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Long-term outcomes of peripheral atherectomy for femoropopliteal endovascular interventions

Anna K. Krawisz[1,2,3], MD; Aishwarya Raja[4], MD; W. Schuyler Jones[5], MD; Peter Schneider[6], MD; Changyu Shen[1], PhD; Marc Schermerhorn[7], MD; Eric A. Secemsky[1,2,3]*, MD, MSc

1. Department of Medicine, Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology, Beth Israel Deaconess Medical Center, Boston, MA, USA; 2. Harvard Medical School, Boston, MA, USA; 3. Division of Cardiology, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, MA, USA; 4. Department of Medicine, Icahn School of Medicine at Mount Sinai, New York, NY, USA; 5. Division of Cardiology, Department of Medicine, Duke University Health System, Durham, NC, USA; 6. Division of Vascular and Endovascular Surgery, University of California San Francisco, San Francisco, CA, USA; 7. Division of Vascular Surgery, Beth Israel Deaconess Medical Center, Boston, MA, USA

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KEYWORDS

- atherectomy
- claudication
- critical limb ischaemia
- femoropopliteal disease

Abstract

Background: The use of atherectomy during peripheral endovascular interventions (PVI) has increased dramatically, but data regarding its safety and effectiveness are lacking.

Aims: This study sought to determine the long-term safety of atherectomy in contemporary practice.

Methods: Medicare fee-for-service beneficiaries who underwent femoropopliteal artery PVI from 2015-2018 were identified in a 100% sample of inpatient, outpatient, and carrier file data using procedural claims codes. The primary exposure was the use of atherectomy. Inverse probability of treatment weighting was used to adjust for measured differences in patient populations. Kaplan-Meier methods and multivariable Cox proportional hazards regression were used to compare outcomes.

Results: Among 168,553 patients who underwent PVI, 59,142 (35.1%) underwent atherectomy. The mean patient age was 77.0±7.6 years, 44.9% were female, 81.9% were white, and 46.7% had chronic limb-threatening ischaemia. Over a median follow-up time of 993 days (interquartile range 319-1,377 days), atherectomy use was associated with no difference in the risk of either the composite endpoint of death and amputation (adjusted hazard ratio [aHR] 0.99, 95% confidence interval [CI]: 0.97-1.01; p=0.19) or of major adverse limb events (aHR 1.02, 95% CI: 0.99-1.05; p=0.26). Patients who underwent atherectomy had a modest reduction in the risk of subsequently undergoing amputation or surgical revascularisation (aHR 0.92, 95% CI: 0.90-0.94; p<0.01) but an increase in the risk of undergoing a subsequent PVI (aHR 1.19, 95% CI: 1.16-1.21; p<0.01).

Conclusions: The use of atherectomy during femoropopliteal artery PVI was not associated with an increase in the risk of long-term adverse safety outcomes among patients with peripheral artery disease.

**Corresponding author: Beth Israel Deaconess Medical Center, Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology, 375 Longwood Avenue, 4th Floor, Boston, MA 02215, USA. E-mail: esecemsk@bidmc.harvard.edu*

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Abbreviations

aHR	adjusted hazard ratio
CI	confidence interval
CLTI	chronic limb-threatening ischaemia
CMS	Centers for Medicare & Medicaid Services
CPT	current procedural terminology
FFS	fee-for-service
HR	hazard ratio
ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
ICD-9-CM, ICD-10-CM	International Classification of Diseases, 9th and 10th Revision, Clinical Modification
IQR	interquartile range
MALE	major adverse limb events
PAD	peripheral artery disease
PVI	peripheral endovascular intervention
SMD	standardised mean difference

Introduction

Peripheral artery disease (PAD) affects over 200 million people worldwide, and its prevalence is increasing[1]. Advanced PAD has devastating consequences for patients, including limitations in mobility, foot pain, ulceration, gangrene, and limb amputations. Revascularisation is a critical component of the management of advanced PAD, as it may prevent amputation and improve quality of life. With the development of endovascular revascularisation, there have been dramatic changes in the strategies used for revascularisation of patients with PAD over the last 2 decades, with a significant increase in the use of an endovascular approach[2,3].

As the scope of the percutaneous approach expands to treat more complex lesion subtypes, a need for innovation in endovascular devices, specifically for the management of heavily calcified stenoses, has arisen[2]. Vascular calcification is associated with worse long-term patency and may inhibit the impact of drug delivery[4]. As such, numerous atherectomy devices have been developed to modify lesions, to allow for adequate vessel expansion, to address device-uncrossable stenoses, and to facilitate drug transfer. As the number of devices on the market increases, the need to define the short- and long-term safety associated with their use grows.

In the United States (US), atherectomy use during peripheral endovascular intervention (PVI) has increased substantially over the last decade despite a lack of data supporting its long-term safety or clinical advantages over other methods, such as balloon angioplasty alone. For example, in the Vascular Quality Initiative, the proportion of PVI procedures performed with atherectomy increased by 64%: from 11% in 2010 to 18% in 2016[5]. Similarly, in an analysis of Centers for Medicare & Medicaid Services (CMS) data, investigators found an increase in the age- and sex-adjusted procedure rates of atherectomies performed from 2006 to 2011, with a disproportionate increase in atherectomy use in the outpatient setting and a particularly high use among privately owned office-based laboratories[6,7]. Atherectomy is also being used more commonly in patients with milder disease, e.g., those with intermittent claudication[5,8]. Throughout the world, atherectomy has been adopted into vascular practice to a variable degree.

This increase in atherectomy use in the US has occurred in the context of CMS modifying the reimbursement structures for PVI in 2008. This policy change was designed to shift PVI use from the inpatient to the outpatient setting, with the goal of reducing total expenditures for PVI[9]. Along with this change, in 2011, the Current Procedural Terminology (CPT) coding system was updated to increase the reimbursement for PVI, particularly those utilising atherectomy[10]. The combined result of these changes was an increase in the total number of PVI, with a disproportionate increase in PVI involving atherectomy. The total expenditures for PVI have also increased over this time period, with a large portion attributable to the greater use of atherectomy[7].

To date, there are insufficient and conflicting data regarding the long-term safety and effectiveness of atherectomy during PVI[11-15]. Safety data are critically needed as the use of atherectomy devices has become pervasive. Therefore, this study was designed to evaluate the long-term safety of atherectomy among a contemporary cohort of Medicare patients with PAD undergoing femoropopliteal artery PVI in both inpatient and outpatient settings.

Methods

STUDY POPULATION

Medicare fee-for-service (FFS) beneficiaries ≥66 years of age who underwent PVI of the femoropopliteal arterial segment between 1 April 2015 and 31 December 2018 were included in the study. Inpatient procedures were only included after 1 October 2015 due to the change to the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) claims codes, which have more specific coding for atherectomy. Patients were excluded if they had less than 1 year of Medicare claims data prior to their index procedure. Patients were also excluded if they were treated at a private non-institutional clinic (i.e., office-based lab or ambulatory surgical centre) due to differences in claims data and reimbursement. Inpatient procedures were identified in the Medicare Provider Analysis and Review files using ICD-10-PCS codes **(Supplementary Table 1)**. Patients who underwent outpatient PVI were identified in a 100% sample of the carrier FFS files using CPT codes. For patients who underwent multiple procedures during the study period, the first procedure was defined as the index procedure and subsequent procedures were considered reinterventions.

PRIMARY EXPOSURE

The use of atherectomy was identified among patients who underwent outpatient procedures through specific CPT procedural billing claims codes that include atherectomy use **(Supplementary Table 1)**. Among patients undergoing in-hospital procedures, specific ICD-10-PCS claims codes for atherectomy (04CK3ZZ, 04CL3ZZ, 04CM3ZZ, 04CN3ZZ) were used. Different types of atherectomy devices could not be identified using claims codes.

BASELINE CHARACTERISTICS

Baseline sociodemographics were ascertained as of the index procedure date. Patient comorbidities were determined using the Chronic Conditions Data Warehouse. It includes data on 27 comorbidities established using a lookback period of 1 to 3 years and involving claims from multiple clinical sites (i.e., inpatient and outpatient medical claims)[16]. In addition to these comorbidities, International Classification of Diseases, 9th and 10th Revision, Clinical Modification (ICD-9-CM, ICD-10-CM) claims codes were applied over a 1-year lookback period to identify current or prior tobacco use, chronic limb-threatening ischaemia (CLTI), and prior amputation **(Supplementary Table 2)**. Procedural characteristics included balloon angioplasty (drug-coated and uncoated balloons), stent placement (bare metal and drug-eluting), and procedural setting (inpatient or outpatient). Hospital characteristics were retrieved from the 2016 American Heart Association Annual Survey file which includes hospital teaching status, region, and bed capacity. In addition, the femoropopliteal artery revascularisation procedure volumes of each institution during the study period were computed.

OUTCOMES

The primary outcomes were major adverse limb events (MALE) and the composite of all-cause death and amputation. MALE included amputation and thrombosis/embolism. Amputations included any amputation of the lower extremity through the forefoot but excluded minor amputations of individual toes. Major amputations were those that occurred at the ankle and more proximally. Minor amputations were distal to the ankle and included toe amputations. Secondary endpoints included all-cause death, all-cause readmission, amputation, major amputation, minor amputation, surgical revascularisation, amputation or surgical revascularisation, and repeat endovascular revascularisation. Both surgical revascularisation and repeat endovascular procedures could involve either leg, as coding was not specific enough to evaluate target vessel revascularisation. Three falsification endpoints were used to evaluate the possibility of residual confounding between treatment groups: hospitalisation for myocardial infarction, congestive heart failure, and pneumonia[17].

STATISTICAL METHODS

All metrics and normally distributed variables were reported as means±standard deviations and compared using the Student's t-test. Categorical variables were presented as frequencies and percentages and compared using the chi-square test. Standardised mean differences (SMD) were calculated to compare characteristics; values of greater than 0.01 represented meaningful differences between groups[18]. Kaplan-Meier methods were used to estimate the cumulative incidence of events for each group. Log-rank tests were used for between-group comparisons.

Inverse probability of treatment weighting was used to account for differences in measured characteristics **(Supplementary Table 3)**. In the first step, a propensity score model was fit, connecting treatment exposure (atherectomy versus no atherectomy) with patient, procedure and hospital characteristics. The probability of receiving atherectomy, or the propensity score, p, was then computed. The weight variable, w, was then defined as 1/p for subjects in the atherectomy group and as 1/(1-p) in the non-atherectomy group. Next, a Cox regression model was fit with group membership as the only covariate. Statistical inference was performed using the bootstrap method. For outcomes that did not include death, the Fine-Gray method was used to account for the competing risk of death[19]. Prespecified subgroup analyses included female patients, procedural setting (outpatient vs inpatient), advanced age (≤75 vs >75 years), presence of chronic kidney disease, and disease severity (CLTI vs non-CLTI).

A p-value of less than 0.05 was considered significant. SAS statistical software version 9.4 (SAS Institute) was used for all analyses. The Institutional Review Board at the Beth Israel Deaconess Medical Center evaluated this study and waived the need for approval because human subject research was not involved.

Results

PATIENT CHARACTERISTICS

The study cohort included 168,553 patients who underwent PVI, 35.1% (N=59,142) of whom underwent atherectomy. The mean age of the PVI cohort was 77.0±7.6 years, 44.9% were female, and 81.9% were white **(Table 1)**. CLTI was present in 46.7% of patients, 7.9% had undergone a prior amputation, and 49.0% were current or prior tobacco users.

There were no major differences in comorbidities between patients who were treated with atherectomy and those who were not **(Table 1)**. Specifically, the rates of prior myocardial infarction, chronic kidney disease, diabetes, ischaemic heart disease, stroke/transient ischaemic attack, CLTI, and tobacco use were not significantly different between the 2 groups (SMD <0.1). After adjustment, all SMD were less than 0.01.

PRACTICE SETTING AND REGIONAL VARIATION

Regions with the greatest proportional use of atherectomy included the Central Southwest (43.2% of PVI), Central Southeast (40.2% of PVI), and Mountain (39.4% of PVI). The Northeast region had the lowest proportional use of atherectomy (23.5% of PVI). Smaller hospitals used more atherectomy than larger hospitals, with atherectomy being used in nearly 40% of all PVI among hospitals with fewer than 200 beds. In addition, non-teaching hospitals used more atherectomy (40.8% of PVI) compared with teaching hospitals (32.9% of PVI) **(Table 1)**.

OUTCOMES

The median follow-up was 993 days (interquartile range [IQR] 319-1,377). Prior to adjustment, atherectomy was associated with a lower risk of both primary outcomes: MALE (3-year cumulative incidence: 11.38% for atherectomy vs 12.62% for no atherectomy, hazard ratio [HR] 0.89, 95% confidence interval [CI]: 0.86-0.92; p<0.01) and the composite outcome of death and amputation

Table 1. Baseline characteristics of patients who underwent femoropopliteal endovascular revascularisation stratified by receiving atherectomy.

		Total population (168,553)	No atherectomy (N=109,411)	Atherectomy (N=59,142)	SMD
Demographics					
Age		77.02±7.59	77.18±7.76	76.73±7.45	0.06
Female		75,744 (44.9)	49,485 (45.2)	26,259 (44)	0.02
Race	White	138,026 (81.9)	90,261 (82.5)	47,766 (80.8)	0.04
	Black	21,765 (12.9)	13,533 (12.4)	8,232 (13.9)	0.05
	Asian	1,500 (0.9)	986 (0.9)	514 (0.9)	0.00
	Hispanic	4,086 (2.4)	2,561 (2.3)	1,525 (2.6)	0.02
	Native	1,115 (0.7)	684 (0.6)	431 (0.7)	0.01
	Other	2,061 (1.2)	1,387 (1.3)	673 (1.1)	0.01
Comorbidities					
Alzheimer's dementia		28,904 (17.1)	19,125 (17.5)	9,779 (16.5)	0.03
Alzheimer's disease		7,636 (4.5)	4,961 (4.5)	2,675 (4.5)	0.00
Anaemia		77,592 (46.0)	50,678 (46.3)	26,914 (45.5)	0.02
Asthma		9,989 (5.9)	6,586 (6.0)	3,403 (5.8)	0.01
Atrial fibrillation		31,051 (18.4)	20,407 (18.7)	10,644 (17.0)	0.02
Breast cancer		4,264 (2.5)	2,847 (2.6)	1,417 (2.4)	0.01
Cataract		23,563 (14.0)	15,011 (13.7)	8,552 (14.5)	0.02
CHF		63,796 (37.8)	41,614 (38.0)	22,182 (37.5)	0.01
CKD		84,519 (50.1)	55,008 (50.3)	29,511 (49.9)	0.01
CLTI		78,665 (46.7)	52,042 (47.6)	26,623 (45.0)	0.05
Colorectal cancer		3,294 (2.0)	2,198 (2.0)	1,096 (1.9)	0.01
COPD		49,949 (29.6)	32,296 (29.5)	17,653 (29.8)	0.01
Current or prior tobacco use		82,554 (49.0)	54,267 (49.6)	28,287 (47.8)	0.04
Depression		36,501 (21.7)	24,011 (21.9)	12,490 (21.1)	0.02
Diabetes		85,880 (51.0)	54,960 (50.2)	30,920 (52.3)	0.04
Endometrial cancer		638 (0.4)	425 (0.4)	213 (0.4)	0.00
Glaucoma		13,103 (7.8)	8,293 (7.6)	4,810 (8.1)	0.02
Hip fracture		2,390 (1.4)	1,600 (1.5)	790 (1.3)	0.01
Hyperlipidaemia		118,567 (70.3)	75,562 (69.1)	43,005 (72.7)	0.08
Hyperparathyroidism		21,676 (12.9)	14,112 (12.9)	7,564 (12.8)	0.00
Hyperthyroidism		135,272 (80.3)	86,759 (79.3)	48,513 (82.0)	0.07
Hypothyroidism		29,418 (17.5)	19,045 (17.4)	10,373 (17.5)	0.00
Ischaemic heart disease		110,100 (65.3)	70,357 (64.3)	39,743 (67.2)	0.06
Lung cancer		3,630 (2.2)	2,348 (2.1)	1,282 (2.2)	0.00
MI		7,748 (4.6)	5,168 (4.7)	2,580 (4.3)	0.02
Osteoporosis		12,524 (7.4)	8,301 (7.6)	4,223 (7.1)	0.02
Prior amputation		13,296 (7.9)	9,232 (8.4)	4,064 (6.9)	0.06
Prostate cancer		7,625 (4.5)	4,868 (4.4)	2,757 (4.7)	0.01
Rheumatoid/osteoarthritis		66,730 (39.6)	42,951 (39.3)	23,779 (40.2)	0.02
Stroke/TIA		15,715 (9.3)	10,175 (9.3)	5,540 (9.4)	0.00
Geography					
Northeast		7,234 (4.3)	5,535 (5.1)	1,700 (2.9)	0.11
Mid-Atlantic		21,927 (13.0)	15,180 (13.9)	6,749 (11.4)	0.07
Central Northeast		29,325 (17.4)	18,890 (17.3)	10,434 (17.6)	0.01
Central Southeast		13,429 (8.0)	8,032 (7.3)	5,396 (9.1)	0.06
Central Northwest		12,979 (7.7)	8,898 (8.1)	4,082 (6.9)	0.05
Central Southwest		23,140 (13.7)	13,134 (12.0)	10,003 (16.9)	0.14
South Atlantic		35,243 (20.9)	22,716 (20.8)	12,527 (21.2)	0.01
Mountain		8,483 (5.0)	5,136 (4.7)	3,346 (5.7)	0.04
Pacific		16,034 (9.5)	11,306 (10.3)	4,730 (8.0)	0.08
Other regions		758 (0.4)	584 (0.5)	175 (0.3)	0.04

Table 1. Baseline characteristics of patients who underwent femoropopliteal endovascular revascularisation stratified by receiving atherectomy (cont'd).

	Total population (168,553)	No atherectomy (N=109,411)	Atherectomy (N=59,142)	SMD
Hospital characteristics				
6-24 beds	147 (0.1)	93 (0.1)	55 (0.1)	0.00
25-49 beds	1,414 (0.8)	788 (0.7)	625 (1.1)	0.04
50-99 beds	7,110 (20.1)	4,249 (3.9)	2,860 (4.8)	0.05
100-199 beds	27,153 (16.1)	16,467 (15.1)	10,684 (18.1)	0.08
200-299 beds	34,342 (20.4)	22,157 (20.3)	12,185 (20.6)	0.01
300-399 beds	31,470 (18.7)	19,832 (18.1)	11,638 (19.7)	0.04
400-499 beds	19,263 (11.4)	12,775 (11.7)	6,488 (11.0)	0.02
≥500 beds	47,655 (28.3)	33,051 (30.2)	14,607 (24.7)	0.12
Teaching hospital	122,061 (72.4)	81,895 (74.9)	40,170 (67.9)	0.15
Procedural characteristics				
Inpatient procedure	80,228 (47.6)	55,640 (50.9)	24,588 (41.6)	0.19
Stent implantation	69,122 (41.0)	50,268 (45.9)	18,854 (31.9)	0.29
Bare metal stent	39,779 (23.6)	30,197 (27.6)	9,522 (16.1)	0.28
Drug-eluting stent	29,396 (17.4)	20,081 (18.4)	9,315 (15.8)	0.07
Drug-coated balloon	70,584 (41.9)	40,609 (37.1)	29,975 (50.7)	0.28

Age is expressed as mean±standard deviation. All other values are n (%). *SMD >0.1 is considered significant. CHF: congestive heart failure; CKD: chronic kidney disease; CLTI: chronic limb-threatening ischaemia; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction; SMD: standardised mean difference; TIA: transient ischaemic attack

(3-year cumulative incidence: 41.85% for atherectomy vs 45.56% for no atherectomy, HR 0.88, 95% CI: 0.87-0.90; p<0.01) **(Table 2, Figure 1)**. Patients who underwent atherectomy had a lower unadjusted risk of amputation, surgical revascularisation, and either amputation or surgical revascularisation **(Table 2, Supplementary Table 4)**. Conversely, patients treated with atherectomy had a higher unadjusted risk of subsequent endovascular procedures to either leg **(Table 2)**. There were lower unadjusted risks of all-cause

Table 2. Unadjusted and adjusted analyses for primary and secondary endpoints comparing patients who underwent PVI with atherectomy compared with those who underwent PVI without atherectomy.

	Unadjusted		Adjusted	
	Hazard ratio (95% CI)	*p*-value	Hazard ratio (95% CI)	*p*-value
Primary endpoints				
Composite of death and amputation	0.88 (0.87-0.90)	<0.01	0.99 (0.97-1.01)	0.19
MALE	0.89 (0.86-0.92)	<0.01	1.02 (0.99-1.05)	0.26
Secondary endpoints				
All-cause death	0.92 (0.90-0.93)	<0.01	1.00 (0.98-1.01)	0.85
Amputation	0.82 (0.80-0.85)	<0.01	0.94 (0.91-0.97)	<0.01
Amputation or surgical revascularisation	0.82 (0.80-0.84)	<0.01	0.92 (0.90-0.94)	<0.01
Surgical revascularisation	0.80 (0.77-0.83)	<0.01	0.89 (0.86-0.92)	<0.01
Surgical or endovascular revascularisation	1.16 (1.14-1.18)	<0.01	1.13 (1.11-1.15)	<0.01
Endovascular revascularisation	1.25 (1.22-1.27)	<0.01	1.19 (1.16-1.21)	<0.01
Major amputation	0.83 (0.80-0.86)	<0.01	0.95 (0.91-0.98)	<0.01
Minor amputation	0.82 (0.79-0.86)	<0.01	0.93 (0.89-0.96)	<0.01
All-cause readmission	0.92 (0.90-0.93)	<0.01	0.98 (0.97-1.00)	0.04
Myocardial infarction	0.96 (0.93-0.99)	0.02	0.98 (0.95-1.02)	0.34
Congestive heart failure	0.93 (0.92-0.95)	<0.01	0.98 (0.96-1.00)	0.02
Pneumonia	0.99 (0.96-1.01)	0.32	1.01 (0.99-1.04)	0.37

CI: confidence interval; MALE: major adverse limb events; PVI: peripheral endovascular intervention

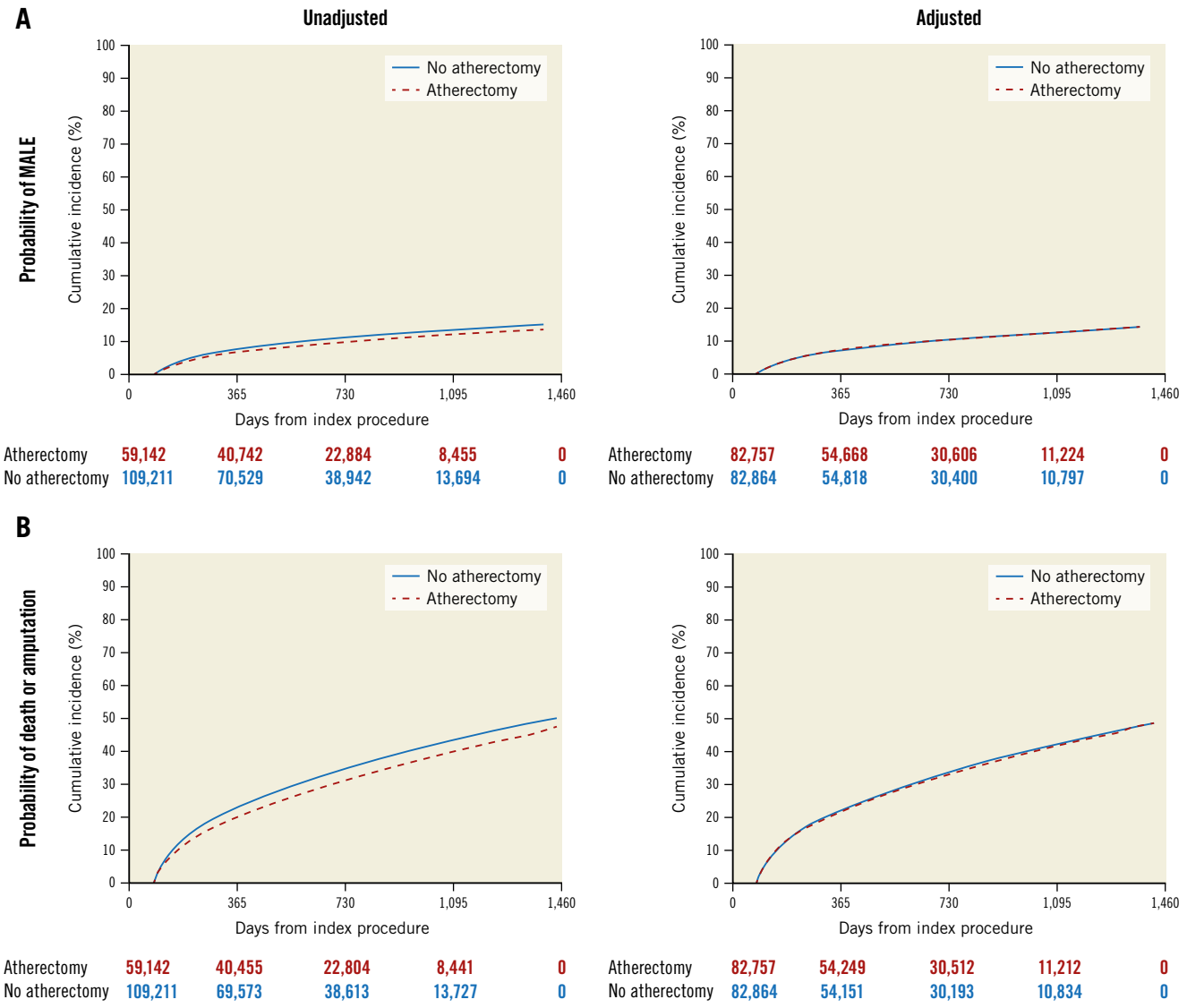

Figure 1. *Unadjusted and adjusted risk of MALE and a composite of amputation and death among patients who underwent PVI with or without atherectomy. Kaplan-Meier curves demonstrating that there was a lower unadjusted risk of major adverse limb events (MALE) and no difference in the adjusted risk of MALE over time in patients who underwent atherectomy compared with those who did not undergo atherectomy (A). Prior to adjustment, there was a lower risk of the composite endpoint of death and amputation over time in patients who underwent atherectomy compared with those who did not undergo atherectomy. After adjustment, there was no difference in the composite endpoint of death and amputation over time among patients who underwent atherectomy versus no atherectomy (B). PVI: peripheral endovascular intervention*

readmission and all-cause death **(Table 2)**. In terms of the falsification endpoints, prior to adjustment, there was a lower risk of congestive heart failure among those treated with atherectomy, but there was no difference in the risk of myocardial infarction or pneumonia for patients who underwent PVI with or without atherectomy **(Table 2)**.

After adjustment, there was no difference in the risk of the composite outcome of death and amputation (3-year cumulative incidence: 43.77% for atherectomy vs 44.30% for no atherectomy, adjusted hazard ratio [aHR] 0.99, 95% CI: 0.97-1.01; p=0.19) or MALE (3-year cumulative incidence: 12.15% for atherectomy vs 12.22% for no atherectomy, aHR 1.02, 95% CI: 0.99-1.05; p=0.26) among patients who underwent PVI with atherectomy versus PVI without atherectomy. After adjustment, the reduction in the risk of amputation (3-year cumulative incidence: 13.15% for atherectomy vs 13.99% for no atherectomy, aHR 0.94, 95% CI: 0.91-0.97; p<0.01), surgical revascularisation (3-year cumulative incidence: 8.30% for atherectomy vs 9.20% for no atherectomy, aHR 0.89, 95% CI: 0.86-0.92; p<0.01), and amputation or surgical revascularisation associated with atherectomy remained (3-year cumulative incidence: 37.00% for atherectomy vs 33.60% for no atherectomy; aHR 0.92, 95% CI: 0.90-0.94; p<0.01) **(Table 2, Figure 1)**. After adjustment, atherectomy remained associated with a higher risk of subsequent endovascular procedures (3-year

cumulative incidence: 33.28% for atherectomy and 20.06% for no atherectomy, aHR 1.19, 95% CI: 1.16-1.21; p<0.01) **(Table 2, Figure 2)**. There were no differences in the risk of the falsification endpoints of myocardial infarction and pneumonia between treatment groups and there was an attenuation of the association between atherectomy use and congestive heart failure **(Table 2)**.

SUBGROUP ANALYSES

Among the prespecified subgroups, there was no association between the use of atherectomy and death for any subgroup. Outpatients who underwent PVI with atherectomy had a modest reduction in the risk of the composite endpoint of all-cause death and amputation, whereas inpatient PVI with atherectomy was associated with a modestly increased risk **(Table 3)**. Women had a modest increase in the risk of the composite endpoint (aHR 1.03, 95% CI: 1.00-1.05; p=0.04). There was no association between atherectomy use and the composite endpoint of all-cause death and amputation by age (≤75 vs >75), PAD severity (CLTI vs non-CLTI), chronic kidney disease, or diabetes **(Table 3)**.

Discussion

The global impact of PAD is significant and is increasing over time[1]. Defining safe and effective revascularisation approaches for complex PAD is critical. In this nationwide, longitudinal analysis

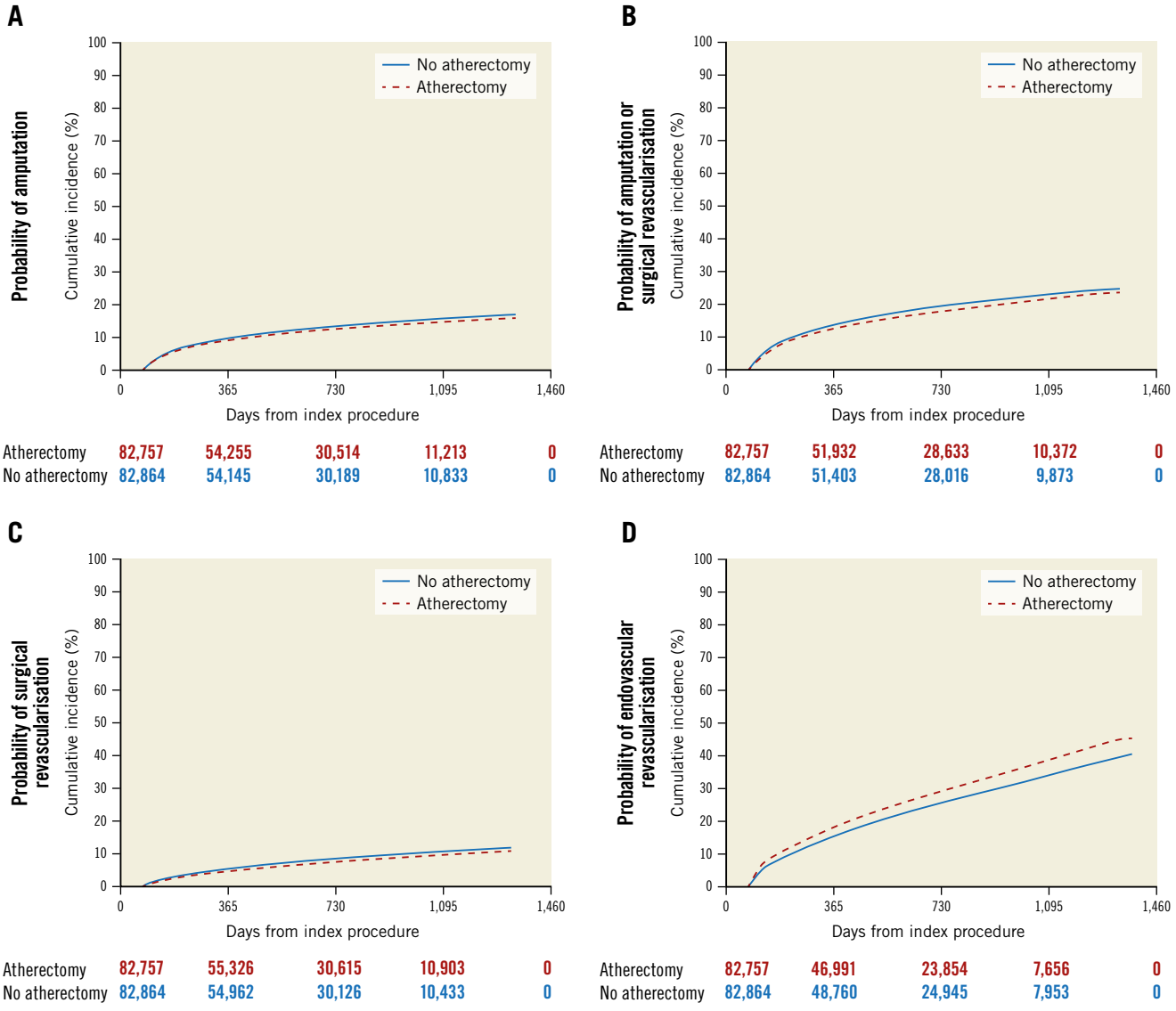

Figure 2. *Adjusted risk of subsequent procedures in patients who underwent PVI with or without atherectomy. Kaplan-Meier curves of secondary endpoints including amputation (A), the combined endpoint of amputation and surgical revascularisation (B), surgical revascularisation (C), and endovascular revascularisation (D) among patients who underwent atherectomy versus no atherectomy. Patients who underwent atherectomy had a modestly lower risk of amputation, surgical revascularisation, and the composite endpoint of amputation and surgical revascularisation. Patients who underwent atherectomy had a significant increase in the risk of a subsequent endovascular procedure compared with those who did not undergo atherectomy. PVI: peripheral endovascular intervention*

Table 3. Adjusted risks of outcomes among key subgroups.

Subgroup analyses	All-cause death		Composite of death and amputation		Amputation	
	Hazard ratio (95% CI)	*p*-value	Hazard ratio (95% CI)	*p*-value	Hazard ratio (95% CI)	*p*-value
Age >75	1.00 (0.98-1.02)	0.89	1.00 (0.98-1.02)	1.00	0.92 (0.88-0.96)	<0.01
Age ≤75	1.00 (0.98-1.03)	0.77	1.00 (0.97-1.03)	1.00	0.99 (0.95-1.04)	0.81
CKD	1.00 (0.98-1.02)	0.89	1.00 (0.98-1.02)	0.83	0.96 (0.93-1.00)	0.06
Diabetes	0.99 (0.97-1.01)	0.25	0.99 (0.97-1.01)	0.42	0.96 (0.93-1.00)	0.05
Women	1.01 (0.99-1.03)	0.34	1.03 (1.00-1.05)	0.04	0.97 (0.93-1.02)	0.27
Inpatients	1.02 (0.96-1.04)	0.13	1.03 (1.01-1.05)	0.01	0.98 (0.94-1.02)	0.31
Outpatients	0.98 (0.95-1.00)	0.02	0.95 (0.93-0.98)	<0.01	0.90 (0.86-0.95)	<0.01
Non-CLTI PAD	1.00 (0.98-1.03)	0.61	1.02 (1.00-1.05)	0.88	0.96 (0.93-0.99)	0.01
CLTI	1.00 (0.98-1.02)	0.67	0.98 (0.96-1.00)	0.07	0.93 (0.90-0.96)	<0.01

CI: confidence interval; CKD: chronic kidney disease; CLTI: chronic limb-threatening ischaemia; PAD: peripheral artery disease

of Medicare patients undergoing PVI with atherectomy of the femoropopliteal arterial segment, we found that PVI with atherectomy was not associated with a higher risk of death, amputation, MALE, or the need for surgical revascularisation compared with PVI without atherectomy over a median follow-up of approximately 2.7 years **(Central illustration)**. Atherectomy also appeared safe in several critical subgroups, including elderly patients and those with diabetes, chronic kidney disease, and CLTI.

Peripheral atherectomy has been an adjunct during endovascular intervention for several decades, yet its use remains variable. In the US, the frequency of use has been high, but primarily in privately owned clinics secondary to reimbursement incentives[5-8]. However, this pattern is not seen among hospitalised patients, and, globally, practice patterns in atherectomy are highly variable by country and region. Notably, this increase in atherectomy utilisation in the US has occurred without robust evidence supporting the effectiveness of atherectomy or comparative data supporting the clinical advantages of atherectomy over other approaches. For instance, in a meta-analysis of 4 randomised controlled trials comprising 220 patients comparing PVI with and without atherectomy, there was no benefit of atherectomy in terms of primary patency at 6 and 12 months or target lesion revascularisation[11].

In addition to effectiveness, the appraisal of the long-term safety of atherectomy versus other revascularisation strategies in broad,

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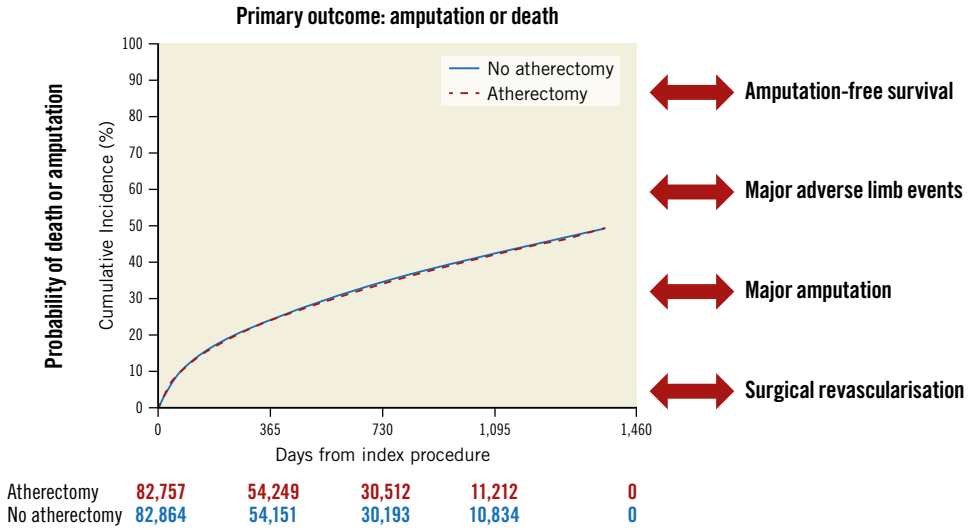
CENTRAL **ILLUSTRATION** Long-term outcomes following peripheral atherectomy.



Kaplan-Meier curve demonstrating that, after adjustment, there is no increase in risk of the composite outcome of amputation or death in patients who underwent PVI with atherectomy compared with those who underwent PVI without atherectomy. Outcomes are equivocal for amputation-free survival, major adverse limb events, major amputation, and surgical revascularisation. PVI: peripheral endovascular intervention

real-world patients has, to date, been limited. Many global studies of atherectomy devices have demonstrated overall low event rates, but these have primarily been single-armed studies with relatively short-term endpoints[20-22]. Our study is unique as it demonstrates that peripheral atherectomy appears safe beyond 1 year after the index procedure, with similar rates of amputation-free survival and a lower risk of subsequent surgical procedures. These findings are important as patients with claudication, who have overall low risks of amputation, were included in the study population. As such, any signal of harm would be meaningful. Critically, the falsification endpoints were negligibly different between treatment groups after adjustment, suggesting a low likelihood of residual confounding. These findings persisted in key subgroups, including in the outpatient setting, which has seen the greatest growth in atherectomy use.

These results differ from a prior US study involving patients in the Vascular Quality Initiative registry, which reported higher rates of amputations among patients who received atherectomy compared with those who received percutaneous transluminal angioplasty alone, as well as more limb events with atherectomy relative to stenting[12]. There are several reasons why the findings differed between that analysis and ours. First, the prior study included patients treated for lesions in multiple arterial segments (iliac, femoropopliteal, and tibial), whereas our study focused on patients treated primarily for lesions in the femoropopliteal segment. In addition, this prior study did not allow for combined procedures such as atherectomy and stenting, which are commonly used in clinical practice. Furthermore, the prior study was performed during an earlier time period when atherectomy was shifting from the inpatient to the outpatient setting. Thus, the population who received atherectomy at that time may have been markedly different from those treated in the present study. Finally, the prior study involved procedures from a predominantly surgical registry, which may have selected a more complex patient population compared with the broad population in the present study. A strength of this analysis was that the database included more granular procedural data. Interestingly, a different analysis that examined outcomes of interventional strategies in patients with CLTI demonstrated lower rates of amputation in patients treated with atherectomy compared with those treated with percutaneous transluminal angioplasty, stenting, or surgical bypass[13].

Limitations

There are several limitations of this study. First, this is a retrospective, observational study. As such, patients were not randomised to PVI with or without atherectomy and, thus, the analysis could be subject to unmeasured confounding. However, we used falsification endpoints to evaluate the impact of residual imbalances between groups, and these associations were negligible. Second, the population in our study was primarily white and elderly, and, therefore, the results may not be applicable to the general population. Third, Medicare claims data do not provide information regarding the specific atherectomy device type used or anatomic factors and lesion characteristics that may have influenced the selection of atherectomy. As such, this analysis was unable to assess whether different types of atherectomy yielded different outcomes. In addition, this analysis is unable to further clarify clinical questions such as which lesion characteristics may be best suited to treatment with atherectomy in general or to treatment with specific atherectomy subtypes. Fourth, although insurance claims data lack the granularity to track procedural events like distal embolisation, the major clinical sequelae of these events, including arterial thrombosis/embolism and amputation, are captured and should reflect any major consequence of such events. Last, we excluded atherectomy procedures performed in private office-based labs, and it is possible that this practice setting may have distinct patient outcomes.

Conclusions

In this large analysis of Medicare patients treated with femoropopliteal artery PVI, atherectomy was not associated with an increased risk of adverse outcomes over time, including amputation, the composite of death and amputation, and major adverse limb events. These findings remained consistent in high-risk subgroups, including the elderly and patients with chronic kidney disease, diabetes, or CLTI. In addition, among patients treated in the outpatient setting, there were no additional long-term risks associated with atherectomy use. Further studies are needed to establish the clinical effectiveness of atherectomy during PVI.

Impact on daily practice

This analysis in a large, nationwide cohort demonstrated that the use of atherectomy was not associated with a higher risk of adverse safety outcomes, including amputation and a composite of amputation and death, compared with PVI without atherectomy. Further research is needed to determine whether there is a clinical benefit of atherectomy and to define the patient populations that derive the greatest benefit from atherectomy.

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Conflict of interest statement

W. Schuyler Jones reports research grants from Boehringer Ingelheim, Bristol-Myers Squibb, the Doris Duke Charitable Foundation, Merck, the National Institutes of Health, and the Patient-Centered Outcomes Research Institute; and honoraria for advisory committees from Bayer, Bristol-Myers Squibb, and Janssen Pharmaceuticals. P. Schneider is a member of consulting/scientific advisory boards at Boston Scientific, Medtronic, CSI, Surmodics, Philips, Silk Road, PQ Bypass, Cagent, and LimFlow. C. Shen is an employee at

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Biogen. M. Schermerhorn is a consultant for Abbott Vascular and Medtronic. E.A. Secemsky is a member of consulting/scientific advisory boards at Abbott, Bayer, BD, Boston Scientific, Cook, CSI, Inari Medical, Janssen, Medtronic, Philips, and VentureMed; and has received research grants from AstraZeneca, BD, Boston Scientific, Cook, CSI, Laminate Medical, Medtronic, and Philips. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Table 1. Procedural billing codes used to identify patients who underwent atherectomy and patients who underwent peripheral endovascular intervention without atherectomy.

Supplementary Table 2. Additional claims codes for comorbidities.

Supplementary Table 3. Variables included in the inverse probability of treatment weighting model.

Supplementary Table 4. Weighted and unweighted cumulative incidences of primary and secondary outcomes in patients who underwent atherectomy and in those who did not undergo atherectomy at 1, 2, and 3 years.

Supplementary Table 5. Adjusted risks of secondary endpoints among key subgroups comparing patients who underwent PVI with atherectomy to those who underwent PVI without atherectomy.

Supplementary Figure 1. Love plot of covariates before and after adjustment using inverse probability of treatment weighting.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-22-00609

Supplementary data

Supplementary Table 1. Procedural billing codes used to identify patients who underwent atherectomy and patients who underwent peripheral endovascular intervention without atherectomy.

Procedure (Femoral, Popliteal)	ICD-10	CPT
Peripheral Procedures		
Atherectomy	04CK3ZZ 04CL3ZZ 04CM3ZZ 04CN3ZZ	37225 37227 37229 37231 37233 37235 0238T
Drug-coated stent	047K341 047K346 047K34Z 047K356 047K35Z 047K366 047K36Z 047K376 047K37Z 047L341 047L346 047L34Z 047L356 047L35Z 047L366 047L36Z 047L376 047L37Z 047M341 047M346 047M34Z 047M356 047M35Z 047M366 047M36Z 047M376 047M37Z 047N341 047N346	

	047N34Z 047N356 047N35Z 047N366 047N36Z 047N376 047N37Z	
Drug-coated balloon	047K3D1 047K3Z1 047L3D1 047L3Z1 047M3D1 047M3Z1 047N3D1 047N3Z1	
Bare metal stent	047K3D6 047K3DZ 047K3E6 047K3EZ 047K3F6 047K3FZ 047K3G6 047K3GZ 047L3D6 047L3DZ 047L3E6 047L3EZ 047L3F6 047L3FZ 047L3G6 047L3GZ 047M3D6 047M3DZ 047M3E6 047M3EZ 047M3F6 047M3FZ 047M3G6 047M3GZ 047N3D6 047N3DZ 047N3E6 047N3EZ 047N3F6 047N3FZ 047N3G6	

	047N3GZ	
Percutaneous transluminal angioplasty	047K3Z6 047K3ZZ 047L3Z6 047L3ZZ 047M3Z6 047M3ZZ 047N3Z6 047N3ZZ	

Supplementary Table 2. Additional claims codes for comorbidities.

Comorbidity	ICD-10 Codes	ICD-9 Codes
Chronic Limb Threatening Ischemia	I7022, I7023, I7024, I7026, I7032, I7033, I7034, I7036, I7042, I7043, I7044, I7046, I7052, I7053, I7054, I7056, I7062, I7063, I7064, I7066, I7072, I7073, I7074, I7076, E1052, E10621, E1152, E11621	440.20, 440.21, 440.22, 440.23, 440.24, 440.29, 440.30, 440.31, 440.32, 440.9, 440.0, 249.70, 249.71, 250.70, 250.71, 250.72, 250.73, 443.81, 443.9, 443.1, 444.22, 444.81, 785.4, or 440.4 plus ≥1 of the following: 440.22, 440.23, 707.10, 707.11, 707.12, 707.13, 707.14, 707.15, 707.19, 730.05, 730.06, 730.07, 730.15, 730.16, 730.17, 682.6, 682.7, 681.10, V49.70, V49.71, V49.72, V49.73, V49.74, V49.75, V49.76, V49.77
Prior Amputation	Z89.41, Z89.42, Z89.43, Z89.44, Z89.51, Z89.52, Z89.61, Z89.62	V49.70, V49.71, V49.72, V49.73, V49.74, V49.75, V49.76, V49.77
Current or Prior Tobacco Use	F172, F1720, F17200, F17201, F17203, F17208, F1720, F1721, F17210, F17211, F17213, F17218, F17219, F1722, F17220, F17221, F17223, F17228, F17229, F1729, F17290, F17291, F17293, F17298, F17299, Z720, Z87891	305.1, 649.00–649.04, V15.82

Supplementary Table 3. Variables included in the inverse probability of treatment weighting model.

Demographics
Age
Female
Race
White
Black
Asian
Hispanic
Native
Other
Comorbidities
Alzheimers Dementia
Alzheimers Disease
Anemia
Asthma
Atrial Fibrillation
Breast Cancer
Cataract
CHF
CKD
CLTI
Colorectal Cancer
COPD
Current or Prior Tobacco Use
Depression
Diabetes
Endometrial Cancer
Glaucoma
Hip Fracture
Hyperlipidemia
Hyperparathyroidism
Hyperthyroidism
Hypothyroidism
Ischemic Heart Disease
Lung Cancer
MI
Osteoporosis
Prior amputation
Prostate Cancer
Rheumatoid/Osteoarthritis
Stroke/TIA
Geography
Northeast
Mid-Atlantic
Central Northeast

Central Southeast
Central Northwest
Central Southwest
South Atlantic
Mountain
Pacific
Other Region
Hospital Characteristics
6-24 Beds
25-49 Beds
50-99 Beds
100-199 Beds
200-299 Beds
300-399 Beds
400-499 Beds
≥500 Beds
Teaching Hospital
Procedural Characteristics
Inpatient Procedure
Stent Implantation
Bare Metal Stent
Drug-eluting Stent
Drug-coated Balloon

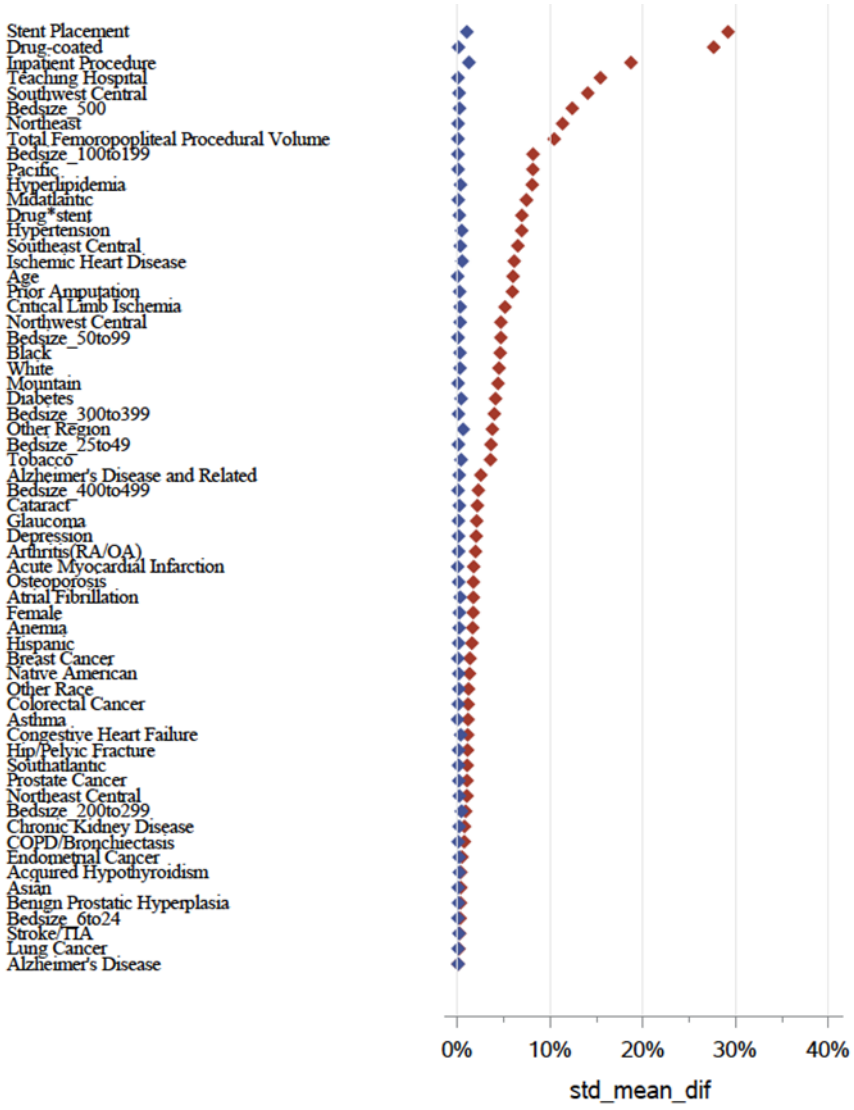
Supplementary Table 4. Weighted and unweighted cumulative incidences of primary and secondary outcomes in patients who underwent atherectomy and in those who did not undergo atherectomy at 1, 2, and 3 years.

	Time Point	Unweighted Cumulative Incidence		Weighted Cumulative Incidence	
		Atherectomy	No Atherectomy	Atherectomy	No Atherectomy
Primary Endpoints					
Composite of Death and Amputation	1-Year	23.43%	26.51%	25.30%	25.42%
	2-Year	33.55%	37.23%	35.53%	36.01%
	3-Year	41.85%	45.56%	43.77%	44.30%
MALE	1-Year	7.79%	8.58%	8.47%	8.24%
	2-Year	10.00%	11.06%	10.78%	10.68%
	3-Year	11.38%	12.62%	12.15%	12.22%
Secondary Endpoints					
All-Cause Death	1-Year	16.98%	18.70%	18.23%	18.00%
	2-Year	26.46%	28.66%	27.85%	27.83%
	3-Year	36.84%	39.27%	38.27%	38.32%
Amputation	1-Year	8.72%	10.36%	9.39%	9.89%
	2-Year	10.93%	12.96%	11.65%	12.41%
	3-Year	12.48%	14.57%	13.15%	13.99%
Amputation or Surgical Revascularization	1-Year	12.24%	14.84%	13.16%	14.28%
	2-Year	15.73%	18.70%	16.68%	18.08%
	3-Year	18.28%	21.13%	19.15%	20.52%
Surgical Revascularization	1-Year	4.55%	5.89%	4.94%	5.73%
	2-Year	6.46%	7.96%	6.89%	7.80%
	3-Year	7.93%	9.33%	8.30%	9.20%
Surgical or Endovascular Revascularization	1-Year	22.62%	19.91%	22.17%	20.05%
	2-Year	31.29%	27.55%	30.53%	27.86%
	3-Year	38.14%	33.10%	37.00%	33.60%
Endovascular Revascularization	1-Year	19.63%	15.83%	18.92%	16.10%
	2-Year	27.84%	22.93%	26.85%	23.36%
	3-Year	34.66%	28.44%	33.28%	29.06%
Major Amputation	1-Year	5.31%	6.24%	5.74%	5.97%
	2-Year	6.86%	8.05%	7.35%	7.73%
	3-Year	7.83%	9.15%	8.31%	8.80%
Minor Amputation	1-Year	4.45%	5.37%	4.75%	5.12%
	2-Year	5.64%	6.79%	5.95%	6.50%
	3-Year	6.62%	7.67%	6.90%	7.35%

All-Cause Readmission	1-Year	26.41%	28.79%	27.66%	27.98%
	2-Year	42.35%	45.29%	43.56%	44.47%
	3-Year	56.66%	59.08%	57.51%	58.41%
Myocardial Infarction	1-Year	5.30%	5.64%	5.45%	5.50%
	2-Year	8.44%	8.79%	8.57%	8.67%
	3-Year	10.77%	11.14%	10.80%	11.06%
Congestive Heart Failure	1-Year	22.71%	24.77%	23.56%	24.13%
	2-Year	31.06%	32.81%	31.72%	32.22%
	3-Year	36.77%	38.33%	37.29%	37.84%
Pneumonia	1-Year	10.01%	10.37%	10.29%	10.20%
	2-Year	15.89%	16.12%	16.13%	15.96%
	3-Year	20.23%	20.34%	20.38%	20.22%

Supplementary Table 5. Adjusted risks of secondary endpoints among key subgroups comparing patients who underwent PVI with atherectomy to with those who underwent PVI without atherectomy.

	Inpatient		Outpatient	
	Adjusted Hazard Ratio (95% CI)	**P-value**	**Adjusted Hazard Ratio (95% CI)**	**P-value**
Secondary Endpoints				
Post-Procedure Hospitalization	1.00 (0.98, 1.01)	p=0.77	0.98 (0.96, 0.99)	p<0.01
Surgical Revascularization	1.03 (0.97, 1.09)	p=0.40	0.81 (0.76, 0.85)	p<0.01
Amputation	0.98 (0.94, 1.02)	p=0.31	0.90 (0.86, 0.95)	p<0.01
Amputation or Surgical Revascularization	0.99 (0.96, 1.03)	p=0.78	0.87 (0.84, 0.91)	p<0.01
Endovascular Revascularization	1.21 (1.17, 1.25)	p<0.01	1.23 (1.20, 1.26)	p<0.01
Myocardial Infarction	0.97 (0.92, 1.02)	p=0.27	0.98 (0.93, 1.02)	p=0.27
Congestive Heart Failure	0.95 (0.93, 0.98)	p<0.01	0.99 (0.97, 1.02)	p=0.60
Pneumonia	1.02 (0.98, 1.05)	p=0.39	1.00 (0.97, 1.03)	p=1.00



Supplementary Figure 1. Love plot of covariates before (red diamonds) and after (blue diamonds) adjustment using inverse probability of treatment weighting.

Love plot of covariates before and after adjustment using inverse probability of treatment weighting. After adjustment, standard mean difference scores for all covariates were less than 1%.