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Endovascular vs. Open Revascularization for Peripheral Arterial Disease

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MINI-ABSTRACT

We determine whether endovascular or open revascularization provides an advantageous approach in treatment of symptomatic peripheral arterial disease for propensity-score matched cohorts of Medicare beneficiaries. We demonstrate that an endovascular approach is associated with improved long-term amputation free survival with only a modest relative increased risk of subsequent intervention.

Abstract

Objective—To determine whether endovascular or open revascularization provides an advantageous approach to symptomatic peripheral arterial disease (PAD) over the longer term.

Summary Background Data: The optimal revascularization strategy for symptomatic lower extremity PAD is not established.

Methods—We evaluated amputation free survival, overall survival and relative rate of subsequent vascular intervention after endovascular or open lower extremity revascularization for propensity-score matched cohorts of Medicare beneficiaries with PAD from 2006 through 2009.

Results—Among 14,685 eligible patients, 5,928 endovascular and 5,928 open revascularization patients were included in matched analysis. Patients undergoing endovascular repair had improved amputation free survival compared to open repair at 30-days (7.4 vs. 8.9%, p=0.002). This benefit persisted over the long-term: At 4-years, 49% of endovascular patients had died or received major amputation compared to 54% of open patients (p<0.001). An endovascular procedure was associated with a risk-adjusted 16% decreased risk of amputation or death compared to open over the study period (hazard ratio: 0.84; 95% confidence interval, 0.79–0.89; p<0.001). The amputation free survival benefit associated with an endovascular revascularization was more

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pronounced in patients with congestive heart failure or ischemic heart disease than in those without (p=0.021 for interaction term). The rate of subsequent intervention at 30-days was 7.4% greater for the endovascular versus the open revascularization cohort. At 4-years, this difference remained stable at 8.6%.

Conclusions—Using population-based data, we demonstrate that an endovascular approach is associated with improved amputation free survival over the long-term with only a modest relative increased risk of subsequent intervention.

INTRODUCTION

Lower extremity peripheral arterial disease (PAD) is the most under-diagnosed cardiovascular disorder in the United States and affects over 12 million individuals.[1–5] Patients with symptomatic PAD classically experience intermittent claudication (i.e. exertional muscular calf or thigh pain during walking that resolves with rest), with progression to critical limb ischemia (i.e. rest pain, ulceration, gangrene necrosis) in up to 25% of patients.[6] Treatment for symptomatic patients who fail conservative management has traditionally been surgical revascularization. However beginning in the 1980's, patients are more often offered a less invasive endovascular approach which is now widely utilized.[7,8]

The optimal revascularization strategy for symptomatic lower extremity PAD is not well established. Existing randomized controlled trials comparing endovascular to open revascularization for lower extremity PAD have been limited by patient selection and the inability to generalize findings beyond specialized centers.[9–16] Given the lack of high-quality comparative data, two additional randomized controlled trials comparing open to endovascular intervention for lower extremity PAD have recently begun enrolling subjects.[17,18] However, because endovascular therapy has become so prominent, these trials may have difficulty enrolling patients because patients' prefer "less invasive" options making the establishment of clinical equipoise challenging.[19] Moreover, these studies may take they several years to complete and thus the eventual results may not reflect contemporary clinical practice.

In this evaluation, our objective is to conduct a comparative evaluation of open versus endovascular treatment of lower extremity revascularization using nationally representative Medicare data. We examine immediate as well as long-term outcomes including rates of subsequent intervention to determine whether the relative benefit of these interventions changes over time.

METHODS

Data acquisition and cohort selection

We analyzed data from the Centers for Medicare & Medicaid Services Chronic Conditions Warehouse for 2006 to 2009, a longitudinal 5% sample representative of Medicare beneficiaries nationally.[20] Records include patient demographics, clinical characteristics, Medicare enrollment data, and facility and provider claims. We selected all inpatients with a diagnosis for PAD using International Classification of Disease, ninth revision (ICD-9) codes, as previously described.[21,22] We selected patients over age 65 who underwent an open or endovascular lower extremity revascularization procedure (see Table 1S, Supplemental Digital Content 1, which displays respective codes).[22–24] We excluded patients who had incomplete data from enrollment in Medicare Part A and Part B, coverage by a Medicare health maintenance organization (HMO), railroad benefits in the year prior to surgery and trauma-related revascularization.[22]

Primary Outcome

Our primary outcome was the incidence of major amputation or death. We classified amputation as major when performed at the transtibial level or above as previously described.[7,24,25] We did not include amputations at the metatarsal level or below as these do not represent failures of limb salvage.[7] Because the purpose of revascularization is to preserve limb and life, any major amputation or death represents a failure of the procedure consistent with existing literature.[9]

Variables

Explanatory variables are listed in Table 1. We identified patients with diabetes using validated methodology published by Hebert et al.[26] Severity of lower extremity PAD was dichotomized into claudication or critical limb ischemia based upon the diagnosis on admission (see Table 1S, Supplemental Digital Content 1, which displays respective codes).[27] We examined validated Elixhauser comorbidities and defined cancer as a composite variable of lymphoma and metastatic cancer.[28] Because the rate of endovascular interventions for PAD increased systematically over the study period, analysis adjusted for year of procedure. Patient's residence and hospital location were classified using Rural-Urban Commuting Area (RUCA) codes.[29,30] Origin of admission included: Referral (i.e. referral from physician, clinic, or HMO), transfer (i.e. transfer from hospital, skilled nursing facility, or another health care facility) or the emergency department.

Propensity Score

Given the differences in baseline characteristics between groups receiving endovascular and open procedures, we used propensity score matching to ensure that patient cohorts had similar covariate distribution. We first estimated the propensity score as the probability of receiving an endovascular intervention, conditioned on all preoperative characteristics and their interactions with renal failure, diabetes, and presence of critical limb ischemia.[31] Matching was performed using a 1:1 protocol without replacement (nearest neighbor approach) with a caliper width equal to 0.25 of the standard deviation of the propensity score.[32] We assessed balance between the groups before and after matching using standardized differences; values less than 10% for a given variable denote a relatively small imbalance.[33] We present descriptive statistics for both unmatched and matched cohorts; all subsequent analyses are on matched cohorts.

Statistical Analysis

Chi-square tests evaluate unadjusted 30-day post-operative amputation and mortality rates between patient groups. Kaplan Meier curves depict overall survival and amputation free survival by procedure type, and log-rank tests identify differences between groups. We censored patients without incidence of amputation or death on December 31, 2009. We evaluated predictors of amputation free survival using a multivariable Cox proportional hazards model. Hazard ratios and 95% confidence intervals (95% CI) are presented with 2-sided p-values (alpha=0.05).

Interactions

We examined interactions between procedure type (endovascular and open) and common morbidities in the PAD population (extent of disease, diabetes, congestive heart failure/ ischemic heart disease (CHF/IHD) and renal failure)[34] to assess whether a significant disease burden moderates the association between procedure type and outcome. We also examined selected interactions between diabetes and comorbid conditions - history of myocardial infarction (MI), CHF/IHD, stroke, and eye disease - to explore if diabetes was associated with diminished amputation free survival.

Secondary interventions

We identified endovascular (i.e., angiogram, thrombolysis, angioplasty, stent-placement, atherectomy) and open (i.e., thrombectomy, open-bypass) interventions that occurred subsequent to the qualifying procedure (see Table 2S, Supplemental Digital Content 1, which displays respective codes) and determined the time to first intervention (Kaplan-Meier life tables) and the frequency of subsequent interventions. The data do not indicate laterality of secondary procedures. Assuming the frequency of subsequent intervention in the contralateral leg was equivalent in both the open and endovascular cohorts, we used the difference in intervention rates between the groups as a proxy measure of reintervention in the ipsilateral limb.

Sensitivity Analysis

To determine if our estimation of the treatment effect is valid using propensity score matching, we repeated the analysis using (1) propensity score standardized mortality ratio (SMR) weighting estimation and (2) propensity score stratification by quintiles, and compared these results to those obtained by matching.[35]

RESULTS

Study Sample

A total of 14,685 patients met sample inclusion criteria. Of these, 8,206 (55.9%) underwent endovascular and 6,479 (44.1%) underwent open revascularization. In the unmatched cohort, patients who underwent endovascular treatment were more often female, more frequently had comorbid conditions such as diabetes and renal failure, and less frequently had severe vascular disease manifested by critical limb ischemia. The numeric differences between cohorts with regard to these factors were small, suggesting that similar patients were treated with both techniques (Table 1). In the matched cohort, standardized differences in measured variables were well below 10%. The C-statistic for the propensity score logistic regression model was 0.627. The mean follow-up time for patients in the matched cohort was 618 days for endovascular and 597 days for open intervention.

Short-term Outcomes

Table 2 shows the 30-day post-operative amputation and mortality rates after lower extremity revascularization in propensity score matched cohorts. Patients undergoing an endovascular procedure experienced early amputation free survival advantage (7.4 vs. 8.9%, p=0.002) driven by a diminished mortality (5.3% mortality vs. 6.7%, p=0.001); there were no significant differences in early amputation rates between the endovascular and open cohorts. Stratified by extent of vascular disease, the amputation free survival benefit associated with an endovascular approach persisted for patients with critical limb ischemia, but not claudication.

Long-term Outcomes

Figure 1 shows 4-year amputation free survival by procedure (panel A) and 4-year survival by procedure (panel B) using matched cohorts. Within 1 year, an estimated 24.8% of endovascular and 29.4% of open patients either died or underwent amputation. This 5% differential persisted for the study duration; at 4-years an estimated 48.6% of endovascular and 54.0% of open patients experienced amputation or death (p<0.001).

Comparing amputation free (Figure 1, panel A) to overall survival (Figure 1, panel B), the majority of events are attributable to death rather than amputation; at 4 years, only an estimated 3.1% of endovascular patients versus 4.2% of open patients underwent amputation.

Amputation Free Survival

Table 3 shows the results of the multivariable Cox proportional hazards model predicting amputation free survival in the matched cohorts. After controlling for baseline characteristics, an endovascular procedure conferred a 16% lower risk of amputation or death compared to an open procedure over the study period (hazard ratio: 0.84, 95% CI: 0.79–0.89).

Major risk factors associated with amputation or death included: diagnosis of critical limb ischemia vs. claudication (HR: 1.93; 95% CI: 1.78–2.08), renal failure (HR: 1.47; 95% CI: 1.38–1.57), history of MI (HR: 1.24; 95% CI: 1.15–1.34) and diabetes (HR: 1.18; 95% CI: 1.11–1.35).

Interactions

The majority of comorbidities did not influence relative outcomes (endovascular conferring a slight advantage, regardless of diabetes, renal failure, or critical limb ischemia) except for CHF or IHD. Specifically, in patients with CHF or IHD, the advantage of an endovascular intervention was enhanced (hazard ratio: 0.80, 95% CI: 0.75–0.85) (see Figure 1S, Supplemental Digital Content 1, which displays survival curves for interactions). Additionally, tested interactions between diabetes with history of myocardial infarction, stroke, and eye disease were not significant (p>0.05).

Subsequent Interventions

Secondary interventions were relatively more common after endovascular than open repair in matched patients (Table 4). During the first 30-days, patients who had an initial endovascular revascularization underwent subsequent intervention 7.4% more often than open patients. The relative rate of subsequent intervention did not further increase over time; at 4-years the rate of subsequent intervention was 8.6% higher for endovascular versus open patients. Absolute rates of subsequent interventions (unadjusted for contralateral interventions) are provided in Table 3S, Supplemental Digital Content, for reference. Interestingly, the majority of patients who underwent a subsequent intervention following either procedure did so only once (endovascular cohort 60.4%, open cohort: 58.8%).

Sensitivity Analysis

We found similar results after repeating the multivariable Cox proportional hazards model analysis predicting amputation free survival using SMR weighting (endovascular versus open revascularization hazard ratio: 0.84; 95% CI: 0.80–0.88) and propensity score stratification by quintiles (endovascular versus open revascularization hazard ratio: 0.84; 95% CI: 0.74–0.95) (see Table 4S and 5S, Supplemental Digital Content 1, which displays results of Cox proportional hazards model analyses and propensity score quintiles respectively).

DISCUSSION

Our results indicate that in a cohort of Medicare beneficiaries with symptomatic lower extremity PAD, endovascular treatment is associated with improved amputation free survival compared to an open surgery, particularly among patients with congestive heart failure or ischemic heart disease. This benefit is pronounced in the short-term, persists over the long-term, and is largely driven by an early differential in mortality. We also examined the frequency of subsequent interventions and found that they are somewhat more frequent after endovascular interventions during the first year, but thereafter the differential between the two cohorts remains constant. We used propensity score matching to equalize the patient cohorts.

We found that in the first year, patients who underwent an endovascular procedure had lower risk of amputation or death compared to open patients (24.8 vs. 29.4%). Furthermore, we found that the early amputation free survival advantage in the endovascular procedure persisted at 4-years. Our findings contrast with those reported in the BASIL trial, the most prominent randomized controlled trial to date.[9] In BASIL, there was no difference in amputation free survival overall, and when investigators examined patients two years beyond randomization, they found that open surgery was associated with a decreased risk of amputation or death.[9] Three phenomena may explain the contrast between our results and those observed in BASIL. First, endovascular technology and surgical technique have improved over time, and the BASIL trial (1999–2004) predates our study period. Second, we studied patients with claudication and critical limb ischemia, whereas the BASIL trial included only patients with severe limb ischemia albeit our findings in the limb threat cohort revealed an advantage of endovascular intervention.[7,36,37] Third, distinct study populations may explain the difference: The BASIL trial was conducted in the United Kingdom with patients meeting specific inclusion criteria and intense follow-up, and our dataset is comprised of older adults treated as part of usual practice in the United States.

We hypothesized that patients with common, systemic comorbidity and severe vascular disease would be less likely to tolerate an open procedure than those without comorbidity. We also hypothesized that the relative outcome of the two interventions might be influenced by conditions such as diabetes or renal failure because of their effect on disease anatomy such as increased calcification, or that the differential in outcomes would be altered in patients with limb threat versus claudication related to extent of disease. To test this, we evaluated interactions between procedure type and select comorbidity burden in predicting outcomes. These hypotheses were largely unsupported, although we found partially consistent results for patients with CHF/IHD. Specifically, patients with CHF/IHD had decreased risk of amputation or death after an endovascular procedure compared to an open procedure; patients without CHF/IHD did not experience the same benefit from an endovascular approach. Remarkably, the lack of significance for the remainder of tested interactions shows that comorbidity did not alter the benefit associated with an endovascular approach. It appears that, although these comorbid conditions are associated with worse overall amputation free survival, the advantage of an endovascular procedure is consistent across patient populations.

Historically, and consistent with our findings, long-term mortality in patients with symptomatic PAD, particularly in patients with critical limb ischemia, is very high ranging from 40–70% at 5-years.[10,36,38–41] However over the short-term, we found a strikingly high perioperative mortality rate after revascularization, regardless of the intervention used. This was particularly so in patients with critical limb ischemia: 6.5% and 8.3% of patients died within 30-days of an endovascular or open procedure, respectively. These findings contradict the common belief that minimally invasive approaches are associated with insignificant morbidity and mortality. Our results highlight that in a real-world setting, the prognosis after lower extremity revascularization for symptomatic PAD is poor, regardless of approach.

A common criticism of endovascular repair is that it may be less durable, requiring additional interventions to maintain limb salvage.[7,15,42,43] We did identify an increased rate of subsequent intervention for endovascular procedures over the first 30 days. However the differential between endo and open during this time period was only 7%. Moreover, beyond 30-days the rate of subsequent intervention was identical for the two cohorts. Thus, at least over a four year period, the reintervention rate for endovascular procedures is only slightly increased compared to open revascularization.

Our results should be interpreted in the context of several limitations. First, anatomical characteristics are not available in this data set. Nevertheless, extant literature has demonstrated that clinical phenotypes for PAD correlate closely with the prevalence of specific patient comorbidities such as diabetes,[44,45] renal failure,[46,47] and critical limb ischemia.[48,49] By matching these factors in our model, we feel that we have succeeded in matching patient anatomy. We are also unable to determine laterality of procedures, subsequent amputations, or subsequent interventions. We presume some percentage of amputations or subsequent procedures occurred in the contralateral extremity. Given the high likelihood that both groups had subsequent interventions on the contralateral extremity at approximately the same rate, the relative difference in the rates of subsequent interventions likely reflects the true discrepancy in reintervention rates.[42] Furthermore, undergoing a major amputation, regardless of side, indicates a failure of the procedure concurrent with the rationale previously described.[9] Finally, the generalizability of our analysis is limited to Medicare inpatients (although these represent the majority of patients undergoing lower extremity revascularization);[50] and is also limited to the population represented by endovascular patients that were matched. In performing a sensitivity analysis using alternative propensity score techniques, we found almost identical results, suggesting that our estimates of treatment effect on the population studied are valid and reproducible.

CONCLUSION

Determining an optimal revascularization strategy for patients with symptomatic lower extremity PAD requires integration of surgeon and patient preferences, available resources, patient comorbidity and relevant anatomy. Given availability of both endovascular and open revascularization options, we show that an endovascular approach is associated with improved long-term amputation free survival. There is initially an increased risk of subsequent intervention after an endovascular procedure; however, this risk is modest and confined to the first 30 days after primary intervention. As always, the selection of interventions cannot be generalized and should be individualized for each patient based upon multiple factors and local expertise.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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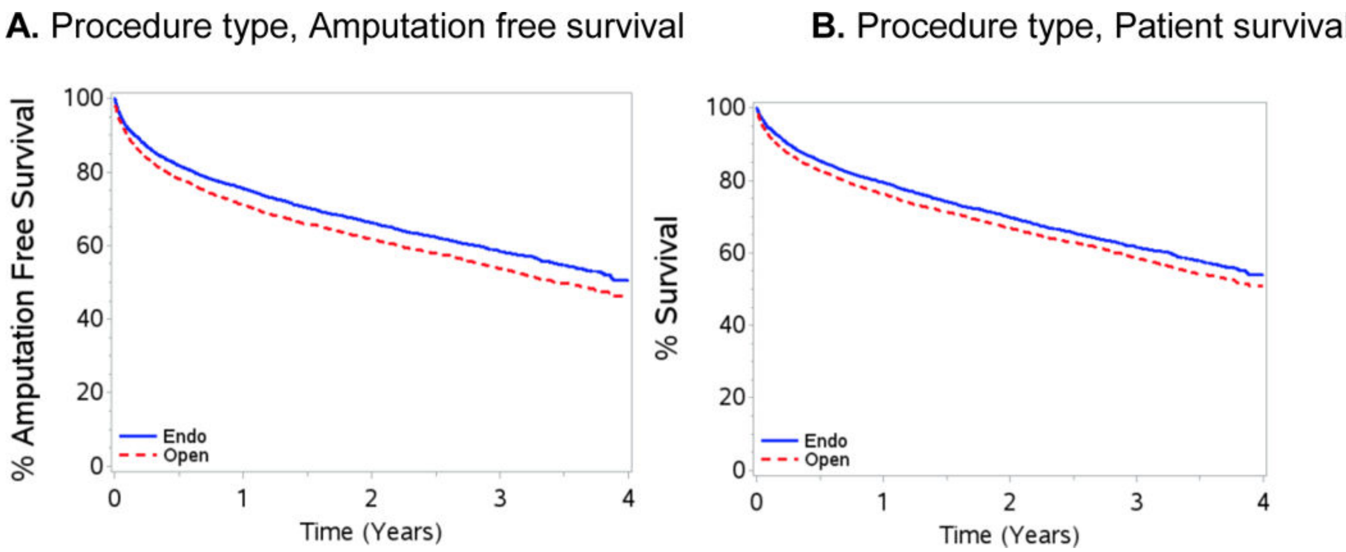

Figure 1.

A, 4-year amputation free survival by procedure type and **B**, 4-year survival by procedure type. *Endo,* endovascular

Table 1:

Patient demographics, preoperative characteristics, and perioperative factors before and after propensity score matching

	Before Matching			After Matching		
Characteristic	Endo (n=8,206)	Open (n=6,479)	Standardized Difference, %	Endo (n=5,928)	Open (n=5,928)	Standardized Difference, %
Age, years (SD)	77.7 (6.9)	77.2 (6.8)	7	77.5 (6.9)	77.4 (6.8)	0
Proportion male, %	43.7	50.4	13	48.5	48.3	1
Race, %						
White	83.2	86.2	−8	85.7	85.9	0
Black	12.2	10.6	0	10.5	10.6	0
Other	4.7	3.2	8	3.7	3.5	0
RUCA, %						
Urban	73.6	73.3	1	73.1	73.3	0
Large Town	13.1	13.8	−2	13.7	13.7	0
Rural	13.2	12.9	1	13.3	13.0	1
Medicaid, %	22.5	19.6	7	19.8	20.0	1
Hospital RUCA, %						
Urban	92.0	91.9	0	91.4	91.8	−1
Non-Urban	8.0	8.1	0	8.6	8.2	1
Admitted from, %						
On referral	76.1	75.1	2	75.5	75.7	−1
Emergency Department	18.7	19.8	−3	19.2	19.0	1
On transfer	5.3	5.1	1	5.3	5.3	0
Teaching Hospital, %	50.8	53.5	−5	51.6	52.4	0
Extent of Disease, %						
Claudication	33.5	24.1	21	26.5	25.7	1
Critical Limb Ischemia	66.5	75.9	−21	73.5	74.3	−1
Myocardial Infarction, %	11.6	9.8	6	10.4	10.2	0
CHF / Ischemic Heart Disease, %	77.2	73.7	8	74.6	74.9	0
Stroke, %	15.1	14.3	2	15.0	14.8	0
Eye Disease, %	1.2	0.9	3	0.8	0.9	0
Diabetes, %	51.3	44.2	14	46.2	46.0	0
Electrolyte disorder, %	35.0	31.5	8	32.5	32.4	2
Renal Failure, %	27.3	21.4	14	22.6	22.5	1
Deficiency anemia, %	37.5	33.3	9	33.9	34.0	1
Chronic blood loss anemia, %	5.5	5.6	0	5.6	5.5	1
Coagulopathy, %	7.4	7.2	−1	7.1	7.2	0
RA or collagen vascular disease, %	6.8	6.2	3	6.1	6.2	0
Chronic pulmonary disease, %	38.7	40.2	−3	39.0	39.2	1

	Before Matching			After Matching		
Characteristic	**Endo (n=8,206)**	**Open (n=6,479)**	**Standardized Difference, %**	**Endo (n=5,928)**	**Open (n=5,928)**	**Standardized Difference, %**
Hypertension, complicated, %	77.2	77.2	0	76.8	77.0	0
Obesity, %	5.4	7.5	9	5.9	5.7	1
Paralysis, %	5.2	4.8	2	4.9	4.6	1
Neurological disorder, %	11.1	9.6	5	10.0	9.7	−1
Dementia, %	4.8	5.0	−1	5.0	5.0	−2
Pulmonary circulation disorder, %	6.5	5.6	4	5.8	5.9	1
Weight loss, %	8.0	7.9	0	7.8	7.6	−2
Benign tumor, %	10.1	11.9	−6	11.6	11.3	0
Cancer, %	2.8	3.0	−1	2.9	2.9	0
Year, %						
2006	30.3	32.0	−4	30.9	31.2	0
2007	26.7	25.3	3	26.0	25.9	0
2008	23.2	22.4	2	23.1	22.8	1
2009	19.8	20.3	−1	20.0	20.1	−1

The standardized differences are reported as percentages; a difference of less than 10% indicates a relatively small imbalance. *Endo*, endovascular; *SD*, standard deviation; *RUCA*, rural urban commuting area; *RA*, rheumatoid arthritis

Table 2:

30-day post-operative amputation and mortality rates after lower extremity revascularization in propensity score matched cohorts

All Patients	Endo (n=5,928)	Open (n=5,928)	P-value
Amputation or Mortality, %	7.4	8.9	0.002
Amputation, %	2.5	2.7	0.416
Mortality, %	5.3	6.7	0.001
Patients with Claudication	**Endo (n=1,572)**	**Open (n=1,524)**	**P-value**
Amputation or Mortality, %	1.8	2.5	0.215
Amputation, %	0.1	0.3	0.239
Mortality, %	1.7	2.2	0.366
Patients with CLI	**Endo (n=4,356)**	**Open (n=4,404)**	**P-value**
Amputation or Mortality, %	9.3	11.2	0.005
Amputation, %	3.3	3.5	0.580
Mortality, %	6.5	8.3	0.001

Percentages are compared using Chi-squared comparisons of proportions. *Endo*, endovascular; *CLI*, critical limb ischemia

Table 3:

Cox proportional hazard model predicting amputation or death in propensity score matched groups

Characteristic	Hazard Ratio	95% CI	P-value
Procedure type			
Open	Ref	.	.
Endo	0.84	0.79–0.89	<0.001
Age, years	1.05	1.04–1.05	<0.001
Male sex	1.12	1.06–1.19	<0.001
Extent of Disease			
Claudication	Ref	.	.
Critical Limb Ischemia	1.93	1.78–2.08	<0.001
Diabetes	1.18	1.11–1.35	<0.001
Renal Failure	1.47	1.38–1.57	<0.001
CHF / Ischemic Heart Disease	1.05	0.98–1.13	0.156
Myocardial Infarction	1.24	1.15–1.34	<0.001
Stroke	1.11	1.03–1.20	0.006
Electrolyte disorder	1.21	1.13–1.30	<0.001
Deficiency anemia	1.19	1.11–1.27	<0.001
Coagulopathy	1.15	1.05–1.26	0.003
Chronic pulmonary disease	1.16	1.10–1.23	<0.001
Neurological disorder	1.42	1.31–1.53	<0.001
Dementia	1.19	1.07–1.31	0.001
Pulmonary circulation disorder	1.22	1.11–1.35	<0.001
Weight loss	1.23	1.12–1.34	<0.001
Cancer	1.34	1.16–1.54	<0.001

The model is additionally adjusted for race, eye disease, chronic blood loss anemia, rheumatoid arthritis or collagen vascular disease, complicated hypertension, obesity, benign tumor, Medicaid eligibility ever, hospital and patient rural urban commuting area, hospital type, origin of admission and year of procedure. *Endo*, endovascular; *CHF*, congestive heart failure.

Table 4:

Relative rate of undergoing a subsequent intervention after primary endovascular or open lower extremity revascularization in matched cohorts

	Relative rate: Endovascular vs. Open, % (95% confidence interval)				
Subsequent Intervention	30-days	Year 1	Year 2	Year 3	Year 4
Any	+7.4 (6.3–8.5)	+7.6 (5.7–9.5)	+7.0 (4.9–9.1)	+6.3 (3.9–8.7)	+8.6 (5.5–11.7)

Absolute subsequent intervention rates (shown in supplemental appendix table 3) are cumulative over time.