

Peripheral Artery Disease Prevalence and Incidence Estimated From Both Outpatient and Inpatient Settings Among Medicare Fee-for-Service Beneficiaries in the Atherosclerosis Risk in Communities (ARIC) Study

Corey A. Kalbaugh, PhD, MS; Anna Kucharska-Newton, PhD, MPH; Lisa Wruck, PhD, MSPH; Jennifer L. Lund, PhD, MSPH; Elizabeth Selvin, PhD, MPH; Kunihiro Matsushita, MD, PhD; Lindsay G. S. Bengtson, PhD, MPH; Gerardo Heiss, MD, PhD; Laura Loehr, MD, PhD

Background—Outpatient ascertainment of peripheral artery disease (PAD) is rarely considered in the measurement of PAD clinical burden; therefore, the clinical burden of PAD likely has been underestimated while contributing to a decreased awareness of PAD in comparison to other circulatory system disorders.

Methods and Results—The purpose of this study was to estimate the age-standardized annual period prevalence and incidence of PAD in the outpatient and inpatient settings using data from the Atherosclerosis Risk in Communities (ARIC) study linked with Centers for Medicare and Medicaid Services claims. The majority (>70%) of all PAD encounters occurred in the outpatient setting. The weighted mean age-standardized prevalence and incidence of outpatient PAD was 11.8% (95% CI 11.5–12.1) and 22.4 per 1000 person-years (95% CI 20.8–24.0), respectively. Black patients had higher weighted mean age-standardized prevalence (15.6%; 95% CI 14.6–16.4) compared with white patients (11.4%; 95% CI 11.1–11.7). Black women had the highest weighted mean age-standardized prevalence (16.9%; 95% CI 16.0–17.8). Black patients also had a higher incidence rate of PAD (31.3 per 1000 person-years; 95% CI 27.3–35.4) compared with white patients (25.4 per 1000 person-years; 95% CI 23.5–27.3). PAD prevalence and incidence did not differ by sex alone.

Conclusions—This study provides comprehensive estimates of PAD in the inpatient and outpatient settings where the majority of PAD burden was found. PAD is an important circulatory system disorder similar in prevalence to stroke and coronary heart disease. (*J Am Heart Assoc.* 2017;6:e003796. DOI: 10.1161/JAHA.116.003796.)

Key Words: aging • Atherosclerosis Risk in Communities • claims • epidemiology • Medicare • peripheral artery disease • population science

Peripheral artery disease (PAD) is a progressive atherosclerotic disorder that can lead to poor quality of life,¹ an increased risk of hospitalization and limb amputation,² high mortality,³ and high costs of care.⁴ Early PAD detection in the outpatient setting combined with ambulatory follow-up care could help slow disease progression and reduce PAD-related hospitalizations and sequelae.⁵ However,

the extent to which PAD is managed in the outpatient setting is not well documented.

Reported estimates of clinical PAD prevalence and incidence tend to focus on only hospitalized cases.^{6–12} Estimates of disease occurrence in both inpatient and outpatient settings could provide a broader, more comprehensive understanding of PAD and could lead to improved resource

From the Department of Surgery, School of Medicine (C.A.K.), Department of Epidemiology, Gillings School of Global Public Health (A.K.-N., J.L.L., G.H., L.L.), and Cecil G. Sheps Center for Health Services Research (A.K.-N.), The University of North Carolina at Chapel Hill, NC; Center for Preventive Medicine, Duke Clinical Research Institute, Durham, NC (L.W.); Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD (E.S., K.M.); Health Economics and Outcomes Research, Life Sciences Optum, Eden Prairie, MN (L.G.S.B.).

Accompanying Tables S1 through S6 and Figure S1 are available at <http://jaha.ahajournals.org/content/6/5/e003796/DC1/embed/inline-supplementary-material-1.pdf>

Correspondence to: Corey A. Kalbaugh, PhD, MS, 3024 Burnett-Womack Bldg, CB 7212, Chapel Hill, NC 27599-7212. E-mail: corey_kalbaugh@med.unc.edu

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allocation to prevent PAD-related complications. Administrative claims data capture comprehensive services across the spectrum of health care settings and provide an opportunity for a more inclusive assessment of PAD burden.

We estimated the age-standardized annual period prevalence and incidence of PAD in the inpatient and outpatient setting over a 10-year period (2003–2012) using data from the biracial Atherosclerosis Risk in Communities (ARIC) study cohort¹³ linked with the Centers for Medicare and Medicaid Services (CMS) claims information for Medicare fee-for-service (FFS) beneficiaries aged ≥ 65 years. To further inform prevention efforts, we examined differences in estimates of annual PAD period prevalence and incidence across strata of age, sex, and race.

Methods

Study Population

The ARIC cohort study

The biracial ARIC cohort, established to examine the etiology of atherosclerosis and its clinical manifestations, includes 15 792 participants (aged 45–64 years at baseline) enrolled between 1987 and 1989. The ARIC cohort was selected by probability sampling from 4 US communities: Washington County, Maryland; Forsyth County, North Carolina; the city of Jackson, Mississippi; and the suburbs of Minneapolis, Minnesota.¹³ ARIC participants enrolled continuously for at least 1 year in Medicare Parts A and B through an FFS plan from 2003 to 2012 were eligible for inclusion. Data were collected on cohort participants at 5 clinic examinations and through annual follow-up telephone interviews.

Linkage of ARIC cohort data with CMS claims

An interagency agreement between the National Heart, Lung, and Blood Institute and CMS has enabled Medicare claims information to be obtained for the 14 899 ARIC cohort participants who were Medicare eligible between the years 1991 and 2012. Data for ARIC cohort participants were linked with CMS claims data, matching on participants' social security numbers, sex, and date of birth. Of the 14 899 Medicare-eligible participants, 14 702 ARIC cohort identifiers (98.7%) were matched successfully.

Participant information on enrollment in Medicare FFS was obtained from monthly enrollment indicators for Part A, Part B, and Medicare Advantage buy-in available through annual CMS Medicare beneficiary summary files. Continuous enrollment periods were created to indicate uninterrupted CMS Medicare FFS coverage, defined as enrollment in CMS Medicare Part A and Part B and lack of enrollment in a Medicare Advantage plan. Participants contributed data to

calendar years in which they had uninterrupted FFS coverage. Participants were excluded if they had continuous Medicare Advantage enrollment or gaps in FFS coverage because of (1) missing enrollment information, (2) discontinuation of enrollment, or (3) enrollment in a Medicare Advantage plan at any month in the observation year. Participants aged < 65 years and those of a race other than black or white were also excluded (see Table S1). For those with multiple enrollment periods, the longest enrollment period was selected to give the best opportunity to capture relevant claims. The enrollment period selected was the first enrollment period for 10 144 participants (97%). The final analytic sample included 10 481 ARIC participants with 67 492 person-years of FFS enrollment time.

Demographics and comorbidities

Demographic information on age (at beginning of enrollment year), race, and sex was obtained from annual Medicare beneficiary summary files. Age was categorized as 65 to 74 years of age and ≥ 75 years of age. The Klabunde adaptation of the Charlson Comorbidity Index was used to identify comorbidity burden using claims from the inpatient and outpatient settings.^{14,15} All claims present in each calendar year (prior to a PAD case) were used to calculate an annual Charlson Comorbidity Index score.

Ascertainment of PAD

PAD-related outpatient office visits, outpatient diagnostic tests, inpatient visits, and procedures were identified from the MedPAR (Medicare Provider Analysis and Review) records and the Carrier and Outpatient claims files using codes from the International Classification of Diseases, Ninth Revision (ICD); Current Procedural Terminology, 4th edition (CPT); Healthcare Common Procedure Coding System (HCPCS); and Federally Qualified Healthcare Center (FQHC) (Table S2). Codes used in the present study were adapted from previous PAD-related administrative studies.^{16,17}

Prevalence of PAD

Annual PAD period prevalence was estimated for 2003 to 2012 using information on any PAD encounters in the inpatient and outpatient settings, including both prevalence cases from prior years and new incident cases during the year of observation. Overall mean annual prevalence, weighted to reflect the distribution of cases across all years, was also estimated. The denominator for annual period prevalence estimates included cohort participants alive at the beginning of the year with continuous enrollment in FFS for the entire year of observation or until death. For each year of observation, prevalent *inpatient* PAD was defined as ≥ 1 hospitalization with a PAD code in any of the 25 diagnosis or

procedure positions; prevalent *outpatient* PAD was defined as ≥ 1 claim with PAD diagnosis or procedure codes in any of the 12 diagnosis positions or 6 procedure positions. A sensitivity analysis using ≥ 2 outpatient claims was conducted to address the possibility of rule-out diagnoses (Table S3).

Incidence of PAD

A 2-year look back period was chosen to minimize misclassification of prevalent events as incident events¹⁸; therefore, the shortest enrollment window of ARIC participants was >24 months. ARIC participants with a prevalent PAD-related inpatient or outpatient code occurring any time within 2 years of the year in question were excluded from annual incidence analyses. Annual incidence rates are presented for the years 2005 to 2012. Overall mean incidence, weighted to reflect the distribution of events across all years, was also estimated. The denominator for annual incidence estimates included cohort participants' time at risk in continuous enrollment during the year of observation or until death if it occurred during the year of observation.

Annual inpatient PAD incidence was defined as ≥ 1 hospitalization with a PAD-related ICD diagnosis or procedure code during each year of observation. Annual outpatient PAD incidence was defined as ≥ 2 claims within 12 consecutive months with a PAD-related ICD, CPT, HCPCS, or FQHC code; the claims had to occur ≥ 1 day apart, and the incident date was defined as the date of the second claim. If a singular outpatient encounter preceded an inpatient encounter within 365 days, the incident date was the inpatient date of discharge. Singular outpatient encounters occurring with no hospitalizations or outpatient encounters within 365 days were not considered incident PAD. This definition of incidence was chosen to reduce the misclassification of rule-out diagnoses resulting from a singular encounter in the outpatient setting.¹⁹ Each individual contributed between 1 and 12 months to each yearly estimate of incidence. Time contributed to the study for each ARIC participant was converted to and reported in person-years.

Statistical Analysis

Direct standardization was used to estimate age-standardized overall and annual prevalence of PAD with 95% CIs from 2003 to 2012. Direct standardization was used to estimate age-standardized overall and annual incidence of PAD (per 1000 person-years) with 95% CI from 2005 to 2012. Prevalence estimates were age-standardized to reflect the age, race, and sex distribution of the 2005 Medicare population aged ≥ 65 years. Age categories for standardization of prevalence estimates included 65 to 69, 70 to 74, 75 to 79, and ≥ 80 years of age. Incidence estimates were age-standardized to reflect the age, race, and sex distribution of the 2005

Medicare population aged ≥ 67 years, given a 2-year look-back period for excluding prevalence cases. Estimates were calculated overall; by health care setting (inpatient versus outpatient setting); and by age, race, sex, and race/sex subgroups. Age categories for incidence estimate standardization included 67 to 69, 70 to 74, 75 to 79, and ≥ 80 years of age. All analyses were performed using SAS version 9.4 (SAS Institute Inc.). Written informed consent was obtained from participants, and all institutional review boards approved the study.

Results

The 10 481 ARIC cohort members who met eligibility requirements generally reflected the demographic distribution in the original ARIC cohort at baseline. The majority were female (58%) and white (76%), with black men (8%) as the least represented group (Table 1). Mean comorbidity scores were similar across race, sex, and race/sex strata. Mean comorbidity score increased as the cohort aged from 2003 to 2012 (Table 1).

Age-Standardized Annual Prevalence and Weighted Mean Annual Prevalence of PAD

Age-standardized annual and weighted mean annual estimates of the prevalence of PAD across all study years (2003–2012), overall and stratified by health care setting, are provided in Table 2. The weighted mean annual PAD period prevalence was 12.4% (95% CI 12.2–12.8%). Overall age-standardized prevalence varied modestly from year to year, ranging from 10.3% (95% CI 8.6–12.0%) to 13.5% (95% CI 12.4–14.6%).

Higher annual PAD period prevalence was identified in the outpatient setting compared with the inpatient setting (11.8% versus 1.6%) (Table 2). The majority of all unique PAD claims ($>70\%$) identified were from outpatient settings. Prevalence of outpatient PAD claims ranged across years of observation from 9.5% (95% CI 7.9–11.2%) in 2003 to 12.9% (95% CI 11.9–14.0%) in 2012. By comparison, prevalence of inpatient PAD ranged across years of observation from 1.4% (95% CI 1.1–1.7%) in 2005 to 1.8% (95% CI 1.4–2.3%) in 2012.

Estimates of annual PAD period prevalence were further stratified by demographic groups. Age-standardized annual PAD period prevalence and mean annual prevalence were consistently higher among those aged ≥ 75 years compared with those aged 65 to 74 years (Figure 1). Weighted mean annual PAD prevalence among those aged ≥ 75 years and 65 to 74 years was 16.8% and 8.4%, respectively. From 2003 to 2012, annual PAD prevalence in the age group ≥ 75 years ranged from 12.5% (95% CI 9.0–15.9%) in 2003 to 18.5% (95%

Table 1. ARIC Fee-for-Service Enrollees by Year and Demographic Groups, 2003–2012

	2003 (n=7293)	2004 (n=7678)	2005 (n=7708)	2006 (n=7372)	2007 (n=7060)	2008 (n=6995)	2009 (n=6504)	2010 (n=6183)	2011 (n=5914)	2012 (n=5546)
Age, %, y										
65–74	72	69	66	63	60	57	54	49	44	40
≥75	28	31	34	37	40	43	46	51	56	60
Sex, %										
Female	57	57	58	57	58	58	59	60	60	61
Male	43	43	42	43	42	42	41	40	40	39
Race, %										
Black	26	26	26	23	21	22	23	24	24	24
White	74	74	74	77	79	78	77	76	76	76
Race/sex, %										
Black woman	17	17	18	15	14	14	15	16	16	16
Black man	9	9	9	8	7	7	8	8	8	8
White women	40	40	40	42	44	44	45	44	44	44
White man	34	34	33	35	35	34	32	32	32	32
Overall mean comorbidity score* (SD)	1.7 (2.2)	1.8 (2.3)	1.9 (2.2)	1.9 (2.2)	2.1 (2.3)	2.1 (2.3)	2.3 (2.5)	2.4 (2.5)	2.5 (2.5)	2.6 (2.6)
Overall median comorbidity score*	1 (0, 3)	1 (0, 3)	1 (0, 3)	1 (0, 3)	2 (0, 3)	2 (0, 3)	2 (0, 3)	2 (0, 3)	2 (0, 4)	2 (1, 4)

ARIC indicates atherosclerosis risk in communities.

*Klabunde adaptation¹⁵ of Charlson comorbidity index.

CI 17.1–20.0%) in 2012. Annual PAD prevalence among those aged 65 to 74 years ranged from 8.0% (95% CI 7.2–8.8%) to 9.0% (95% CI 8.0–10.0%) over the same time frame.

Table 2. Age-Standardized* Overall and Annual Prevalence of Peripheral Artery Disease Claims Overall and by Health Care Setting: The ARIC Cohort Study (2003–2012)

	Prevalence, % (95% CI)		
	Overall	Outpatient Setting	Inpatient Setting
2003	10.3 (8.6–12.0)	9.5 (7.9–11.2)	1.5 (1.0–1.9)
2004	11.2 (10.0–12.4)	10.4 (9.3–11.6)	1.8 (1.3–2.3)
2005	11.4 (10.5–12.4)	10.8 (9.8–11.7)	1.4 (1.1–1.7)
2006	12.1 (11.1–13.0)	11.5 (10.6–12.4)	1.8 (1.4–2.1)
2007	12.3 (11.4–13.2)	11.5 (10.7–12.4)	1.4 (1.1–1.7)
2008	11.8 (10.9–12.6)	11.2 (10.4–12.0)	1.6 (1.3–1.9)
2009	12.6 (11.7–13.4)	12.0 (11.1–12.8)	1.4 (1.1–1.7)
2010	13.2 (12.3–14.1)	12.7 (11.8–13.5)	1.4 (1.1–1.7)
2011	13.1 (12.2–14.0)	12.7 (11.7–13.5)	1.6 (1.3–1.9)
2012	13.5 (12.4–14.6)	12.9 (11.9–14.0)	1.8 (1.4–2.3)
Weighted mean	12.4 (12.2–12.8)	11.8 (11.5–12.1)	1.6 (1.5–1.7)

ARIC indicates atherosclerosis risk in communities.

*Standardized to reflect age distribution of 2005 Medicare population.

Black participants had higher mean annual prevalence of PAD compared with white participants (15.6% versus 11.4%) and had higher annual prevalence of PAD across most years of the observation period (Figure 2). From 2003 to 2012, PAD prevalence among black participants ranged from 13.8% (95% CI 10.4–17.2%) to 17.3% (95% CI 15.0–19.7%), whereas PAD prevalence among white participants ranged from 9.0% (95% CI 7.1–10.9%) to 12.8% (95% CI 11.6–14.0%). Regarding race/sex stratification, black women had the highest weighted mean annual PAD prevalence (16.9%), followed by black men (13.2%), white men (12.1%), and white women (10.9%) (Table S4).

Age-standardized prevalence of PAD did not differ by sex alone in any year of observation (2003–2012). Overall, women had higher prevalence of PAD, although confidence intervals overlapped across many years of this study (Table S5).

Age-Standardized Annual Incidence and Weighted Mean Annual Incidence of PAD

Overall and age-standardized annual estimates of the incidence of PAD across all observation years (2005–2012), stratified by health care setting, are provided in Table 3. The mean age-standardized PAD incidence rate across all observation years (2005–2012) was 26.8 per 1000 person-years

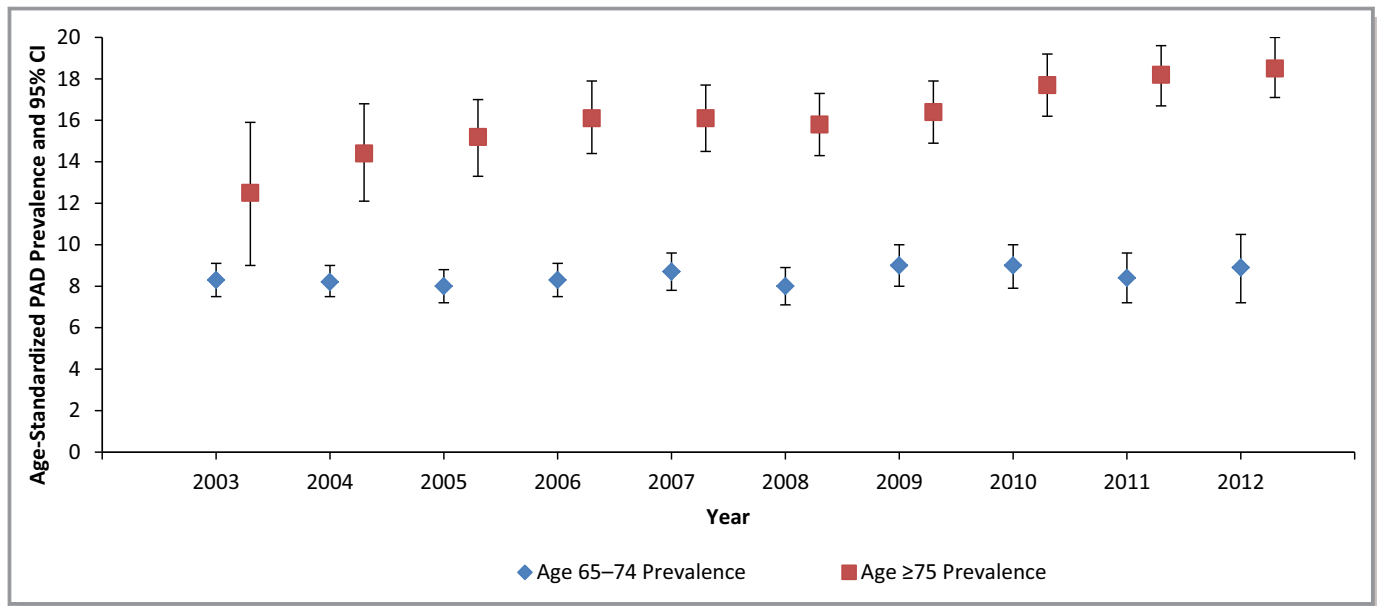


Figure 1. Age-standardized annual prevalence of peripheral artery disease (PAD) by age group. The ARIC (Atherosclerosis Risk in Communities) study, 2003–2012. Estimates are standardized to the 2005 Medicare population.

(95% CI 25.1–28.6). The age-standardized incidence of PAD remained relatively consistent across the study period (2005–2012), ranging from 25.6 per 1000 person-years (95% CI 20.8–30.4) in 2007 to 30.3 per 1000 person-years (95% CI 24.9–35.7) in 2012 (Table 3).

The first PAD-related claim most commonly was found in the outpatient setting (83%), at >5 times the incidence in the inpatient setting (Table 3). Rates of PAD incidence in the outpatient setting per 1000 person-years ranged from 20.0 (95% CI 15.2–24.8) to 26.0 (95% CI 21.0–30.9). Records of

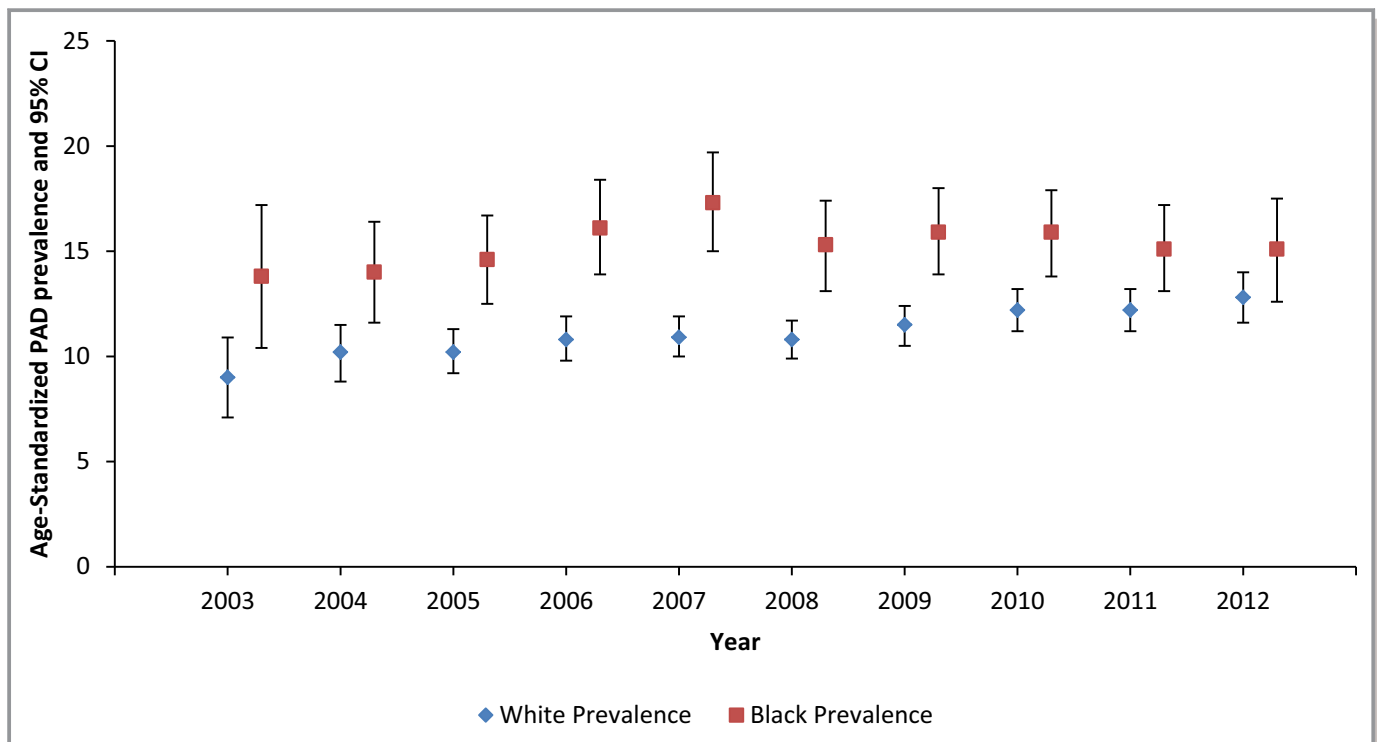


Figure 2. Age-standardized annual prevalence (percentage) of peripheral artery disease (PAD) by race group. The ARIC (Atherosclerosis Risk in Communities) study, 2003–2012. Estimates are age-standardized to 2005 Medicare population.

Table 3. Age-Standardized* Overall and Annual Incidence of Peripheral Artery Disease Claims Overall and by Health Care Setting of Incident Claim: The ARIC Cohort Study (2005–2012)

	Age-Standardized Rate, Per 1000 Person-Years (95% CI)*		
	Overall	Outpatient	Inpatient
2005	26.6 (20.7–32.6)	20.3 (15.1–25.4)	6.4 (3.4–9.3)
2006	25.8 (20.3–31.3)	20.0 (15.2–24.8)	5.8 (3.1–8.5)
2007	25.6 (20.8–30.4)	21.5 (17.2–25.9)	4.0 (2.0–6.1)
2008	26.0 (21.0–31.0)	21.2 (16.7–25.7)	4.8 (2.7–6.9)
2009	25.6 (20.9–30.3)	20.6 (16.4–24.8)	5.0 (2.9–7.1)
2010	29.3 (24.2–34.4)	25.9 (21.1–30.7)	3.4 (1.7–5.0)
2011	26.5 (21.7–31.4)	23.3 (18.8–27.9)	3.2 (1.5–4.8)
2012	30.3 (24.9–35.7)	26.0 (21.0–30.9)	4.3 (3.7–5.1)
Weighted mean	26.8 (25.1–28.6)	22.4 (20.8–24.0)	4.4 (3.7–5.1)

ARIC indicates atherosclerosis risk in communities.

*Standardized to reflect age distribution of 2005 Medicare population.

PAD-related hospitalizations were rare; for the years 2005 to 2012, the annual age-standardized incidence rates per 1000 person-years ranged from 3.2 (95% CI 1.5–4.8) in 2011 to 6.4 (95% CI 3.4–9.3) in 2005.

Annual estimates of PAD incidence were stratified by demographic groups. Age-standardized annual PAD incidence was different by age strata at all years examined except 2009 and 2012 (Figure 3). Incidence of PAD was higher among

those aged ≥ 75 years compared with 65 to 74 years. From 2005 to 2012, estimates of annual PAD incidence per 1000 person-years among those aged ≥ 75 years ranged from 31.6 (95% CI 24.1–39.2) in 2009 to 37.2 (95% CI 29.5–45.0) in 2012. Estimates among those aged 65 to 74 years ranged from 16.2 per 1000 person-years (95% CI 12.3–20.1) to 21.7 per 1000 person-years (95% CI 14.3–29.1) over the same time period.

PAD incidence rates were different by race (Figure 4), with higher mean annual (2005–2012) PAD incidence among black participants (31.3 per 1000 person-years; 95% CI 27.3–35.4) compared with white participants (25.4 per 1000 person-years; 95% CI 23.5–27.3). Black participants had a higher incidence rate of PAD than white participants across most observation years, although annual differences were attenuated due to low precision resulting from a small sample size among black participants (Figure 4). Incidence rates of PAD among black participants ranged from 28.4 per 1000 person-years (95% CI 16.4–40.3) to 32.7 per 1000 person-years (95% CI 21.3–44.1), whereas incidence of PAD among white participants ranged from 23.2 per 1000 person-years (95% CI 17.1–29.4) to 29.6 per 1000 person-years (95% CI 23.7–35.6).

The age-standardized annual incidence of PAD did not differ by sex (Table S6). Mean annual incidence of PAD (2005–2012) was higher among black men and black women (31.8 and 30.9 per 1000 person-years, respectively) than among white men and white women (25.5 and 25.3 per 1000 person-years, respectively), although confidence

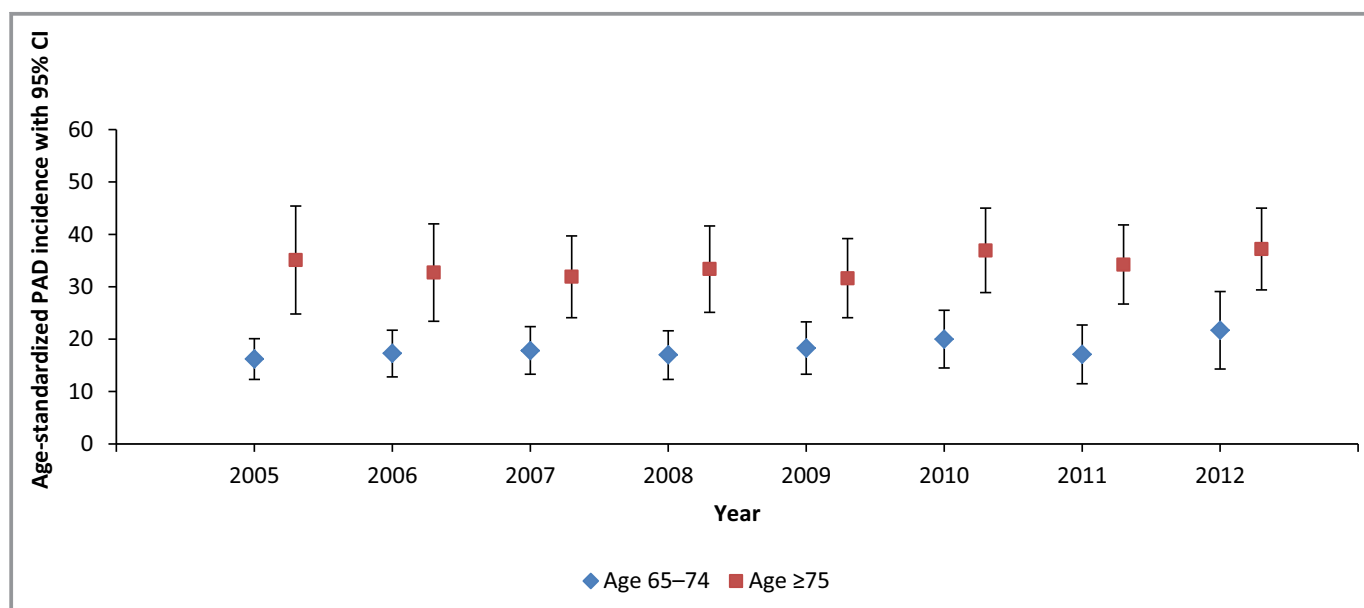


Figure 3. Age-standardized annual incidence (per 1000 person-years) of peripheral artery disease (PAD) by age group. The ARIC (Atherosclerosis Risk in Communities) study, 2005–2012. Estimates are age-standardized to 2005 Medicare population; rates are per 1000 person-years.

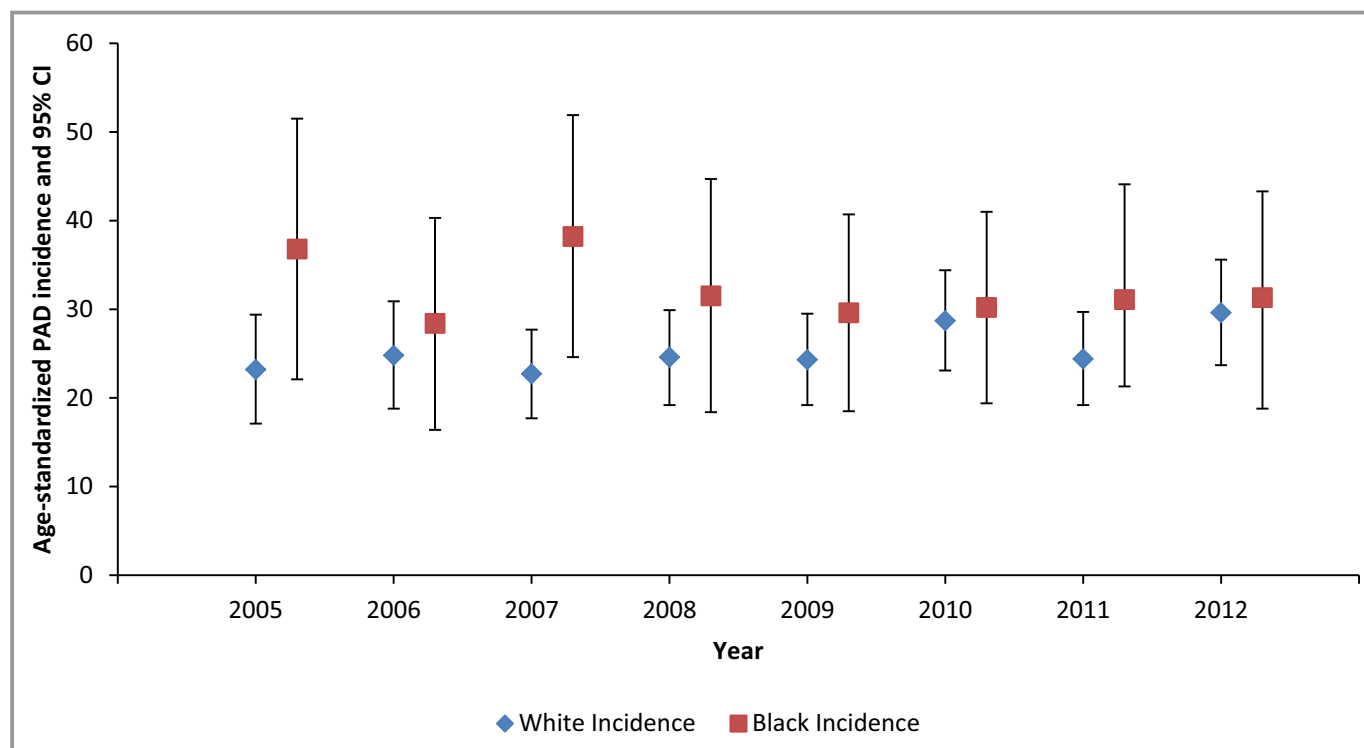


Figure 4. Age-standardized annual incidence of peripheral artery disease (PAD; per 1000 person-years), by race groups. The ARIC (Atherosclerosis Risk in Communities) study, 2005–2012. Estimates are age-standardized to 2005 population; rates are per 1000 person-years.

intervals overlapped in many years of observation. Small sample sizes precluded annual assessment of PAD incidence across race/sex groups (Figure S1).

Discussion

We found that the majority of all clinical PAD encounters occurred in the outpatient setting among a biracial, probability-based sample of 4 US communities, including men and women aged ≥ 65 years with enrollment in a Medicare FFS program. Studies that focus exclusively on hospitalized events underreport burden and provide a perspective of PAD skewed toward more severe manifestations occurring later in the course of the disease. Black participants had higher prevalence of PAD than white participants, including both men and women. Incidence of PAD was also higher among black participants, although the relatively small proportion of black participants in our study (24%) limited our ability to make inferences in race- and race/sex- stratified analyses of PAD incidence.

Although sources of administrative claims are increasingly used to study PAD burden, methodological and source population differences make it difficult to compare PAD estimates across studies. In particular, it is well documented that PAD prevalence increases with age^{16,20}; however, prior claims-based work did not report age-adjusted estimates of

PAD prevalence, limiting comparisons across populations with differing age groups. A recent study using the MarketScan database, for example, reported higher annual PAD prevalence among Medicare beneficiaries than the present study (14–21% versus 10–14%)¹⁶; however, the population in the MarketScan study was older and had more comorbidity. Conversely, a study of a healthier group of managed care enrollees found a lower prevalence of PAD (2%) than what was observed in the present study.² In the context of these other studies, age-standardized estimates of PAD prevalence (overall 12.4%) in the present study are within the expected range, given the estimates from younger and older populations.

Estimates of PAD incidence are rare in the literature and, as with prevalence studies, are difficult to compare because of differing study populations and inconsistency in the definition of PAD. When using administrative claims data for the estimation of disease incidence, the use of an appropriate look-back period is important for the correct identification of index events. Recent analyses suggest that for most chronic diseases, a 2-year look-back period is necessary for the exclusion of preexisting conditions.¹⁸ Studies that do not include a sufficiently long look-back period have the potential to reflect prevalent disease that is misclassified as incident (up to 30%).¹⁸ Results of the current study, in which we used a 2-year look-back period, suggest that 2% to 3% (26.8 per 1000 person-years) of Medicare beneficiaries had an incident

PAD occurrence within any particular observation year (2005–2012). Although our incidence estimates are lower, they are comparable to those in existing studies.¹⁶

Prior literature suggests differences in PAD burden by race.²¹ Black participants were observed to have higher PAD prevalence than white participants in the following studies: NHANES (National Health and Nutrition Examination Survey), SDPS (San Diego Population Study), MESA (Multi-Ethnic Study of Atherosclerosis), and CHS (Cardiovascular Health Study).^{6,7,22,23} In the current study, we found that the mean annual prevalence and incidence of PAD was higher among black than white participants, which confirms these prior observations. The current study adds the finding that PAD burden was higher among black participants despite known access to care issue in this population. This study further adds to estimates of PAD burden by providing race/sex analyses. We observed that black women consistently had the highest PAD prevalence, whereas white women had the lowest PAD prevalence across all years of observation (2003–2012) (Table S4). Black men had the highest mean PAD incidence followed by black women (Figure S1). Findings from this study suggest black persons aged ≥ 65 years have a higher burden of PAD and thus could benefit from prevention efforts targeting individuals well before they become age-eligible for Medicare.

The American Heart Association (AHA) recently identified sex-specific estimates of PAD, particularly for women, as a knowledge gap in the literature. The present study answers a challenge from the AHA to produce age-standardized, sex-specific estimates.²⁴ Men in this study had nearly identical age-standardized PAD estimates compared with women overall (mean annual prevalence 12.4% versus 12.5%; mean annual incidence 26.9 versus 26.8 per 1000 person-years) and at most years of observation. The minimal differences observed in PAD burden by sex were in accordance with the limited literature regarding sex-specific estimates of PAD prevalence and incidence.^{10,20} We acknowledge the potential sex-based differences in evaluation of PAD and agree with others that these differing practices (1) likely have caused historical underestimation of PAD burden among women and (2) led clinicians to identify male sex as a PAD risk factor.²² Although we are unable to verify this type of sex bias in our study, our data add to a growing body of research suggesting that the burden of PAD is at least similar for women and men.

Finally, despite the known coexistence of PAD with other major circulatory system disorders,^{25,26} health professional and public awareness of PAD is low in comparison to the awareness of diseases such as stroke, coronary heart disease, heart failure, and atrial fibrillation.^{9,27} Interestingly, PAD prevalence estimates in this study are similar to recent assessments of prevalence of stroke (5–6% in those aged 60–79 years; 14–16% in those aged ≥ 80 years) and coronary heart disease (10–20% in those aged 60–79 years, 19–32% in

those aged ≥ 80 years).²¹ Still, although these estimates suggest a significant PAD burden in this population, clinicians often do not evaluate for the presence of PAD. Furthermore, up to 50% of persons with PAD are asymptomatic and might not be actively seeking PAD-related care.⁹ Our claims-based estimates, which capture PAD in a clinical setting and thus would be unlikely to include asymptomatic PAD, are likely an underestimation of the prevalence and incidence of PAD in the Medicare-aged population.

Strengths and Limitations

The most important strength of this study is the inclusion of outpatient in addition to inpatient clinical encounters in the assessment of prevalent and incident PAD. Prior studies have provided limited information on the burden of PAD stratified by the setting of health care delivery (inpatient versus outpatient). Although a study by Hirsch et al found that inpatient visits represent up to 90% of PAD-related costs,²⁸ $>70\%$ of all PAD claims in the current study were found in the outpatient records. In addition, $>80\%$ of all incident PAD events were found to have occurred in the outpatient setting. These estimates are age-standardized, and look-back periods for incidence are in accordance with recent recommendations, providing a further strength of this study.

Because this study was based on inpatient and outpatient care among CMS Medicare enrollees in FFS programs, our estimates are not generalizable to Medicare beneficiaries enrolled in Medicare Advantage, who have been reported to be healthier than those in FFS.²⁹ Our estimates reflect cohort survivors, and we did not attempt to quantify PAD prior to enrollment in FFS in 2003. Administrative claims data reflect billing practices; therefore, diagnostic coding found in claims data is not always accurate in relation to documented diagnoses or procedures. Codes selected were not independently validated, which could lead to misclassification of PAD occurrence. Upcoding might increase billing by as much as 15%,³⁰ and illness severity is not readily obtainable from claims data.

Conclusions

Findings from this study suggest that PAD is an important circulatory system disorder similar in prevalence to stroke and coronary heart disease. This study addresses an important gap in the existing literature by providing accurate estimates of PAD in the outpatient setting, where the majority of PAD burden was found. PAD estimates stratified by race corroborated other population-based studies that reported a higher burden among black compared with white participants; future work should focus on identifying effective prevention of PAD and its sequelae in this group.

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Disclosures

None.

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SUPPLEMENTAL MATERIAL

Table S1. Exclusion criteria to arrive at final dataset. The ARIC Study, 2003-2012

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Total in dataset	9948	10380	10821	11250	11563	11657	11440	11085	10718	10355
Exclusions for										
HMO	2013	2140	2640	3478	4200	4495	4863	4856	4759	4670
race	39	44	44	45	41	40	41	41	40	37
age <65	603	518	429	355	262	127	32	5	5	2
Final Enrollees	7293	7678	7708	7372	7060	6995	6504	6183	5914	5546

ARIC= Atherosclerosis Risk in Communities

Table S2. International Classification of Diseases, Ninth Revision (ICD-9-CM), Current Procedural Terminology, 4th edition (CPT-4), Healthcare Common Procedure Coding System (HCPCS), and Federally Qualified Healthcare Revenue Center (FQHC) codes used to identify peripheral artery disease in claims.

Code Type	Codes
ICD-9-CM	249.70, 249.71, 250.70, 250.71, 250.72, 250.73, 440.20, 440.21, 440.22, 440.23, 440.24, 440.29, 440.30, 440.31, 440.32, 440.4, 440.8, 440.9, 443.1, 443.22, 443.81, 443.89, 443.9, 444.22, 444.81, 445.02 * 38.08, 38.16, 38.18, 38.38, 38.48, 39.25, 39.29, 39.49, 39.50, 39.56, 39.57, 39.58, 39.90, 84.10, 84.12, 84.13, 84.14, 84.15, 84.16, 84.17, 84.18, 84.3, 84.91
HCPCS/CPT-4	27295, 27590, 27591, 27592, 27594, 27596, 27598, 27599, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 28810, 28820, 28825, 35221, 35226, 35256, 35286, 35302, 35303, 35304, 35305, 35306, 35331, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35452, 35454, 35456, 35459, 35470, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35500, 35521, 35533, 35537, 35538, 35539, 35540, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, 35671, 35681, 35682, 35700, 35875, 35876, 35879, 35881, 35883, 35884, 35903 * 35683, 35686, 35571, 72191, 72198, 73706, 73725, 74175, 74185, 75630, 75631, 75635, 75710, 75711, 75712, 75716, 75717, 75718, 93922, 93924, 93925, 93926, 93978, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99216, 99241, 99242, 99243, 99244, 99245, 99385, 99386, 99387, 99395, 99396, 99397
Revenue Center Codes	*0320,0321,0322,0323,0324,0329,0360,0361,0370,0371,0372,0379,0402,0490,0499,0510,0517,0519,0520,0521,0610,0616,0710,0760,0761,0762,0769,0921

* Must be accompanied with a PAD-related ICD-9-CM code

ICD-9-CM Diagnosis Codes for PAD: Definitions	
Description	Code

Atherosclerosis: of native arteries of the extremities of bypass graft of the extremities of other specified arteries	440.2x 440.3x 440.8x
Generalized and unspecified atherosclerosis: arteriosclerotic vascular disease NOS Peripheral vascular disease, unspecified	440.9x 443.9x
Chronic total occlusion of artery of the extremities	440.4
Arterial embolism and thrombosis of lower extremity	444.22
Embolism and thrombosis of iliac artery	444.81
Atheroembolism of lower extremity	445.02
Diabetes with peripheral circulatory disorders, Type II or unspecified type, not stated as uncontrolled	250.70
Diabetes with peripheral circulatory disorders, Type I (Juvenile type), not stated as uncontrolled	
Diabetes with peripheral circulatory disorders, Type II or unspecified type, uncontrolled	250.71
Diabetes with peripheral circulatory disorders, Type I (Juvenile type), uncontrolled	250.72 250.73

ICD-9-CM Surgical/Intervention Procedure Codes for PAD: Definitions	
Description	Code
Amputation of lower limb	84.1x
Amputation not otherwise specified	
Aorta-iliac-femoral bypass	84.91
Other (peripheral) vascular shunt or bypass	39.25
Incision of lower limb arteries	
Endarterectomy, abdominal arteries	39.29
Endarterectomy, lower limb arteries	
Resection of vessel with anastomosis, lower limb arteries	38.08
Resection of vessel with replacement, lower limb arteries	
Other excision of vessels, lower limb arteries	38.16
Other revision of vascular procedure	38.18
Angioplasty or atherectomy of other non-coronary vessel(s)	38.38
Insertion of non-drug-eluting peripheral vessel stent(s)	38.48
Repair of blood vessel with tissue patch graft	38.68
Repair of blood vessel with synthetic patch graft	39.49
Repair of blood vessel with unspecified type of patch graft	39.50
	39.90
	39.56
	39.57
	39.58

CPT-4 codes for PAD-related surgical or intervention procedures: Definitions	
Description	Code
Repair blood vessel lower extremity; direct with vein graft with graft other than vein	35226

	35256
	35286
Thromboendarterectomy, including patch graft, if performed; superficial femoral artery	
popliteal artery	35302
tibioperoneal trunk artery	
tibial or peroneal artery, initial vessel	35303
each additional tibial or peroneal artery	35304
	35305
	35306
Thromboendarterectomy, with or without patch graft;	
abdominal aorta (35331);	35331
iliac (35351);	
iliofemoral (35355);	35351
combined aortoiliac (35361);	
combined aortoiliofemoral (35363);	35355
common femoral (35371);	
deep (profunda) femoral (35372);	35361
femoral and/or popliteal, and/or tibioperoneal (35381)	35363
	35371
	35372
	35381
In-situ vein bypass;	
aortofemoral-popliteal (only femoral-popliteal portion in-situ)	

femoral-popliteal	35582
femoral-anterior tibial, posterior tibial, or peroneal artery	35583
popliteal-tibial, peroneal	35585
	35587
Bypass graft, with vein;	
axillary-femoral	35521
axillary-femoral-femoral	
aortoiliac	35533
aortobi-iliac	35537
aortofemoral	
aortobifemoral	35538
aortoiliac or bi-iliac	
aortofemoral or bifemoral	35539
aortoiliofemoral, unilateral	
aortoiliofemoral, bilateral	35540
aortofemoral-popliteal	
femoral-popliteal	35541
femoral-femoral	
ilioiliac	35546
iliofemoral	
femoral-anterior tibial, posterior tibial, peroneal artery or other distal vessels	35548
popliteal-tibial,-peroneal artery or other distal vessels	35549
	35551
	35556
	35558

	35563
	35565
	35566
	35571
Percutaneous: aortic iliac femoral-popliteal tibioperoneal trunk and branches	35491
	35492
	35493
	35495
Transluminal peripheral atherectomy, Open: aortic iliac femoral-popliteal tibioperoneal trunk and branches	35481
	35482
	35483
	35485
Transluminal balloon angioplasty, percutaneous; tibioperoneal trunk and branches, each vessel aortic iliac femoral-popliteal	35470
	35472
	35473

	35474
Transluminal balloon angioplasty, open;	
aortic (35452);	35452
iliac (35454);	
femoral-popliteal (35456);	35454
tibioperoneal trunk and branches (35459);	35456
	35459
Bypass graft, with other than vein;	
axillary-femoral	35621
axillary-popliteal or –tibial	
aortoiliac	35623
aortobi-iliac	
aortoiliac or bi-iliac	35637
aortofemoral or bifemoral	
aortofemoral	35638
aortofemoral-popliteal	
axillary-femoral-femoral	35641
femoral-popliteal	
femoral-femoral	35646
ilioiliac	
iliofemoral	35647
femoral-anterior tibial, posterior tibial, or peroneal artery	
popliteal-tibial or -peroneal artery	35651
	35654
	35656
	35661

	35663
	35665
	35666
	35671
Exploration, reoperation, femoral-popliteal or femoral (popliteal) -anterior tibial, posterior tibial, peroneal artery or other distal vessels, more than one month after original operation (List separately in addition to code for primary procedure)	35700
Exploration (not followed by surgical repair), with or without lysis of artery;	
femoral artery	35721
popliteal artery	35741
Thrombectomy of arterial or venous graft, with revision of arterial or venous graft	35876
Revision, lower extremity arterial bypass, without thrombectomy, open;	
with vein patch angioplasty	35879
with segmental vein interposition	35881
Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open;	
with non autogenous patch graft (e.g., Dacron, ePTFE, bovine pericardium)	35883
with autogenous vein patch graft	35884

<p>Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intra procedural pharmacological thrombolytic injection(s);</p> <p>initial vessel</p> <p>second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)</p>	<p>37184</p> <p>37185</p>
<p>Secondary percutaneous transluminal thrombectomy (e.g., non primary mechanical, snare basket, suction technique), noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intra procedural pharmacological thrombolytic injections, provided in conjunction with another percutaneous intervention other than primary mechanical thrombectomy (List separately in addition to code for primary procedure)</p>	<p>37186</p>
<p>Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous;</p> <p>initial vessel (37205)</p> <p>each additional vessel (List separately in addition to code for primary procedure)</p>	<p>37205</p> <p>37206</p>
<p>Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), open;</p> <p>each additional vessel (List separately in addition to code for primary procedure)</p>	<p>37208</p>

Disarticulation;	
of hip	27295
at knee	27598
of ankle	27889
Amputation, thigh, through femur, any level	27590
immediate fitting technique including first cast	27591
open, circular (guillotine)	27592
leg, through tibia and fibula	27880
with immediate fitting technique including application of first cast	27881
open, circular (guillotine)	27882
ankle, through malleoli of tibia and fibula (e.g., Syme, Pirogoff type procedures), with plastic closure and resection of nerves	27888
foot; midtarsal (e.g., Chopart type procedure)	28800
transmetatarsal	28805

CPT-4 codes for PAD-related diagnostic procedures: Definitions	
Description	Code
Aortography:	

abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological complete procedure	75630 75631
Angiography, extremity, unilateral, radiological supervision and interpretation complete procedure	75710 75711
bilateral; by serialography, complete procedure	75712
radiological	75716
without serialography; complete procedure	75717
by serialography, complete procedure	75718
Arterial duplex of the lower extremities, unilateral	93925
bilateral	93926
aorta	93978
CT Angiogram Abdomen with & w/o contrast	74175
Pelvis	72191
Lower Extremity	73706
abdominal aorta and bilateral iliofemoral lower extremity runoff	75635
MRA abdomen images from the diaphragm to the umbilicus or iliac crest	74185

Pelvis	72198
Lower extremity w/ or w/o contrast	73725
Non-invasive physiologic studies of lower extremity arteries, single level, bilateral	93922
at rest and following treadmill stress testing, complete bilateral study	93924

Other PAD-related codes: Definitions	
Description	Code
Chronic total occlusion of artery of the extremities	440.4
Arterial embolism and thrombosis of lower extremity	444.22
Embolism and thrombosis of iliac artery	444.81
Atheroembolism of lower extremity	445.02
Diabetes with peripheral circulatory disorders, Type II or unspecified type, not stated as uncontrolled	250.70
Diabetes with peripheral circulatory disorders, Type I (Juvenile type), not stated as uncontrolled	
Diabetes with peripheral circulatory disorders, Type II or unspecified type, uncontrolled	250.71
Diabetes with peripheral circulatory disorders, Type I (Juvenile type), uncontrolled	250.72
	250.73

Endarterectomy, abdominal arteries	38.16
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Table S3. Sensitivity analysis comparing requiring two outpatient claims versus one outpatient claim to identify prevalence of PAD in the outpatient setting. The ARIC Study, 2003-2012

	Outpatient PAD Prevalence ⁺ % (95% CI)	Outpatient PAD Prevalence [*] % (95% CI)
2003	4.0 (3.1, 4.9)	9.5 (7.9, 11.2)
2004	6.7 (5.7, 7.6)	10.4 (9.3, 11.6)
2005	6.7 (5.9, 7.4)	10.8 (9.8, 11.7)
2006	7.2 (6.5, 7.9)	11.5 (10.6, 12.4)
2007	7.3 (6.6, 7.9)	11.5 (10.7, 12.4)
2008	7.6 (6.9, 8.2)	11.2 (10.4, 12.0)
2009	8.0 (7.4, 8.8)	12.0 (11.1, 12.8)
2010	8.7 (8.0, 9.5)	12.7 (11.8, 13.5)
2011	9.5 (8.7, 10.3)	12.7 (11.7, 13.5)
2012	10.0 (9.1, 10.9)	12.9 (11.9, 14.0)
Weighted Mean	7.9 (7.7, 8.2)	11.8 (11.5, 12.1)

⁺ Requires two outpatient claims in a year for prevalence estimates; ^{*} Requires one outpatient claim for prevalence estimates; ARIC= Atherosclerosis Risk in Communities; Estimates are standardized to 2005 Medicare population

Table S4. *Age-standardized annual prevalence of peripheral artery disease in the inpatient and outpatient setting by race-sex groups. The ARIC Study, 2003-2012

	White Males		White Females		Black Males		Black Females	
	Prevalence %	95% CI	Prevalence %	95% CI	Prevalence %	95% CI	Prevalence %	95% CI
2003	9.6	7.4, 11.8	8.8	5.6, 12.0	10.1	6.6, 13.6	16.2	10.8, 21.6
2004	10.9	9.1, 12.8	9.4	7.4, 11.3	10.5	7.8, 13.3	16.6	12.7, 20.4
2005	11.2	9.7, 12.8	9.4	7.9, 10.8	13.5	10.5, 16.4	15.4	12.3, 18.4
2006	12.6	11.0, 14.1	9.2	7.9, 10.5	14.1	10.9, 17.3	16.7	13.7, 19.8
2007	12.0	10.6, 13.4	10.2	8.9, 11.4	15.0	11.5, 18.5	18.7	15.5, 21.9
2008	11.7	10.3, 13.1	10.0	8.8, 11.2	15.3	11.8, 18.8	15.0	12.3, 17.7
2009	12.2	10.7, 13.7	10.9	9.6, 12.1	14.6	11.3, 17.9	16.5	13.8, 19.1
2010	13.0	11.4, 14.6	11.7	10.4, 13.0	12.9	9.8, 16.1	17.8	15.1, 20.6
2011	12.1	10.5, 13.8	12.4	11.0, 13.7	11.6	8.4, 14.8	17.2	14.4, 19.9
2012	12.3	10.4, 14.2	13.3	11.7, 14.8	13.6	9.3, 17.9	16.2	13.1, 19.2
Weighted Mean	12.1	11.6, 12.5	10.9	10.4, 11.3	13.2	12.2, 14.2	16.9	16.0, 17.8

ARIC= Atherosclerosis Risk in Communities; Estimates are standardized to 2005 Medicare population

Table S5. Age-standardized annual prevalence of peripheral artery disease in the inpatient and outpatient setting by sex. The ARIC Study, 2003-2012

	Male		Female	
	Prevalence %	95% CI	Prevalence %	95% CI
2003	9.7	7.8, 11.7	11.1	8.2, 13.9
2004	10.8	9.2, 11.7	11.6	9.8, 13.4
2005	11.8	10.4, 13.2	11.1	9.8, 12.5
2006	13.0	11.6, 14.4	11.1	10.9, 12.3
2007	12.6	11.3, 13.9	12.1	10.1, 13.3
2008	12.4	11.1, 13.7	11.2	11.2, 13.6
2009	12.7	11.4, 14.1	12.4	12.1, 14.6
2010	13.1	11.7, 14.5	13.4	12.5, 15.0
2011	12.2	10.7, 13.6	13.8	12.5, 15.0
2012	12.8	11.0, 14.5	14.2	12.8, 15.6
Weighted Mean	12.4	12.0, 12.8	12.6	12.1, 12.9

ARIC= Atherosclerosis Risk in Communities; Estimates are standardized to 2005 Medicare population

Table S6. Age-standardized annual incidence of peripheral artery disease in the inpatient and outpatient setting by sex. The ARIC Study, 2005-2012

	Male			Female		
	Events	Person-time	Age-standardized rate	Events	Person-time	Age-standardized rate
2005	66	2667	31.5 (22.0, 41.0)	72	3702	22.1 (15.0, 29.2)
2006	57	2530	31.1 (22.0, 40.1)	63	3512	20.5 (14.2, 26.8)
2007	64	2391	28.7 (21.1, 36.3)	70	3382	23.4 (17.3, 29.5)
2008	51	2319	25.2 (18.0, 32.4)	70	3352	26.6 (19.7, 33.5)
2009	57	2096	28.0 (20.6, 35.4)	66	3106	24.2 (18.0, 30.5)
2010	50	1949	26.2 (18.9, 33.5)	84	2944	31.6 (24.6, 38.7)
2011	41	1817	23.2 (16.0, 30.4)	76	2786	29.0 (22.4, 35.7)
2012	48	1655	27.4 (19.2, 35.6)	82	2561	32.8 (25.5, 40.1)
Weighted Mean	434	17423	26.9 (24.3, 29.5)	583	25346	26.8 (24.5, 29.2)

ARIC= Atherosclerosis Risk in Communities; Estimates are standardized to 2005 Medicare population

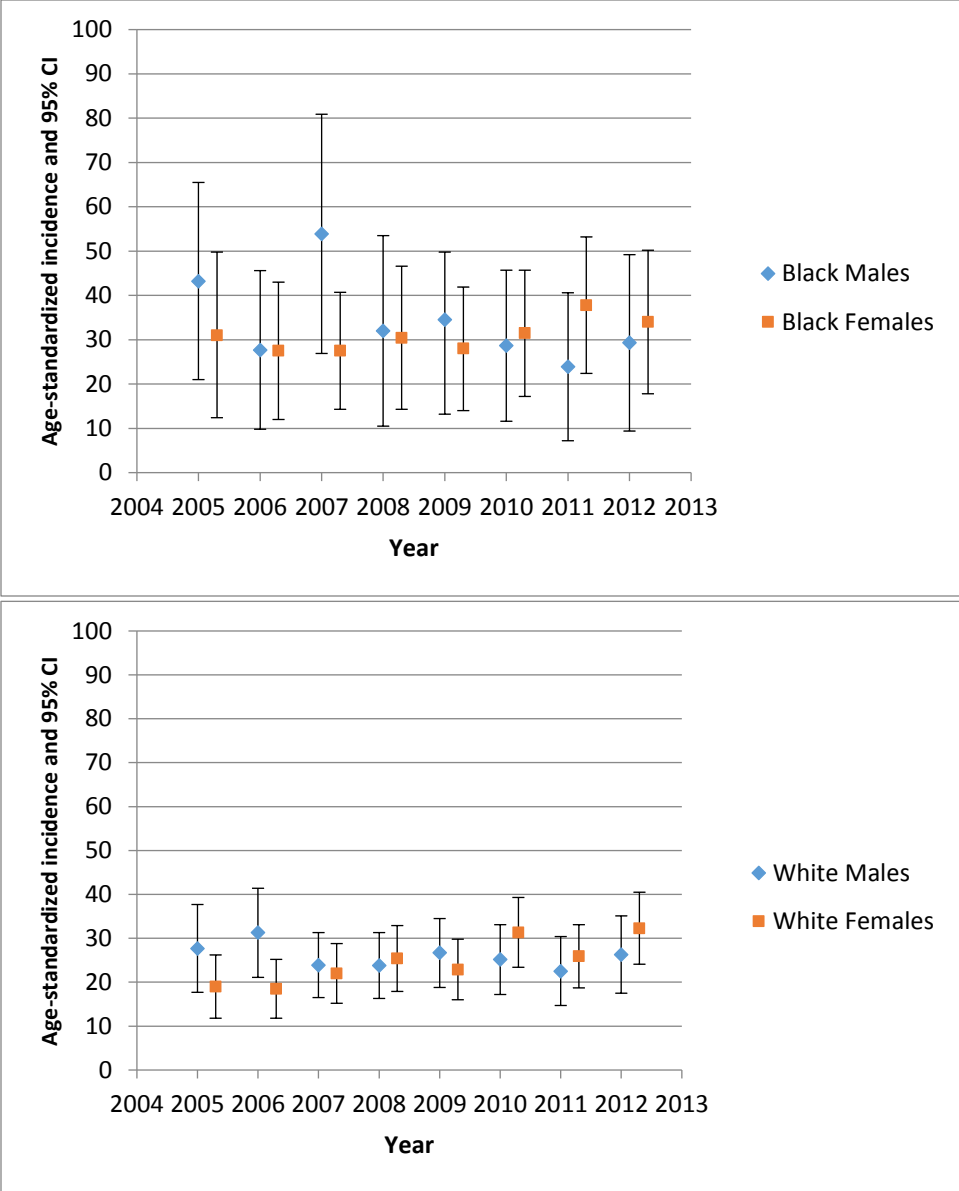


Figure S1. Age-standardized annual incidence of peripheral artery disease in the inpatient and outpatient setting among four race/sex groups. The ARIC Study, 2005-2012

ARIC= Atherosclerosis Risk in Communities; Estimates are age-standardized to 2005 Medicare population rates are per 1000 person-years