LITERATURE HIGHLIGHTS

Study Finds Large Interhospital Variability for CLTI Revascularization

With Aishwarya Raja, MD; Fadi Saab, MD, FACC, FASE, FSCAI; and Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM

In this retrospective cohort study aiming to characterize United States hospital–based practices for chronic limb-threatening ischemia (CLTI) intervention, Raja et al found high variability in revascularization strategies and associated outcomes. Results were published online in *JACC: Cardiovascular Interventions*.[1]

Investigators used claims data from Medicare fee-for-services beneficiaries with CLTI who underwent infrainguinal revascularization from October 1, 2015, to December 31, 2021, to examine trends in institutional use of endovascular revascularization and surgical bypass and related outcomes.

Baseline covariates were age, sex, race, rural location, comorbidities, disease severity, and prior lower extremity amputation. For those who underwent endovascular revascularization, procedure claims codes were used to identify device use. The 2016 American Heart Association Annual Survey File was used for institutional characteristics.

The primary endpoint was major lower extremity amputation, defined as any amputation proximal to the level of the foot, at 1 year after revascularization. Secondary endpoints were major lower extremity amputation or death, death, repeat procedures, and minor amputation at 1 year after revascularization.

Patient, procedural, and institutional characteristics were compared among quintiles of institutions with increasing use of endovascular revascularization or surgical bypass. Endpoints were compared between institutions with the highest and lowest quintiles of use of endovascular revascularization and surgical bypass. A sensitivity analysis was performed to compare median use of endovascular revascularization or surgical bypass in place of quintiles. A generalized logistic regression model was used to account for differences in patient-level factors.

KEY FINDINGS

- Patients were more than twice as likely to receive endovascular treatment between highest- and lowest-quintile institutions, even after adjusting for patient and institutional factors.
- Patients who underwent endovascular treatment at higher-volume institutions had improved rates of major amputation and higher rates of repeat procedures.
- Patients who underwent surgical bypass at higher-volume institutions had higher rates of major amputation but lower rates of repeat procedures.
- No differences were seen in rates of major amputation or death, death, or minor amputation in either group, and this persisted after sensitivity analyses.

Investigators also conducted a subgroup analysis to assess the association between atherectomy use and outcomes.

From claims data, a total of 196,070 patients with CLTI were treated at 1,832 institutions, and of these, 161,771 (82.5%) received endovascular treatment. Those who underwent endovascular treatment were older, more often female, and had more comorbidities, whereas those who underwent surgical bypass had higher rates of tobacco use and rest pain.

Mean institutional rates of endovascular revascularization and surgical bypass were 77.5% and 22.5%, respec-

tively. The unadjusted and adjusted mean odds ratios for receiving an endovascular revascularization were 2.37 (Q1-Q3, 2.29-2.46; *P* < .01) and 2.32 (Q1-Q3, 2.24-2.40; *P* < .01), respectively, showing that revascularization strategies were highly variable across institutions.

Patients who received endovascular treatment at the highest-volume hospitals had a lower major amputation rate (adjusted hazard ratio [HR], 0.82; 95% CI, 0.77-0.88; *P* < .01) and a higher reintervention rate (adjusted HR, 1.37; 95% CI, 1.32-1.43; *P* < .01) compared with lowest-volume hospitals. There were no differences in secondary outcomes.

Compared with lowest-volume hospitals, patients who received surgical bypass at the highest-volume hospitals had a higher major amputation rate (adjusted HR, 1.21; 95% CI, 1.13-1.29; *P* < .01) and a lower rate of repeat procedures (adjusted HR, 0.73; 95% CI, 0.70-0.76; *P* < .01). No differences were seen in secondary outcomes.

During the study period, use of atherectomy declined from 32.5% in quarter 1 2016 to 29.3% in quarter 4 2021. In the subgroup analysis, there were lower rates of major and minor amputation (adjusted HR, 0.92; 95% CI, 0.86-0.99; *P* = .02 and adjusted HR, 0.94; 95% CI, 0.90-0.99; *P* = .04, respectively) in patients who underwent atherectomy at the highest-quintile compared with lowest-quintile hospitals, but rates of death and repeat procedures were higher (adjusted HR, 1.08; 95% CI, 1.04-1.12; *P* < .01 and adjusted HR, 1.22; 95% CI, 1.16-1.27; *P* < .01, respectively).

Sensitivity analyses stratifying by median use of endovascular treatment revealed similar outcomes between highest and lowest median hospitals.

Limitations noted by the investigators included the observational study design, use of claims data, inability to include procedures performed at privately owned centers, potential for treatment misclassification based on claims codes, reduced generalizability of the results to younger patients with lower rates of comorbidities, and inability to identify cause-specific mortality.

This large analysis of United States beneficiaries showed that treatment of CLTI is highly variable across hospitals. Strategies for revascularization for CLTI likely require an approach that considers both patient and institutional factors to improve limb salvage rates, concluded the investigators.

ENDOVASCULAR TODAY ASKS…

The study's authors were asked to provide additional insight into the results and how the results might be applied to real-world practice.

First, which real-world factors most likely led to the wide variations in revascularization strategies?

Dr. Raja: Variation in revascularization strategies across United States hospitals is likely a result of multiple real-world factors. First, significant variability in hospital practices and operator preferences influences the decision to pursue one strategy over another. Second, patient-specific comorbidities, such as diabetes, chronic kidney disease, severity of ischemia, and frailty, can influence revascularization selection. Finally, patient-specific disparities, such as geographic location, socioeconomic status, and race, can contribute to significant differences in treatment. Prior studies found that patients in rural areas are more likely to undergo major amputation, which is compounded by a higher burden of comorbidities.[2] Lower socioeconomic status is also associated with reduced access to subspeciality care.[3] Finally, Black patients are less likely to have access to care and more likely to undergo amputations.[4]

To what do you attribute the higher rate of amputation in patients undergoing surgical bypass at high-volume centers versus lower-volume locations?

Dr. Saab: This finding appears to be in line with the most recent contemporary analysis comparing vein bypass to endovascular therapy. The BASIL-2 trial found a higher rate of mortality in critical limb ischemia (CLI) patients undergoing bypass.[5] Typically, CLI patients tend to have distal disease involving the popliteal and tibial vessels. Bypassing these vessels is technically challenging and poses significant strain on this patient population. CLI patients often have multiple comorbidities that would exclude them from having a major vascular surgery, which might explain the higher mortality. In addition, the failure of an endovascular approach does not necessary mean undergoing a major amputation. The same is not true when it comes to bypass surgery where perioperative complications would increase the risk of major amputation, which in turns translates to higher mortality.

What are the likely reasons for the decline in atherectomy use during the study period?

Dr. Raja: There has been an overall increase in the use of atherectomy in the United States since 2006.[6]

This trend coincides with the 2008 modification of insurance reimbursement structures, which was designed to shift the use of peripheral vascular interventions from the inpatient to outpatient setting.[6] Along with this change, CPT codes were updated in 2011 to increase reimbursement for atherectomy. In parallel, there has also been an increase in complex peripheral artery disease that is being treated with endovascular strategies. The combined result has been an increase in the total number of peripheral vascular interventions and an increase in interventions involving atherectomy.

In our study, we found an overall decrease in atherectomy use from 32.7% to 29.3% during the study period (2016-2021). This discrepancy can in part be explained by our exclusion of procedures performed at privately owned outpatient centers due to the inability to associate these procedures with a hospital system. These centers perform an increasing proportion of endovascular procedures and tend to use more atherectomy. In addition, newer technologies like intravascular lithotripsy have reduced some of the utilization of atherectomy.

From the subset analysis, we see that there were lower rates of amputation in those undergoing atherectomy but higher rates of death and repeat procedures. What might explain the combination of these findings?

Dr. Saab: We may assume that this is a cause-and-effect phenomenon. However, there are a few points that argue against this assumption. Clearly, there was a lower rate of major amputation. This should translate into a lower rate of mortality. One theory would be the possibility of other factors increasing the rate of mortality, such as cardiovascular disease and the COVID epidemic. We certainly have not noticed this trend with other retrospective analyses or randomized controlled trials.[7] Operator and center experience are becoming important distinguishing factors in outcomes, and this appears to be the case in both surgical and endovascular therapy. There are better outcomes when it comes to morbidity and mortality in centers with high-volume operators who treat a large number of CLI patients.[8,9] The trend appears to be stronger in centers that have a high number of CLI patients treated with endovascular therapy.

For operators at lower-volume centers, what might be the most applicable learning points from these findings? And for higher-volume centers?

Dr. Secemsky: I think we all need to be honest about our skill and expertise at the local level. If an endovascular operator is doing a few endovascular cases a year and has high-volume surgical partners, then surgery should be considered among suitable patients. The converse is true as well. As bypass surgery rates have declined over the years, patients treated at high-volume endovascular centers should be considered for endovascular treatment first when clinical equipoise is present. We need to move away from our own personal operator biases and prioritize the needs of the patient.

What does a revascularization strategy that takes both patient and institutional factors into account look like in practice?

Dr. Raja: Determining an optimal revascularization strategy is an individualized decision that should account for both patient- and institutional-level factors. These include patient-specific factors, such as the presence of comorbidities that increase perioperative risk and make endovascular revascularization more appropriate or surgical treatment riskier. Anatomic differences should also be considered; for example, surgical revascularization is generally preferred over an endovascular approach for multilevel chronic total occlusions, common femoral artery disease involving the origin of the profunda femoris artery, or lesions where endovascular revascularization can compromise future surgical options.[6] Alternatively, the lack of suitable venous conduits favors an endovascular strategy. Finally, as our current study found, institutional expertise and volume play a critical role in influencing outcomes. Higher-volume centers with more experience performing endovascular procedures experienced lower rates of major amputations. Therefore, it is important for institutional capabilities and operator expertise to be considered when selecting a revascularization strategy.

What are the main factors that contributed to the more than twofold difference in the odds of receiving endovascular treatment between different institutions?

Dr. Saab: This question really highlights the current trends on an international level. I believe the changes are related to significant advancement in endovascular technology. Morbidity and mortality related to endovascular therapy is low. Currently, the biggest challenge of endovascular therapy is maintenance of vessel patency. With continued evolution of therapy, we can address the most challenging chronic total occlusions. The current research and technology trends are focused on maintaining vessel patency. In addition, endovascular therapy is delivered by multiple disciplines. This includes cardiology, radiology, and vascular surgery. The level of training among operators varies

significantly, with advanced technologies requiring the most training. This translates to some operators utilizing the most basic form of endovascular therapy (eg, balloon angioplasty) as the go-to modality, while more experienced operators are using all different tools, such as drug-eluting technology or plaque modification technology (eg, atherectomy or intravascular lithotripsy). Outcomes are not the same among all endovascular modalities. A clear example of this limitation was evident in the BEST-CLI trial where the majority of operators choose mainly balloon angioplasty. The endovascular arm in that trial showed a high rate of target vessel and target lesion revascularization. This difference showed superiority of venous conduit bypass in terms of patency. A major criticism of the trial was the use of balloon angioplasty as the mainstay of therapy. This is in sharp contrast to contemporary practice in the United States and worldwide.[10] This variation in training and specialty preference might explain the variation among different centers.

How would you summarize how these findings fit into the current landscape of trials for endovascular versus surgical bypass in patients with CLTI? What further data are needed here?

Dr. Secemsky: Coming on the heels of BEST-CLI and BASIL-2, which evaluated surgical-first versus endovascular-first revascularization strategies for patients with CLI, there remain some unanswered questions.[10] These trials showed disparate results. We also know there are many counties in the United States that have no trained vascular surgeons. It's time for us to reorganize how we perform vascular intervention. Again, this needs to be done at a local/regional center and requires operators from all specialties to work together. I think the next generation of evidence is how multidisciplinary limb salvage centers that approach CLI care holistically improve outcomes. These "centers" may look differently based on the expertise available, but the ability to review cases, match patient profiles with the optimal treatment strategy, and prioritize the patient first is what is needed in peripheral vascular care. ■

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Aishwarya Raja, MD
Cardiovascular Fellow
Massachusetts General Hospital
Boston, Massachusetts
araja2@mgh.harvard.edu
Disclosures: None.

Fadi Saab, MD, FACC, FASE, FSCAI
Cardiovascular Medicine-Interventional Cardiology
Medical Director of Endovascular Services
Medical Director of Cardiovascular Research
Michigan Outpatient Vascular Institute
Clinical Associate Professor
Michigan State University, School of Medicine
Dearborn, Michigan
fadisaab17@hotmail.com
Disclosures: Speaker for Philips, Abbott, and Reflow Medical; patent for Reflow Medical; stocks for Cardio Flow.

Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM
Director, Vascular Intervention
Section Head, Interventional Cardiology and Vascular Research, Richard A. and Susan F. Smith Center for Outcomes Research
Beth Israel Deaconess Medical Center
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts
esecemsk@bidmc.harvard.edu
Disclosures: Consultant to Abbott, BD, Boston Scientific, Cook, Cordis, Endovascular Engineering, Evident Vascular, Gore, InfraRedx, Medtronic, Philips, RapidAI, Rampart, R3, Shockwave, Siemens, SoniVie, Teleflex, Terumo, Thrombolex, VentureMed, and Zoll.