



Vascular

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Trends in mortality, readmissions, and complications after endovascular and open infrainguinal revascularization

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ABSTRACT

Background: Although short-term outcomes of endovascular and open infrainguinal revascularization in patients with peripheral arterial disease have been previously reported, 30-day readmission and resource utilization after these procedures remain unknown.

Methods: We used the 2010–2014 Nationwide Readmissions Database and the *International Classification of Diseases, Ninth Edition*, to identify patients with peripheral arterial disease undergoing either in-hospital endovascular or open infrainguinal revascularization.

Results: Of an estimated 574,201 hospitalized patients treated for peripheral arterial disease, 308,056 and 266,145 underwent lower limb endovascular and open infrainguinal revascularization, respectively. Compared with patients who underwent open revascularization, endovascular patients were more commonly female (44.8% vs 36.7%, $P < .001$) and older (69.5 vs 67.2 years, $P < .001$). Moreover, they had higher rates of 30-day readmission (15.6% vs 13.5%, $P < .001$), in-hospital complications (22.3% vs 20.9%, $P < .001$), and in-hospital index mortality (2.1% vs 1.8%, $P < .001$). In contrast, risk-adjusted multivariable analysis found open revascularization to be independently associated with increased odds of 30-day readmission (odds ratio, 1.13; 95% confidence interval 1.10–1.16), index complications (odds ratio, 1.23; 95% confidence interval 1.20–1.27), and mortality (odds ratio, 1.26; 95% confidence interval 1.16–1.36) compared with those who underwent endovascular revascularization. Trend analysis revealed an overall decrease in the utilization of both endovascular and open revascularization procedures in the inpatient setting.

Conclusion: Despite lower rates of adverse events compared to endovascular, open infrainguinal revascularization is independently associated with increased risk of short-term readmission, complications, and mortality. These findings should be considered in the selection of appropriate surgical therapy for lower extremity arterial occlusive disease.

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Lower extremity peripheral arterial disease (PAD) affects 8 million people in the United States and accounts for >400,000 annual hospital admissions.^{1,2} With advances in interventional vascular techniques, rates of procedures aimed at treating PAD have markedly increased throughout the past two decades.¹ Although revascularization typically involves open or endovascular techniques, the latter has gained more rapid adoption

owing to its accelerated recovery and reduced cardiovascular risk.^{3–7} With increasing use of endovascular compared with open infrainguinal revascularization, there is mounting interest in analyzing patient outcomes and economic differences between the methods. Unplanned readmission and mortality within 30 days following lower extremity bypass have been previously reported to range between 12.3% to 23.0% and 0.5% to 2.0%, respectively.^{2,7–9} Postoperative complications after open procedures are well documented and are associated with poor patient outcomes and increased resource use in many specialties, including vascular surgery.^{10–12} Although others have reported clinical outcomes of endovascular and open infrainguinal revascularization in patients with PAD, 30-day readmission

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outcomes and resource utilization after these procedures remain largely uncharacterized.

Given the rapid increase in the utilization of endovascular technologies in the treatment of infrainguinal PAD and concomitant increase in healthcare expenditure, the present study aimed to compare in-hospital mortality and complications as well as 30-day readmissions for endovascular and open methods. We hypothesized that endovascular revascularization would yield lower rates of in-hospital mortality, surgical complications, and 30-day readmissions compared to open procedures.

Methods

Patient data was collected from the 2010 to 2014 Nationwide Readmissions Database (NRD). Developed by the Agency for Healthcare Research and Quality as part of the Healthcare Cost and Utilization Project, the NRD is a publicly available repository that includes all-payer hospital discharge data.¹³ The NRD accrues data from State Inpatient Databases, containing unique patient linkage variables that track patients across hospitals (excluding long-term acute and rehabilitation facilities). The NRD contains more than half of all US hospitalizations and discharges.¹³ Discharge weights assigned to patients and hospitals are used to generate accurate national estimates.

Using the *International Classification of Disease, Ninth Edition* (ICD-9) codes, adult patients (>18 years) with PAD (ICD-9: 440.0, 440.2x, 440.3x, 440.9, 443.9) undergoing in-hospital lower limb endovascular revascularization (ICD-9: 39.50, 39.90) or open infrainguinal revascularization (ICD-9: 38.18, 38.48, 39.25, 39.29, 39.49, 39.57) were identified. The aforementioned ICD-9 codes were chosen in our study based on previously published methods for analysis of PAD in vascular patients.^{1,14} Patients with concomitant operations, such as coronary artery bypass grafting, valve repair or replacement, or aortic arch interventions were excluded. Subjects who underwent operations in December also were excluded owing to insufficient data on 30-day readmissions. Patients were divided into 2 cohorts based on treatment approach: endovascular (endo) or open infrainguinal revascularization (open).

Baseline characteristics for the study included patient age, sex, insurance status, and comorbidities such as anemia, chronic kidney disease, chronic lung disease, congestive heart failure, diabetes, hypertension, hypothyroidism, liver disease, neurologic disorders, and obesity. The burden of chronic comorbidities was characterized using the Elixhauser comorbidity index.¹⁵ Hospital level variables included teaching institution and metropolitan status as well as bed size. In-hospital complications were defined using ICD-9 codes and then categorized by systems, including cardiovascular, gastrointestinal, infectious, neurological, renal, respiratory, and thromboembolic.

The primary outcomes of interest for this study were 30-day unplanned readmissions in patients with PAD undergoing either endovascular or open infrainguinal revascularization. Secondary outcomes included postoperative complications, in-hospital mortality, duration of stay, index hospitalization costs, readmission costs, and temporal trends in revascularization procedures for PAD. Hospitalization costs were calculated by multiplying the charge of hospitalization by the NRD cost-to-charge ratios and were then adjusted for inflation using the gross-domestic product adjustments available through the US Bureau of Labor Statistics Consumer Price Index, with 2014 as the baseline year.

All statistical analyses for this study were performed using Stata 15.0 (StataCorp, College Station, TX). Survey-weighted univariate Student's *t* test and χ^2 analysis were used for continuous and categorical variables, respectively. The independent impact of surgical approach on mortality, complications, and readmission was

assessed using multivariable logistic regression and was risk-adjusted for patient and hospital variables. The number of operations per 100,000 in the US population was obtained using estimates from the United States Census Bureau. The Royston Ptrend method was used to assess temporal trends in categorical variables.¹⁶ Because the NRD is a publicly available database containing deidentified data, this study was deemed exempt from our Institutional Review Board at the University of California, Los Angeles.

Results

Incidence of peripheral arterial disease

Of an estimated 574,201 patients treated for PAD during the study period, 308,056 (53.6%) received endovascular and 266,145 (46.4%) open infrainguinal revascularization. The overall annual rate of inpatient procedural treatment significantly declined ($P = .003$) for both methods, as shown in [Figure](#). Per capita, similar reductions were noted for endovascular (22.0–18.1 per 100,000, $P < .001$) and open approaches (20.417.8 per 100,000, $P < .001$; [Figure, A and B](#)).

Patient and hospital characteristics

Baseline patient and hospital characteristics are shown in [Table I](#). Compared with open, the endo cohort was older (69.5 vs 67.2 years, $P < .001$) and more commonly female (44.8% vs 36.7%, $P < .001$). Endo patients had higher rates of all comorbidities except for chronic pulmonary disease and had overall greater Elixhauser comorbidity indices (4.4% vs 3.9, $P < .001$). Those in the endo group were less likely to be privately insured (13.9% vs 20.9%, $P < .001$) and had higher rates of Medicare coverage (74.1% vs 66.3%, $P < .001$). Compared with the open, primary treatment indication in the endo cohort was more likely for limb threat (43.5% vs 40.5%, $P < .001$) and less frequently for claudication (21.2% vs 28.7%). Open infrainguinal revascularization was performed more often in teaching hospitals (58.4% vs 61.8%, $P < .001$) compared with endovascular revascularization. Nearly all operations (99.7%) were performed in urban hospitals. No significant differences were found regarding hospital bed size between the 2 cohorts ([Table I](#)).

Rates of mortality, complications, 30-day readmission, and resource utilization

Adverse postoperative outcomes and resource utilization associated with each operative approach are illustrated in [Table II](#). On unadjusted analysis, the endo cohort had higher rates of in-hospital mortality (2.1% vs 1.8%, $P < .001$), postoperative complications (22.3% vs 20.9%, $P < .001$), and emergent 30-day readmission (15.6% vs 13.5%, $P < .001$) compared with the open cohort. Similarly, endo patients were associated with higher costs of hospitalization during index admission (\$25,782 vs \$22,646, $P < .001$), and 30-day readmission (\$16,840 vs \$16,017, $P < .001$; [Table II](#)).

Independent impact of endovascular versus open infrainguinal revascularization on outcomes

Using a multivariable logistic regression adjusting for baseline differences among groups, the open approach was associated with increased risk of adverse outcomes when compared with endovascular, as shown in [Table III](#). Open infrainguinal revascularization was independently associated with increased in-hospital mortality (odds ratio [OR] 1.26; 95% confidence interval [CI], 1.16–1.36), postoperative complications (OR 1.23; 95% CI, 1.20–1.27), and 30-day readmissions (OR 1.13; 95% CI, 1.10–1.16; [Table III](#)).

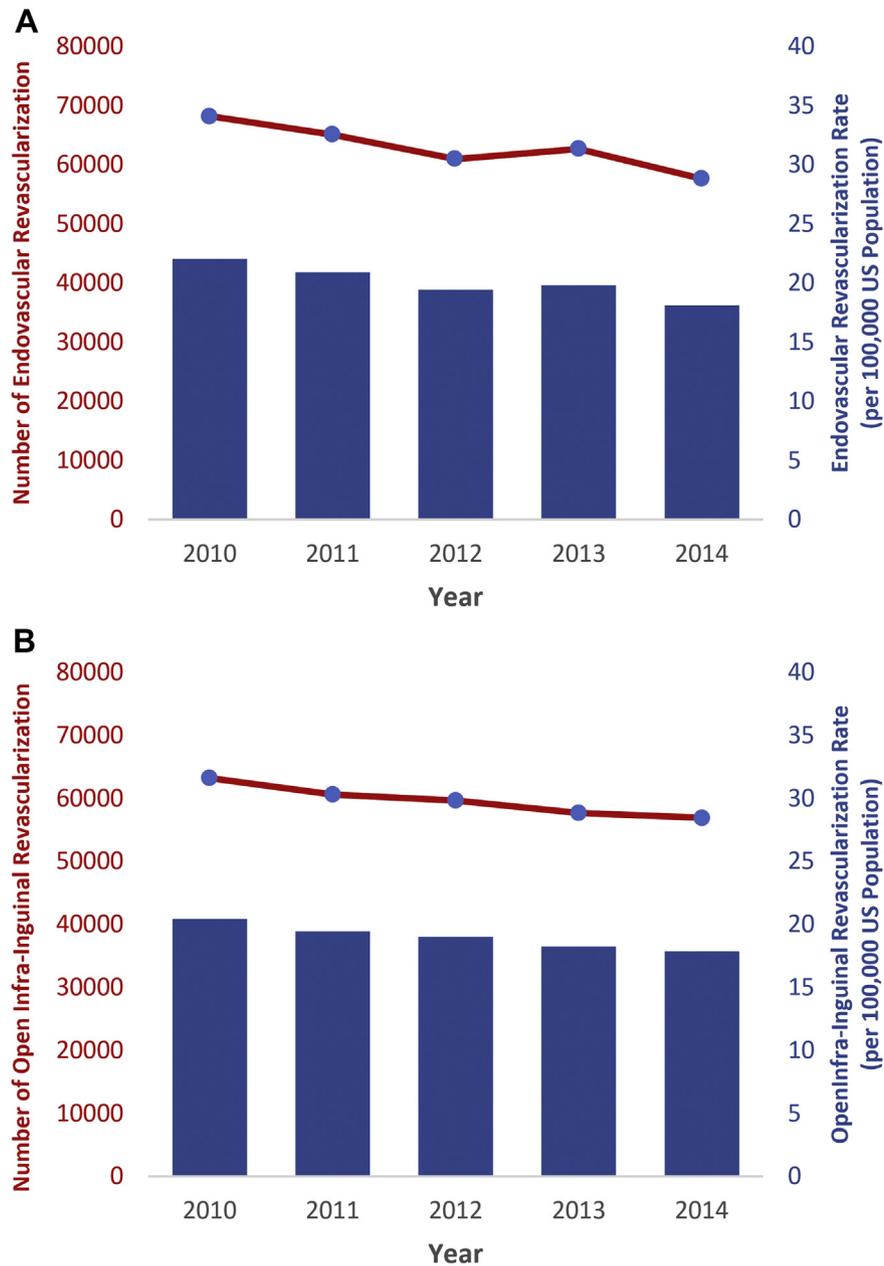


Figure. Incidence of in-hospital endovascular and open infrainguinal revascularization. (A) Incidence of endovascular revascularization. (B) Incidence of open infrainguinal revascularization.

Discussion

With an aging population and increased medical surveillance in the United States, the incidence of PAD has increased during the past several decades, affecting ≈ 10 million at the present time.^{17,18} Although PAD is asymptomatic in a subset of patients, it may present as intermittent claudication or critical limb ischemia in many. Characterizing the optimal approach for treating symptomatic PAD is critical to reducing the associated morbidity of these procedures and enhancing the overall value of care. In this nationwide analysis comparing inpatient endovascular and open infrainguinal revascularization for a wide range of lower extremity PAD, we report several important findings. Rates of both open and endovascular in-hospital procedures for the treatment of infrainguinal disease have significantly decreased during the past 5 years with open exhibiting a more dramatic decline. Second, patients who undergo

endovascular revascularization are generally older and have more chronic illnesses likely contributing to the observed increase in mortality, complications, and readmissions with this approach. Third, the treatment of PAD contributes to significant increases in costs to the healthcare system. Most important, open infrainguinal revascularization is independently associated with increased risk of mortality, complications, and readmissions. These findings warrant further discussion.

Several prior trend analyses have examined patterns of PAD treatment in the United States.^{1,7,14} Using the National Inpatient Sample Database, others have reported a decline in open but an increase in utilization of endovascular revascularization during 1998 to 2003,⁷ 1996 to 2005,¹ and 2003 to 2011.¹⁴ Our findings indicate a reduction in rates of both endovascular and open infrainguinal in-hospital revascularization during 2010 to 2014, with the latter exhibiting a more rapid decline. Earlier detection of PAD and

Table I
Baseline patients and hospital characteristics

	Endovascular (n = 308,056)	Open (n = 266,145)	P value
Age, y	69.5	67.2	<.001
Age >75 y, %	33.6	24.4	<.001
Female, %	44.8	36.7	<.001
Insurance, %			
Private	13.9	20.9	<.001
Medicare	74.1	66.3	
Medicaid	7.6	8.2	
Other	4.4	4.7	
Comorbidities, %			
Anemia	24.6	17.0	<.001
Chronic kidney disease	32.7	17.8	<.001
Chronic pulmonary disease	23.2	29.6	<.001
Congestive heart failure	8.5	3.3	<.001
Diabetes	49.1	37.7	<.001
Hypertension	77.8	78.0	.552
Hypothyroidism	10.4	8.4	<.001
Liver disease	1.8	1.6	<.001
Neurologic disorders	5.6	4.6	<.001
Obesity	10.4	9.4	<.001
Elixhauser comorbidity index, n	4.4	3.9	<.001
Treatment indication			
Claudication	21.2	28.7	<.001
Limb threat	43.5	40.5	<.001
Other peripheral arterial disease	35.3	30.8	<.001
Teaching hospital, %	58.4	61.8	<.001
Hospital location, %			
Urban	99.7	99.7	.212
Rural	0.3	0.3	
Hospital bed size, %			
Small	8.8	9.5	.131
Medium	22.6	21.3	
Large	68.6	69.2	

Table II
Postoperative adverse events and resource utilization

	Endovascular (n = 308,056)	Open (n = 266,145)	P value
In-hospital mortality, %	2.1	1.8	<.001
In-hospital complications, %	22.3	2.9	<.001
Cardiovascular	6.5	4.7	<.001
Gastrointestinal	.6	.3	<.001
Infectious	5.3	4.0	<.001
Renal	.8	.5	<.001
Respiratory	1.1	12.8	<.001
Neurologic	2.1	1.9	.001
Thromboembolic	2.8	1.8	<.001
Index duration of stay, d	7.0	7.2	.033
Index hospitalization cost, \$	25,782	22,646	<.001
30-d readmission, %	15.6	13.5	<.001
Cost of readmission, \$	16,840	16,017	<.001

Table III
Independent impact of open infrainguinal revascularization in mortality, complications, and 30-day readmission (with endovascular revascularization as reference)

Operation	Outcome	Odds ratio	95% confidence interval	P value
Endovascular revascularization	Reference	Reference	Reference	Reference
Open revascularization	Mortality	1.26	1.16–1.36	<.001
	Complications	1.23	1.20–1.27	<.001
	30-d readmissions	1.13	1.10–1.16	<.001

improved medical management of the disease may explain the decline in revascularization procedures. The plateau effect seen in endovascular revascularization procedures also may be partly due to decreased rates of reintervention with newer generation therapies and stent-grafts in particular.¹⁹ Recent increases and incentivization of facilities to perform ambulatory endovascular procedures may be

an important driver for our observation. Moreover, we found that endovascular revascularization was performed more commonly than open infrainguinal revascularization for the treatment of lower limb PAD, as previously reported.^{3,14}

The benefits of endovascular compared with open infrainguinal revascularization have been well-documented in the literature.

Endovascular revascularization has been associated with decreased wound complications, shorter duration of stay, and decreased costs.^{1,20–25} Furthermore, endovascular interventions have proved useful in patients who are poor candidates for open infrainguinal revascularization.³ Last, endovascular revascularization is associated with decreased in-hospital mortality compared with open infrainguinal revascularization.¹⁴ In the present analysis, we found open, and not endovascular, infrainguinal revascularization to be an independent predictor of in-hospital mortality and complications after adjusting for baseline characteristics. The observed association of endovascular revascularization with increased rates of mortality and complications is likely due to increased adverse patient characteristics. For instance, patients undergoing endovascular revascularization had higher rates of risk factors for adverse cardiovascular events, such as diabetes, congestive heart failure, and chronic kidney disease. The endovascular approach was independently associated with fewer complications despite a lower overall socioeconomic status in this group.

The present study provides unique insight into the prevalence of 30-day readmission with each revascularization approach. Thirty-day readmission after hospitalization for critical limb ischemia has traditionally ranged between 14.0% and 29.6%.^{9,26–32} However, few have compared unplanned readmission after lower limb open infrainguinal and endovascular revascularization. Jackson et al reported a readmission rate of 14.6% to 7.3% for open and endovascular lower extremity revascularization, respectively.²⁶ However, this study was limited by a small sample size. Kolte et al recently characterized 30-day readmission for revascularization to treat critical limb ischemia³² and found a higher rate of readmission in the endovascular approach (21.2%) compared with open (17.8%), yet they did not find either endo or open to be independently associated with readmission. Using the same database as Kolte et al, we included a larger cohort of patients and found lower rates of readmission for both modalities. More importantly, on multivariable analysis, we found open infrainguinal revascularization to be independently associated with greater odds of 30-day readmission, likely because of its invasive nature.

A concerning finding in our study was the significant increase in healthcare costs associated with readmissions after lower limb revascularization. Readmissions have been associated with worse outcomes after many types of operations³³ and have placed a significant financial burden on patients and the healthcare system.³⁴ We found the average costs of readmissions for both open and endovascular methods of revascularization to be ≈\$16,000, accounting for an estimated annual expenditure of >\$280 million. Although the value of readmission reduction has been questioned, such unplanned rehospitalizations are at the very least extremely costly to the healthcare system. Our findings may provide a tangible target for policymakers and hospital institutions interested in increasing value of healthcare.

This study has several important limitations. First, the nature of this study is retrospective and is subject to selection bias. Second, the variables within the database are generated using procedural and diagnostic codes, which are subject to coding and reporting biases. Third, the NRD does not include race or clinical information regarding medications or laboratory values, which are important variables in patient outcomes. Fourth, the cohort characterized in this study represented a wide range of patients with PAD, making our results applicable to a broad mixture of patients with lower extremity occlusive disease. We attempted to reduce the impact of such limitations by analyzing all-payer patient data and using risk-adjusted multivariable methodologies. Furthermore, the NRD only captures in-hospital procedures and does not capture procedures undertaken in an ambulatory setting. Last, anatomic differences are likely present between the 2 procedures but cannot be anticipated

in the database and were not included in the study. The Trans-Atlantic Inter-Society Consensus generally recommends endovascular and open bypass revascularization to be performed on shorter segment diseases and multiple occlusive diseases, respectively, leading to further bias in our findings.³⁵

In conclusion, the benefits of endovascular revascularization compared with open infrainguinal revascularization for lower limb peripheral arterial disease has not been fully characterized. Our study analyzed the outcomes and resource utilization after revascularization modalities and is the first to report significant results on the independent impact of open infrainguinal revascularization on in-hospital mortality, complications, and 30-day readmissions. Future prospective studies and clinical trials are essential to the continued optimization of treatment algorithms for the treatment of lower limb peripheral arterial disease.

Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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