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Journal

Journal of Vascular Surgery

ISSN

0741-5214

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Publication Date

2025-12-01

DOI

10.1016/j.jvs.2025.12.156

Peer reviewed

From the Society for Vascular Surgery

Outcomes after infrainguinal interventions for intermittent claudication in patients with end-stage renal disease are poor

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ABSTRACT

Background: Intermittent claudication (IC) interventions are predicated on safety, durability, and long-term expected benefit. Patients with end-stage renal disease (ESRD) have a higher risk of complications after many surgical procedures and have lower overall survival. Our goal was to assess perioperative and 1-year outcomes of IC interventions in patients with ESRD.

Methods: The Vascular Quality Initiative was queried from 2010 to 2020 for peripheral vascular interventions (PVI) and infrainguinal bypasses (IIBs) for IC. Demographics, comorbidities, procedural details, and outcomes were analyzed in patients with and without ESRD.

Results: There were 83,698 PVIs (2% ESRD and 98% non-ESRD) and 10,935 IIBs (1.2% ESRD and 98.8% non-ESRD) performed for IC. For PVI, ESRD patients more often underwent femoropopliteal (65.1% vs 59.5%) and infrapopliteal (26.5% vs 10.1%), and less often iliac interventions (32.1% vs 46.4%) (all $P < .001$). There were no differences in access site complications; however, ESRD patients had higher 30-day mortality (2.2% vs 0.4%; $P < .001$). At 1 year, ESRD patients less often ambulated independently (74.3% vs 90.4%; $P < .001$). On Kaplan-Meier analysis, patient with ESRD had lower 1-year freedom from reintervention/major amputation/death (62.8% vs 86.7%), major amputation/death (67.8% vs 93.9%), and survival (81.7% vs 96.6%) (all $P < .001$). On multivariable analysis, ESRD was associated with reintervention/major amputation/death (hazard ratio [HR], 2.46; 95% confidence interval [CI], 2.1-2.8; $P < .001$), major amputation/death (HR, 3.72; 95% CI, 3.1-4.4; $P < .001$), and death (HR, 3.8; 95% CI, 3.2-4.58; $P < .001$). For IIB, ESRD patients more often had an infrapopliteal target (33.3% vs 20%; $P < .001$) and similar great saphenous vein use (43.9% vs 50.3%; $P = .33$). ESRD patients had more cardiac complications (8.7% vs 3.2%; $P = .001$) with a similar risk of 30-day mortality (1.6% vs 0.5%; $P = .11$). At 1 year, ESRD patients less often ambulated independently (66.7% vs 88.5%; $P = .006$). On Kaplan-Meier analysis, ESRD patients had lower 1-year freedom from reintervention/major amputation/death (66.7% vs 81.3%), major amputation/death (70.3% vs 93.7%), and survival (81.6% vs 96.3%) (all $P < .001$). On multivariable analysis, ESRD was associated with reintervention/major amputation/death (HR, 1.72; 95% CI, 1.04-2.87; $P = .034$), major amputation/death (HR, 2.87; 95% CI 1.59-5.15; $P = .001$), and death (HR, 3.58; 95% CI, 1.86-6.9; $P < .001$).

Conclusions: Patients with ESRD have higher perioperative morbidity and long-term ambulatory impairment, limb loss, and mortality. The risks/benefit profile should be carefully assessed, and noninvasive interventions should be maximized in this population. (J Vasc Surg 2025;■:1-10.)

Keywords: Infrainguinal bypass; Leg bypass; Endovascular; Dialysis; Renal disease

The natural history of patients with intermittent claudication (IC) has a reported 1% to 2% incidence at 5 year for developing chronic limb-threatening ischemia

(CLTI), while the remainder have stable or worsening IC.^{1,2} Major amputation rates remain low for those with IC treated with conservative therapy.³⁻⁵ Interventions

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Presented at the 2023 Vascular Annual Meeting, of the Society for Vascular Surgery, National Harbor, Maryland, June 14-17, 2023.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

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<https://doi.org/10.1016/j.jvs.2025.12.156>

for IC are prevalent with approximately 14,000 endovascular interventions and approximately 2100 infrainguinal bypasses (IIBs) performed from 2010 to 2021 in the Vascular Quality Initiative (VQI).⁶

Many society guidelines recommend shared decision-making when considering revascularization for IC and the Society for Vascular Surgery guideline states that invasive treatment should be reserved for patients with a 2-year reintervention-free likelihood of >50%.^{1,7-9} Further endeavors have been published to reinforce careful selection for invasive intervention in patients with severe lifestyle-limiting IC such as by the Society for Vascular Surgery appropriate use criteria for IC.¹⁰

Previous analyses have shown that patients undergoing lower extremity interventions for IC may be at risk for worsening functional status and limb loss.¹¹ Factors associated with limb loss and poor survival include end-stage renal disease (ESRD).^{6,12,13} An analysis of Medicare patients undergoing interventions for IC has shown that ESRD is the leading associated factor for long-term mortality.

Currently, there are few large datasets analyzing outcomes in patients with ESRD undergoing infrainguinal endovascular and open revascularization for IC. Our objective was to analyze the perioperative and long-term outcomes of patients with ESRD who undergo infrainguinal lower extremity intervention for IC. The VQI allows for analysis of these patients both for survival and limb-associated outcomes.

METHODS

The VQI was queried from 2010 to 2020 for peripheral vascular interventions (PVI) and IIBs. The VQI is a prospectively maintained database that includes demographics, comorbidities, procedural details, and perioperative/1-year outcomes. There are >1000 academic and nonacademic centers participating in the registry. The Boston University Institutional Review Board and the VQI National Research Advisory Committee approved this study. Patient consent was waived.

PVI and IIB performed for IC were included. PVI and IIB performed for acute limb ischemia, CLTI, aneurysmal disease, or trauma were excluded. Patients who underwent renal transplantation were not included owing to inadequate numbers. Patients were then stratified by whether they had ESRD.

Demographics recorded were age, sex, race, ethnicity, smoking status (never, prior, current), primary payer (Medicare, Medicaid, commercial [other (military/Veteran Affairs, non-United States insurance, and self-pay)]), ambulatory status, and preoperative living status (home, nursing home, homeless). Comorbidities included were hypertension (HTN), diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), coronary artery disease (CAD), coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI),

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective review of prospectively collected data in the Vascular Quality Initiative database
- **Key Findings:** There were 83,698 peripheral vascular interventions (PVIs) (2% end-stage renal disease [ESRD] and 98% non-ESRD) and 10,935 infrainguinal bypasses (IIBs) (1.2% ESRD and 98.8% non-ESRD) performed for intermittent claudication. At 1 year, ESRD patients less often ambulated independently after PVI or IIB. On Kaplan-Meier analysis, patient with ESRD had lower 1-year freedom from reintervention/major amputation/death, major amputation/death, and survival after PVI or IIB. On multivariable analysis, ESRD was associated with reintervention/major amputation/death, major amputation/death, and death after PVI and IIB.
- **Take Home Message:** Patients with ESRD have higher perioperative morbidity and long-term ambulatory impairment, limb loss, and mortality. The risks/benefit profile should be carefully assessed, and noninvasive interventions should be maximized in this population.

congestive heart failure (CHF), preoperative anemia (<10 g/dL), body mass index (BMI), and obesity (BMI ≥ 30 kg/m²). Vascular history included prior inflow PVI/bypass, lower extremity PVI/bypass, minor amputation, and major amputation (defined as above-the-ankle amputation). Preoperative medications recorded were aspirin, P2Y12 inhibitors, anticoagulants, and statins.

For patients who underwent PVI for IC, procedural details included were access guidance technique (none, fluoroscopy, ultrasound, open, combination), sheath size (median [interquartile range]), and any closure device used. Areas of intervention on vascular beds included iliac, femoropopliteal, and infrapopliteal regions. Types of interventions included balloon angioplasty, stent/stent graft placement, and mechanical atherectomy. Technical results recorded were successful (stenosis $\leq 30\%$), residual stenosis ($>30\%$ or 10-mm gradient), target lesion occlusion, and technical failure/unable to cross lesion.

For patients who underwent IIB for IC, procedural details analyzed were bypass graft origin (external iliac artery, common femoral artery, profunda artery, superficial femoral artery, above-/below-knee popliteal artery, or infrapopliteal artery) and bypass graft target (common femoral artery, profunda artery, superficial femoral artery, above-/below-knee popliteal artery, or infrapopliteal artery). Bypass graft conduits recorded were great saphenous vein, other vein, and prosthetic. Concomitant endarterectomy was also included in the analysis.

Perioperative outcomes for PVI analyzed were any hematoma, any stenosis/occlusion, or 30-day death. Perioperative outcomes for IIB analyzed were postoperative length of stay (LOS), 30-day death, return to the operating room, cardiac complications (new postoperative dysrhythmia, CHF, myocardial infarction), pulmonary complications (pneumonia or unplanned intubation), change in renal function, wound complication, and major/minor ipsilateral amputation. One-year outcomes for PVI and IIB included ambulatory status, reintervention (surgical, endovascular, or hybrid), any major amputation, or death. A composite outcome that included reintervention, any major amputation, or death was used.

Statistical analyses. Patient demographics, procedural characteristics, and outcomes were reported as categorical variables, number (%), or continuous variables, mean $\pm$ standard deviation or median with range, as appropriate. We performed *t* tests and χ^2 tests for continuous and categorical variables, respectively, to compare between patients with and without ESRD. Kaplan-Meier analysis was completed to compare 1-year outcomes between cohorts. Multivariable regression was conducted to determine associations with 1-year outcomes. All multivariable models included variables found to be statistically different in unadjusted analyses (using a *P* value of $<.2$). Backward elimination procedure (with a .5 level to remain in the model) was then used to reduce the models. The relationships were expressed as hazard ratios (HRs) with corresponding 95% confidence intervals (CIs). A *P* value of $<.05$ was set as statistically significant. All analyses were performed using SAS 9.3 software (SAS Institute).

To ensure the ESRD and non-ESRD groups comparability in multivariable analyses, 5:1 propensity matching with a caliper of 0.2 standard deviations was conducted for patients who underwent PVI or IIB. Logistic regression models were used to determine propensity scores. Factors included in the model for patients who underwent PVI for IC included age, sex, race, ethnicity, BMI, smoking, insurance, ambulatory and living status, HTN, DM, COPD, CAD, CHF, history of inflow PVI or bypass, leg PVI or bypass, prior amputation, preoperative medication use (aspirin, P2Y12 inhibitor, anticoagulation, and statin), access guidance modality, closure device use, type of intervention (angioplasty, stent, and atherectomy), sheath size, area of intervention (iliac, femoropopliteal, and infrapopliteal), and discharge medications (aspirin, P2Y12 inhibitor, anticoagulation, and statin). Factors included in the model in patients who underwent IIB for IC included age, sex, race, ethnicity, BMI, smoking, insurance, ambulatory and living status, HTN, DM, COPD, CAD, CHF, CABG/PCI, history of inflow PVI or bypass, leg PVI or bypass, prior amputation, preoperative hemoglobin, preoperative medication use (aspirin,

P2Y12 inhibitor, anticoagulation, and statin), graft origin, graft recipient, conduit type, concomitant endarterectomy, and discharge medications (aspirin, P2Y12 inhibitor, anticoagulation, and statin). Matching was then confirmed by matched group comparison.

RESULTS

There were 83,698 PVIs (2% ESRD and 98% non-ESRD) and 10,935 IIBs (1.2% ESRD and 98.8% non-ESRD) performed for IC. Overall, the mean age for those who underwent PVI was 67.5 years, 61.3% were male, and 40% were current smokers. The mean age for those who underwent IIB was 65.3 years, 70.6% were male, and 41.7% were current smokers.

Demographics, comorbidities, and medical history: PVIs. For PVI, patients with ESRD, compared with those without ESRD, were less often of White race (52.2% vs 83.4%), current smokers (21% vs 40.4%), and independently ambulatory (75.2% vs 90.4%) and more often on Medicare insurance (72.5% vs 53%), of Hispanic ethnicity (16% vs 4.4%), and living at home (99.4% vs 98%) (all *P* $<.001$) (Table I). Patients with ESRD, compared with those without ESRD, more often had comorbidities including HTN (95.4% vs 86.7%), DM (70.7% vs 39.3%), CAD (42.9% vs 32%), prior CABG (26% vs 19%), prior PCI (31.4% vs 25.7%), CHF (35.4% vs 12%), and preoperative anemia (26.1% vs 4.6%) (all *P* $<.001$). Patients with ESRD less often had COPD (22.4% vs 27.1%; *P* $<.001$). Obesity was similar between patients with ESRD and without ESRD (33.5% vs 32.7%; *P* = .51).

In terms of vascular history for PVI, patients with ESRD less often had a prior inflow PVI (11.2% vs 15.4%; *P* $<.001$) and prior inflow bypass (3% vs 3.9%; *P* = .035) and more often had prior any amputation (14.1% vs 3%; *P* $<.001$), prior major amputation (4.1% vs .9%; *P* $<.001$), or prior minor amputation (10.4% vs 2.1%; *P* $<.001$) compared with those without ESRD, respectively. Patients with ESRD had similar prior lower extremity PVI (22.5% vs 22.1%; *P* = .7) and bypass (8.6% vs 8.5%; *P* = .87) compared with those without ESRD, respectively. Preoperative medications differed between patients with ESRD and without ESRD, respectively, for aspirin (68.1% vs 75.3%), anticoagulants (17% vs 12.5%), and statins (71.2% vs 76.3%) (all *P* $<.001$).

Procedural details: PVIs. Patients with ESRD, compared with those without ESRD, more often had ultrasound access guidance (66.6% vs 63%) and less often had closure device deployed (93.5% vs 99.2%) after PVI (all *P* $<.001$) (Table II). Patients with ESRD more often underwent femoropopliteal (65.1% vs 59.5%) and infrapopliteal (26.5% vs 10.1%) interventions, and less often iliac interventions (32.1% vs 46.4%) (all *P* $<.001$). Patients with ESRD less often had stent/stent graft placement (45.4% vs 62.3%; *P* $<.001$) and more often had mechanical atherectomy performed (20% vs 17.8%; *P* = .011).

Table I. Baseline characteristics for patients undergoing peripheral vascular intervention (PVI) for intermittent claudication (IC) with or without end-stage renal disease (ESRD)

Characteristic	Overall (n = 83,698)	ESRD (n = 1866)	No ESRD (n = 81,832)	P value
Demographics				
Age, years	67.5 ± 10.1	64.9 ± 10.8	67.6 ± 10.1	<.001
Male sex	51,266 (61.3)	1154 (61.8)	50,112 (61.2)	.6
White race	69,190 (82.7)	973 (52.2)	68,217 (83.4)	<.001
Hispanic ethnicity	3878 (4.7)	299 (16)	3579 (4.4)	<.001
Smoking				
Never	11,077 (13.2)	619 (33.3)	10,458 (12.8)	<.001
Prior	39,130 (46.8)	849 (45.7)	38,281 (46.8)	
Current	33,427 (40)	390 (21)	33,037 (40.4)	
Primary payer				
Medicare	41,670 (53.4)	1296 (72.5)	40,374 (53)	<.001
Medicaid	5023 (6.4)	103 (5.8)	4920 (6.5)	
Commercial	29,300 (37.6)	372 (20.8)	28,928 (38)	
Other	1995 (2.4)	17 (1)	1978 (2.4)	
Ambulatory status				
Ambulatory	75,353 (90)	1403 (75.2)	73,950 (90.4)	<.001
Ambulatory with assistance	8345 (10)	463 (24.8)	7882 (9.6)	
Living status				
Home	81,980 (99.4)	1816 (98)	80,164 (99.4)	<.001
Nursing home	423 (0.5)	38 (2)	385 (0.5)	
Homeless	88 (0.1)	0 (0)	88 (0.1)	
Medical history				
HTN	72,543 (86.9)	1772 (95.4)	70,771 (86.7)	<.001
DM	33,481 (40)	1319 (70.7)	32,162 (39.3)	<.001
COPD	22,562 (27)	417 (22.4)	22,145 (27.1)	<.001
CAD	26,959 (32.2)	798 (42.9)	26,161 (32)	<.001
CABG	14,944 (19.2)	464 (26)	14,480 (19)	<.001
PCI	20,163 (25.9)	562 (31.4)	19,601 (25.7)	<.001
CHF	10,444 (12.5)	659 (35.4)	9785 (12)	<.001
Preoperative anemia (<10 g/dL)	1451 (5.1)	151 (26.1)	1300 (4.6)	<.001
BMI	28.1 ± 5.8	28.1 ± 6.1	28.1 ± 5.8	.93
Obese (BMI ≥30 kg/m ²)	27,315 (32.7)	620 (33.5)	26,695 (32.7)	.51
Vascular history				
Inflow PVI	12,709 (15.3)	197 (11.2)	12,512 (15.4)	<.001
Inflow bypass	3248 (3.9)	52 (3)	3196 (3.9)	.035
Leg PVI	18,331 (22.1)	396 (22.5)	17,935 (22.1)	.7
Leg bypass	7017 (8.5)	151 (8.6)	6866 (8.5)	.87
Prior any amputation	2735 (3.3)	260 (14.1)	2475 (3)	<.001
Prior major amputation	787 (.9)	79 (4.1)	711 (.9)	<.001
Prior minor amputation	1915 (2.3)	191 (10.4)	1724 (2.1)	<.001
Preoperative medications				
Aspirin	62,841 (75.2)	1260 (68.1)	61,581 (75.3)	<.001
P2Y12 inhibitor	33,084 (39.6)	744 (40.2)	32,340 (39.6)	.56
Anticoagulant	10,549 (12.6)	314 (17)	10,235 (12.5)	<.001
Statin	63,663 (76.2)	1319 (71.2)	62,344 (76.3)	<.001

BMI, Body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HTN, hypertension; PCI, percutaneous coronary intervention.
Values are mean ± standard deviation or number (%).

Table II. Procedural details and discharge medications for patients undergoing peripheral vascular intervention (PVI) for intermittent claudication (IC) with or without end-stage renal disease (ESRD)

Characteristic	Overall (n = 83,698)	ESRD (n = 1866)	No ESRD (n = 81,832)	P value
Access guidance				
None	11,791 (14.3)	237 (13.5)	11,554 (14.3)	<.001
Fluoroscopy	12,401 (15)	266 (15.1)	12,135 (15)	
Ultrasound	52,034 (63)	1172 (66.6)	50,862 (63)	
Open	4907 (5.9)	69 (3.9)	4838 (6)	
Combination	1415 (1.7)	17 (1)	1398 (1.7)	
Sheath size	6 (4-8)	6 (4-8)	6 (4-8)	
Closure device used	82,882 (99)	1744 (93.5)	81,138 (99.2)	<.001
Area of intervention				
Iliac	38,298 (46.1)	565 (32.1)	37,733 (46.4)	<.001
Femoropopliteal	49,549 (59.6)	1144 (65.1)	48,405 (59.5)	<.001
Infrapopliteal	8695 (10.5)	465 (26.5)	8230 (10.1)	<.001
Type of intervention				
Stent/stent graft	51,867 (62)	847 (45.4)	51,020 (62.3)	<.001
Mechanical atherectomy	14,919 (17.8)	374 (20)	14,545 (17.8)	.011
Technical result				
Successful (stenosis ≤30%)	78,035 (95)	1603 (93.2)	76,432 (95)	<.001
Residual stenosis	1570 (1.9)	46 (2.7)	1524 (1.9)	
Target lesion occlusion	245 (0.3)	15 (0.9)	230 (0.3)	
Technical failure, unable to cross lesion	2334 (2.8)	56 (3.3)	2278 (2.8)	
Medications at discharge				
Aspirin	68,344 (82.1)	1361 (74.7)	66,983 (82.2)	<.001
P2Y12 inhibitor	62,656 (75.3)	1200 (65.9)	61,456 (75.5)	<.001
Anticoagulant	11,881 (14.3)	329 (18.1)	11,552 (14.2)	<.001
Statin	67,008 (80.5)	1381 (75.8)	65,627 (80.6)	<.001

Values are median (range) or number (%).

Medications at discharge differed between patients with ESRD and those without for aspirin (74.7% vs 82.2%), P2Y12 inhibitors (65.9% vs 75.5%), anticoagulants (18.1% vs 14.2%), and statins (75.8% vs 80.6%) (all $P < .001$). Medication therapy at discharge and remained at the 1-year follow-up for aspirin was 89.1%, P2Y12 inhibitor was 73.6%, anticoagulation was 83.2%, and statin was 93.1%.

Outcomes: PVIs. There were no differences in access site complications after PVI, but patients with ESRD had higher 30-day mortality (2.2% vs 4%; $P < .001$) (Table III). At 1 year, patients with ESRD less often ambulated independently (74.3% vs 90.4%; $P < .001$). On Kaplan-Meier analysis, patients with ESRD had lower 1-year freedom from reintervention/amputation/death (62.8% vs 86.7%), major amputation/death (67.8% vs 93.9%), and survival (81.7% vs 96.6%) (all $P < .001$). On multivariable analysis for 1-year outcomes, ESRD was associated with reintervention/amputation/death (HR, 2.46; 95% CI, 2.14-2.83), major amputation/death (HR, 3.72; 95% CI, 3.15-4.4), and death (HR, 3.81; 95% CI, 3.17-4.58) (all $P < .001$) (Table IV).

Demographics, comorbidities, and medical history:

IIB. For IIB, patients with ESRD, compared with those without ESRD, were less often male (62.2% vs 70.7%), of White race (62.2% vs 83.5%), current smokers (21.3% vs 41.9%), and independently ambulatory (72.4% vs 87.7%) and more often had Medicare insurance (79.7% vs 46.2%) (all $P < .05$) (Table V). Patients with ESRD, compared with those without ESRD, again had more comorbidities such as HTN (91.7% vs 84.9%), DM (70.1% vs 38.3%), CAD (48.8% vs 29%), prior CABG/PCI (50.8% vs 34.7%), CHF (38.6% vs 10.2%), and preoperative anemia (36.2% vs 6.8%) (all $P < .05$). Prior inflow and lower extremity procedures as well as major amputations were similar between the cohorts. Preoperative aspirin, P2Y12 inhibitor, anticoagulation, and statin use were similar between groups.

Procedural details and outcomes: IIB. In IIB, patients with ESRD more often had an infrapopliteal target (33.3% vs 20%; $P < .001$) and similar great saphenous vein use (43.9% vs 50.3%; $P = .33$) (Table VI). Medications at discharge were similar except for aspirin, which was

Table III. Perioperative and 1-year outcomes for patients undergoing peripheral vascular intervention (PVI) or infrainguinal bypass (IIB) for intermittent claudication (IC) with or without end-stage renal disease (ESRD)

Characteristic	Overall (n = 83,698)	ESRD (n = 1866)	No ESRD (n = 81,832)	P value
PVI perioperative outcomes				
Any hematoma	2147 (2.6)	43 (2.3)	2104 (2.6)	.47
Any stenosis/occlusion	178 (0.2)	4 (0.2)	174 (0.2)	.99
30-day death	362 (4)	40 (2.2)	322 (0.4)	<.001
PVI 1-year outcomes				
Ambulatory status				
Ambulatory	9747 (90.2)	133 (74.3)	9614 (90.4)	<.001
Ambulatory with assistance	918 (8.5)	37 (20.7)	881 (8.3)	
Nonambulatory	146 (1.4)	9 (5)	137 (1.3)	
IIB perioperative outcomes				
LOS, days	3.8 ± 3.7	8 ± 12.7	3.7 ± 3.4	<.001
30-day death	59 (0.5)	2 (1.6)	57 (0.5)	.11
Return to operating room	423 (3.9)	12 (9.5)	411 (3.8)	.001
Cardiac complication	358 (3.3)	11 (8.7)	347 (3.2)	.001
Respiratory complication	98 (0.9)	3 (2.4)	95 (0.9)	.078
Change in renal function	258 (2.4)	11 (8.7)	247 (2.3)	<.001
Wound complication	189 (1.7)	9 (7.1)	180 (1.7)	<.001
Major ipsilateral amputation	25 (0.2)	5 (3.9)	20 (0.2)	<.001
Minor ipsilateral amputation	94 (0.9)	6 (4.7)	88 (0.8)	<.001
IIB 1-year outcomes				
Ambulatory status				
Ambulatory	1595 (88.3)	8 (66.7)	1587 (88.5)	.006
Ambulatory with assistance	162 (9)	2 (16.7)	160 (8.9)	
Nonambulatory	49 (2.7)	2 (16.7)	47 (2.6)	

LOS, Length of stay.
Values are mean ± standard deviation or number (%).

Table IV. Multivariable analysis in patients with intermittent claudication (IC) who underwent lower extremity revascularization for 1-year outcomes

Covariate (ESRD vs no ESRD)	HR	95% CI	P value
PVI			
Reintervention/major amputation/death	2.46	2.14-2.83	<.001
Major amputation/death	3.72	3.15-4.4	<.001
Death	3.81	3.17-4.58	<.001
Infrainguinal bypass			
Reintervention/major amputation/death	1.73	1.04-2.87	.034
Major amputation/death	2.86	1.59-5.15	.001
Death	3.58	1.86-6.9	<.001

CI, Confidence interval; ESRD, end-stage renal disease; HR, hazard ratio.
Analysis was performed with propensity matched data (5:1) and compared patients with ESRD with patients without ESRD.

prescribed less often in patients with ESRD (79.5% vs 85.8%; $P = .044$). Patients with ESRD had a significantly longer mean LOS (8.0 days vs 3.7 days; $P < .001$) compared with those without ESRD (Table III). Patients with ESRD more often returned to the operating room (9.5% vs 3.8%), had cardiac complications (8.7% vs 3.2%; $P = .001$), wound complications (7.1% vs 1.7%),

minor ipsilateral amputation (4.7% vs 0.8%), and major ipsilateral amputation (3.9% vs 0.2%) (all $P < .05$). However, patients with ESRD and those without ESRD had similar 30-day mortality rates (1.6% vs 0.5%; $P = .11$). At 1 year, patients with ESRD less often ambulated independently (66.7% vs 88.5%; $P = .006$). Propensity-matched data showed similar results. On Kaplan-Meier analysis,

Table V. Baseline characteristics and preoperative medications for patients undergoing infrainguinal bypass (IIB) for intermittent claudication (IC) with or without end-stage renal disease (ESRD)

Characteristic	Overall (n = 10,935)	ESRD (n = 127)	No ESRD (n = 10,808)	P value
Demographics				
Age, years	65.3 ± 10.0	64.9 ± 10.2	65.3 ± 10.0	.68
Male sex	7720 (70.6)	79 (62.2)	7641 (70.7)	.037
White race	9098 (83.2)	79 (62.2)	9019 (83.5)	<.001
Hispanic ethnicity	366 (3.4)	4 (3.1)	362 (3.4)	.89
Smoking				
Never	1088 (10)	33 (26)	1055 (9.8)	<.001
Prior	5286 (48.4)	67 (52.8)	5219 (48.3)	
Current	4557 (41.7)	27 (21.3)	4530 (41.9)	
Primary payer				
Medicare	4671 (46.6)	94 (79.7)	4577 (46.2)	<.001
Medicaid	789 (7.9)	5 (4.2)	784 (7.9)	
Commercial	4224 (42.2)	19 (16.1)	4205 (42.5)	
Other	333 (3)	0 (0)	333 (3.1)	
Ambulatory status				
Ambulatory	9551 (87.5)	92 (72.4)	9459 (87.7)	<.001
Ambulatory with assistance	1362 (12.5)	35 (27.6)	1327 (12.3)	
Living status				
Home	10,809 (99.1)	124 (97.6)	10,685 (99.1)	.24
Nursing home	69 (0.6)	2 (1.6)	67 (0.6)	
Homeless	32 (0.3)	1 (0.8)	31 (0.3)	
Medical history				
HTN	8255 (84.9)	100 (91.7)	8155 (84.9)	.046
DM	4231 (38.7)	89 (70.1)	4142 (38.3)	<.001
COPD	2933 (26.8)	30 (23.6)	2903 (26.9)	.41
CAD	3191 (29.2)	62 (48.8)	3129 (29)	<.001
CABG/PCI	3498 (34.8)	60 (50.8)	3438 (34.7)	<.001
CHF	1153 (10.5)	49 (38.6)	1104 (10.2)	<.001
Preoperative anemia (<10 g/dL)	777 (7.2)	46 (36.2)	731 (6.8)	<.001
BMI	28.2 ± 5.7	27.7 ± 5.8	28.2 ± 5.7	.29
Obese (BMI ≥30 kg/m ²)	3661 (33.5)	42 (33.1)	3619 (33.5)	.91
Vascular history				
Inflow PVI	2162 (19.8)	17 (13.4)	2145 (19.9)	.069
Inflow bypass	938 (8.6)	8 (6.3)	930 (8.6)	.36
Leg PVI	4045 (37)	37 (29.1)	4008 (37.1)	.064
Leg bypass	1915 (17.5)	20 (15.7)	1895 (17.5)	.6
Prior major amputation	107 (1)	3 (2.4)	104 (1)	.11
Prior minor amputation	300 (2.7)	16 (12.6)	284 (2.6)	<.001
Preoperative medications				
Aspirin	8130 (74.4)	86 (67.7)	8044 (74.4)	.084
P2Y12 inhibitor	3813 (34.9)	49 (38.6)	3764 (34.8)	.38
Anticoagulant	1520 (15.2)	16 (13.7)	1504 (15.2)	.65
Statin	8385 (76.7)	94 (74)	8291 (76.7)	.47

BMI, Body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HTN, hypertension; PCI, percutaneous coronary intervention.
Values are mean ± standard deviation or number (%).

Table VI. Procedural details and discharge medications for patients undergoing infrainguinal bypass (IIB) for intermittent claudication (IC) with or without end-stage renal disease (ESRD)

Characteristic	Overall (n = 10,935)	ESRD (n = 127)	No ESRD (n = 10,808)	P value
Procedure				
Graft origin				
External iliac artery	356 (3.3)	6 (4.8)	350 (3.3)	.15
Common femoral artery	8418 (77.4)	96 (76.8)	8322 (77.4)	
Profunda artery	227 (2.1)	0 (0)	227 (2.1)	
Superficial femoral artery	1422 (13.1)	16 (12.8)	1406 (13.1)	
Above-knee popliteal artery	332 (3.1)	3 (2.4)	329 (3.1)	
Below-knee popliteal artery	114 (1)	4 (3.2)	110 (1)	
Infrapopliteal artery	13 (0.1)	0 (0)	13 (0.1)	
Graft target				
Common femoral artery	466 (4.3)	3 (2.4)	463 (4.3)	<.001
Profunda artery	180 (1.7)	5 (4)	175 (1.6)	
Superficial femoral artery	241 (2.2)	6 (4.8)	235 (2.2)	
Above-knee popliteal artery	4199 (38.6)	27 (21.4)	4172 (38.8)	
Below-knee popliteal artery	3606 (33.1)	43 (34.1)	3563 (33.1)	
Infrapopliteal artery	2192 (20.1)	42 (33.3)	2150 (20)	
Graft type				
Great saphenous vein	5434 (50.2)	54 (43.9)	5380 (50.3)	.33
Other vein	394 (3.6)	6 (4.9)	388 (3.6)	
Prosthetic	4987 (46.1)	63 (51.2)	4924 (46.1)	
Concomitant endarterectomy	3320 (30.4)	49 (38.6)	3271 (30.3)	.044
Medications at discharge				
Aspirin	9362 (85.7)	101 (79.5)	9261 (85.8)	.044
P2Y12 inhibitor	5502 (50.4)	58 (45.7)	5444 (50.5)	.28
Anticoagulant	2320 (21.3)	35 (27.6)	2285 (21.2)	.081
Statin	9011 (82.5)	98 (77.2)	8913 (82.6)	.11

Values are number (%).

patients with ESRD had lower 1-year freedom from reintervention/major amputation/death (66.7% vs 81.3%), major amputation/death (70.3% vs 93.7%), and survival (81.6% vs 96.3%) (all $P < .001$). On multivariable analysis for 1-year outcomes, ESRD was associated with reintervention/major amputation/death (HR, 1.72; 95% CI, 1.04-2.87; $P = .034$), amputation/death (HR, 2.87; 95% CI 1.59-5.15; $P = .001$), and death (HR, 3.58; 95% CI, 1.86-6.9; $P < .001$) (Table IV). Medication therapy at discharge and remained at the 1-year follow-up for aspirin was 86.9%, P2Y12 inhibitor was 76.8%, anticoagulation was 75.1%, and statin was 91.8%.

DISCUSSION

Our analysis demonstrated that patients with ESRD had higher 1-year major amputation/death, MALE/death, and death rates after PVI or IIB compared with those without ESRD. Patients with ESRD after PVI had similar perioperative access site complications, but had higher 30-day mortality. Patients with ESRD after IIB had longer LOS and had higher rates of cardiac and wound

complications as well as any ipsilateral amputation. After PVI or IIB, patients with ESRD less often ambulated independently at 1 year.

ESRD in our study was independently associated with 1-year major amputation/death after PVI or IIB. This finding is broadly consistent with other studies. However, these studies analyzed patients with CKD and ESRD as one group and mostly included those with CLTI, whereas our study focuses on patient with ESRD and IC.¹² One meta-analysis compared major amputation after lower extremity intervention for IC and CLTI between patients with CKD or ESRD and those without CKD or ESRD.¹⁴ The rate of major amputation was not surprisingly higher in patients with CKD or ESRD after intervention. Interventions performed for CLTI, between patients with CKD or ESRD and those without, was more likely associated with major amputation, whereas interventions performed for IC was similar for major amputation. This conflicting finding is likely related to the homogeneous study population of patients with CKD and ESRD being analyzed. A large Swedish population-based

study demonstrated a 1-year major amputation rate of 0.2% after revascularization.¹⁵ However, a study using the US Renal Data System (USRDS) database reported a 3.2% major amputation at 30 days and 8.7% major amputation/death at 30 days after revascularization for claudication.¹⁶ Further analysis of 30-day outcomes demonstrated that PVI compared with IIB, respectively, had a similar 30-day major amputation rate, but IIB had a higher 30-day major amputation/death rate that was largely driven by death.¹⁶

ESRD was associated with 1-year reintervention/major amputation/death after PVI or IIB in our analysis. An analysis using the vascular targeted National Surgical Quality Improvement Program database reported a similar 30-day reintervention/major amputation rate after PVI (3.2%) and lower extremity bypass (4%).¹⁷ Infrapopliteal intervention and prior bypass were associated with 30-day reintervention/major amputation. ESRD was not associated with 30-day reintervention/major amputation on multivariable analysis, but it was associated with 30-day myocardial infarction, stroke, or death. In our study, 26.5% of PVI were in the infrapopliteal vascular bed and 33.3% of IIBs had an infrapopliteal target for IC. In a VQI study that analyzed PVI performed for IC in patients without a prior history of lower extremity PVI or bypass demonstrated that tibial interventions were associated with increased odds for major or minor amputation.¹⁸ Another study showed that infrapopliteal bypasses at 1 year were independently associated with increased occlusion/death, major ipsilateral amputation/death, and ipsilateral reintervention/amputation/death, but had similar patient survival.¹⁹ These interventions are associated with an increased risk for patients and a shared decision-making process that carefully balances the patient's anatomy, comorbidities, quality of life, and durability of the intervention.

The 30-day mortality rate was similar to other studies, including ones that analyzed the National Inpatient Sample and the USRDS.^{16,20} In the USRDS study, 67% of patients with IC were alive at 1 year. Patients with ESRD who underwent PVI had slightly higher survival rate compared with those who underwent open surgical revascularization. In our multivariable analysis, ESRD was independently associated with 1-year death after PVI or IIB. Death was higher in patients with CKD or ESRD in those undergoing lower extremity intervention compared with those without CKD or ESRD.¹⁴ In a Medicare-linked VQI Vascular Implant Surveillance and Interventional Outcomes Network analysis, ESRD was associated with 5-year mortality in patients who underwent PVI (37.2%) or IIB (37.8%) for IC.⁶ This high mortality rate suggest that patients may not gain meaningful benefit from an intervention for IC given that long-term survival is poor. As such, the decision to intervene should be weighed carefully.

Ambulatory status is a cornerstone outcome measure after lower extremity interventions. At 1 year, patients with ESRD who underwent PVI or IIB in our study were more often ambulating with assistance or nonambulatory. In the Vascular Study Group of New England, reported ambulatory status at 1 year after PVIs, IIBs, and suprainguinal bypasses performed for IC demonstrated that those who were initially ambulating independently became ambulatory with assistance or nonambulatory after PVI.¹¹ At 1 year after IIB, patients who were initially ambulating independently became ambulatory with assistance or nonambulatory.¹¹ These changes in ambulatory status are important to balance against when considering performing revascularization in those with IC. Furthermore, 25% of patients with ESRD were not ambulatory independently preoperatively, which further suggests that the overuse of PVI and IIB for IC may be more prevalent than expected; one Medicare study demonstrated that early PVI rate (defined as <6 months of IC diagnosis) at the physician level was 0% to 58.3% among 5664 physicians, of which 5.6% had an early PVI rate of $\geq 14.0\%$.²¹ These interventions were more often performed at an ambulatory surgical center or office setting.²¹ As such, in patients with claudication with ESRD, it should be a shared decision-making process between the patient and the surgeon to determine whether to pursue a more aggressive operation for claudication based on the patient's anatomy, comorbidities, quality of life, and durability of the intervention. The Society for Vascular Surgery appropriate use criteria guideline for IC states that invasive treatment should be considered in select patients with IC who have a low physiological and technical risk as well as to consider the long-term durability of treatment modality.¹⁰ In the femoropopliteal segment, invasive treatment should be carefully selected and reserved for patients with severe lifestyle-limiting claudication.¹⁰ In the infrapopliteal segment, it is unclear whether invasive treatment is beneficial or could be harmful.¹⁰ The risks and benefits should be carefully discussed with patients and all nonoperative measures should be implemented before consideration for an invasive intervention.

Our analysis is limited by its retrospective nature. Selection bias is present in those who undergo an intervention; the VQI only includes patients who underwent an operation and the degree of claudication is subjectively reported. However, the VQI undergoes annual audits to verify its accuracy and completeness. In addition, the type of operation (PVI vs IIB) being selected influences outcomes as well as the 1-year follow-up for each cohort. However, these data provide further insights on the risks and benefits of revascularization in this high-risk patient population.

CONCLUSIONS

Patients with ESRD have greater perioperative morbidity and long-term ambulatory impairment, limb loss, and mortality. The risks/benefit profile should be assessed carefully, and noninvasive interventions should be maximized in this population.

AUTHOR CONTRIBUTIONS

Conception and design: TC

Analysis and interpretation: TC, AF, MH, EK, ST, AA, KN, CH, MM, DR, JS

Data collection: TC, DR, JS

Writing the article: TC

Critical revision of the article: TC, AF, MH, EK, ST, AA, KN, CH, MM, DR, JS

Final approval of the article: TC, AF, MH, EK, ST, AA, KN, CH, MM, DR, JS

Statistical analysis: TC, DR, JS

Obtained funding: Not applicable

Overall responsibility: JS

FUNDING

None.

DISCLOSURES

None.

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Submitted Aug 3, 2025; accepted Dec 5, 2025.