed tomographic angiography	242 (7.3)	927 (6.5)	0.11
Magnetic resonance angiography	148 (4.5)	826 (5.8)	0.002
Invasive angiography	1209 (36.6)	5541 (39.1)	0.007
Any arterial testing in the previous 2 y	2281 (69.1)	10 231 (72.3)	<0.001

known PAD, and previous evaluation by a vascular specialist were associated with greater likelihoods of preamputation arterial testing.

### Discussion

Treatment options for PAD are expanding but are limited to patients for whom a diagnosis of PAD has been made. In our study of Medicare beneficiaries who undergo nontraumatic lower extremity amputation, only 68.4% received peripheral arterial testing of any kind in the preceding 12 months, including basic testing such as ABI measurement. Preamputation testing was associated with age, race, sex, diabetes mellitus, renal disease, PAD status, geography, and previous evaluation by a vascular specialist. Despite publication of the first American College of Cardiology/American Heart Association guidelines for PAD and a concurrent PAD awareness campaign by the National Heart, Lung, and Blood Institute in 2005 to 2006, rates of preamputation arterial testing improved only modestly (65.7% versus 69.2%) between 2002 and 2010.

Although declining in incidence, lower extremity amputation still carries a significant burden of morbidity and economic cost for individual patients.<sup>1,3,4</sup> As a result, current guidelines state that lower extremity amputation, at least in

**Figure 1.** Trends in unadjusted rates of arterial testing before amputation by amputation location, 2002 to 2010.**Figure 2.** Trends in unadjusted rates of arterial testing before amputation by testing modality, 2002 to 2010.

part, because of arterial insufficiency is reserved for patients without medical or revascularization options.<sup>1</sup> These guideline recommendations rest on the assumption that clinicians will identify accurately the presence and pathological contribution of arterial insufficiency to an extremity under consideration for nontraumatic amputation.

Previous studies have highlighted the difficulty of relying on patient history and physical examination alone for the diagnosis of PAD in patients with or without lower extremity symptoms.<sup>15</sup> In light of its high sensitivity and specificity,<sup>16,17</sup> correlation with disease severity,<sup>18</sup> ability to predict future cardiovascular events,<sup>19</sup> ease of performance, and low cost, the ABI has long been considered the gold standard for the diagnosis of PAD. Although not specifically validated as a screening tool in patients undergoing nontraumatic amputation, given the cost, morbidity, and decrement in quality of life associated with lower extremity amputation,<sup>20–22</sup> the threshold for measurement of the ABI should be low. For these reasons,

**Table 4. Use of Arterial Testing Before Amputation by Peripheral Arterial Disease Status\***

Test	Disease Status, n (%)		P Value
	No Peripheral Arterial Disease (n=8016)	Peripheral Arterial Disease (n=9447)	
Any arterial testing	4980 (62.1)	6965 (73.7)	<0.001
Ankle-brachial index	3304 (41.2)	4989 (52.8)	<0.001
Duplex ultrasound	2139 (26.7)	3287 (34.8)	<0.001
Computed tomographic angiography	525 (6.5)	644 (6.8)	0.48
Magnetic resonance angiography	381 (4.8)	593 (6.3)	<0.001
Invasive angiography	2775 (34.6)	3975 (42.1)	<0.001
Any arterial testing in the previous 2 y	5008 (62.5)	7504 (79.4)	<0.001

\*Peripheral arterial disease status defined by *International Classification of Diseases, Ninth Revision, Clinical Modification* code or revascularization 12 to 24 mo before amputation.

**Table 5. Factors Associated With Arterial Testing Before Amputation**

Variable	Unadjusted RR (95% CI)	P Value	Adjusted RR (95% CI)	P Value
Age group, y				
<50	0.80 (0.75–0.86)	<0.001	0.78 (0.73–0.83)	<0.001
50–54	0.94 (0.88–1.00)	0.07	0.90 (0.84–0.95)	<0.001
55–59	0.96 (0.91–1.01)	0.11	0.91 (0.86–0.95)	<0.001
60–64	1.02 (0.97–1.06)	0.45	0.95 (0.91–0.99)	0.03
65–69	1.03 (0.99–1.07)	0.12	0.99 (0.96–1.03)	0.70
70–74	1.03 (0.99–1.06)	0.13	1.01 (0.98–1.05)	0.39
75–79	1.00 (Reference)		1.00 (Reference)	
80–84	0.99 (0.96–1.03)	0.74	1.02 (0.99–1.06)	0.17
85–89	0.98 (0.94–1.02)	0.30	1.03 (1.00–1.07)	0.09
≥90	0.90 (0.85–0.94)	<0.001	0.98 (0.94–1.04)	0.54
Women	0.91 (0.89–0.93)	<0.001	0.91 (0.89–0.93)	<0.001
Race				
Black	1.10 (1.07–1.12)	<0.001	1.10 (1.08–1.13)	<0.001
White	1.00 (Reference)		1.00 (Reference)	
Other	1.07 (1.03–1.12)	0.002	1.08 (1.03–1.13)	<0.001
Comorbid conditions				
Cancer	1.04 (1.01–1.07)	0.02	0.98 (0.95–1.01)	0.27
Cerebrovascular disease	1.11 (1.09–1.14)	<0.001	1.04 (1.02–1.06)	<0.001
Chronic obstructive pulmonary disease	1.09 (1.07–1.11)	<0.001	1.03 (1.01–1.05)	0.01
Congestive heart failure	1.16 (1.13–1.18)	<0.001	1.02 (1.00–1.04)	0.08
Dementia	0.90 (0.86–0.94)	<0.001	0.87 (0.84–0.91)	<0.001
Diabetes mellitus	1.20 (1.17–1.22)	<0.001	1.09 (1.06–1.12)	<0.001
Hypertension	1.18 (1.15–1.22)	<0.001	1.03 (1.00–1.06)	0.07
Ischemic heart disease	1.19 (1.17–1.22)	<0.001	1.04 (1.02–1.07)	0.001
Peripheral arterial disease	1.19 (1.16–1.21)	<0.001	1.10 (1.07–1.12)	<0.001
Renal disease	1.21 (1.19–1.24)	<0.001	1.10 (1.08–1.13)	<0.001
Outpatient evaluation and management visit	1.20 (1.18–1.23)	<0.001	1.09 (1.06–1.11)	<0.001
Rural location	0.92 (0.90–0.95)	<0.001	0.95 (0.93–0.97)	<0.001
US Census region				
East North Central	1.07 (1.04–1.10)	<0.001	1.07 (1.04–1.10)	<0.001
East South Central	0.96 (0.92–1.00)	0.03	0.99 (0.95–1.03)	0.65
Middle Atlantic	1.07 (1.03–1.10)	<0.001	1.05 (1.02–1.09)	0.002
Mountain	0.82 (0.76–0.88)	<0.001	0.85 (0.80–0.91)	<0.001
New England	0.95 (0.90–1.00)	0.07	0.95 (0.90–1.01)	0.09
Pacific	0.95 (0.91–0.99)	0.01	0.96 (0.92–1.00)	0.045
South Atlantic	1.00 (Reference)		1.00 (Reference)	
West North Central	0.94 (0.90–0.99)	0.01	1.00 (0.95–1.04)	0.94
West South Central	1.01 (0.97–1.04)	0.69	1.02 (0.98–1.05)	0.38
Year of index amputation				
2002	1.00 (Reference)		1.00 (Reference)	
2003	1.01 (0.97–1.05)	0.69	0.99 (0.95–1.04)	0.80
2004	1.03 (0.98–1.07)	0.24	1.02 (0.98–1.06)	0.35
2005	1.07 (1.03–1.12)	<0.001	1.05 (1.01–1.10)	0.01
2006	1.06 (1.02–1.11)	0.004	1.04 (1.00–1.09)	0.05
2007	1.04 (1.00–1.09)	0.05	1.03 (0.98–1.07)	0.22
2008	1.05 (1.01–1.10)	0.020	1.04 (1.00–1.09)	0.05
2009	1.07 (1.03–1.12)	0.001	1.05 (1.01–1.09)	0.03
2010	1.05 (1.01–1.10)	0.02	1.03 (0.99–1.07)	0.18

CI indicates confidence interval; and RR, risk ratio.

the PAD guidelines recommend ABI as part of the initial management of patients undergoing amputation.<sup>1</sup>

The optimal amount of preamputation arterial testing has yet to be defined based on test characteristics, outcomes studies, and cost-effectiveness studies. Patients with poor functional status have had poorer outcomes with surgical revascularization<sup>23,24</sup>; however, there is disagreement about what represents a salvageable limb.<sup>25</sup> Given the proven benefit of revascularization in amputation-free survival and quality of life,<sup>26–29</sup> it seems that arterial testing should be offered to most patients facing lower extremity amputation. Indeed, small studies have demonstrated favorable 1-year survival and amputation-free survival with the use of aggressive screening and revascularization programs in patients facing amputation.<sup>30</sup>

Despite these recommendations and data, we observed a rate of preamputation ABI measurement of only 47.5% and an overall arterial testing rate of 68.4%. The change in overall preamputation arterial testing from 2002 to 2010 was clinically negligible, despite a statistically and clinically significant increase in preamputation ultrasound and computed tomographic angiography. Given that the magnitudes of increase in duplex ultrasound and computed tomographic angiography were greater than the magnitude of change in overall preamputation arterial testing, it is likely that a subset of patients received multiple tests, perhaps indicating attempts at preamputation revascularization. This disproportionate increase in the rate of preamputation anatomic imaging in the face of relatively unchanged overall preamputation arterial testing rates is consistent with previously described differences in the intensity of vascular care.<sup>7</sup>

Although patients undergoing above-knee amputation lose more tissue and have a larger decrement in mobility than patients undergoing below-knee amputation, the rates of preamputation arterial testing were lower among patients undergoing above-knee amputation. The reasons for this discrepancy are unclear. If the observed testing rates in patients undergoing above-knee amputation correlate with arterial testing rates in all patients being considered for above-knee amputation, then the discrepancy may be a reason that above-knee amputation continues to occur 30% more frequently than below-knee amputation.<sup>5</sup>

Stratification of preamputation arterial testing rates by PAD diagnosis revealed that, even in patients with known PAD, arterial testing occurs in <75% of patients and anatomic arterial testing occurs in even fewer. Current guidelines suggest that if a patient facing amputation is considered a candidate for revascularization, then the patient should undergo anatomic arterial testing.<sup>1</sup> However, unlike surgical revascularization, there is little evidence-based guidance on nonanatomic predictors of successful endovascular revascularization. Thus, clinicians who choose not to obtain initial or repeat anatomic testing in patients with known PAD presenting for consideration of lower extremity amputation may be missing an opportunity to prevent amputation.

Despite potentially missing opportunities to prevent amputation, our findings that black patients and patients with renal disease, PAD, and diabetes mellitus are more likely to receive preamputation arterial testing imply that clinicians are indeed focusing testing on patients with the highest pretest

likelihoods of PAD.<sup>31</sup> These same patients are less likely to receive attempted revascularization,<sup>7</sup> implying that this discrepancy in care is not because of a lack of recognition of PAD but rather the extent of disease or procedure-related factors. Our finding that women are less likely to receive preamputation arterial testing is consistent with a recent American Heart Association scientific statement outlining the under-recognition and undertreatment of PAD in women.<sup>32</sup>

We included patients <65 years of age in this analysis because guidelines suggest an elevated risk of PAD in patients >50 years of age with risk factors.<sup>8</sup> Although patients <60 years of age were also less likely to undergo preamputation arterial testing, this finding should be interpreted with caution. Because of fee-for-service Medicare eligibility requirements, enrolled patients <65 years of age are more likely to be permanently disabled or be on dialysis. Thus, our findings may be consistent with clinicians forgoing arterial testing because of perceived lack of candidacy for revascularization or a lack of recognition of PAD in younger patients.

Although rates of revascularization and lower extremity amputation have shown significant regional variation in previous reports,<sup>5,7</sup> with the exception of the Mountain region, we found only minor regional variation in the use of preamputation arterial imaging after adjustment for other characteristics. Although receipt of testing was associated with a prior visit with a vascular specialist, predominately cardiologists, it may fall to practicing cardiologists to drive national improvements in this category.

Our study has some limitations. First, the analysis only includes patients enrolled in fee-for-service Medicare, so the generalizability to patients not enrolled in fee-for-service Medicare is unclear. Second, the analysis did not capture data on unbilled bedside Doppler or ABI exams. It is unlikely, however, that these tests occur frequently in outpatient settings because of a lack of reimbursement. Furthermore, informal and nonstandard bedside physiological testing in the face of impending amputation is fraught with issues of quality control and ensuring adequate operator qualifications. Third, we limited our assessment of preamputation arterial testing to 12 months before amputation. However, previous studies have assessed vascular care during longer intervals before amputation and found little difference in their effect sizes.<sup>33</sup> Indeed, our findings changed little when we increased our ascertainment period to  $\leq 24$  months before amputation.

In conclusion, many patients, both with and without known PAD, undergo lower extremity amputation without arterial testing in the year before amputation. Given the morbidity, mortality, and quality of life costs associated with lower extremity amputation, current guidelines suggest that ABI measurement should be part of the initial examination of patients considered for nontraumatic lower extremity amputation. Consistent with under-recognition and undertreatment of PAD in women, women are less likely to receive preamputation arterial testing. Given that cardiologists see the most patients who will go on to need lower extremity amputation, practicing cardiologists will be responsible for increasing the frequency of preamputation arterial testing. Future work should focus on delineating the relationship between arterial testing and attempted revascularization, as

well as arterial testing and mortality in patients undergoing lower extremity amputation.

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### References

- Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, Hiratzka LF, Murphy WR, Olin JW, Puschett JB, Rosenfield KA, Sacks D, Stanley JC, Taylor LM Jr, White CJ, White J, White RA, Antman EM, Smith SC Jr, Adams CD, Anderson JL, Faxon DP, Fuster V, Gibbons RJ, Hunt SA, Jacobs AK, Nishimura R, Ornato JP, Page RL, Riegel B; American Association for Vascular Surgery; Society for Vascular Surgery; Society for Cardiovascular Angiography and Interventions; Society for Vascular Medicine and Biology; Society of Interventional Radiology; ACC/AHA Task Force on Practice Guidelines Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease; American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; Vascular Disease Foundation. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease); endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation*. 2006;113:e463–e654.
- Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007;45(Suppl S):S5–S67.
- Peacock JM, Keo HH, Duval S, Baumgartner I, Oldenburg NC, Jaff MR, Henry TD, Yu X, Hirsch AT. The incidence and health economic burden of ischemic amputation in Minnesota, 2005–2008. *Prev Chronic Dis*. 2011;8:A141.
- Cruz CP, Eidt JF, Capps C, Kirtley L, Moursi MM. Major lower extremity amputations at a Veterans Affairs hospital. *Am J Surg*. 2003;186:449–454.
- Jones WS, Patel MR, Dai D, Subherwal S, Stafford J, Calhoun S, Peterson ED. Temporal trends and geographic variation of lower extremity amputation in patients with peripheral artery disease: results from U.S. Medicare 2000–2008. *J Am Coll Cardiol*. 2012;60:2230–2236.
- Goodney PP, Beck AW, Nagle J, Welch HG, Zwolak RM. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. *J Vasc Surg*. 2009;50:54–60.
- Goodney PP, Travis LL, Nallamothu BK, Holman K, Suckow B, Henke PK, Lucas FL, Goodman DC, Birkmeyer JD, Fisher ES. Variation in the use of lower extremity vascular procedures for critical limb ischemia. *Circ Cardiovasc Qual Outcomes*. 2012;5:94–102.
- Rooke TW, Hirsch AT, Misra S, Sidawy AN, Beckman JA, Findeiss LK, Goltzarian J, Gornik HL, Halperin JL, Jaff MR, Moneta GL, Olin JW, Stanley JC, White CJ, White JV, Zierler RE; Society for Cardiovascular Angiography and Interventions; Society of Interventional Radiology; Society for Vascular Medicine; Society for Vascular Surgery. 2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2011;58:2020–2045.
- Rural Health Research Center. RUCA Data: using RUCA Data. <http://depts.washington.edu/uwruca/ruca-uses.php>. Accessed November 16, 2012.
- Economic Research Service, US Department of Agriculture. Rural-Urban Commuting Area Codes. <http://www.ers.usda.gov/Data/RuralUrbanCommuteAreaCodes/>. Accessed November 16, 2012.
- Birman-Deych E, Waterman AD, Yan Y, Nilasena DS, Radford MJ, Gage BF. Accuracy of ICD-9-CM codes for identifying cardiovascular and stroke risk factors. *Med Care*. 2005;43:480–485.
- Quan H, Sundararajan V, Halfon P, Fong A, Burnand B, Luthi JC, Saunders LD, Beck CA, Feasby TE, Ghali WA. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. *Med Care*. 2005;43:1130–1139.
- Jaff MR, Cahill KE, Yu AP, Birnbaum HG, Engelhart LM. Clinical outcomes and medical care costs among medicare beneficiaries receiving therapy for peripheral arterial disease. *Ann Vasc Surg*. 2010;24:577–587.
- Zou G. A modified poisson regression approach to prospective studies with binary data. *Am J Epidemiol*. 2004;159:702–706.
- Khan NA, Rahim SA, Anand SS, Simel DL, Panju A. Does the clinical examination predict lower extremity peripheral arterial disease? *JAMA*. 2006;295:536–546.
- Ouriel K, McDonnell AE, Metz CE, Zarins CK. Critical evaluation of stress testing in the diagnosis of peripheral vascular disease. *Surgery*. 1982;91:686–693.
- Baxter GM, Polak JF. Lower limb colour flow imaging: a comparison with ankle: brachial measurements and angiography. *Clin Radiol*. 1993;47:91–95.
- Sacks D, Bakal CW, Beatty PT, Becker GJ, Cardella JF, Raabe RD, Wiener HM, Lewis CA. Position statement on the use of the ankle-brachial index in the evaluation of patients with peripheral vascular disease: a consensus statement developed by the standards division of the society of cardiovascular & interventional radiology. *J Vasc Interv Radiol*. 2002;13:353.
- Doobay AV, Anand SS. Sensitivity and specificity of the ankle-brachial index to predict future cardiovascular outcomes: a systematic review. *Arterioscler Thromb Vasc Biol*. 2005;25:1463–1469.
- Thompson MM, Sayers RD, Reid A, Underwood MJ, Bell PR. Quality of life following infragenicular bypass and lower limb amputation. *Eur J Vasc Endovasc Surg*. 1995;9:310–313.
- Fratezi AC, Albers M, De Luccia ND, Pereira CA. Outcome and quality of life of patients with severe chronic limb ischaemia: a cohort study on the influence of diabetes. *Eur J Vasc Endovasc Surg*. 1995;10:459–465.
- Hernández-Osma E, Cairois MA, Martí X, Barjau E, Riera S. Impact of treatment on the quality of life in patients with critical limb ischaemia. *Eur J Vasc Endovasc Surg*. 2002;23:491–494.
- Simons JP, Goodney PP, Nolan BW, Cronenwett JL, Messina LM, Schanzer A; Vascular Study Group of Northern New England. Failure to achieve clinical improvement despite graft patency in patients undergoing infrainguinal lower extremity bypass for critical limb ischemia. *J Vasc Surg*. 2010;51:1419–1424.
- Goodney PP, Nolan BW, Schanzer A, Eldrup-Jorgensen J, Bertges DJ, Stanley AC, Stone DH, Walsh DB, Powell RJ, Likosky DS, Cronenwett JL; Vascular Study Group of Northern New England. Factors associated with amputation or graft occlusion one year after lower extremity bypass in northern New England. *Ann Vasc Surg*. 2010;24:57–68.
- Connelly J, Airey M, Chell S. Variation in clinical decision making is a partial explanation for geographical variation in lower extremity amputation rates. *Br J Surg*. 2001;88:529–535.
- O'Hare AM, Berenthal D, Sidawy AN, Shlipak MG, Sen S, Chren MM. Renal insufficiency and use of revascularization among a national cohort



- of men with advanced lower extremity peripheral arterial disease. *Clin J Am Soc Nephrol*. 2006;1:297–304.
27. Kalra M, Gloviczki P, Bower TC, Panneton JM, Harmsen WS, Jenkins GD, Stanson AW, Toomey BJ, Canton LG. Limb salvage after successful pedal bypass grafting is associated with improved long-term survival. *J Vasc Surg*. 2001;33:6–16.
  28. Nguyen LL, Moneta GL, Conte MS, Bandyk DF, Clowes AW, Seely BL; PREVENT III Investigators. Prospective multicenter study of quality of life before and after lower extremity vein bypass in 1404 patients with critical limb ischemia. *J Vasc Surg*. 2006;44:977–983; discussion 983.
  29. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, Fowkes FG, Gillespie I, Ruckley CV, Raab G, Storkey H; BASIL trial participants. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. *Lancet*. 2005;366:1925–1934.
  30. Shah AP, Klein AJ, Sterrett A, Messenger JC, Albert S, Nehler MR, Hiatt WR, Casserly IP. Clinical outcomes using aggressive approach to anatomic screening and endovascular revascularization in a veterans affairs population with critical limb ischemia. *Catheter Cardiovasc Interv*. 2009;74:11–19.
  31. Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999–2000. *Circulation*. 2004;110:738–743.
  32. Hirsch AT, Allison MA, Gomes AS, Corriere MA, Duval S, Ershow AG, Hiatt WR, Karas RH, Lovell MB, McDermott MM, Mendes DM, Nussmeier NA, Treat-Jacobson D; American Heart Association Council on Peripheral Vascular Disease; Council on Cardiovascular Nursing; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Surgery and Anesthesia; Council on Clinical Cardiology; Council on Epidemiology and Prevention. A call to action: women and peripheral artery disease: a scientific statement from the American Heart Association. *Circulation*. 2012;125:1449–1472.
  33. Holman KH, Henke PK, Dimick JB, Birkmeyer JD. Racial disparities in the use of revascularization before leg amputation in Medicare patients. *J Vasc Surg*. 2011;54:420–426, 426.e1.