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Contextualizing the BEST-CLI Trial Results in Clinical Practice

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Abstract

Background: Chronic limb-threatening ischemia (CLTI) is associated with poor long-term outcomes. Although prompt revascularization is recommended, the optimal revascularization strategy remains uncertain. The BEST-CLI trial compared endovascular and open surgical revascularization for CLTI, but the generalizability of this study to the clinical population with CLTI has not been evaluated.

Methods: We included Medicare beneficiaries aged 65–85 years with CLTI who underwent revascularization and would be eligible for enrollment in BEST-CLI between 2016 and 2019. The primary exposure was type of revascularization (endovascular vs autologous graft [cohort 1] vs nonautologous graft [cohort 2]), and the primary outcome was a composite of major adverse limb

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Ethics statement and patient consent

The study was approved by the institutional review board of Beth Israel Deaconess Medical Center with a waiver of informed consent for retrospective data analysis.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2023.101036.

events (MALE) and death. MALE included above-ankle amputation and major intervention, which was defined as new bypass of index limb, thrombectomy, or thrombolysis.

Results: A total of 66,153 patients were included in this study (10,125 autologous grafts; 7867 nonautologous grafts; 48,161 endovascular). Compared with those enrolled in BEST-CLI cohort 1, patients in this study were older (mean age, 73.5 ± 5.7 vs 69.9 ± 9.9 years), more likely to be female (38.3% [22,340/58,286] vs 28.5% [408/1434]), and presented with more comorbidities. Endovascular operators for the study population vs BEST-CLI cohort 1 were less likely to be surgeons (55.9% [26,924/48,148] vs 73.0% [520/708]) and more likely to be cardiologists (25.5% [5900/48,148] vs 14.5% [103/78]). When assessing long-term outcomes, the crude risk of death or MALE in this cohort was higher with surgery (56.6% autologous grafts vs 42.6% BEST-CLI cohort 1 at a median of follow-up 2.7 years; 51.6% nonautologous grafts vs 42.8% BEST-CLI cohort 2 at a median follow-up of 1.6 years) but similar with the endovascular cohort (58.7% Medicare vs 57.4% cohort 1 at 2.7 years; 47.0% Medicare vs 47.7% cohort 2 at 1.6 years). Of those who received endovascular treatment, the risk of incident major intervention was less than half in this cohort compared with the trial cohort (10.0% Medicare vs 23.5% cohort 1 at 2.7 years; 8.6% Medicare vs 25.6% cohort 2 at 1.6 years), although technical endovascular failures were not captured.

Conclusions: These results suggest that the findings of the BEST-CLI trial may not be applicable to the entirety of the Medicare population of patients with CLTI undergoing revascularization.

Keywords

chronic limb-threatening ischemia; endovascular; outcomes; revascularization

Introduction

Chronic limb-threatening ischemia (CLTI), the most severe stage of peripheral artery disease, is associated with poor long-term outcomes.[1] Although prompt revascularization is recommended in multiple major societal guidelines,[2,3] the optimal revascularization strategy (surgical vs endovascular) remains uncertain.[4]

The Best Endovascular Versus Best Surgical Therapy for Patients with Critical Limb Ischemia (BEST-CLI) trial was a large pragmatic randomized controlled trial comparing endovascular or open surgical revascularization for CLTI (cohort 1: single segment of great saphenous vein; cohort 2: alternative bypass conduit).[5,6] However, significant obstacles, such as potential subject procedural preference, previous limb stent placement, and excessive risk for surgical bypass, led to difficulties in enrollment,[7] terminating before meeting the targeted sample size. With these issues arose concern that the characteristics of randomized patients, procedural techniques, proportion of patients with suitable surgical risk and venous conduits, and postprocedural outcomes may differ from that observed in clinical practice.

Therefore, this study examined patients who underwent revascularization in a sample of Medicare patients who would be eligible for enrollment to emulate the BEST-CLI trial and evaluate its external validity.

Methods

Population

All Medicare fee-for-service beneficiaries aged 65–85 years between January 1, 2016, and October 31, 2019, were included if they had either: (1) an inpatient endovascular or surgical revascularization in the Centers for Medicare and Medicaid Services (CMS) MedPAR database based on International Classification of Diseases (ICD) 9 or ICD 10 PCS codes with a primary discharge diagnosis of CLTI; or (2) an outpatient endovascular procedure in the CMS Carrier and Institutional Outpatient files using Current Procedural Terminology codes and a CLTI diagnosis within the preceding year of the procedure (Supplemental Table 1). Then, ICD codes were used to mimic the exclusion criteria in the BEST-CLI trial (Supplemental Table 1). In addition, outpatients from whom laterality of the procedure could not be determined based on endovascular Current Procedural Terminology codes were excluded. Surgical bypass codes were stratified by autologous grafts (cohort 1) and nonautologous grafts (cohort 2).

Variables

Patient sociodemographics, smoking status, and medical history were ascertained using the Chronic Conditions Warehouse coding algorithms.[8] The specialty of physicians performing the procedures based on taxonomy codes were identified from physician billing claims.

End points

The primary outcome was a composite of major adverse limb events (MALE) and death, similar to the BEST-CLI trial.[6] MALE included above-ankle amputation and major intervention, which was defined as new bypass of index limb, thrombectomy, or thrombolysis. Additional end points included minor intervention, myocardial infarction, and stroke.

Statistical analysis

Baseline characteristics of patients were compared between revascularization groups using standardized differences. Cumulative incidences for outcomes were examined and differences between groups were evaluated using Gray test for nondeath outcomes and log-rank tests for outcomes including death. Adjusted hazard ratios (HRs) were estimated using Cox regression. Trial sites were identified in the CMS database, and patients particularly treated at these sites were compared with those treated at nontrial sites. A P value of <.05 was considered significant.

Results

A total of 66,153 patients were included in this study (10,125 autologous grafts; 7867 nonautologous grafts; 48,161 endovascular) (Figure 1). Compared with those enrolled in

BEST-CLI cohort 1, this study cohort of patients revascularized either endovascularly or with autologous grafts were older (mean age, 73.5 ± 5.7 vs 69.9 ± 9.9 years), more likely to be female (38.3% [22,340/58,286] vs 28.5% [408/1434]), and presented with a higher burden of comorbidities (Table 1). In addition, when comparing treatment strategies within the Medicare cohort, patients who received endovascular revascularization vs autologous grafts were more likely to be female (40.0% [19,259/48,161] vs 30.4% [3081/10,125]) and present with an increased frequency of all comorbidities examined. Similar findings were observed between BEST-CLI cohort 2 and the cohort of those revascularized endovascularly or with nonautologous grafts (Supplemental Table 2). Compared with BEST-CLI cohort 1, endovascular operators in this study were less likely to be surgeons (55.9% [26,924/48,148] vs 73.0% [520/708]) and more likely to be cardiologists (25.5% [5900/48,148] vs 14.5% [103/708]). The proportion of endovascular procedures performed by interventional radiologists was similar in both BEST-CLI and this population (12.3% [12,254/48,148] vs 13.4% [95/708]).

When assessing long-term outcomes in comparison with BEST-CLI, the crude risk of death or MALE in this cohort was higher with surgery (56.6% autologous grafts vs 42.6% BEST-CLI cohort 1 at a median follow-up of 2.7 years; 51.6% nonautologous grafts vs 42.8% BEST-CLI cohort 2 at a median follow-up of 1.6 years) but similar with endovascular revascularization (58.7% Medicare vs 57.4% cohort 1 at 2.7 years; 47.0% Medicare vs 47.7% cohort 2 at 1.6 years) (Central Illustration and Tables 2 and 3). Notably, among those receiving endovascular treatment, the frequency of major intervention was less than half in this cohort compared with the BEST-CLI trial (10.0% Medicare vs 23.5% cohort 1 at 2.7 years; 8.6% Medicare vs 25.6% cohort 2 at 1.6 years), although technical endovascular failures were not captured. The frequency of minor intervention was similar (33.5% Medicare vs 33.1% cohort 1 at 2.7 years; 30.7% Medicare vs cohort 2 32.2% at 1.6 years). Mortality within 30 days of either procedure was low (4.1% for endovascular; 4.4% for surgery), and early crossover from surgery to endovascular treatment occurred infrequently (3.3% at 90 days).

In adjusted analyses, among patients treated endovascularly or with autologous grafts, the hazard of MALE or death at a median 3.15 years was 5% higher with surgery compared with that of endovascular treatment (HR, 1.05; 95% CI, 1.02–1.08) (Table 2). This differed from what was observed in the BEST-CLI trial (cohort 1: HR, 0.68; 95% CI, 0.59–0.79). Results were driven primarily by an increased risk of MALE (HR, 1.11; 95% CI, 1.07–1.16). Similar to BEST-CLI, the risk of minor intervention was significantly higher with endovascular treatment (HR, 2.22; 95% CI, 2.13–2.33). The relationship between surgery and MALE or death was stronger among those who received nonautologous grafts (HR, 1.21; 95% CI, 1.17–1.24) (Table 3).

Among patients who received care at BEST-CLI trial sites vs those at nontrial sites, there was no difference in baseline characteristics (Supplemental Table 3); however, the adjusted hazard of primary and select secondary end points was higher at nontrial sites for both surgical and endovascular approaches compared with trial sites (Supplemental Table 4 and Supplemental Figure 1). Furthermore, most of the top enrolling trial sites treated more Medicare patients than were enrolled in the BEST-CLI trial (Supplemental Figure 2).

Discussion

In this large study of Medicare patients with CLTI who underwent revascularization, patients were more often older, females, presented with more comorbidities, and underwent revascularization by a diversity of clinical specialties compared with patients treated in the BEST-CLI trial. We found that the cumulative incidence of events for Medicare patients treated with surgical revascularization was higher than those observed in BEST-CLI, irrespective of autologous or nonautologous grafts. Although cumulative endovascular events of the primary end point were comparable, the frequency of major intervention was less than half for Medicare patients than observed in the BEST-CLI trial, albeit technical failures were not captured.

It is notable that our Medicare study differs in many ways from the BEST-CLI trial results, although most patients with CLTI in the United States are of Medicare age. Our real-world cohort was older and sicker than the BEST-CLI trial cohort; however, major patient characteristics did not differ between Medicare trial and nontrial sites, suggesting the selective enrollment of healthier patients at trial sites. This was further supported by trial sites showing better outcomes when compared with nontrial sites. Notably, the top enrolling BEST-CLI sites treated few Medicare patients during the study period. In addition to variations in the patient population, the treating physician cohort differed as well. Compared with national practice patterns, vascular surgeons performed significantly more of the endovascular procedures in the trial (73%) compared with that in the real-world population (55.9%).

Short-term outcomes, such as periprocedural death after endovascular treatment and crossover to surgical treatment, were worse in our Medicare population than observed in the trial cohort. In addition, major intervention, which contributed the most events to the primary end point in the BEST-CLI trial, occurred infrequently among real-world patients undergoing endovascular treatment. We noted that technical endovascular failures, 15% to 20% in BEST-CLI, could not be captured in this claims-based study. These differences in observed outcomes between our Medicare cohort emulation and randomized the BEST-CLI trial may arise from differences in unobserved baseline characteristics and lack of equipoise in treatment in this nonrandomized descriptive study in the Medicare population. Nevertheless, such results provide valuable complementary evidence to the BEST-CLI trial by answering important questions on treatment effects in clinical practice.[9] The magnitude of differences in the findings between the trial and the Medicare cohort is suggestive of the lack of generalizability of this trial's findings to the Medicare population of patients.

These findings need to be interpreted in context of this study's limitations. First, this is an observational study that cannot consider treatment selection bias. Hence, it is possible that our trial emulation could experience unmeasured confounding, and our goal was not a primary analysis comparing endovascular with surgical treatment. Nonetheless, our results would be biased in favor of surgery given that endovascular patients likely have an increased unmeasured risk. Second, not all patients in this study were likely eligible for the BEST-CLI trial because clinical equipoise between surgical and endovascular treatment may occur less frequently among older patients with CLTI, and our study lacked the anatomical criteria

necessary to determine enrollment eligibility. Third, not all patients in the BEST-CLI trial were eligible for Medicare, and we were unable to directly compare findings in our Medicare cohort of patients with results from only the subset of BEST-CLI patients eligible for Medicare. Fourth, intervention rates could be influenced by less-intensive follow-up that occurs outside of a trial. Fifth, patient-level data from the BEST-CLI trial were not available; hence, adjusted analyses between the Medicare population and the BEST-CLI population could not be performed. Finally, the BEST-CLI results were based on intention-to-treat population, whereas this analysis examined an as-treated population.

The BEST-CLI trial enrolled a specific population of patients with CLTI, included for low surgical risk and equipoise between endovascular and surgical revascularization. In that enrolled population, the BEST-CLI trial provides robust evidence regarding the comparative efficacy of the treatment strategies tested that can inform clinical decision making. However, the results of this hypothesis-generating descriptive study suggest that the findings of the BEST-CLI trial do not mirror what is found, on average, in a Medicare population of patients with CLTI undergoing revascularization. These results complement the BEST-CLI trial and suggest that further analyses in other real-world populations may be helpful to better contextualize the BEST-CLI trial results to aid clinicians.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Declaration of competing interest

Eric Secemsky has received consulting fees from Abbott, Bayer, BD, Boston Scientific, Cook, Cordis, CSI, Inari, Medtronic, Philips, Shockwave, and VentureMed and receives funding from the National Heart, Lung, and Blood Institute (grant K23HL150290). Sahil Parikh has received institutional grants/research support from Abbott Vascular, Shockwave Medical, TriReme Medical, Sumodics, Silk Road Medical, and the National Institutes of Health; received consulting fees from Terumo and Abiomed; and served on the Advisory Boards of Abbott, Medtronic, Boston Scientific, CSI, Janssen, and Philips. Joshua Beckman has received consulting fees from anOne, Janssen, and Novartis and has ownership in Janacare. Robert Lookstein receives consulting fees from Boston Scientific. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Abbreviations:

BEST-CLI	Best Endovascular Versus Best Surgical Therapy for Patients with Critical Limb Ischemia
CLTI	chronic limb-threatening ischemia
CMS	Centers for Medicare and Medicaid Services
HR	hazard ratio
ICD	International Classification of Diseases

MALE	major adverse limb events

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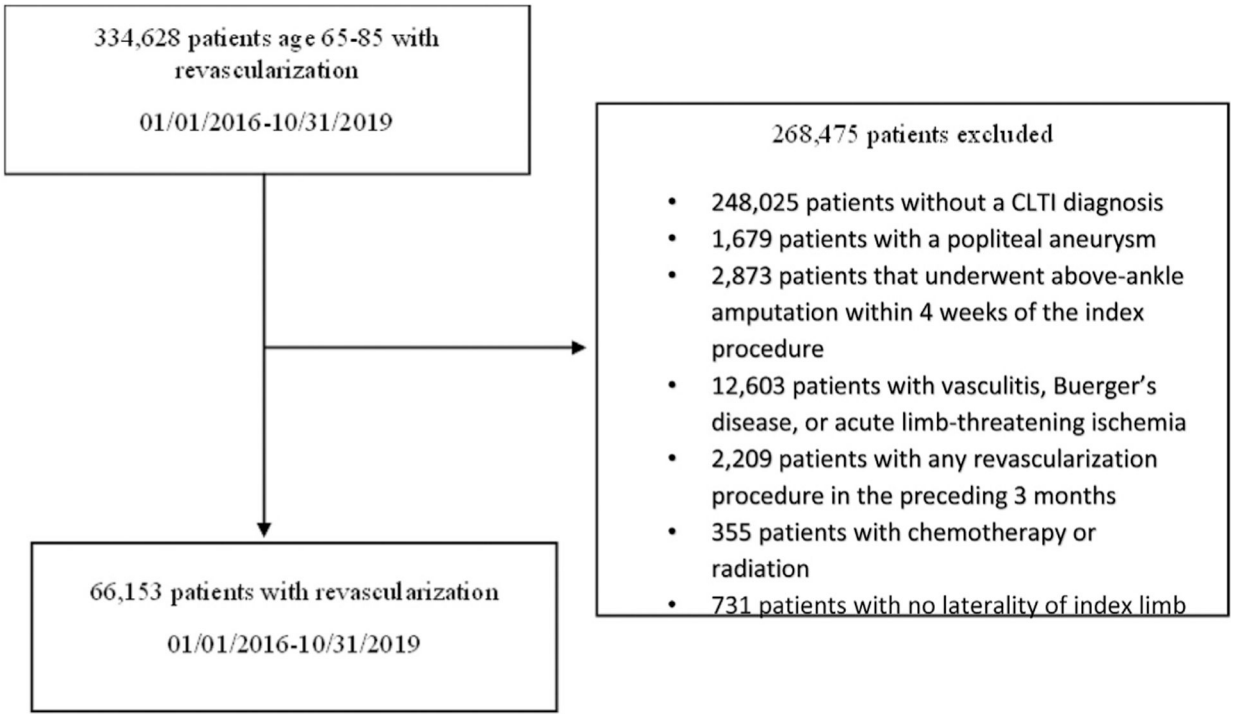
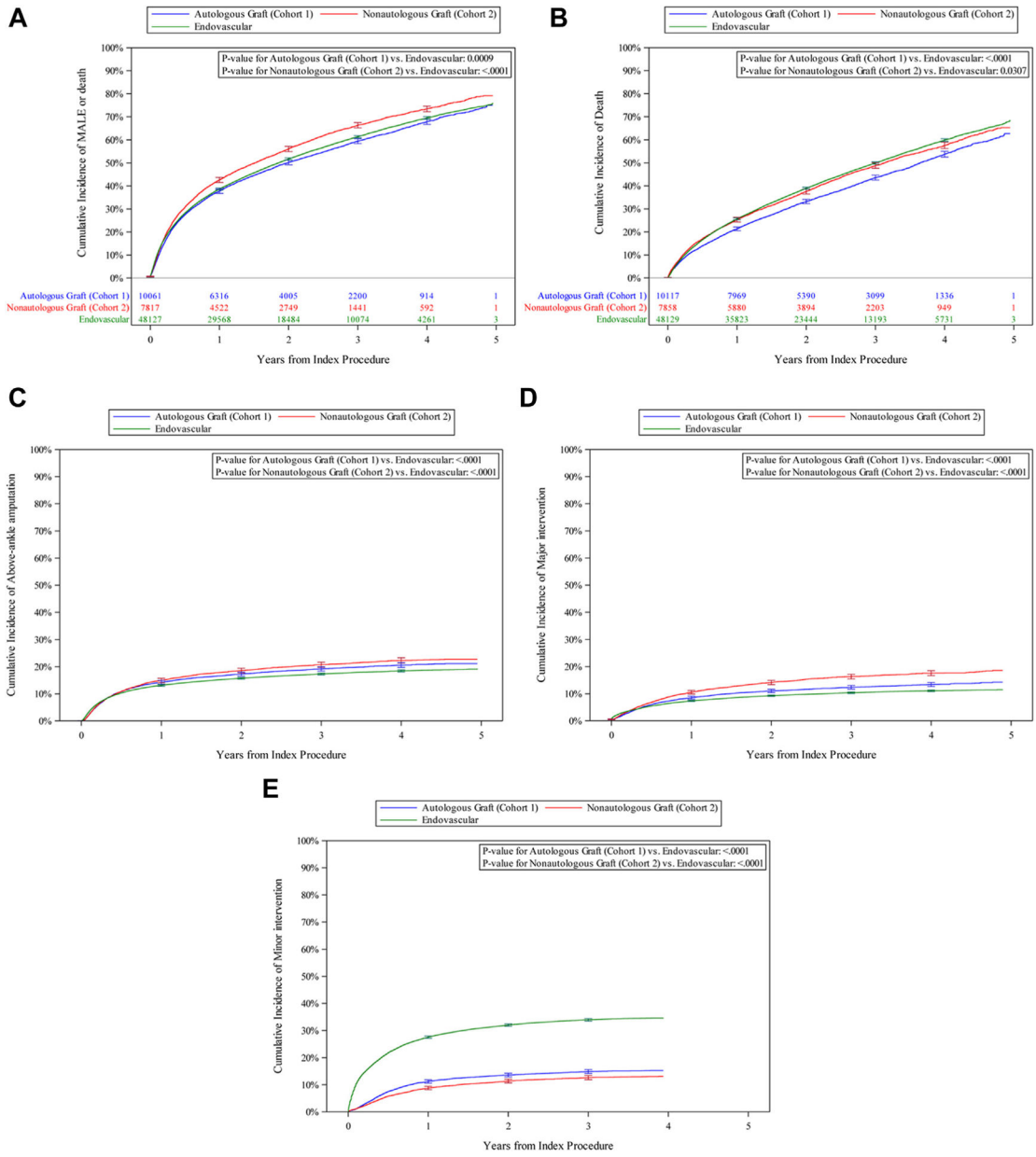


Figure 1. CONSORT study flow diagram.
CLTI, chronic limb-threatening ischemia.



Central Illustration. Cumulative incidences of the primary and secondary outcomes through complete follow-up by revascularization type.

Displayed are the cumulative incidences of the primary and secondary end points among Medicare patients through a median of 3.15 years of follow-up. For all end points including death, cumulative incidences were estimated using Kaplan-Meier methods, displaying the numbers at risk. For end points not including death, cumulative incidences were estimated using the cumulative incidence function to consider the competing risk of death, with no numbers at risk being displayed. (**A**) MALE or death; (**B**) death; (**C**) above-ankle amputation; (**D**) major intervention; and (**E**) minor intervention. MALE, major adverse limb events.

Table 1.

Baseline characteristics of patients receiving revascularization in BEST-CLI Cohort 1 and Medicare population: autologous graft cohort

Subject characteristic	BEST-CLI (cohort 1), n = 1434	n Overall, N = 58,286	Standardized difference (%)[a]	Autologous graft, n = 10,125	Endovascular, n = 48,161	Standardized difference (%)[b]
Age, y	69.9 ± 9.9	73.5 ± 5.7	−60.1	73.2 ± 5.8	73.5 ± 5.7	−5.1
Female, %	28.5% (408/1434)	38.3% (22,340/58,286)	−21.2	30.4% (3081/10,125)	40.0% (19,259/48,161)	−20.1
Race/Ethnicity, %						
White	72.2% (1028/1423)	75.6% (44,043/58,286)	−10.0	75.1% (7605/10,125)	75.7% (36,438/48,161)	−1.3
Black	19.3% (275/1423)	16.5% (9595/58,286)	9.8	18.2% (1841/10,125)	16.1% (7754/48,161)	5.5
Asian	1.4% (20/1423)	1.1% (634/58,286)	1.0	1.1% (112/10,125)	1.1% (522/48,161)	0.2
Other	7.0% (100/1423)	2.6% (1506/58,286)	18.4	1.9% (194/10,125)	2.7% (1312/48,161)	−5.4
Hispanic	13.0% (187/1333)	3.2% (1876/58,286)	36.8	2.5% (250/10,125)	3.4% (1626/48,161)	−5.4
Medical history, %						
Hypertension	86.9% (1238/1424)	93.4% (54,459/58,286)	−22.3	80.1% (8109/10,125)	96.2% (46,350/48,161)	−51.6
Hyperlipidemia	73.2% (1041/1423)	87.1% (50,757/58,286)	−35.3	71.8% (7266/10,125)	90.3% (43,491/48,161)	−48.7
Diabetes	71.8% (1023/1424)	79.1% (46,098/58,286)	−23.4	63.7% (6451/10,125)	82.3% (39,647/48,161)	−42.9
Current smoking	35.7% (509/1424)	35.6% (20,766/58,286)	−0.3	32.9% (3333/10,125)	36.2% (17,433/48,161)	−6.9
Coronary artery disease	43.3% (617/1424)	76.8% (44,782/58,286)	−69.2	62.2% (6302/10,125)	79.9% (38,480/48,161)	−39.7
Congestive heart failure	5.6% (79/1422)	57.0% (33,204/58,286)	−132.3	39.1% (3956/10,125)	60.7% (29,248/48,161)	−44.4
Stroke	13.3% (190/1424)	46.0% (26,833/58,286)	−75.2	34.0% (3446/10,125)	48.6% (23,387/48,161)	−29.8
COPD	14.6% (208/1424)	27.7% (16,139/58,286)	−31.0	18.6% (1888/10,125)	29.6% (14,251/48,161)	−25.8
End-stage kidney disease	10.6% (151/1423)	14.0% (8165/58,286)	−10.0	9.8% (992/10,125)	14.9% (7173/48,161)	−15.5
Endovascular operator						
Surgeon	73.4% (520/708)	55.9% (26,924/48,148)	36.3	–	–	–
Interventional Cardiologist	14.5% (103/708)	25.5% (5900/48,148)	−32.0	–	–	–
Interventional Radiologist	13.4% (95/708)	12.3% (12,254/48,148)	2.3	–	–	–
Other	0.4% (3/708)	6.4% (3070/48,148)	−29.0	–	–	–

Values are mean ± SD or % (n/N). Standardized difference of >10% suggests imbalance.

COPD, chronic obstructive pulmonary disease.

[a] Represents standardized difference between the BEST-CLI trial and Medicare cohort.

[b] Represents standardized difference between surgery and endovascular in the Medicare cohort.

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Table 2.

Crude cumulative incidence of events and adjusted hazards among the Medicare cohort of patients with CLTI who received revascularization (autologous grafts).

Outcome	Autologous graft, n = 10,125[a], %	Endovascular, n = 48,161[b], %	Adjusted hazard ratio: autologous graft vs endovascular[b]	P
MALE or death	56.6 (55.5–57.6)	58.7 (58.2–59.1)	1.05 (1.02–1.08)	<.001
Death	40.2 (39.1–41.2)	46.8 (46.3–47.3)	0.98 (0.95–1.01)	.11
MALE	26.5 (25.6–27.4)	23.9 (23.5–24.3)	1.11 (1.07–1.16)	<.001
Above-ankle amputation	18.7 (17.9–19.5)	16.9 (16.5–17.2)	1.11 (1.06–1.17)	<.001
Major intervention	12.0 (11.3–12.6)	10.0 (9.8–10.3)	1.20 (1.13–1.28)	<.001
Minor intervention	14.5 (13.8–15.2)	33.5 (33.1–34.0)	0.45 (0.43–0.47)	<.001
Myocardial infarction	14.8 (14.1–15.6)	17.4 (17.1–17.8)	1.01 (0.96–1.06)	.84
Stroke	14.3 (13.7–15.1)	22.1 (21.7–22.5)	0.81 (0.77–0.85)	<.001

MALE included above-ankle amputation, new bypass of index limb, thrombectomy, or thrombolysis. Major intervention included new bypass of index limb, thrombectomy, or thrombolysis.

CLTI, chronic limb-threatening ischemia; MALE, major adverse limb events.

[a]Cumulative incidence at 2.7 years of follow-up.

[b]Hazard ratios at the complete follow-up (median, 3.15 years), adjusted for all subject characteristics presented in Table 1.

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Table 3.

Crude cumulative incidence of events and adjusted hazards among Medicare cohort of patients with CLTI who received revascularization (nonautologous grafts).

Outcomes	Nonautologous graft, n = 7867[a], %	Endovascular, n = 48,161[a], %	Adjusted hazard ratio: nonautologous graft vs endovascular[b]	P
MALE or death	51.2 (50.1–52.3)	47.0 (46.6–47.4)	1.21 (1.17–1.24)	<.001
Death	32.7 (31.7–33.8)	33.9 (33.5–34.3)	1.07 (1.04–1.11)	<.001
MALE	26.3 (25.3–27.3)	21.1 (20.8–21.5)	1.29 (1.24–1.35)	<.001
Above-ankle amputation	17.5 (16.6–18.3)	14.9 (14.6–15.2)	1.24 (1.18–1.31)	<.001
Major intervention	12.9 (12.2–13.7)	8.6 (8.4–8.9)	1.51 (1.41–1.60)	<.001
Minor intervention	10.5 (9.8–11.2)	30.7 (30.3–31.1)	0.36 (0.34–0.38)	<.001
Myocardial infarction	11.7 (11.0–12.4)	13.9 (13.6–14.2)	1.00 (0.94–1.06)	.92
Stroke	11.9 (11.2–12.6)	18.8 (18.4–19.1)	0.75 (0.71–0.80)	<.001

MALE included above-ankle amputation, new bypass of index limb, thrombectomy, or thrombolysis. Major intervention included new bypass of index limb, thrombectomy, or thrombolysis.

CLTI, chronic limb-threatening ischemia; MALE, major adverse limb events.

[a]Cumulative incidence at 1.6 years of follow-up.

[b]Hazard ratios at the complete follow-up (median, 3.15 years), adjusted for all subject characteristics presented in Table 1.

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