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ORIGINAL RESEARCH

Safety and effectiveness of drug-coated devices in chronic limb-threatening ischaemia: a nationwide analysis

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ABSTRACT

BACKGROUND: Endovascular therapy is a cornerstone for chronic limb-threatening ischaemia (CLTI), yet the optimal device strategy remains uncertain.

AIMS: Our objective was to compare the clinical and economic outcomes between plain balloon angioplasty±bare metal stents (PBA±BMS), drug-coated balloons (DCBs)±BMS, and drug-eluting stents (DES) in a national real-world CLTI cohort.

METHODS: Medicare beneficiaries aged ≥66 years who underwent femoropopliteal revascularisation for CLTI between 2016 and 2023 were included. Patients were grouped by index device. Outcomes included a composite of all-cause mortality or major amputation, as well as major adverse limb events (MALE) and reintervention. Patients were followed from the index procedure until death, loss to follow-up, or the end of the study period. Time-to-event and cost outcomes were analysed using multivariable Cox and gamma regression models, respectively.

RESULTS: Among 108,304 CLTI patients, 52.5% received PBA±BMS, 30.7% DCBs, and 16.8% DES. At 2 years, the composite outcome occurred in 50.54% (PBA±BMS), 43.08% (DCB±BMS), and 43.71% (DES); at 5 years, it occurred in 75.69%, 71.19%, and 71.71%, respectively. Compared with PBA±BMS, DCB±BMS (hazard ratio [HR] 0.92, 95% confidence interval [CI]: 0.90-0.93) and DES (HR 0.93, 95% CI: 0.92-0.95) were associated with a lower risk of the composite outcome. DCBs were associated with reduced major amputation (HR 0.87, 95% CI: 0.84-0.91), mortality (HR 0.93, 95% CI: 0.91-0.94), MALE (HR 0.96, 95% CI: 0.94-0.98), and reintervention (HR 0.97, 95% CI: 0.96-0.99) compared with PBA±BMS. The proportion of BMS use was 10.1% in the PBA±BMS group and 3.1% in the DCB±BMS group.

CONCLUSIONS: In this national CLTI cohort, drug-coated devices were associated with reduced amputation and mortality. Data from this study suggest that DCBs may offer consistent benefit without increased costs.

KEYWORDS: chronic limb-threatening ischaemia; cost-effectiveness; endovascular revascularisation; healthcare utilisation; major amputation; reintervention rates

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Chronic limb-threatening ischaemia (CLTI) is defined by ischaemic rest pain, non-healing ulcers, or gangrene and is associated with high morbidity and mortality, with amputation or death occurring in up to 25% of patients within 1 year if left untreated[1-3]. Prompt revascularisation is the cornerstone of therapy and is essential to improve limb salvage and survival[4,5].

Over the past decade, endovascular therapy has emerged as a first-line strategy complementing open surgery in patients with CLTI due to its less invasive nature, rapid recovery, and evolving technological innovation[3,6,7]. Although drug-eluting technology has become the most frequently used strategy for the femoropopliteal (FP) segment, its efficacy and safety have been incompletely studied in the CLTI population because of limited representation in device approval trials[8]. In response to this lack of data, the BASIL-3 randomised trial was conducted in the United Kingdom to evaluate the impact of drug-coated devices on CLTI outcomes[9]. Despite its pragmatic design and clinical relevance, the trial had challenges with enrolment and, in a limited sample, did not identify differences between drug-coated and non-drug-coated devices for improving amputation-free survival.

Given its pragmatic design, BASIL-3 nonetheless provided important insights into contemporary endovascular management, although its external validity remains limited. Similarly, the BASIL-2 trial – focused on infrapopliteal disease – enrolled only a small and highly selected subset of patients, with limited generalisability to the broader CLTI population[9,10]. We aimed to assess whether the results of BASIL-3 were generalisable to a broader and more diverse CLTI population, characterised by older age; greater comorbidity burden, ethnic and socioeconomic diversity; and varied access to care[11-13]. The objective of this observational cohort study was to emulate BASIL-3 in a national Medicare population and compare the safety, effectiveness, and costs of plain balloon angioplasty±bare metal stents (PBA±BMS), drug-coated balloons (DCBs)±BMS, and drug-eluting stents (DES) for FP revascularisation in patients with CLTI.

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Impact on daily practice

This nationwide analysis supports a paradigm shift towards the routine use of drug-coated balloons (DCBs) in femoropopliteal revascularisation for patients with chronic limb-threatening ischaemia. In a high-risk Medicare population, DCBs significantly reduced major amputation, mortality, and reintervention, without increasing overall costs. These findings endorse DCBs as a first-line endovascular strategy, combining clinical efficacy with economic efficiency. In daily practice, DCBs offer a compelling option to optimise outcomes in frail patients, limit the use of permanent implants, and preserve future revascularisation strategies, thus aligning with the principles of durable, patient-centred limb salvage.

Methods

STUDY DESIGN AND DATA SOURCES

This retrospective observational cohort study was conducted using all complete Medicare Fee-For-Service (FFS) claims data covering the period from 1 January 2016 to 31 December 2023. Incomplete or partially adjudicated claims were excluded to ensure comprehensive procedural and outcome ascertainment. The data sources included the Master Beneficiary Summary File (MBSF) for demographic and enrolment data, Inpatient files for inpatient claims, and the Outpatient and Carrier files for institutional and physician services. Information on chronic comorbidities was obtained from the Chronic Condition Data Warehouse using validated algorithms. Procedures and devices were identified through a combination of ICD-10-CM, ICD-10-PCS, Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS) codes as detailed in **Supplementary Table 1-Supplementary Table 14**[14]. To ensure consistent longitudinal ascertainment, all codes were selected based on their validity across the entire study period (2016-2023). When coding changes occurred (e.g., code retirements, updates, or replacements), older codes were mapped to their most accurate contemporary equivalents through expert clinical review, and crosswalks were provided by Centers for Medicare & Medicaid Services (CMS) and American Hospital Association coding guidelines, allowing harmonisation across all years. The study protocol was approved by the Institutional Review Board of Beth Israel Deaconess Medical Center, with a waiver of informed consent granted given the retrospective design. This study followed the STROBE guidelines for reporting observational cohort studies[15].

STUDY POPULATION

All Medicare beneficiaries aged 66 years and older who underwent percutaneous endovascular revascularisation for CLTI involving the FP segment during the study period were included. CLTI was defined by the presence of ischaemic rest pain, tissue loss, or gangrene as captured through administrative claims **(Supplementary Table 1-Supplementary Table 3)**. Patients with a procedure date between 2016 and 2023 were included. For each patient, continuous enrolment was verified in Medicare FFS during the 12 months preceding their index procedure using the MBSF, which was available from 2015 onwards. In order to allow for consistent baseline characterisation, only patients with at least 12 months of continuous enrolment in Medicare FFS before the index procedure were included. The first qualifying procedure within the study period was considered the index intervention, and all subsequent procedures were considered outcome events. Patients were excluded if they had a prior major lower extremity amputation or if critical procedural data, including device type, were missing or unidentifiable in

Abbreviations

BMS	bare metal stent	**DCB**	drug-coated balloon	**MALE**	major adverse limb events
CLTI	chronic limb-threatening ischaemia	**DES**	drug-eluting stent	**PBA**	plain balloon angioplasty

their claims. Because claims submitted by privately-owned facilities, such as office-based laboratories and ambulatory surgical centres, do not report the device information needed to identify drug-coated technologies, the procedures performed in these settings were excluded from the primary analysis to ensure accurate classification of treatment strategy, as has been the approach in prior work[16]. Patient selection is summarised in **Supplementary Figure 1**.

DEVICE CLASSIFICATION

Patients were categorised into three mutually exclusive treatment groups based on the devices used during the index procedure to emulate the BASIL-3 trial. The PBA±BMS group included patients treated with PBA, with or without the use of BMS. The DCB±BMS group included patients who received DCB angioplasty, with or without adjunctive BMS implantation. The DES group included those who received drug-eluting stents, regardless of whether DCBs or BMS were additionally used. In cases where multiple device types were coded within the same intervention, a hierarchical classification was applied, with DES prioritised over DCBs and DCBs prioritised over PBA±BMS, following the same logic used in prior Medicare-based device evaluations[11].

COVARIATES

Baseline covariates included demographic characteristics (age, sex, and race/ethnicity), markers of socioeconomic vulnerability (dual Medicare and Medicaid eligibility status, defined as concurrent enrolment in both programmes and serving as a proxy for low income and socioeconomic disadvantage in the US healthcare system; residential community-level economic distress based on the Distressed Communities Index; and location in a rural or urban area), and comorbid conditions (such as diabetes; tobacco use; chronic kidney disease; ischaemic heart disease; congestive heart failure; myocardial infarction; hypertension; hyperlipidaemia; obesity; Alzheimer's disease, related disorders or senile dementia; cancer; chronic obstructive pulmonary disease; and stroke/transient ischaemic attack). CLTI severity was characterised using claims-based indicators of rest pain, ulceration, and gangrene. The care setting of the primary procedure was categorised as either hospital inpatient or hospital outpatient. Additional covariates included geographic region, calendar year of treatment, and the arterial segment treated (femoropopliteal alone, femoropopliteal with tibial, or multilevel interventions), concomitant use of atherectomy, annual institutional endovascular revascularisation volume, academic status, and hospital bed size. The standardised mean differences of baseline covariates between groups before and after matching are shown in **Supplementary Figure 2** and **Supplementary Figure 3**.

OUTCOMES

The primary outcome of interest was defined as the composite of all-cause mortality or major amputation of the lower extremity. Major amputation was defined as an above-the-ankle amputation **(Supplementary Table 15-Supplementary Table 21)**. Secondary outcomes included all-cause mortality, major amputation alone, major adverse limb events (MALE; defined as any repeat intervention or major amputation), major adverse cardiovascular events (MACE; including myocardial infarction, stroke, or death), and the need for repeat endovascular or surgical reintervention to either limb. Healthcare utilisation was assessed by index procedure length of stay and post-discharge emergency room visits and hospitalisations. Additionally, total healthcare costs were evaluated, including overall charges, Medicare payments, and provider payments, to assess the economic impact of each endovascular strategy.

STATISTICAL ANALYSIS

Continuous variables are summarised using means with standard deviations or medians with interquartile ranges as appropriate, and categorical variables are presented as frequencies with corresponding percentages. Differences in baseline characteristics were evaluated using standardised mean differences (SMDs), with an SMD greater than 10% considered indicative of a meaningful imbalance[17]. Cumulative incidences of the primary outcome were estimated using Kaplan-Meier methods. For outcomes that did not include death, the cumulative incidence function was used to address the competing risk of death[18]. To account for patient clustering within hospitals, marginal Cox regression was used to compare outcomes between treatment groups, with adjustment for all the variables specified above[19]. Due to the long follow-up periods and high frequency of death in this population, incidences of events were reported at 2 years, 5 years, and longest follow-up.

We used Cox proportional hazards and Fine-Gray models for time-to-event outcomes, and Poisson and gamma regressions for healthcare utilisation and cost analyses, adjusting for predefined covariates **(Supplementary Table 22)**. The proportional hazards assumption was tested and met for all Cox models.

Subgroup analyses were conducted by age (66-75 years, 76-85 years, >85 years), sex, race/ethnicity, community distress, geographic region, arterial segment treated (femoropopliteal alone, femoropopliteal and tibial, or multilevel), and rural versus urban location. To further assess the robustness of our findings, sensitivity analyses included inverse probability of treatment weighting and falsification endpoints (pneumonia and hip fracture)[20].

Temporal trends in the use of each endovascular modality were evaluated across calendar years using linear regression models. The annual proportion of patients receiving PBA±BMS, DCB±BMS, or DES was calculated, and trend estimates were reported with corresponding 95% confidence intervals (CIs) and p-values.

Statistical analyses were conducted using SAS software, version 9.4 (SAS Institute). A 2-sided p-value below 0.05 was considered statistically significant. There were no missing data for key demographic, procedural, or outcome variables, as the CMS claims datasets used in this analysis provide complete records for the variables of interest. Although claims data may lack clinical granularity, all the variables required for inclusion and modelling were available for the entire cohort.

Results

STUDY POPULATION

Between 1 January 2016 and 31 December 2023, a total of 108,304 patients underwent FP endovascular

revascularisation for CLTI and were included in the final analytic cohort. Among them, 56,875 (52.5%) patients received PBA±BMS, 33,276 (30.7%) were treated with DCB±BMS, and 18,153 (16.8%) received DES during their index procedure **(Supplementary Table 23)**. The proportion of BMS use was 10.1% in the PBA±BMS group and 3.1% in the DCB±BMS group. The mean age was 77.76±7.97 years, and 46.3% of the cohort were females. Black patients represented 12.64% of the population, and 19.93% of all patients were dually enrolled in Medicare and Medicaid. Overall, 68.9% of patients presented with tissue loss, including ulceration (38.2%) or gangrene (30.68%). Comorbid conditions were highly prevalent, with 69.13% of patients having diabetes and 72.15% being diagnosed with chronic kidney disease. Compared with the PBA±BMS group, patients treated with DCB±BMS or DES were younger, more frequently treated in hospital outpatient settings, and more often managed in urban regions and high-volume centres. The distribution of baseline characteristics by treatment group is detailed in **Table 1**.

TRENDS IN DEVICE UTILISATION FOR CLTI DURING THE STUDY PERIOD

From 2016 to 2023, the relative use of DES increased (+0.17%, 95% CI: 0.07-0.27%; p=0.001), while the use of DCB±BMS decreased slightly (–0.19%, 95% CI: –0.71 to 0.33%; p=0.46), and that of PBA±BMS remained stable (+0.02%, 95% CI: –0.53 to 0.57%; p=0.95) **(Figure 1)**.

PRIMARY OUTCOME RESULTS

Over a median follow-up period of 5.11 years (interquartile range: 2.88-6.81 years) and a maximum of 9.01 years, the cumulative incidence of the primary outcome was consistently lower in patients treated with DCB±BMS or DES compared with those treated with PBA±BMS.

At 2 years, the cumulative incidence was 50.54% (95% CI: 50.12-50.95) in the PBA±BMS group, 43.08% (95% CI: 42.54-43.62) in the DCB±BMS group, and 43.71% (95% CI: 42.97-44.44) in the DES group (p<0.001). The corresponding adjusted hazard ratios (HRs) were 0.88 (95% CI: 0.86-0.89; p<0.0001) for DCB±BMS, and 0.90 (95% CI: 0.88-0.93; p<0.0001) for DES.

At 5 years, the cumulative incidence reached 75.69% (95% CI: 75.28-76.09) in the PBA±BMS group, 71.19% (95% CI: 70.62-71.75) in the DCB±BMS group, and 71.71% (95% CI: 70.93-72.47) in the DES group, with adjusted HRs of 0.91 (95% CI: 0.90-0.93; p<0.0001) for DCB±BMS and 0.93 (95% CI: 0.91-0.95; p<0.0001) for DES **(Figure 2)**.

SECONDARY OUTCOMES RESULTS

Among the secondary endpoints, the composite endpoint occurred in 91.04% of the PBA±BMS group, 88.64% of the DCB±BMS group, and 89.15% of the DES group. Major amputation occurred in 14.85%, 12.82%, and 12.99% of patients, respectively. MALE rates were 48.19%, 50.29% and 50.80%, respectively. In a prespecified sensitivity analysis restricted to 80,613 patients with baseline procedural modifiers available (enabling laterality-specific event classification), the findings were consistent with those from the primary cohort. In this subgroup, ipsilateral major amputation occurred in 14.8% of PBA±BMS patients, 12.8% of DCB±BMS patients, and 13.0% of DES patients. Adjusted subdistribution HRs for ipsilateral major amputation were 0.89 (95% CI: 0.85-0.94; p<0.0001) for DCB±BMS and 0.93 (95% CI: 0.88-0.99; p=0.0292) for DES, compared with PBA±BMS **(Supplementary Table 24)**.

After adjustment, DCB±BMS versus PBA±BMS was associated with lower risks of major amputation (HR 0.87, 95% CI: 0.84-0.91; p<0.0001), all-cause mortality (HR 0.93, 95% CI: 0.91-0.94; p<0.0001), MALE (HR 0.96, 95% CI: 0.94-0.98; p<0.0001), and any repeat revascularisation (HR 0.97, 95% CI: 0.96-0.99; p=0.0103). DES versus PBA±BMS was similarly associated with lower adjusted risks of major amputation (HR 0.90, 95% CI: 0.86-0.94; p<0.0001) and all-cause mortality (HR 0.94, 95% CI: 0.92-0.96; p<0.0001) but not MALE (HR 1.00, 95% CI: 0.98-1.02; p=0.8596) or repeat revascularisation (HR 1.02, 95% CI: 1.00-1.05; p=0.054). The risk of MACE was similar across all groups. Finally, neither DCB±BMS nor DES was associated with a meaningful reduction in emergency department evaluation or readmission risk after revascularisation compared with PBA±BMS **(Figure 3)**.

MULTIVARIABLE ANALYSIS OF PREDICTORS OF THE PRIMARY OUTCOME

Multivariable Cox regression analyses revealed several patient-level factors independently associated with the primary outcome. Patients aged >85 years had a 30% higher risk of all-cause mortality or major amputation than those aged 76-85 years (adjusted HR 1.30, 95% CI: 1.28-1.33; p<0.0001), while patients aged 66-75 years had a 13% lower risk (vs 76-85 years: adjusted HR 0.87, 95% CI: 0.86-0.89; p<0.0001). Patients of female versus male sex had a lower risk of the primary outcome (adjusted HR 0.92, 95% CI: 0.91-0.93; p<0.0001), while Black versus White race was not significantly associated with the primary outcome (HR 1.00, 95% CI: 0.98-1.02; p=0.8586). Severe ischaemia was a major determinant of prognosis, with patients presenting with gangrene exhibiting nearly double the risk of amputation or death compared with those with rest pain (adjusted HR 1.83, 95% CI: 1.79-1.86; p<0.0001), and for those with ulcers, a 47% elevated risk of the primary outcome (adjusted HR 1.47, 95% CI: 1.44-1.49; p<0.0001). Chronic kidney disease, diabetes, tobacco dependence, and dual enrolment were also associated with worse outcomes **(Figure 4)**.

SENSITIVITY ANALYSIS

In sensitivity analyses, results were consistent across multiple approaches. When stratified by arterial segment, patients with combined femoropopliteal and tibial disease (HR 1.06, 95% CI: 1.05-1.08), iliac plus femoropopliteal disease (HR 1.06, 95% CI: 1.03–1.08), and multilevel disease (HR 1.17, 95% CI: 1.11-1.23) had a significantly higher risk of major amputation or death compared with those with isolated femoropopliteal disease (all p<0.0001). Importantly, the relative treatment effects of DCB±BMS and DES compared with PBA±BMS were consistent across all anatomical subgroups, with no significant interaction detected (all p for interaction>0.05). Treatment effects were consistent across rural and urban settings (interaction p=0.449). Among rural patients, the adjusted HR for DCB±BMS versus PBA±BMS

Table 1. Baseline characteristics of patients who underwent CLTI fempop endovascular revascularisation with laterality, stratified by modality category – primary analytic cohort.

Subject characteristics	All patients (N=80,613)	PBA±BMS (N=48,955)	DCB±BMS (N=20,165)	DES (N=11,493)	SMD: DCB vs PBA±BMS	SMD: DES vs PBA±BMS	*p*-value
Age, years	77.77±8.03	77.82±8.07	77.67±7.97	77.74±7.97	–1.8	–1.0	0.084
Age, years	77 [71-84]	77 [71-84]	77 [71-84]	77 [71-84]	-	-	0.084
Female	36,801 (45.65)	22,534 (46.03)	9,319 (46.21)	4,948 (43.05)	0.4	–6.0	<0.001
Race/ethnicity							<0.001
White	63,985 (79.37)	38,640 (78.93)	16,005 (79.37)	9,340 (81.27)	1.1	5.9	
Black	10,710 (13.29)	6,723 (13.73)	2,599 (12.89)	1,388 (12.08)	–2.5	–4.9	
Asian	1,003 (1.24)	611 (1.25)	263 (1.30)	129 (1.12)	0.5	–1.2	
Other	4,915 (6.10)	2,981 (6.09)	1,298 (6.44)	636 (5.53)	1.4	–2.4	
Dual enrolment	16,498 (20.47)	10,048 (20.52)	4,204 (20.85)	2,246 (19.54)	0.8	–2.5	0.019
Distressed community	14,422 (18.47)	8,917 (18.82)	3,611 (18.48)	1,894 (16.97)	–0.9	–4.8	<0.001
Rural locations	3,450 (4.29)	2,070 (4.23)	929 (4.61)	451 (3.93)	1.8	–1.5	0.010
Region							<0.001
Northeast	13,726 (17.33)	8,051 (16.75)	3,233 (16.28)	2,442 (21.71)	–1.3	12.6	
Midwest	11,224 (14.17)	6,537 (13.60)	3,147 (15.85)	1,540 (13.69)	6.3	0.3	
South	42,043 (53.09)	26,129 (54.35)	10,344 (52.08)	5,570 (49.52)	–4.5	–9.7	
West	12,192 (15.40)	7,359 (15.31)	3,136 (15.79)	1,697 (15.09)	1.3	–0.6	
Medical comorbidities							
Acute myocardial infarction	14,258 (17.69)	8,550 (17.47)	3,627 (17.99)	2,081 (18.11)	1.4	1.7	0.117
Atrial fibrillation	27,171 (33.71)	16,656 (34.02)	6,775 (33.60)	3,740 (32.54)	–0.9	–3.1	0.010
Chronic kidney disease	59,410 (73.70)	35,814 (73.16)	15,288 (75.81)	8,308 (72.29)	6.1	–2.0	<0.001
Heart failure	48,690 (60.40)	29,528 (60.32)	12,350 (61.24)	6,812 (59.27)	1.9	–2.1	0.002
Diabetes	56,351 (69.90)	33,854 (69.15)	14,574 (72.27)	7,923 (68.94)	6.9	–0.5	<0.001
Hyperlipidaemia	72,954 (90.50)	44,359 (90.61)	18,302 (90.76)	10,293 (89.56)	0.5	–3.5	<0.001
Hypertension	77,285 (95.87)	47,004 (96.01)	19,342 (95.92)	10,939 (95.18)	–0.5	–4.1	<0.001
Ischaemic heart disease	64,480 (79.99)	39,242 (80.16)	16,066 (79.67)	9,172 (79.81)	–1.2	–0.9	0.303
Stroke/TIA	24,826 (30.80)	15,183 (31.01)	6,176 (30.63)	3,467 (30.17)	–0.8	–1.8	0.174
Obesity	28,959 (35.92)	17,622 (36.00)	7,408 (36.74)	3,929 (34.19)	1.5	–3.8	<0.001
Tobacco dependency	26,685 (33.10)	16,206 (33.10)	6,335 (31.42)	4,144 (36.06)	–3.6	6.2	<0.001
Atherectomy	36,534 (45.40)	23,333 (47.77)	9,514 (47.20)	3,687 (32.11)	–1.2	–32.4	<0.001
Peripheral artery disease severity							**<0.001**
Rest pain	23,186 (28.76)	15,164 (30.98)	4,815 (23.88)	3,207 (27.90)	–16.0	–6.7	
Ulceration	27,834 (34.53)	16,226 (33.14)	7,652 (37.95)	3,956 (34.42)	10.0	2.7	
Gangrene	29,593 (36.71)	17,565 (35.88)	7,698 (38.18)	4,330 (37.68)	4.8	3.7	
Arterial segment of intervention categories							**<0.001**
Fempop alone	36,702 (45.53)	23,785 (48.59)	7,873 (39.04)	5,044 (43.89)	–19.3	–9.4	
Iliac and fempop	9,568 (11.87)	5,750 (11.75)	2,271 (11.26)	1,547 (13.46)	–1.5	5.2	
Fempop and tibial	31,808 (39.46)	17,936 (36.64)	9,408 (46.66)	4,464 (38.84)	20.4	4.5	
All levels	2,535 (3.14)	1,484 (3.03)	613 (3.04)	438 (3.81)	0.0	4.3	
Place of service							**<0.001**
Hospital-based inpatient	60,272 (74.77)	36,061 (73.66)	15,170 (75.23)	9,041 (78.67)	3.6	11.8	
Hospital-based outpatient	20,341 (25.23)	12,894 (26.34)	4,995 (24.77)	2,452 (21.33)	–3.6	–11.8	

Table 1. Baseline characteristics of patients who underwent CLTI fempop endovascular revascularisation with laterality, stratified by modality category – primary analytic cohort (cont'd).

Subject characteristics	All patients (N=80,613)	PBA±BMS (N=48,955)	DCB±BMS (N=20,165)	DES (N=11,493)	SMD: DCB vs PBA±BMS	SMD: DES vs PBA±BMS	*p*-value
Hospital characteristics (excluding ASCs/OBLs)							
Teaching hospital	53,507 (67.41)	32,758 (67.92)	12,912 (64.96)	7,837 (69.56)	–6.3	3.5	<0.001
Bed size							<0.001
6 to 49	730 (0.92)	485 (1.01)	171 (0.86)	74 (0.66)	–1.5	–3.8	
50 to 99	3,000 (3.78)	1,914 (3.97)	721 (3.63)	365 (3.24)	–1.8	–3.9	
100 to 299	29,207 (36.80)	17,349 (35.97)	7,800 (39.24)	4,058 (36.02)	6.8	0.1	
300 to 499	23,512 (29.62)	14,524 (30.11)	5,600 (28.17)	3,388 (30.07)	–4.3	–0.1	
≥500	22,923 (28.88)	13,958 (28.94)	5,584 (28.09)	3,381 (30.01)	–1.9	2.3	
Endovascular revascularisation volume (annual, all centres)	108.22±82.78	105.65±81.08	111.89±83.87	112.69±87.46	7.6	8.3	<0.001
Surgical revascularisation volume (annual, all centres)	18.09±15.99	18.30±16.12	17.56±15.71	18.11±15.87	–4.6	–1.1	<0.001
Length of stay of index procedure, days (all centres)	6.96±8.64	7.03±8.80	6.78±8.51	6.95±8.11	–2.8	–0.9	0.003

All values are n (%), median [interquartile range], or mean±standard deviation. ASC: ambulatory surgery centre; BMS: bare metal stent; CLTI: chronic limb-threatening ischaemia; DCB: drug-coated balloon; DES: drug-eluting stent; fempop: femoropopliteal; OBL: office-based laboratory; PBA: plain balloon angioplasty; SMD: standardised mean difference; TIA: transient ischaemic attack

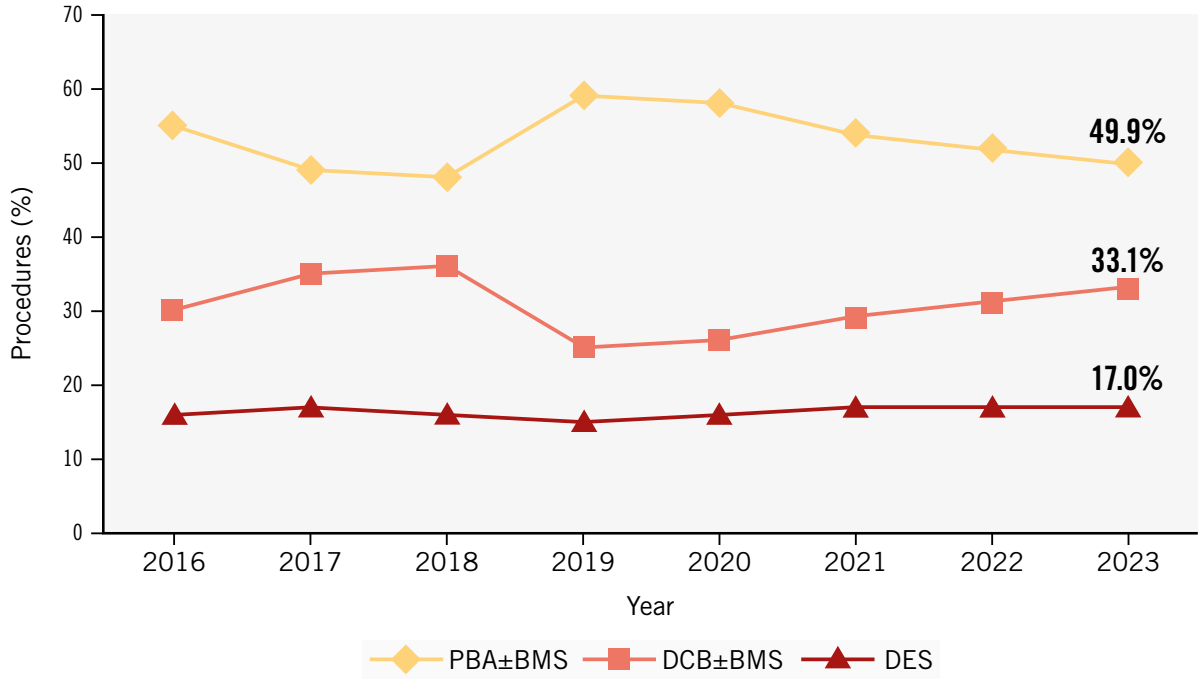
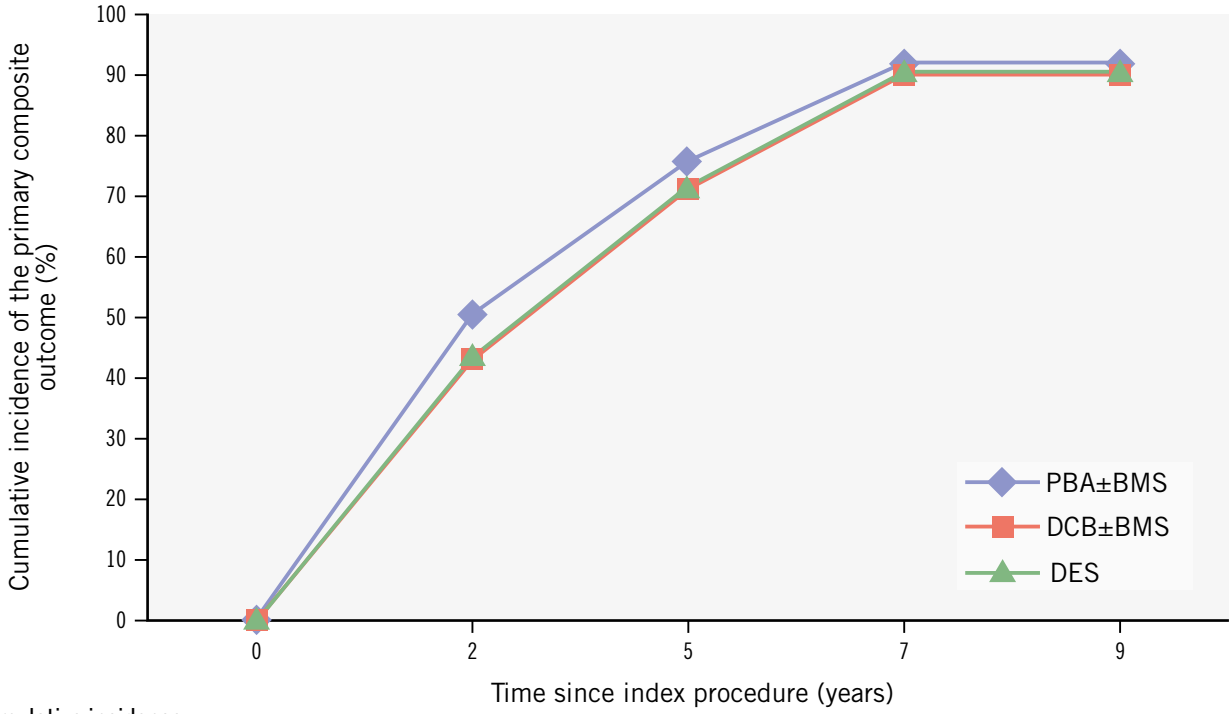


Figure 1. *Revascularisation trends during the study period by modality. BMS: bare metal stent; DCB: drug-coated balloon; DES: drug-eluting stent; PBA: plain balloon angioplasty*

was 0.95 (95% CI: 0.88-1.03) and for DES versus PBA±BMS, it was 0.94 (95% CI: 0.85-1.04), both of which were non-significant. In additional analyses using inverse probability of treatment weighting, baseline covariates were well balanced across treatment groups (all SMD <0.1), and weighted results were consistent with the main analysis: at 2 years, the adjusted hazard ratio for the composite outcome was 0.88 (95% CI: 0.86-0.90; p<0.0001) for DCB±BMS versus PBA±BMS,



Cumulative incidence					
PBA±BMS	0	50.54	75.69	92.08	92.08
DCB±BMS	0	43.08	71.19	89.99	89.99
DES	0	43.71	71.71	90.41	90.41

	DCB±BMS vs PBA±BMS	DES vs PBA±BMS
2-year follow-up	HR 0.88 (95% CI: 0.86-0.89); p<0.0001	HR 0.90 (95% CI: 0.88-0.93); p<0.0001
5-year follow-up	HR 0.91 (95% CI: 0.90-0.93); p<0.0001	HR 0.93 (95% CI: 0.91-0.95); p<0.0001
Maximum follow-up	HR 0.92 (95% CI: 0.90-0.93); p<0.0001	HR 0.93 (95% CI: 0.92-0.95); p<0.0001

Figure 2. *Cumulative incidence of the primary composite outcome: major amputation or all-cause death. BMS: bare metal stent; CI: confidence interval; DCB: drug-coated balloon; DES: drug-eluting stent; HR: hazard ratio; PBA: plain balloon angioplasty*

and 0.92 (95% CI: 0.89-0.94; p<0.0001) for DES versus PBA±BMS. At 5 years, results remained consistent (HR 0.91 and 0.94; both p<0.0001). In falsification endpoint analyses (pneumonia and hip fracture), adjusted cumulative incidences were similar across treatment groups **(Supplementary Table 25)**.

Intravascular ultrasound (IVUS) use was identified from physician (Carrier) claims and was available for a subset of procedures. Among these, IVUS was coded in 884 of 20,878 procedures with PBA±BMS (4.2%), 796 of 18,127 with DCB±BMS (4.4%), and 831 of 9,129 with DES (9.1%)

HEALTHCARE COSTS

Total healthcare costs varied substantially across device strategies. Cost values reflect cumulative expenditures from the index procedure to the end of follow-up. Compared with PBA±BMS, DES were associated with significantly higher overall Medicare payments (adjusted cost ratio 1.22, 95% CI: 1.21-1.24; p<0.0001) and higher total provider payments (adjusted cost ratio 1.19, 95% CI: 1.18-1.21; p<0.0001). In contrast, DCB±BMS was associated with no difference in Medicare payments (adjusted cost ratio 1.00, 95% CI: 0.99-1.01; p<0.5) and no significant difference in provider payments (adjusted cost ratio 0.99, 95% CI: 0.99-1.00; p=0.12). A visual summary of clinical and economic outcomes is presented in the **Central illustration**.

Discussion

Given the paucity of prospective data evaluating the role of drug-coated devices in CLTI revascularisation, our findings contribute important long-term, real-world evidence on the safety and clinical effectiveness of these devices. In this large national cohort of patients with CLTI undergoing FP revascularisation, we noted that many patients with CLTI required multilevel interventions, rather than only FP interventions. In this context, the use of drug-coated devices was associated with improved outcomes. These findings, consistent with the trends observed in BASIL-3, support

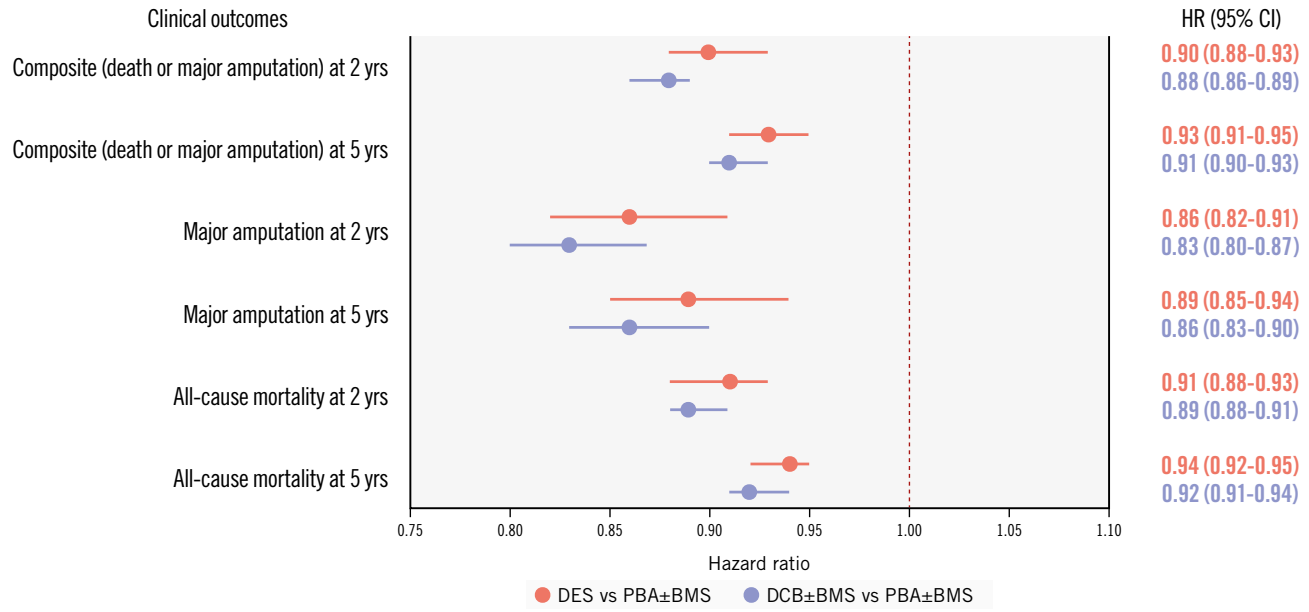


Figure 3. *Risk of amputation or mortality with drug-coated versus uncoated endovascular devices at 2 and 5 years in CLTI. BMS: bare metal stent; CI: confidence interval; CLTI: chronic limb-threatening ischaemia; DCB: drug-coated balloon; DES: drug-eluting stent; HR: hazard ratio; PBA: plain balloon angioplasty*

the clinical value of drug-based therapies in high-risk CLTI patients. While secondary outcomes showed some divergence, with DCB±BMS demonstrating more consistent benefits on limb-related endpoints, both DCB±BMS and DES appear to offer meaningful improvements over uncoated devices for CLTI patients, which is also in line with recent guideline recommendations on the management of intermittent claudication[21].

Compared with PBA±BMS, the use of DCB±BMS was associated with a 9% relative reduction in major amputation and a 2% reduction in reintervention. While absolute risk reductions were modest – approximately 2-3% at 2 years – this translated into a number needed to treat of 33 for major amputation and 27 for the composite outcome, reflecting a clinically meaningful impact in this high-risk population **(Table 2, Figure 3).** These findings align with previous randomised trials in patients with less severe disease, including IN.PACT SFA and LEVANT 2, where DCBs improved primary patency and freedom from target lesion revascularisation[22,23]. While those trials primarily enrolled patients with claudication, our data extend the benefits of DCBs to a broader, sicker, and more diverse CLTI population. DCBs may be especially suitable for frail CLTI patients because of the absence of a permanent implant, reduced procedural time, and preserved surgical options[24,25]. These advantages are reflected in real-world registries, such as the IN.PACT Global Study, which showed a durable benefit in complex anatomies[26]. Paclitaxel's antiproliferative properties likely contribute to sustained patency and improved limb outcomes in CLTI. To confirm the robustness of these findings, we conducted a prespecified sensitivity analysis restricted to patients with available procedural laterality modifiers, allowing for precise attribution of amputations to the treated limb. In this rigorously defined subgroup, both DCBs and DES remained significantly associated with a lower risk of ipsilateral major amputation compared with PBA±BMS. These results strengthen the internal validity of our findings and mitigate concerns about potential misclassification or outcome dilution related to non-lateralised events.

In contrast, DES were associated with significant reductions in both all-cause mortality and major amputation but did not meaningfully reduce MALE rates compared with PBA±BMS. This disconnect between amputation-free survival and reintervention rates suggests benefits beyond target lesion patency. Notably, DES-treated patients incurred the highest costs across all treatment strategies, which could be driven by a greater use of combined therapies, such as DCBs with DES. These results should be interpreted in the context of prior randomised trials conducted in patients with intermittent claudication, where DES have consistently demonstrated improved patency and a reduced need for reintervention. For instance, in the EMINENT and SPORTS trials, the Eluvia DES (Boston Scientific) showed superior patency and reduced reinterventions compared with BMS and DCBs[27]. While the EMINENT trial exclusively enrolled claudicants, the SPORTS trial included a minority of patients with ischaemic rest pain (Rutherford category 4). However, both trials underrepresented the full clinical spectrum of CLTI, especially patients with tissue loss, which underscores the importance of our study's focus on a real-world CLTI population.

Notably, our results align in part with the BASIL-3 trial, which showed numerical trends, albeit non-significant, towards improvement in amputation-free survival with drug-coated devices[9]. Our results are also consistent with prior large observational studies such as SAFE-PAD, which found no excess mortality associated with paclitaxel exposure over long-term follow-up among both claudicants and patients with CLTI, and the SFA-Long study, which reported durable

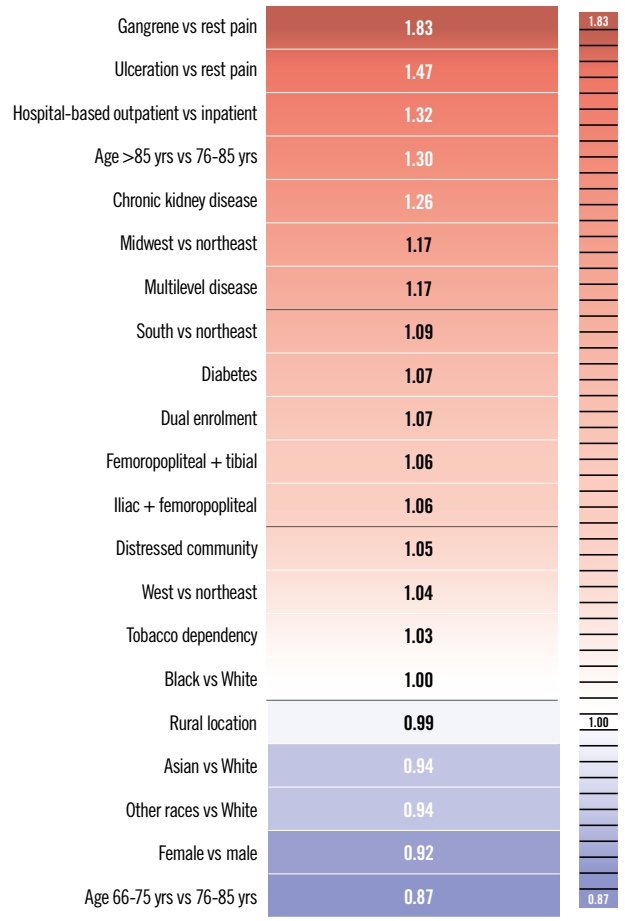


Figure 4. *Adjusted hazard ratios for the primary composite outcome of all-cause mortality or major amputation. Hazard ratios were derived from multivariable regression models and adjusted for demographic, clinical, socioeconomic, and geographical factors. Values >1 indicate increased risk, while values <1 indicate decreased risk relative to the reference category for each covariate.*

benefits of drug-coated balloons in femoropopliteal disease, including in patients with CLTI, with improved amputation-free survival at 5 years[11,28]. With a substantially larger sample size and follow-up period, our analysis yielded similar absolute risk differences to those of BASIL-3, but with sufficient power to meet statistical significance. Several key distinctions are critical for comparing the results across these studies. The BASIL-3 population had milder disease, with fewer cases of gangrene and comorbidities, and the results were affected by crossover. Our study included a sicker population and longer follow-up, providing complementary real-world insight.

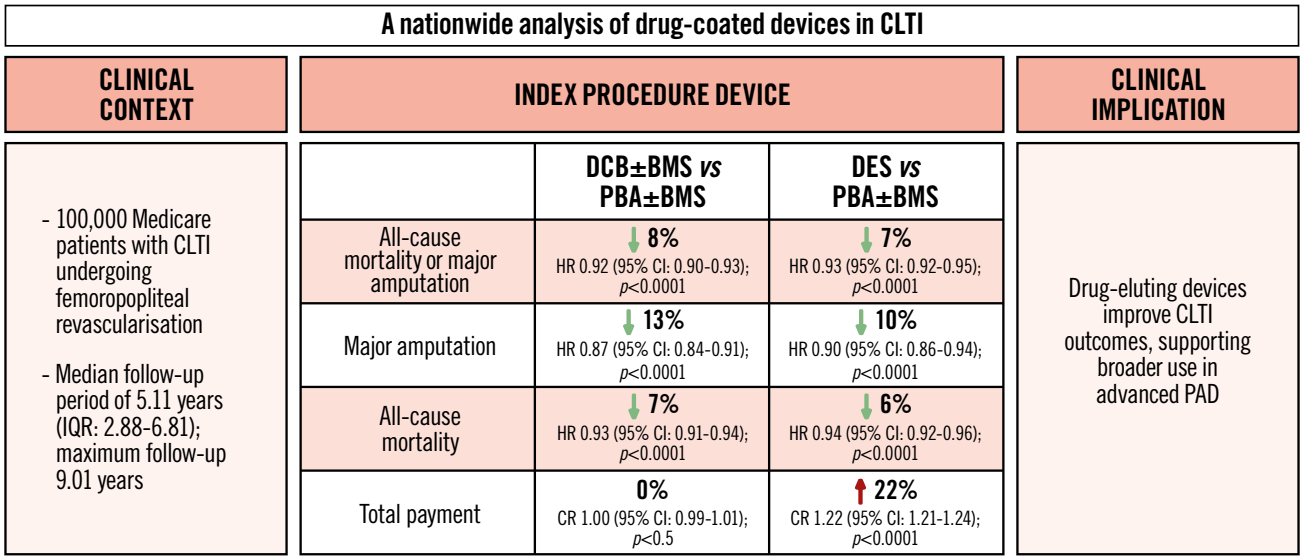
Interestingly, a recent exploratory analysis of the BEST-CLI trial presented at the 2025 Society for Vascular Surgery meeting by Siracuse et al further supports the potential benefit of drug-coated technologies. In this secondary analysis of patients undergoing femoropopliteal endovascular interventions, the use of drug-coated devices was associated with significantly lower mortality (HR 0.53, 95% CI: 0.31-0.91; p=0.02) and fewer major reinterventions (HR 0.57, 95% CI: 0.31-0.91; p=0.02) compared with non-drug devices[29]. Although derived from a small and selected subset of BEST-CLI patients, this analysis supports the hypothesis that fewer limb events may translate into improved survival. While these findings remain exploratory, they echo the signals observed in our Medicare cohort and lend further support to the clinical relevance of drug-coated endovascular strategies.

Another important consideration is the economic footprint of drug-based technologies. The adoption of drug-coated devices in femoropopliteal revascularisations has fluctuated over recent years, reflecting evolving clinical confidence and emerging safety data, particularly concerning their use in the CLTI population[30,31]. This trend likely reflects favourable patency, low complication rates, and growing clinical familiarity with drug-delivery technologies. While this expansion may contribute to higher procedural costs, drug-coated devices still represent a rational investment if these devices provide even modest benefits in outcomes such as wound healing or freedom from reintervention – benefits that can be particularly meaningful in patients with advanced disease. In our study, we observed that most of the clinical benefit with drug-coated devices emerged within the first 24 months, suggesting an early separation of event curves. This temporal profile helps address concerns regarding delayed harm and reinforces the short- to midterm value of these devices in the high-risk CLTI population. This is counterbalanced by the extreme mortality risk of the CLTI population, as highlighted by the high rates of death observed in this analysis. Interestingly, the BASIL-3 trial also included a formal cost-effectiveness analysis, which demonstrated that DES achieved financial superiority over PBA±BMS, while DCBs showed borderline cost-effectiveness, further supporting the value of DES in selected patients[9]. Beyond cost-effectiveness, recent randomised evidence has also provided important reassurance regarding the safety of paclitaxel-coated devices in CLTI. In both the BASIL-3 trial and the SWEDEPAD 2 trial, no excess mortality was observed with paclitaxel-coated balloons or stents compared with uncoated technologies, even with extended follow-up[9,32]. These findings are further supported by the SAFE-PAD study, which specifically included patients with CLTI and confirmed the absence of an association between paclitaxel dose and long-term mortality[11,33]. Together, these findings mitigate the earlier concerns of dose-dependent toxicity raised by *post hoc* meta-analyses and support the long-term safety of drug-coated devices in real-world CLTI practice.

Limitations

This study has important limitations. The observational design and use of administrative data may introduce residual confounding. Furthermore, claims-based data have limited granular detail regarding anatomical and procedural characteristics, such as lesion length, calcification severity, and runoff status. In addition, this study was unable to capture patient-reported outcomes, quality of life, or limb function – all increasingly important in the CLTI population. Although we adjusted for disease severity, comorbidities, and hospital-level characteristics, residual confounding by indication cannot be fully excluded. In this context, contemporary US guidelines recommend the use of drug-coated devices

Comparative effectiveness of drug-coated devices for CLTI in a national Medicare cohort.



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This illustration summarises the comparative effectiveness and economic impact of drug-coated devices in over 100,000 Medicare patients with CLTI compared with treatment with PBA. DCBs and DES were both associated with a reduced risk of major amputation or death. DCBs also reduced reintervention rates and were cost-neutral, while DES showed similar clinical benefit but with increased healthcare costs. These findings support the use of drug-coated devices – particularly DCBs – in femoropopliteal revascularisation for CLTI and highlight the need for personalised, outcome-driven device selection. BMS: bare metal stent; CI: confidence interval; CLTI: chronic limb-threatening ischaemia; CR: cost ratio; DCB: drug-coated balloon; DES: drug-eluting stent; HR: hazard ratio; IQR: interquartile range; PAD: peripheral artery disease; PBA: plain balloon angioplasty

Table 2. Primary composite and individual outcomes with absolute risk differences and number needed to treat.

Comparison	Endpoint	ARD at 2 years	NNT (2 years)	ARD at 5 years	NNT (5 years)
DCB±BMS vs PBA±BMS	Composite* (death or amputation)	7.46%	13	4.50%	22
DCB±BMS vs PBA±BMS	Major amputation	2.51%	40	2.24%	45
DES vs PBA±BMS	Composite	6.83%	15	3.98%	25
DES vs PBA±BMS	Major amputation	2.33%	43	2.01%	50

*Composite: major amputation, death (all-cause), or reintervention. ARD: absolute risk difference; BMS: bare metal stent; DCB: drug-coated balloon; DES: drug-eluting stent; NNT: number needed to treat; PBA: plain balloon angioplasty

across the spectrum of CLTI presentations, not restricted to specific patient subsets; this mitigates the concern that these technologies were selectively used in more favourable anatomies[34]. Finally, we were unable to directly assess index lesion patency with the different treatment modalities, as angiographic or duplex ultrasound-based patency data are not available in the Medicare claims database. However, we reported clinically relevant endpoints – major amputation, mortality, reintervention, and healthcare utilisation – that serve as indirect surrogates of device performance in this real-world population. Because our study cohort consisted exclusively of older US Medicare beneficiaries, the generalisability of our findings to younger patients or to health systems outside the United States remains limited. However, this study also has key strengths, including a large, diverse, and representative national cohort of patients; complete follow-up ascertainment; clinically relevant endpoints; and robust subgroup and temporal analyses – all of which make the findings highly generalisable to real-world CLTI care.

Conclusions

In this national cohort of over 100,000 real-world patients undergoing FP revascularisation for CLTI, drug-coated devices were associated with modest but consistent reductions in major amputation or death compared to uncoated devices. These findings differ from the recent BASIL-3 randomised trial, which showed similar numerical trends towards benefit with drug-coated devices but failed to reach statistical

significance in any comparison. In addition to the need for more prospective randomised trial data, clinical decision-making in CLTI should continue to prioritise outcome-driven, cost-conscious strategies informed by both randomised and real-world evidence.

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Conflict of interest statement

J. Sobocinski declares consulting fees for Abbott and W. L. Gore & Associates. J.M. Kim is supported by the NIH T32 HL160522 grant. Y. Gouëffic reports research funding from PrediSurge, Biotronik, W. L. Gore & Associates, and GE HealthCare; and honoraria from Abbott, BD, Bentley, Biotronik, Boston Scientific, Cook Medical, Eclevar Medtech, GE HealthCare, iVascular, Medtronic, Penumbra, Sensome, Shockwave Medical, and W. L. Gore & Associates (consulting, medical advisory board, educational course, speaking). O. Iida declares: consulting for Abbott, Boston Scientific, Gore Medical, Kaneka Medix, Tokai Medical, OrbusNeich, and Otsuka Medical; and honoraria from Boston Scientific, Gore Medical, Kaneka Medix, Tokai Medical, OrbusNeich, Otsuka Medical, Medtronic, Terumo, Nipro, and Canon. E.A. Secemsky receives funding from NIH/NHLBI K23HL150290 and the U.S. Food & Drug Administration; has institutional grants from Abbott/CSI, BD, Boston Scientific, Cook Medical, Medtronic, and Philips; and receives speaking/consulting fees from Abbott/CSI, BD, BMS, Boston Scientific, Cagent, Conavi, Cook Medical, Cordis, Endovascular Engineering, W. L. Gore & Associates, InfraRedx, Medtronic, Philips, RapidAI, Rampart, Shockwave Medical, Siemens, Teleflex, Terumo, Thrombolex, VentureMed, and Zoll. The other authors have no conflicts of interest to declare.

References

1. Kreutzburg T, Peters F, Kuchenbecker J, Marschall U, Lee R, Kriston L, Debus ES, Behrendt CA. Editor's Choice - The GermanVasc Score: A Pragmatic Risk Score Predicts Five Year Amputation Free Survival in Patients with Peripheral Arterial Occlusive Disease. *Eur J Vasc Endovasc Surg*. 2021;61:248-56.

2. Peters F, Behrendt CA; IDOMENEO Collaborators. Limb Related Outcomes of Endovascular vs. Open Surgical Revascularisation in Patients with Peripheral Arterial Occlusive Disease: A Report from the Prospective GermanVasc Cohort Study. *Eur J Vasc Endovasc Surg*. 2023;66:85-93.

3. Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, Mills JL, Ricco JB, Suresh KR, Murad MH, Aboyans V, Aksoy M, Alexandrescu VA, Armstrong D, Azuma N, Belch J, Bergoeing M, Bjorck M, Chakfé N, Cheng S, Dawson J, Debus ES, Dueck A, Duval S, Eckstein HH, Ferraresi R, Gambhir R, Gargiulo M, Geraghty P, Goode S, Gray B, Guo W, Gupta PC, Hinchliffe R, Jetty P, Komori K, Lavery L, Liang W, Lookstein R, Menard M, Misra S, Miyata T, Moneta G, Munoa Prado JA, Munoz A, Paolini JE, Patel M, Pomposelli F, Powell R, Robless P, Rogers L, Schanzer A, Schneider P, Taylor S, De Ceniga MV, Veller M, Vermassen F, Wang J, Wang S; GVG Writing Group for the Joint Guidelines of the Society for Vascular Surgery (SVS), European Society for Vascular Surgery (ESVS), and World Federation of Vascular Societies (WFVS). Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia. *Eur J Vasc Endovasc Surg*. 2019;58:S1-109.e33.

4. Berchiolli R, Bertagna G, Adami D, Canovaro F, Torri L, Troisi N. Chronic Limb-Threatening Ischemia and the Need for Revascularization. *J Clin Med*. 2023;12:2682.

5. Ventoruzzo G, Mazzitelli G, Ruzzi U, Liistro F, Scatena A, Martelli E. Limb Salvage and Survival in Chronic Limb-Threatening Ischemia: The Need for a Fast-Track Team-Based Approach. *J Clin Med*. 2023;12:6081.

6. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, Fowkes FG, Gillepsie 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;366:1925-34.

7. Dubosq-Lebaz M, Fels A, Chatellier G, Gouëffic Y. Systematic Review and Meta-analysis of Clinical Outcomes After Endovascular Treatment in Patients With Femoropopliteal Lesions Greater Than 50 mm. *J Endovasc Ther*. 2025;32:593-604.

8. Kim JM, Li S, Song Y, Yeh RW, Secemsky EA. Dynamic Trends and Practice Patterns in Femoropopliteal Revascularization From 2016 Through 2023. *J Am Coll Cardiol*. 2025;85:645-8.

9. Bradbury AW, Hall JA, Popplewell MA, Meecham L, Bate GR, Kelly L, Deeks JJ, Moakes CA; BASIL-3 Investigators. Plain versus drug balloon and stenting in severe ischaemia of the leg (BASIL-3): open label, three arm, randomised, multicentre, phase 3 trial. *BMJ*. 2025;388:e080881.

10. Popplewell MA, Meecham L, Davies HOB, Kelly L, Ellis T, Bate GR, Moakes CA, Bradbury AW. Editor's Choice - Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL) Prospective Cohort Study and the Generalisability of the BASIL-2 Randomised Controlled Trial. *Eur J Vasc Endovasc Surg*. 2024;67:146-52.

11. Secemsky EA, Shen C, Schermerhorn M, Yeh RW. Longitudinal Assessment of Safety of Femoropopliteal Endovascular Treatment With Paclitaxel-Coated Devices Among Medicare Beneficiaries: The SAFE-PAD Study. *JAMA Intern Med*. 2021;181:1071-80.

12. Secemsky EA, Kirksey L, Quiroga E, King CM, Martinson M, Hasegawa JT, West NEJ, Wadhera RK. Impact of Intensity of Vascular Care Preceding Major Amputation Among Patients With Chronic Limb-Threatening Ischemia. *Circ Cardiovasc Interv*. 2024;17:e012798.

13. Butala NM, Chandra V, Beckman JA, Parikh SA, Lookstein R, Misra S, Secemsky EA. Contextualizing the BEST-CLI Trial Results in Clinical Practice. *J Soc Cardiovasc Angiogr Interv*. 2023;2:101036.

14. Raja A, Song Y, Li S, Parikh SA, Saab F, Yeh RW, Secemsky EA. Variations in Revascularization Strategies for Chronic Limb-Threatening Ischemia: A Nationwide Analysis of Medicare Beneficiaries. *JACC Cardiovasc Interv*. 2025;18:352-63.

15. Cuschieri S. The STROBE guidelines. *Saudi J Anaesth*. 2019;13:S31-4.

16. Secemsky EA, Raja A, Shen C, Valsdottir LR, Schermerhorn M, Yeh RW; SAFE-PAD Investigators. Rationale and Design of the SAFE-PAD Study. *Circ Cardiovasc Qual Outcomes*. 2021;14:e007040.

17. Austin PC. Using the Standardized Difference to Compare the Prevalence of a Binary Variable Between Two Groups in Observational Research. *Communications in Statistics - Simulation and Computation*. 2009;38:1228-34.

18. Austin PC, Lee DS, Fine JP. Introduction to the Analysis of Survival Data in the Presence of Competing Risks. *Circulation*. 2016;133:601-9.

19. Wei LJ, Lin DY, Weissfeld L. Regression Analysis of Multivariate Incomplete Failure Time Data by Modeling Marginal Distributions. *Journal of the American Statistical Association*. 1989;84:1065-73.

20. Wimmer NJ, Resnic FS, Mauri L, Matheny ME, Yeh RW. Comparison of transradial versus transfemoral percutaneous coronary intervention in routine practice: evidence for the importance of "falsification hypotheses" in

observational studies of comparative effectiveness. *J Am Coll Cardiol.* 2013;62:2147-8.

21. Nordanstig J, Behrendt CA, Baumgartner I, Belch J, Bäck M, Fitridge R, Hinchliffe R, Lejay A, Mills JL, Rother U, Sigvant B, Spanos K, Szeberin Z, van de Water W; ESVS Guidelines Committee; Antoniou GA, Björck M, Gonçalves FB, Coscas R, Dias NV, Van Herzeele I, Lepidi S, Mees BME, Resch TA, Ricco JB, Trimarchi S, Twine CP, Tulamo R, Wanhainen A; Document Reviewers; Boyle JR, Brodmann M, Dardik A, Dick F, Goëffic Y, Holden A, Kakkos SK, Kolh P, McDermott MM. Editor's Choice -- European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Asymptomatic Lower Limb Peripheral Arterial Disease and Intermittent Claudication. *Eur J Vasc Endovasc Surg.* 2024;67:9-96.

22. Zeller T, Micari A, Scheinert D, Baumgartner I, Bosiers M, Vermassen FEG, Banyai M, Shishehbor MH, Wang H, Brodmann M; IN.PACT DEEP Trial Investigators. The IN.PACT DEEP Clinical Drug-Coated Balloon Trial: 5-Year Outcomes. *JACC Cardiovasc Interv.* 2020;13:431-43.

23. Jaff MR, Rosenfield K, Scheinert D, Rocha-Singh K, Benenati J, Nehler M, White CJ. Drug-coated balloons to improve femoropopliteal artery patency: Rationale and design of the LEVANT 2 trial. *Am Heart J.* 2015;169:479-85.

24. Parikh SA, Finn MT. Can Paclitaxel Coated Balloons Have a Deep Impact on Critical Limb Ischemia? *JACC Basic Transl Sci.* 2021;6:428-30.

25. Rajan A, Sima RR, Natarajan S. Endovascular Management of Chronic Limb-Threatening Ischemia (CLTI) in the Elderly: A Focus on Frailty, Wound Healing, and Outcomes. *Ann Vasc Surg.* 2024;106:321-32.

26. Scheinert D, Micari A, Brodmann M, Tepe G, Peeters P, Jaff MR, Wang H, Schmahl R, Zeller T; IN.PACT Global Study Investigators. Drug-Coated Balloon Treatment for Femoropopliteal Artery Disease. *Circ Cardiovasc Interv.* 2018;11:e005654.

27. Tepe G. SPORTS Trial: Drug Eluting Stent or Primary Bare Nitinol Stent Application versus Drug Coated Balloons in Long SFA Lesions. TCT 2023. 24 October 2023. San Francisco, CA, USA.

28. Micari A, Vadalà G, Castriota F, Liso A, Grattoni C, Russo P, Marchese A, Pantaleo P, Roscitano G, Cesana BM, Cremonesi A. 1-Year Results of Paclitaxel-Coated Balloons for Long Femoropopliteal Artery Disease: Evidence From the SFA-Long Study. *JACC Cardiovasc Interv.* 2016;9:950-6.

29. Siracuse JJ, Kaufman JA, Farber A, Menard MT, Rosenfield K, Conte MS, Schanzer A, Powell RJ, Venermo M, Doros G, Faries P, Strong MB, Dake MD. Antiproliferative endovascular drug technology is associated with fewer major reinterventions after femoropopliteal interventions for chronic limb-threatening ischemia. *J Vasc Surg.* 2025;82:1375-82.

30. Kadian-Dodov D, Williams AO, Sato R, Vang L, Jaff MR. Trends in the utilization of drug-eluting stents to treat femoropopliteal peripheral artery disease. *JVS-Vascular Insights.* 2024;2:100136.

31. Gouëffic Y, Brodmann M, Deloose K, Dubosq-Lebaz M, Nordanstig J. Drug-eluting devices for lower limb peripheral arterial disease. *EuroIntervention.* 2024;20:e1136-53.

32. Nordanstig J, James S, Andersson M, Andersson M, Delle M, Engström J, Fransson T, Gillgren P, Hilbertson A, Hörer TM, Jacobsson E, Kragsterman B, Lindbäck J, Lindgren H, Ludwigs K, Mellander S, Nelzén O, Olin R, Sigvant B, Skoog P, Starck J, Tegler G, Thorbjørnsen K, Truedson M, Wahlgren CM, Wallinder J, Öjersjö A, Falkenberg M; SWEDEPAD trial investigators. Paclitaxel-coated versus uncoated devices for infrainguinal endovascular revascularisation in patients with intermittent claudication (SWEDEPAD 2): a multicentre, participant-masked, registry-based, randomised controlled trial. *Lancet.* 2025;406:1115-27.

33. Kim JM, Yeh RW, Song Y, Secemsky EA. Drug-coated vs non-drug-coated devices for femoropopliteal artery interventions: long-term outcomes of the SAFE-PAD study. *Eur Heart J.* 2025 Sep 25. [Epub ahead of print].

34. Klein AJ, Jaff MR, Gray BH, Aronow HD, Bersin RM, Diaz-Sandoval LJ, Dieter RS, Drachman DE, Feldman DN, Gigliotti OS, Gupta K, Parikh SA, Pinto DS, Shishehbor MH, White CJ. SCAI appropriate use criteria for peripheral arterial interventions: An update. *Catheter Cardiovasc Interv.* 2017;90:E90-110.

Supplementary data

Supplementary Table 1. ICD-10 codes used to identify CLTI diagnosis between 1 January 2016 and 31 December 2023 – rest pain.

Supplementary Table 2. ICD-10 codes used to identify CLTI diagnosis between 1 January 2016 and 31 December 2023 – ulceration.

Supplementary Table 3. ICD-10 codes used to identify CLTI diagnosis between 1 January 2016 and 31 December 2023 – gangrene.

Supplementary Table 4. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – tibial artery (right).

Supplementary Table 5. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – tibial artery (left).

Supplementary Table 6. CPT codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – tibial artery.

Supplementary Table 7. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – iliac artery (right).

Supplementary Table 8. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – iliac artery (left).

Supplementary Table 9. CPT codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – iliac artery.

Supplementary Table 10. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – fem/pop artery (right).

Supplementary Table 11. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – fem/pop artery (left).

Supplementary Table 12. CPT codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – fem/pop artery.

Supplementary Table 13. ICD-10 codes used to identify atherectomy for endovascular CLTI revascularisation between 1 January 2016 and 31 December 2023.

Supplementary Table 14. CPT codes used to identify atherectomy for endovascular CLTI revascularisation between 1 January 2016 and 31 December 2023.

Supplementary Table 15. ICD-10 codes used to identify prior amputation from 1 January 2016 to 31 December 2023.

Supplementary Table 16. ICD-10-PCS codes used to identify major amputation from 1 January 2016 to 31 December 2023.

Supplementary Table 17. CPT codes used to identify major amputation from 1 January 2016 to 31 December 2023.

Supplementary Table 18. ICD-10-CM and ICD-10-PCS codes used to identify ambulatory status from 1 January 2016 to 31 December 2023.

Supplementary Table 19. CPT codes used to identify ambulatory status from 1 January 2016 to 31 December 2023.

Supplementary Table 20. ICD-10-PCS codes used to identify minor amputation from 1 January 2016 to 31 December 2023.

Supplementary Table 21. CPT codes used to identify minor amputation from 1 January 2016 to 31 December 2023.
Supplementary Table 22. Covariates included in multivariable adjustment models.
Supplementary Table 23. Breakdown of treatment groups according to stent use.
Supplementary Table 24. Hazard ratios for major amputation on the same side at maximum follow-up.
Supplementary Table 25. Adjusted risk estimates of the falsification endpoints.
Supplementary Figure 1. Flowchart.
Supplementary Figure 2. Standardised mean differences between groups before and after weighting (DCB±BMS vs PBA±BMS).
Supplementary Figure 3. Standardised mean differences between groups before and after weighting (DES vs PBA±BMS).

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Supplementary data

Supplementary Table 1. ICD-10 codes used to identify CLTI diagnosis between 1 January 2016 and 31 December 2023 – rest pain.

ICD-10-CM Codes	Descriptions
I70.22	Atherosclerosis of native arteries of extremities with rest pain
I70.221	Atherosclerosis of native arteries of extremities with rest pain, right leg
I70.222	Atherosclerosis of native arteries of extremities with rest pain, left leg
I70.32	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain
I70.321	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, right leg
I70.322	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, left leg
I70.42	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain
I70.421	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, right leg
I70.422	Atherosclerosis of autologous vein bypass graft(s) of the extremities with rest pain, left leg
I70.52	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain
I70.521	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, right leg
I70.522	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with rest pain, left leg
I70.62	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain
I70.621	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, right leg
I70.622	Atherosclerosis of nonbiological bypass graft(s) of the extremities with rest pain, left leg

Supplementary Table 2. ICD-10 codes used to identify CLTI diagnosis between 1 January 2016 and 31 December 2023 – ulceration.

ICD-10-CM Codes	Descriptions
I70.23	Atherosclerosis of native arteries of right leg with ulceration
I70.24	Atherosclerosis of native arteries of left leg with ulceration
I70.33	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration
I70.34	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration
I70.43	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration
I70.44	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration
I70.53	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration
I70.54	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration
I70.63	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration
I70.64	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration
I70.73	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration
I70.74	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration

Supplementary Table 3. ICD-10 codes used to identify CLTI diagnosis between 1 January 2016 and 31 December 2023 – gangrene.

ICD-10-CM Codes	Descriptions
I70.26	Atherosclerosis of native arteries of extremities with gangrene
I70,261	Atherosclerosis of native arteries of extremities with gangrene, right leg
I70.262	Atherosclerosis of native arteries of extremities with gangrene, left leg
I70.36	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene
I70.361	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, right leg
I70.362	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, left leg
I70.46	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene
I70.461	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, right leg
I70.462	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, left leg
I70.56	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene
I70.561	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, right leg
I70.562	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, left leg
I70.66	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene
I70.661	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, right leg
I70.662	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, left leg
I70.76	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene
I70.761	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, right leg
I70.762	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, left leg

Supplementary Table 4. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – tibial artery (right).

ICD 10 PCS Codes	Descriptions
X27P385	Dilation of Right Anterior Tibial Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27P395	Dilation of Right Anterior Tibial Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27P3B5	Dilation of Right Anterior Tibial Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27P3C5	Dilation of Right Anterior Tibial Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27R385	Dilation of Right Posterior Tibial Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27R395	Dilation of Right Posterior Tibial Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27R3B5	Dilation of Right Posterior Tibial Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27R3C5	Dilation of Right Posterior Tibial Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
04CP3ZZ	Extirpation of Matter from Right Anterior Tibial Artery, Percutaneous Approach
047P341	Dilation of Right Anterior Tibial Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047P34Z	Dilation of Right Anterior Tibial Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047P35Z	Dilation of Right Anterior Tibial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047P36Z	Dilation of Right Anterior Tibial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047P37Z	Dilation of Right Anterior Tibial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047P3D1	Dilation of Right Anterior Tibial Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047P3D6	Dilation of Right Anterior Tibial Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047P3DZ	Dilation of Right Anterior Tibial Artery with Intraluminal Device, Percutaneous Approach
047P3EZ	Dilation of Right Anterior Tibial Artery with Two Intraluminal Devices, Percutaneous Approach
047P3E6	Dilation of Right Anterior Tibial Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047P3FZ	Dilation of Right Anterior Tibial Artery with Three Intraluminal Devices, Percutaneous Approach
047P3GZ	Dilation of Right Anterior Tibial Artery with Four or More Intraluminal Devices, Percutaneous Approach
047P3G6	Dilation of Right Anterior Tibial Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047P3Z1	Dilation of Right Anterior Tibial Artery using Drug-Coated Balloon, Percutaneous Approach
047P3ZZ	Dilation of Right Anterior Tibial Artery, Percutaneous Approach

047R341	Dilation of Right Posterior Tibial Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047R34Z	Dilation of Right Posterior Tibial Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047R35Z	Dilation of Right Posterior Tibial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047R36Z	Dilation of Right Posterior Tibial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047R37Z	Dilation of Right Posterior Tibial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047R3D1	Dilation of Right Posterior Tibial Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047R3D6	Dilation of Right Posterior Tibial Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047R3DZ	Dilation of Right Posterior Tibial Artery with Intraluminal Device, Percutaneous Approach
047R3EZ	Dilation of Right Posterior Tibial Artery with Two Intraluminal Devices, Percutaneous Approach
047R3E6	Dilation of Right Posterior Tibial Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047R3FZ	Dilation of Right Posterior Tibial Artery with Three Intraluminal Devices, Percutaneous Approach
047R3F6	Dilation of Right Posterior Tibial Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047R3GZ	Dilation of Right Posterior Tibial Artery with Four or More Intraluminal Devices, Percutaneous Approach
047R3G6	Dilation of Right Posterior Tibial Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047R3Z1	Dilation of Right Posterior Tibial Artery using Drug-Coated Balloon, Percutaneous Approach
047R3ZZ	Dilation of Right Posterior Tibial Artery, Percutaneous Approach
04CR3ZZ	Extirpation of Matter from Right Posterior Tibial Artery, Percutaneous Approach
047T341	Dilation of Right Peroneal Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047T3D1	Dilation of Right Peroneal Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047T3D6	Dilation of Right Peroneal Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047T3DZ	Dilation of Right Peroneal Artery with Intraluminal Device, Percutaneous Approach
047T3E6	Dilation of Right Peroneal Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047T3EZ	Dilation of Right Peroneal Artery with Two Intraluminal Devices, Percutaneous Approach
047T3F6	Dilation of Right Peroneal Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047T3FZ	Dilation of Right Peroneal Artery with Three Intraluminal Devices, Percutaneous Approach
047T3G6	Dilation of Right Peroneal Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047T3GZ	Dilation of Right Peroneal Artery with Four or More Intraluminal Devices, Percutaneous Approach

047T3Z1	Dilation of Right Peroneal Artery using Drug-Coated Balloon, Percutaneous Approach
047T3ZZ	Dilation of Right Peroneal Artery, Percutaneous Approach
04CT3ZZ	Extirpation of Matter from Right Peroneal Artery, Percutaneous Approach
047T34Z	Dilation of Right Peroneal Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047T35Z	Dilation of Right Peroneal Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047T36Z	Dilation of Right Peroneal Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047T37Z	Dilation of Right Peroneal Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047T34Z	Dilation of Right Peroneal Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047T35Z	Dilation of Right Peroneal Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047T36Z	Dilation of Right Peroneal Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047T37Z	Dilation of Right Peroneal Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047V3D1	Dilation of Right Foot Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047V3D6	Dilation of Right Foot Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047V3DZ	Dilation of Right Foot Artery with Intraluminal Device, Percutaneous Approach
047V3E6	Dilation of Right Foot Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047V3EZ	Dilation of Right Foot Artery with Two Intraluminal Devices, Percutaneous Approach
047V3F6	Dilation of Right Foot Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047V3FZ	Dilation of Right Foot Artery with Three Intraluminal Devices, Percutaneous Approach
047V3G6	Dilation of Right Foot Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047V3GZ	Dilation of Right Foot Artery with Four or More Intraluminal Devices, Percutaneous Approach
047V341	Dilation of Right Foot Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047V34Z	Dilation of Right Foot Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047V35Z	Dilation of Right Foot Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047V36Z	Dilation of Right Foot Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047V37Z	Dilation of Right Foot Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047V3Z1	Dilation of Right Foot Artery using Drug-Coated Balloon, Percutaneous Approach
047V3ZZ	Dilation of Right Foot Artery, Percutaneous Approach
04CV3ZZ	Extirpation of Matter from Right Foot Artery, Percutaneous Approach

Supplementary Table 5. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – tibial artery (left).

ICD 10 PCS Codes	Descriptions
X27Q385	Dilation of Left Anterior Tibial Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27Q395	Dilation of Left Anterior Tibial Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27Q3B5	Dilation of Left Anterior Tibial Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27Q3C5	Dilation of Left Anterior Tibial Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27S385	Dilation of Left Posterior Tibial Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27S395	Dilation of Left Posterior Tibial Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27S3B5	Dilation of Left Posterior Tibial Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27S3C5	Dilation of Left Posterior Tibial Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
047Q341	Dilation of Left Anterior Tibial Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047Q34Z	Dilation of Left Anterior Tibial Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047Q35Z	Dilation of Left Anterior Tibial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047Q36Z	Dilation of Left Anterior Tibial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047Q37Z	Dilation of Left Anterior Tibial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047Q3D1	Dilation of Left Anterior Tibial Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047Q3D6	Dilation of Left Anterior Tibial Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047Q3DZ	Dilation of Left Anterior Tibial Artery with Intraluminal Device, Percutaneous Approach
047Q3EZ	Dilation of Left Anterior Tibial Artery with Two Intraluminal Devices, Percutaneous Approach
047Q3E6	Dilation of Left Anterior Tibial Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047Q3FZ	Dilation of Left Anterior Tibial Artery with Three Intraluminal Devices, Percutaneous Approach
047Q3F6	Dilation of Left Anterior Tibial Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047Q3GZ	Dilation of Left Anterior Tibial Artery with Four or More Intraluminal Devices, Percutaneous Approach
047Q3G6	Dilation of Left Anterior Tibial Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047Q3Z1	Dilation of Left Anterior Tibial Artery using Drug-Coated Balloon, Percutaneous Approach
047Q3ZZ	Dilation of Left Anterior Tibial Artery, Percutaneous Approach

047S341	Dilation of Left Posterior Tibial Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047S34Z	Dilation of Left Posterior Tibial Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047S35Z	Dilation of Left Posterior Tibial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047S36Z	Dilation of Left Posterior Tibial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047S37Z	Dilation of Left Posterior Tibial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047S3D1	Dilation of Left Posterior Tibial Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047S3D6	Dilation of Left Posterior Tibial Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047S3DZ	Dilation of Left Posterior Tibial Artery with Intraluminal Device, Percutaneous Approach
047S3EZ	Dilation of Left Posterior Tibial Artery with Two Intraluminal Devices, Percutaneous Approach
047S3E6	Dilation of Left Posterior Tibial Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047S3FZ	Dilation of Left Posterior Tibial Artery with Three Intraluminal Devices, Percutaneous Approach
047S3F6	Dilation of Left Posterior Tibial Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047S3GZ	Dilation of Left Posterior Tibial Artery with Four or More Intraluminal Devices, Percutaneous Approach
047S3G6	Dilation of Left Posterior Tibial Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047S3Z1	Dilation of Left Posterior Tibial Artery using Drug-Coated Balloon, Percutaneous Approach
047S3ZZ	Dilation of Left Posterior Tibial Artery, Percutaneous Approach
047U341	Dilation of Left Peroneal Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047U3D1	Dilation of Left Peroneal Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047U3D6	Dilation of Left Peroneal Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047U3E6	Dilation of Left Peroneal Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047U3F6	Dilation of Left Peroneal Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047U3G6	Dilation of Left Peroneal Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047U3Z1	Dilation of Left Peroneal Artery using Drug-Coated Balloon, Percutaneous Approach
047U3ZZ	Dilation of Left Peroneal Artery, Percutaneous Approach
047W341	Dilation of Left Foot Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047W3D1	Dilation of Left Foot Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047W3D6	Dilation of Left Foot Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach

047W3E6	Dilation of Left Foot Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047W3F6	Dilation of Left Foot Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047W3G6	Dilation of Left Foot Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047W3Z1	Dilation of Left Foot Artery using Drug-Coated Balloon, Percutaneous Approach
047W3ZZ	Dilation of Left Foot Artery, Percutaneous Approach
04CQ3ZZ	Extirpation of Matter from Left Anterior Tibial Artery, Percutaneous Approach
04CS3ZZ	Extirpation of Matter from Left Posterior Tibial Artery, Percutaneous Approach
04CU3ZZ	Extirpation of Matter from Left Peroneal Artery, Percutaneous Approach
04CW3ZZ	Extirpation of Matter from Left Foot Artery, Percutaneous Approach
047U34Z	Dilation of Left Peroneal Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047U35Z	Dilation of Left Peroneal Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047U36Z	Dilation of Left Peroneal Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047U37Z	Dilation of Left Peroneal Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047U3DZ	Dilation of Left Peroneal Artery with Intraluminal Device, Percutaneous Approach
047U3EZ	Dilation of Left Peroneal Artery with Two Intraluminal Devices, Percutaneous Approach
047U3FZ	Dilation of Left Peroneal Artery with Three Intraluminal Devices, Percutaneous Approach
047U3GZ	Dilation of Left Peroneal Artery with Four or More Intraluminal Devices, Percutaneous Approach
047W34Z	Dilation of Left Foot Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047W35Z	Dilation of Left Foot Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047W36Z	Dilation of Left Foot Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047W37Z	Dilation of Left Foot Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047W3DZ	Dilation of Left Foot Artery with Intraluminal Device, Percutaneous Approach
047W3EZ	Dilation of Left Foot Artery with Two Intraluminal Devices, Percutaneous Approach
047W3FZ	Dilation of Left Foot Artery with Three Intraluminal Devices, Percutaneous Approach
047W3GZ	Dilation of Left Foot Artery with Four or More Intraluminal Devices, Percutaneous Approach

Supplementary Table 6. CPT codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – tibial artery.

CPT Codes	Descriptions
37228	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral
37229	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral
37230	Revascularization, Endovascular, Open Or Percutaneous, Tibial, Peroneal Artery, Unilateral, Initial Vessel; With Transluminal Stent Placement(S), Includes Angioplasty Within The Same Vessel, When Performed
37231	Revascularization, Endovascular, Open Or Percutaneous, Tibial, Peroneal Artery, Unilateral, Initial Vessel; With Transluminal Stent Placement(S) And Atherectomy, Includes Angioplasty Within The Same Vessel, When Performed
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral.
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral.
37234	Revascularization, Endovascular, Open Or Percutaneous, Tibial/Peroneal Artery, Unilateral, Each Additional Vessel; With Transluminal Stent Placement(S), Includes Angioplasty Within The Same Vessel, When Performed (List Separately In Addition To Code For Primary Procedure)
37235	Revascularization, Endovascular, Open Or Percutaneous, Tibial/Peroneal Artery, Unilateral, Each Additional Vessel; With Transluminal Stent Placement(S) And Atherectomy, Includes Angioplasty Within The Same Vessel, When Performed (List Separately In Addition To Code For Primary Procedure)
35459	Transluminal balloon angioplasty, open; tibioperoneal trunk and branches
35470	Transluminal balloon angioplasty, percutaneous; tibioperoneal trunk or branches, each vessel

Supplementary Table 7. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – iliac artery (right).

ICD 10 PCS Codes	Descriptions
047C341	Dilation of Right Common Iliac Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047C3D1	Dilation of Right Common Iliac Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047C3Z1	Dilation of Right Common Iliac Artery using Drug-Coated Balloon, Percutaneous Approach
047C3ZZ	Dilation of Right Common Iliac Artery, Percutaneous Approach
047E341	Dilation of Right Internal Iliac Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047E3D1	Dilation of Right Internal Iliac Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047E3Z1	Dilation of Right Internal Iliac Artery using Drug-Coated Balloon, Percutaneous Approach
047E3ZZ	Dilation of Right Internal Iliac Artery, Percutaneous Approach
047H341	Dilation of Right External Iliac Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047H3D1	Dilation of Right External Iliac Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047H3Z1	Dilation of Right External Iliac Artery using Drug-Coated Balloon, Percutaneous Approach
047H3ZZ	Dilation of Right External Iliac Artery, Percutaneous Approach
04CC3ZZ	Extirpation of Matter from Right Common Iliac Artery, Percutaneous Approach
04CE3ZZ	Extirpation of Matter from Right Internal Iliac Artery, Percutaneous Approach
04CH3ZZ	Extirpation of Matter from Right External Iliac Artery, Percutaneous Approach
047C34Z	Dilation of Right Common Iliac Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047C35Z	Dilation of Right Common Iliac Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047C36Z	Dilation of Right Common Iliac Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047C37Z	Dilation of Right Common Iliac Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047C3DZ	Dilation of Right Common Iliac Artery with Intraluminal Device, Percutaneous Approach
047C3EZ	Dilation of Right Common Iliac Artery with Two Intraluminal Devices, Percutaneous Approach
047C3FZ	Dilation of Right Common Iliac Artery with Three Intraluminal Devices, Percutaneous Approach
047C3GZ	Dilation of Right Common Iliac Artery with Four or More Intraluminal Devices, Percutaneous Approach
047E34Z	Dilation of Right Internal Iliac Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047E35Z	Dilation of Right Internal Iliac Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047E36Z	Dilation of Right Internal Iliac Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach

047E37Z	Dilation of Right Internal Iliac Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047E3DZ	Dilation of Right Internal Iliac Artery with Intraluminal Device, Percutaneous Approach
047E3EZ	Dilation of Right Internal Iliac Artery with Two Intraluminal Devices, Percutaneous Approach
047E3FZ	Dilation of Right Internal Iliac Artery with Three Intraluminal Devices, Percutaneous Approach
047E3GZ	Dilation of Right Internal Iliac Artery with Four or More Intraluminal Devices, Percutaneous Approach
047H34Z	Dilation of Right External Iliac Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047H35Z	Dilation of Right External Iliac Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047H36Z	Dilation of Right External Iliac Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047H37Z	Dilation of Right External Iliac Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047H3DZ	Dilation of Right External Iliac Artery with Intraluminal Device, Percutaneous Approach
047H3EZ	Dilation of Right External Iliac Artery with Two Intraluminal Devices, Percutaneous Approach
047H3FZ	Dilation of Right External Iliac Artery with Three Intraluminal Devices, Percutaneous Approach
047H3GZ	Dilation of Right External Iliac Artery with Four or More Intraluminal Devices, Percutaneous Approach

Supplementary Table 8. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – iliac artery (left).

ICD 10 PCS Codes	Descriptions
047D341	Dilation of Left Common Iliac Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047D3D1	Dilation of Left Common Iliac Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047D3Z1	Dilation of Left Common Iliac Artery using Drug-Coated Balloon, Percutaneous Approach
047D3ZZ	Dilation of Left Common Iliac Artery, Percutaneous Approach
047F341	Dilation of Left Internal Iliac Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047F3D1	Dilation of Left Internal Iliac Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047F3Z1	Dilation of Left Internal Iliac Artery using Drug-Coated Balloon, Percutaneous Approach
047F3ZZ	Dilation of Left Internal Iliac Artery, Percutaneous Approach
047J341	Dilation of Left External Iliac Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047J3D1	Dilation of Left External Iliac Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047J3Z1	Dilation of Left External Iliac Artery using Drug-Coated Balloon, Percutaneous Approach
047J3ZZ	Dilation of Left External Iliac Artery, Percutaneous Approach
04CD3ZZ	Extirpation of Matter from Left Common Iliac Artery, Percutaneous Approach
04CF3ZZ	Extirpation of Matter from Left Internal Iliac Artery, Percutaneous Approach
04CJ3ZZ	Extirpation of Matter from Left External Iliac Artery, Percutaneous Approach
047D34Z	Dilation of Left Common Iliac Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047D35Z	Dilation of Left Common Iliac Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047D36Z	Dilation of Left Common Iliac Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047D37Z	Dilation of Left Common Iliac Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047D3DZ	Dilation of Left Common Iliac Artery with Intraluminal Device, Percutaneous Approach
047D3EZ	Dilation of Left Common Iliac Artery with Two Intraluminal Devices, Percutaneous Approach
047D3FZ	Dilation of Left Common Iliac Artery with Three Intraluminal Devices, Percutaneous Approach
047D3GZ	Dilation of Left Common Iliac Artery with Four or More Intraluminal Devices, Percutaneous Approach
047F34Z	Dilation of Left Internal Iliac Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047F35Z	Dilation of Left Internal Iliac Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047F36Z	Dilation of Left Internal Iliac Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047F37Z	Dilation of Left Internal Iliac Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach

047F3DZ	Dilation of Left Internal Iliac Artery with Intraluminal Device, Percutaneous Approach
047F3EZ	Dilation of Left Internal Iliac Artery with Two Intraluminal Devices, Percutaneous Approach
047F3FZ	Dilation of Left Internal Iliac Artery with Three Intraluminal Devices, Percutaneous Approach
047F3GZ	Dilation of Left Internal Iliac Artery with Four or More Intraluminal Devices, Percutaneous Approach
047J34Z	Dilation of Left External Iliac Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
047J35Z	Dilation of Left External Iliac Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
047J36Z	Dilation of Left External Iliac Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
047J37Z	Dilation of Left External Iliac Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
047J3DZ	Dilation of Left External Iliac Artery with Intraluminal Device, Percutaneous Approach
047J3EZ	Dilation of Left External Iliac Artery with Two Intraluminal Devices, Percutaneous Approach
047J3FZ	Dilation of Left External Iliac Artery with Three Intraluminal Devices, Percutaneous Approach
047J3GZ	Dilation of Left External Iliac Artery with Four or More Intraluminal Devices, Percutaneous Approach

Supplementary Table 9. CPT codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – iliac artery.

CPT Codes	Descriptions
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty
37221	Revascularization, Endovascular, Open Or Percutaneous, Iliac Artery, Unilateral, Initial Vessel; With Transluminal Stent Placement(S), Includes Angioplasty Within The Same Vessel, When Performed
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)
37223	Revascularization, Endovascular, Open Or Percutaneous, Iliac Artery, Each Additional Ipsilateral Iliac Vessel; With Transluminal Stent Placement(S), Includes Angioplasty Within The Same Vessel, When Performed (List Separately In Addition To Code For Primary Procedure)

Supplementary Table 10. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – fem/pop artery (right).

ICD 10 PCS Codes	Descriptions
047K3Z1	Dilation of Right Femoral Artery using Drug-Coated Balloon, Percutaneous Approach Angioplasty with drug-coated balloon
047M3Z1	Dilation of Right Popliteal Artery using Drug-Coated Balloon, Percutaneous Approach Angioplasty with drug-coated balloon
047K341	Dilation of Right Femoral Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach Angioplasty and stenting with drug-coated balloon + drug-eluting stent
047M341	Dilation of Right Popliteal Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach Angioplasty and stenting with drug-coated balloon + drug-eluting stent
047K3D1	Dilation of Right Femoral Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach Angioplasty and stenting with drug coated balloon + bare-metal stent
047M3D1	Dilation of Right Popliteal Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach
047K3ZZ	Dilation of Right Femoral Artery, Percutaneous Approach Angioplasty with uncoated percutaneous transluminal angioplasty balloon
047M3ZZ	Dilation of Right Popliteal Artery, Percutaneous Approach
047K34Z	Dilation of Right Femoral Artery with Drug-eluting Intraluminal Device, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047K35Z	Dilation of Right Femoral Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047K36Z	Dilation of Right Femoral Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047K376	Dilation of Right Femoral Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047K37Z	Dilation of Right Femoral Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047M34Z	Dilation of Right Popliteal Artery with Drug-eluting Intraluminal Device, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047M35Z	Dilation of Right Popliteal Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047M36Z	Dilation of Right Popliteal Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047M37Z	Dilation of Right Popliteal Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047M3Z6	Dilation of Right Popliteal Artery, Bifurcation, Percutaneous Approach
047K3DZ	Dilation of Right Femoral Artery with Intraluminal Device, Percutaneous Approach

	Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047K3D6	Dilation of Right Femoral Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047K3EZ	Dilation of Right Femoral Artery with Two Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047K3E6	Dilation of Right Femoral Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047K3FZ	Dilation of Right Femoral Artery with Three Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047K3GZ	Dilation of Right Femoral Artery with Four or More Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047K3Z6	Dilation of Right Femoral Artery, Bifurcation, Percutaneous Approach
047M3DZ	Dilation of Right Popliteal Artery with Intraluminal Device, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047M3EZ	Dilation of Right Popliteal Artery with Two Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047M3EZ	Dilation of Right Popliteal Artery with Two Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047M3FZ	Dilation of Right Popliteal Artery with Three Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047K3F6	Dilation of Right Femoral Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047M3GZ	Dilation of Right Popliteal Artery with Four or More Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047K3G6	Dilation of Right Femoral Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
X27H385	Dilation of Right Femoral Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27H395	Dilation of Right Femoral Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27H3B5	Dilation of Right Femoral Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27H3C5	Dilation of Right Femoral Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27K385	Dilation of Proximal Right Popliteal Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon

X27K395	Dilation of Proximal Right Popliteal Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27K3B5	Dilation of Proximal Right Popliteal Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27K3C5	Dilation of Proximal Right Popliteal Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
04CK3ZZ	Extirpation of Matter from Right Femoral Artery, Percutaneous Approach
04CM3ZZ	Extirpation of Matter from Right Popliteal Artery, Percutaneous Approach

Supplementary Table 11. ICD-10 codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – fem/pop artery (left).

ICD 10 PCS Codes	Descriptions
047L3Z1	Dilation of Left Femoral Artery using Drug-Coated Balloon, Percutaneous Approach Angioplasty with drug-coated balloon
047N3Z1	Dilation of Left Popliteal Artery using Drug-Coated Balloon, Percutaneous Approach Angioplasty with drug-coated balloon
047L341	Dilation of Left Femoral Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach Angioplasty and stenting with drug-coated balloon + drug-eluting stent
047N341	Dilation of Left Popliteal Artery with Drug-eluting Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach Angioplasty and stenting with drug-coated balloon + drug-eluting stent
047L3D1	Dilation of Left Femoral Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach Angioplasty and stenting with drug coated balloon + bare-metal stent
047N3D1	Dilation of Left Popliteal Artery with Intraluminal Device, using Drug-Coated Balloon, Percutaneous Approach Angioplasty and stenting with drug coated balloon + bare-metal stent
047N3D6	Dilation of Left Popliteal Artery, Bifurcation, with Intraluminal Device, Percutaneous Approach
047N3E6	Dilation of Left Popliteal Artery, Bifurcation, with Two Intraluminal Devices, Percutaneous Approach
047N3F6	Dilation of Left Popliteal Artery, Bifurcation, with Three Intraluminal Devices, Percutaneous Approach
047N3G6	Dilation of Left Popliteal Artery, Bifurcation, with Four or More Intraluminal Devices, Percutaneous Approach
047L3ZZ	Dilation of Left Femoral Artery, Percutaneous Approach Angioplasty with uncoated percutaneous transluminal angioplasty balloon
047L3Z6	Dilation of Left Popliteal Artery, Percutaneous Approach Angioplasty with uncoated percutaneous transluminal angioplasty balloon
047N3ZZ	Dilation of Left Popliteal Artery, Percutaneous Approach Angioplasty with uncoated percutaneous transluminal angioplasty balloon
047N3Z6	Dilation of Left Popliteal Artery, Bifurcation, Percutaneous Approach
047L34Z	Dilation of Left Femoral Artery with Drug-eluting Intraluminal Device, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047L35Z	Dilation of Left Femoral Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047L36Z	Dilation of Left Femoral Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047L37Z	Dilation of Left Femoral Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047N34Z	Dilation of Left Popliteal Artery with Drug-eluting Intraluminal Device, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047N35Z	Dilation of Left Popliteal Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach

	Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047N36Z	Dilation of Left Popliteal Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047N37Z	Dilation of Left Popliteal Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
047L3EZ	Dilation of Left Femoral Artery with Two Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon,
047L3FZ	Dilation of Left Femoral Artery with Three Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047L3GZ	Dilation of Left Femoral Artery with Four or More Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047N3DZ	Dilation of Left Popliteal Artery with Intraluminal Device, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047N3EZ	Dilation of Left Popliteal Artery with Two Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047N3FZ	Dilation of Left Popliteal Artery with Three Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047N3GZ	Dilation of Left Popliteal Artery with Four or More Intraluminal Devices, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
047L3DZ	Dilation of Left Femoral Artery with Intraluminal Device, Percutaneous Approach Stenting with bare metal stent, with or without angioplasty with uncoated balloon
X27J385	Dilation of Left Femoral Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27J395	Dilation of Left Femoral Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27J3B5	Dilation of Left Femoral Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27J3C5	Dilation of Left Femoral Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27L385	Dilation of Proximal Left Popliteal Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27L395	Dilation of Proximal Left Popliteal Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon

X27L3B5	Dilation of Proximal Left Popliteal Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
X27L3C5	Dilation of Proximal Left Popliteal Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5 Stenting with drug-eluting stent, with or without angioplasty with uncoated balloon
04CL3ZZ	Extirpation of Matter from Left Femoral Artery, Percutaneous Approach
04CN3ZZ	Extirpation of Matter from Left Popliteal Artery, Percutaneous Approach

Supplementary Table 12. CPT codes used to identify endovascular CLTI revascularisation performed between 1 January 2016 and 31 December 2023 – fem/pop artery.

CPT Codes	Descriptions
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral
37224 + C2623*	Angioplasty, femoral, popliteal artery(ies), unilateral + catheter, transluminal angioplasty, drug-coated, non-laser
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral
37225 + C2623*	Atherectomy, femoral, popliteal artery(ies), unilateral + catheter, transluminal angioplasty, drug-coated, non-laser
37226	Revascularization, Endovascular, Open Or Percutaneous, Femoral, Popliteal Artery(S), Unilateral; With Transluminal Stent Placement(S), Includes Angioplasty Within The Same Vessel, When Performed
37226 + C1874 or C1875	Stent placement(s) and atherectomy, femoral, popliteal artery(ies), unilateral + stent, coated/covered, with or without delivery system
37227	Revascularization, Endovascular, Open Or Percutaneous, Femoral, Popliteal Artery(S), Unilateral; With Transluminal Stent Placement(S) And Atherectomy, Includes Angioplasty Within The Same Vessel, When Performed
37227 + C1874 or C1875	Stent placement(s) and atherectomy, femoral, popliteal artery(ies), unilateral + stent, coated/covered, with or without delivery system
35474	Transluminal balloon angioplasty, percutaneous; femoral-popliteal

Supplementary Table 13. ICD-10 codes used to identify atherectomy for endovascular CLTI revascularisation between 1 January 2016 and 31 December 2023.

ICD-10-PCS Codes	Descriptions
04CC3ZZ	Extirpation of Matter from Right Common Iliac Artery, Percutaneous Approach
04CD3ZZ	Extirpation of Matter from Left Common Iliac Artery, Percutaneous Approach
04CE3ZZ	Extirpation of Matter from Right Internal Iliac Artery, Percutaneous Approach
04CF3ZZ	Extirpation of Matter from Left Internal Iliac Artery, Percutaneous Approach
04CH3ZZ	Extirpation of Matter from Right External Iliac Artery, Percutaneous Approach
04CJ3ZZ	Extirpation of Matter from Left External Iliac Artery, Percutaneous Approach
04CK3ZZ	Extirpation of Matter from Right Femoral Artery, Percutaneous Approach
04CL3ZZ	Extirpation of Matter from Left Femoral Artery, Percutaneous Approach
04CM3ZZ	Extirpation of Matter from Right Popliteal Artery, Percutaneous Approach
04CN3ZZ	Extirpation of Matter from Left Popliteal Artery, Percutaneous Approach
04CP3ZZ	Extirpation of Matter from Right Anterior Tibial Artery, Percutaneous Approach
04CQ3ZZ	Extirpation of Matter from Left Anterior Tibial Artery, Percutaneous Approach
04CR3ZZ	Extirpation of Matter from Right Posterior Tibial Artery, Percutaneous Approach
04CS3ZZ	Extirpation of Matter from Left Posterior Tibial Artery, Percutaneous Approach
04CT3ZZ	Extirpation of Matter from Right Peroneal Artery, Percutaneous Approach
04CU3ZZ	Extirpation of Matter from Left Peroneal Artery, Percutaneous Approach
04CV3ZZ	Extirpation of Matter from Right Foot Artery, Percutaneous Approach
04CW3ZZ	Extirpation of Matter from Left Foot Artery, Percutaneous Approach

Supplementary Table 14. CPT codes used to identify atherectomy for endovascular CLTI revascularisation between 1 January 2016 and 31 December 2023.

ICD-10-PCS Codes	Descriptions
37235	Revascularization, Endovascular, Open Or Percutaneous, Tibial/Peroneal Artery, Unilateral, Each Additional Vessel; With Transluminal Stent Placement(S) And Atherectomy, Includes Angioplasty Within The Same Vessel, When Performed (List Separately In Addition To Code For Primary Procedure)
37225 + C2623*	Atherectomy, femoral, popliteal artery(ies), unilateral + catheter, transluminal angioplasty, drug-coated, non-laser
37227 + C1874 or C1875	Stent placement(s) and atherectomy, femoral, popliteal artery(ies), unilateral + stent, coated/covered, with or without delivery system
37225 +/- C1725‡	Atherectomy, femoral, popliteal artery(ies), unilateral +/- catheter transluminal angioplasty non laser
37227 +/- C1876 or C1877	Stent placement(s) and atherectomy, femoral, popliteal artery(ies), unilateral +/- stent non-coated/non covered with or without delivery system
0236T	Atherectomy (open or percutaneous) for supra-inguinal arteries
0238T	Atherectomy (open or percutaneous) for supra-inguinal arteries

Supplementary Table 15. ICD-10 codes used to identify prior amputation from 1 January 2016 to 31 December 2023.

ICD-10-CM Diagnosis Codes	ICD-10-CM Descriptions
Z89.41	Acquired absence of great toe
Z89.42	Acquired absence of other toe(s)
Z89.43	Acquired absence of foot
Z89.44	Acquired absence of ankle
Z89.51	Acquired absence of leg below knee
Z89.52	Acquired absence of knee
Z89.61	Acquired absence of leg above knee
Z89.62	Acquired absence of hip

Supplementary Table 16. ICD-10-PCS codes used to identify major amputation from 1 January 2016 to 31 December 2023.

ICD-10-PCS and CPT Codes	ICD-10-CM Descriptions
0Y6C0Z1	Detachment at Right Upper Leg, High, Open Approach
0Y6C0Z2	Detachment at Right Upper Leg, Mid, Open Approach
0Y6C0Z3	Detachment at Right Upper Leg, Low, Open Approach
0Y6D0Z1	Detachment at Left Upper Leg, High, Open Approach
0Y6D0Z2	Detachment at Left Upper Leg, Mid, Open Approach
0Y6D0Z3	Detachment at Left Upper Leg, Low, Open Approach
0Y6F0ZZ	Detachment at Right Knee Region, Open Approach
0Y6G0ZZ	Detachment at Left Knee Region, Open Approach
0Y6H0Z1	Detachment at Right Lower Leg, High, Open Approach
0Y6H0Z2	Detachment at Right Lower Leg, Mid, Open Approach
0Y6H0Z3	Detachment at Right Lower Leg, Low, Open Approach
0Y6J0Z1	Detachment at Left Lower Leg, High, Open Approach
0Y6J0Z2	Detachment at Left Lower Leg, Mid, Open Approach
0Y6J0Z3	Detachment at Left Lower Leg, Low, Open Approach
0Y6M0Z0	Detachment at Right Foot, Complete, Open Approach
0Y6N0Z0	Detachment at Left Foot, Complete, Open Approach
0Y620ZZ	Detachment at Right Hindquarter, Open Approach
0Y630ZZ	Detachment at Left Hindquarter, Open Approach
0Y640ZZ	Detachment at Bilateral Hindquarter, Open Approach
0Y670ZZ	Detachment at Right Femoral Region, Open Approach
0Y680ZZ	Detachment at Left Femoral Region, Open Approach

Supplementary Table 17. CPT codes used to identify major amputation from 1 January 2016 to 31 December 2023.

CPT Codes	Descriptions
27590	Amputation, thigh, through femur, any level
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)
27594	Amputation of thigh through thigh bone
27596	Re-amputation of thigh through thigh bone
27598	Disarticulation at knee
27880	Amputation, leg, through tibia and fibula;
27881	Amputation of leg
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)
27884	Amputation, leg, through tibia and fibula; secondary closure or scar revision
27886	Amputation, leg, through tibia and fibula; re-amputation
27888	Amputation, ankle, through malleoli of tibia and fibula (e.g., Syme, Pirogoff type procedures), with plastic closure and resection of nerves
27889	Ankle disarticulation

Supplementary Table 18. ICD-10-CM and ICD-10-PCS codes used to identify ambulatory status from 1 January 2016 to 31 December 2023.

ICD 10 Codes	Descriptions
Z99.3	Dependence on wheelchair
Z99.8	Dependence on other enabling machines and devices
F07Z4EZ	Wheelchair Mobility Treatment using Orthosis
F07Z4UZ	Wheelchair Mobility Treatment using Prosthesis
F07Z4YZ	Wheelchair Mobility Treatment using Other Equipment
F07Z4ZZ	Wheelchair Mobility Treatment
F07Z9CZ	Gait Training/Functional Ambulation Treatment using Mechanical Equipment
F07Z9DZ	Gait Training/Functional Ambulation Treatment using Electrotherapeutic Equipment
F07Z9EZ	Gait Training/Functional Ambulation Treatment using Orthosis
F07Z9FZ	Gait Training/Functional Ambulation Treatment using Assistive, Adaptive, Supportive or Protective Equipment
F07Z9UZ	Gait Training/Functional Ambulation Treatment using Prosthesis
F07Z9YZ	Gait Training/Functional Ambulation Treatment using Other Equipment
F07Z9ZZ	Gait Training/Functional Ambulation Treatment

Supplementary Table 19. CPT codes used to identify ambulatory status from 1 January 2016 to 31 December 2023.

CPT Code	Description
97542	Wheelchair management (e.g., assessment, fitting, training),
97116	Gait training therapy

Supplementary Table 20. ICD-10-PCS codes used to identify minor amputation from 1 January 2016 to 31 December 2023.

ICD 10-PCS Codes	Descriptions
0Y6M0Z4	Detachment at Right Foot, Complete 1st Ray, Open Approach
0Y6M0Z5	Detachment at Right Foot, Complete 2nd Ray, Open Approach
0Y6M0Z6	Detachment at Right Foot, Complete 3rd Ray, Open Approach
0Y6M0Z7	Detachment at Right Foot, Complete 4th Ray, Open Approach
0Y6M0Z8	Detachment at Right Foot, Complete 5th Ray, Open Approach
0Y6M0Z9	Detachment at Right Foot, Partial 1st Ray, Open Approach
0Y6M0ZB	Detachment at Right Foot, Partial 2nd Ray, Open Approach
0Y6M0ZC	Detachment at Right Foot, Partial 3rd Ray, Open Approach
0Y6M0ZD	Detachment at Right Foot, Partial 4th Ray, Open Approach
0Y6M0ZF	Detachment at Right Foot, Partial 5th Ray, Open Approach
0Y6N0Z4	Detachment at Left Foot, Complete 1st Ray, Open Approach
0Y6N0Z5	Detachment at Left Foot, Complete 2nd Ray, Open Approach
0Y6N0Z6	Detachment at Left Foot, Complete 3rd Ray, Open Approach
0Y6N0Z7	Detachment at Left Foot, Complete 4th Ray, Open Approach
0Y6N0Z8	Detachment at Left Foot, Complete 5th Ray, Open Approach
0Y6N0Z9	Detachment at Left Foot, Partial 1st Ray, Open Approach
0Y6N0ZB	Detachment at Left Foot, Partial 2nd Ray, Open Approach
0Y6N0ZC	Detachment at Left Foot, Partial 3rd Ray, Open Approach
0Y6N0ZD	Detachment at Left Foot, Partial 4th Ray, Open Approach
0Y6N0ZF	Detachment at Left Foot, Partial 5th Ray, Open Approach
0Y6P0Z0	Detachment at Right 1st Toe, Complete, Open Approach
0Y6P0Z1	Detachment at Right 1st Toe, High, Open Approach
0Y6P0Z2	Detachment at Right 1st Toe, Mid, Open Approach
0Y6P0Z3	Detachment at Right 1st Toe, Low, Open Approach
0Y6Q0Z0	Detachment at Left 1st Toe, Complete, Open Approach
0Y6Q0Z1	Detachment at Left 1st Toe, High, Open Approach
0Y6Q0Z2	Detachment at Left 1st Toe, Mid, Open Approach
0Y6Q0Z3	Detachment at Left 1st Toe, Low, Open Approach
0Y6R0Z0	Detachment at Right 2nd Toe, Complete, Open Approach
0Y6R0Z1	Detachment at Right 2nd Toe, High, Open Approach
0Y6R0Z2	Detachment at Right 2nd Toe, Mid, Open Approach
0Y6R0Z3	Detachment at Right 2nd Toe, Low, Open Approach
0Y6S0Z0	Detachment at Left 2nd Toe, Complete, Open Approach
0Y6S0Z1	Detachment at Left 2nd Toe, High, Open Approach
0Y6S0Z2	Detachment at Left 2nd Toe, Mid, Open Approach
0Y6S0Z3	Detachment at Left 2nd Toe, Low, Open Approach
0Y6T0Z0	Detachment at Right 3rd Toe, Complete, Open Approach
0Y6T0Z1	Detachment at Right 3rd Toe, High, Open Approach
0Y6T0Z2	Detachment at Right 3rd Toe, Mid, Open Approach
0Y6T0Z3	Detachment at Right 3rd Toe, Low, Open Approach
0Y6U0Z0	Detachment at Left 3rd Toe, Complete, Open Approach
0Y6U0Z1	Detachment at Left 3rd Toe, High, Open Approach
0Y6U0Z2	Detachment at Left 3rd Toe, Mid, Open Approach
0Y6U0Z3	Detachment at Left 3rd Toe, Low, Open Approach
0Y6V0Z0	Detachment at Right 4th Toe, Complete, Open Approach
0Y6V0Z1	Detachment at Right 4th Toe, High, Open Approach
0Y6V0Z2	Detachment at Right 4th Toe, Mid, Open Approach

0Y6V0Z3	Detachment at Right 4th Toe, Low, Open Approach
0Y6W0Z0	Detachment at Left 4th Toe, Complete, Open Approach
0Y6W0Z1	Detachment at Left 4th Toe, High, Open Approach
0Y6W0Z2	Detachment at Left 4th Toe, Mid, Open Approach
0Y6W0Z3	Detachment at Left 4th Toe, Low, Open Approach
0Y6X0Z0	Detachment at Right 5th Toe, Complete, Open Approach
0Y6X0Z1	Detachment at Right 5th Toe, High, Open Approach
0Y6X0Z2	Detachment at Right 5th Toe, Mid, Open Approach
0Y6X0Z3	Detachment at Right 5th Toe, Low, Open Approach
0Y6Y0Z0	Detachment at Left 5th Toe, Complete, Open Approach
0Y6Y0Z1	Detachment at Left 5th Toe, High, Open Approach
0Y6Y0Z2	Detachment at Left 5th Toe, Mid, Open Approach
0Y6Y0Z3	Detachment at Left 5th Toe, Low, Open Approach

Supplementary Table 21. CPT codes used to identify minor amputation from 1 January 2026 to 31 December 2023.

CPT Codes	Descriptions
28820	Amputation, toe; metatarsophalangeal joint
28825	Amputation, toe; interphalangeal joint
28810	Amputation, metatarsal, including toe, single
28805	Amputation, foot; transmetatarsal
28800	Amputation, foot; midtarsal

Supplementary Table 22. Covariates included in multivariable adjustment models.

Category	**Covariate**
Demographics	Age (continuous) Sex (male/female), Race (White, Black, Other)
Socioeconomic	Dual Medicare-Medicaid eligibility Distressed Communities Index Rural/Urban Area
Comorbidities	Diabetes Chronic Kidney Disease Smoking Coronary Artery Disease Congestive Heart Failure Recent Myocardial Infarction Hypertension Hyperlipidemia Obesity Alzheimer's Disease Alzheimer's Disease, Related Disorders or Senile Dementia Cancer COPD Stroke/TIA
CLTI Severity	Presence of rest pain Ulceration Gangrene
Procedure Characteristics	Year of procedure Treatment setting (inpatient vs outpatient) Lesion territory (isolated femoropopliteal vs iliac/tibial involvement) Concomitant Atherectomy Use
Geographic Factors	U.S. region (Northeast, Midwest, South, West)
Hospital Characteristics	Annual institutional endovascular revascularization volume Academic status Bed size

Supplementary Table 23. Breakdown of treatment groups according to stent use.

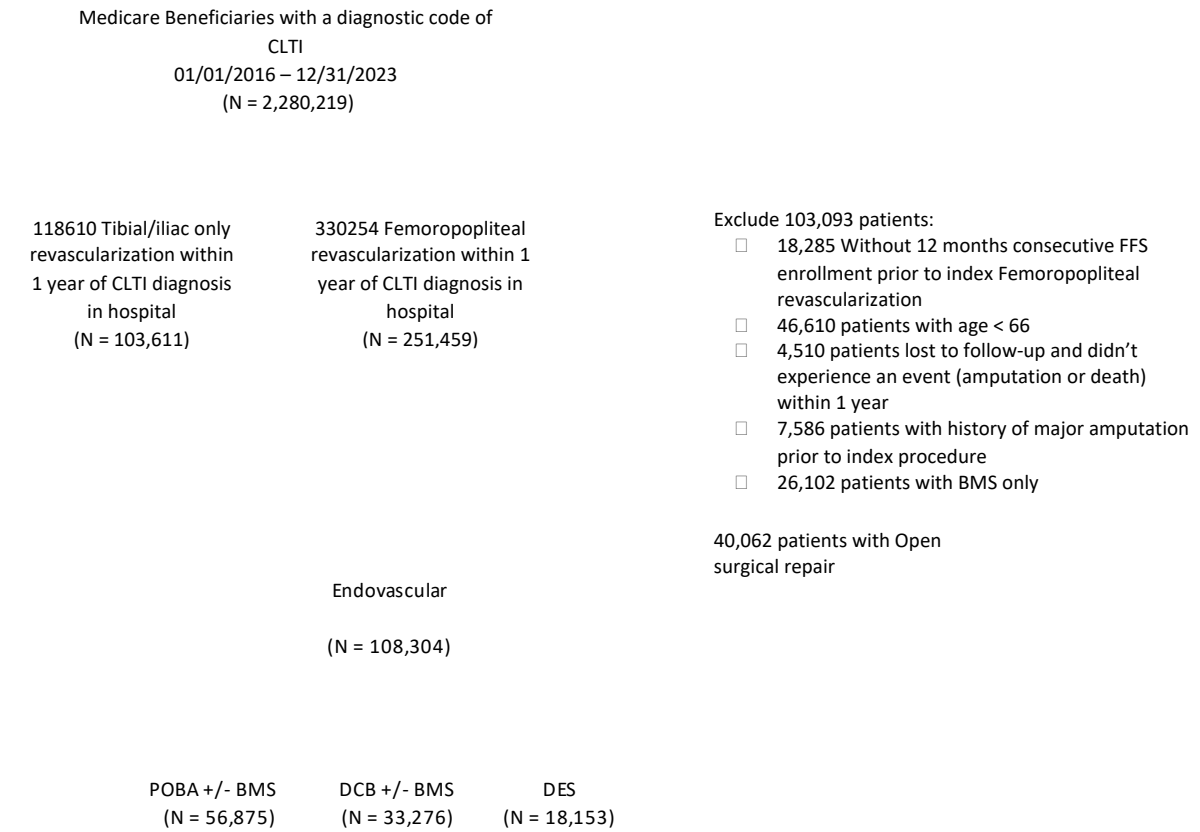
Treatment group	Count	Percentage
PBA without BMS	51,116	89.9%
PBA + BMS	5,759	10.1%
DCB without BMS	32,242	96.9%
DCB + BMS	1,034	3.1%
DES	18,153	–

Supplementary Table 24 Hazard ratios for major amputation on the same side at maximum follow-up.

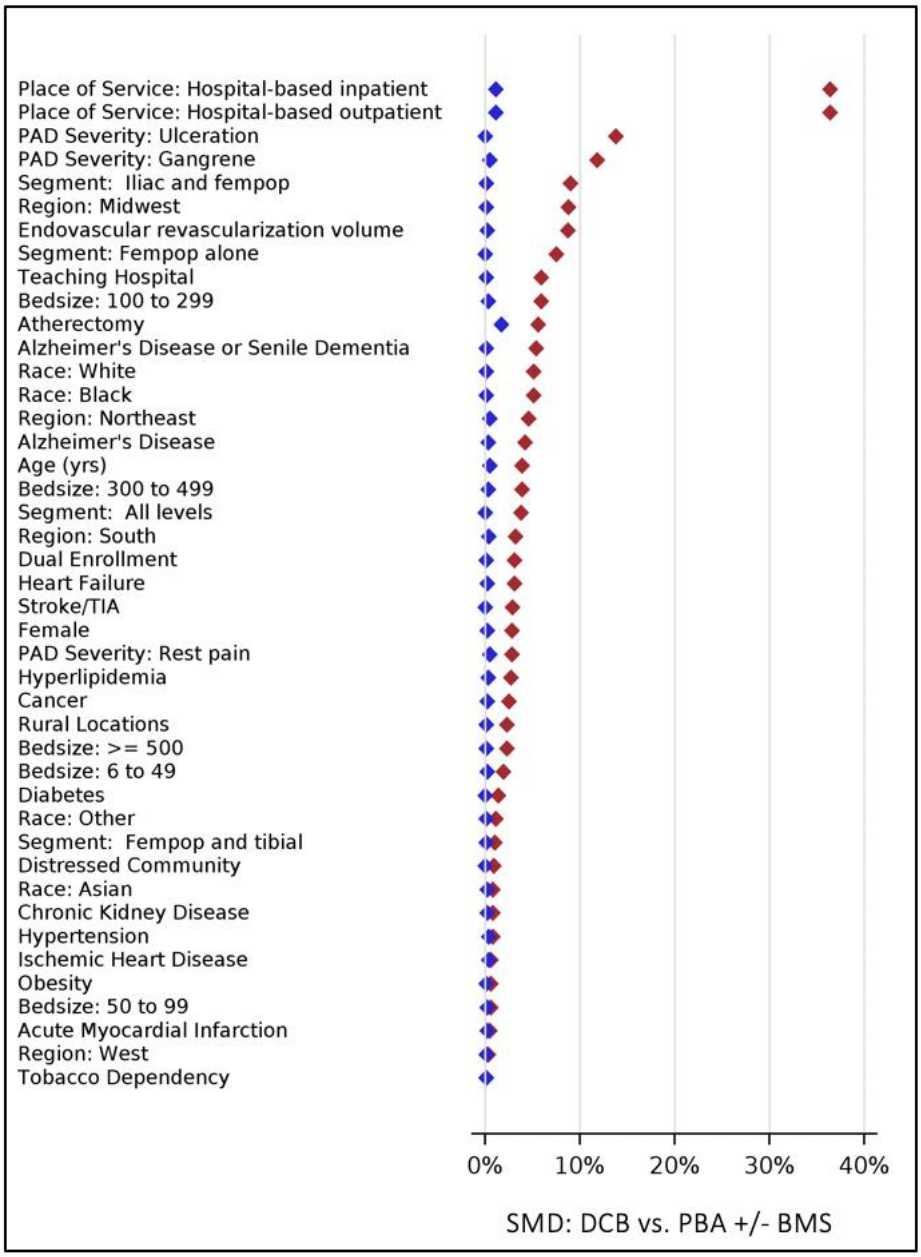
	Unadjusted				Adjusted			
Event	**Unadjusted Subdistribution HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Unadjusted Subdistribution HR (95% CI), p-value DES vs. PBA +/- BMS**	**Unadjusted Cause-Specific HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Unadjusted Cause-Specific HR (95% CI), p-value DES vs. PBA +/- BMS**	**Adjusted Subdistribution HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Adjusted Subdistribution HR (95% CI), p-value DES vs. PBA +/- BMS**	**Adjusted Cause-Specific HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Adjusted Cause-Specific HR (95% CI), p-value DES vs. PBA +/- BMS**
Major amputation on the same side	0.94 (0.90, 0.99), 0.0115	0.96 (0.90, 1.02), 0.1593	0.93 (0.88, 0.98), 0.0033	0.95 (0.89, 1.01), 0.0942	0.89 (0.85, 0.94), <.0001	0.93 (0.88, 0.99), 0.0292	0.88 (0.83, 0.92), <.0001	0.92 (0.86, 0.98), 0.0089

Supplementary Table 25. Adjusted risk estimates of the falsification endpoints.

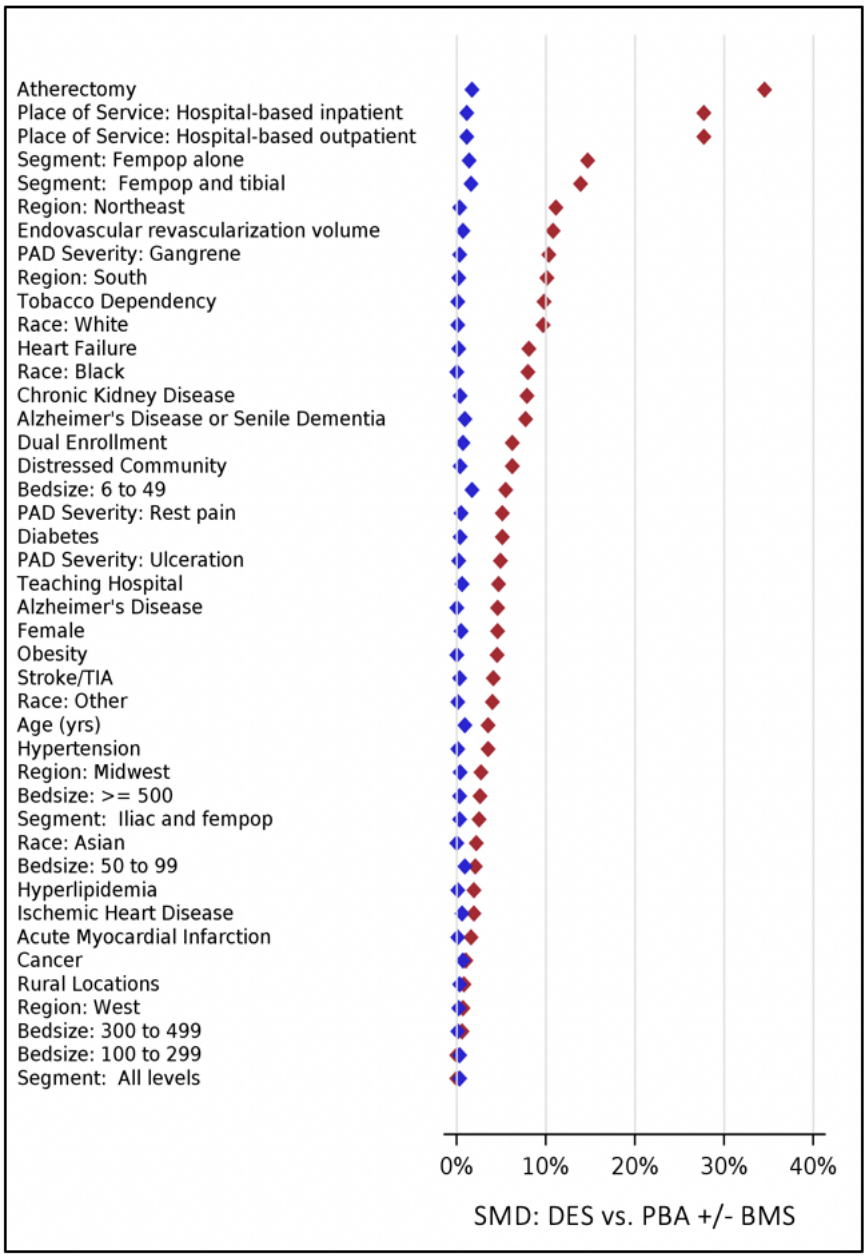
	Unadjusted				Adjusted			
Event	**Unadjusted Subdistribution HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Unadjusted Subdistribution HR (95% CI), p-value DES vs. PBA +/- BMS**	**Unadjusted Cause-Specific HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Unadjusted Cause-Specific HR (95% CI), p-value DES vs. PBA +/- BMS**	**Adjusted Subdistribution HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Adjusted Subdistribution HR (95% CI), p-value DES vs. PBA +/- BMS**	**Adjusted Cause-Specific HR (95% CI), p-value DCB +/- BMS vs. PBA +/- BMS**	**Adjusted Cause-Specific HR (95% CI), p-value DES vs. PBA +/- BMS**
Hospitalization for pneumonia	1.02 (0.99, 1.05), 0.1514	1.00 (0.97, 1.03), 0.9415	0.95 (0.92, 0.97), 0.0001	0.93 (0.90, 0.97), <.0001	1.01 (0.98, 1.04), 0.4650	1.02 (0.98, 1.05), 0.3798	0.97 (0.95, 1.00), 0.0630	0.98 (0.95, 1.02), 0.3958
Hospitalization for hip fracture	1.11 (1.04, 1.19), 0.0012	1.10 (1.02, 1.19), 0.0161	1.02 (0.95, 1.09), 0.5785	1.02 (0.94, 1.11), 0.5977	1.05 (0.98, 1.12), 0.1590	1.06 (0.98, 1.15), 0.1731	1.00 (0.94, 1.07), 0.9781	1.03 (0.95, 1.12), 0.4874



Supplementary Figure 1. Flowchart.



Supplementary Figure 2. Standardised mean differences between groups before and after weighting (DCB±BMS vs PBA±BMS).



Supplementary Figure 3. Standardised mean differences between groups before and after weighting (DES vs PBA±BMS).