

New analysis of critical limb-ischemia patients places BEST-CLI trial into context within real-world setting

May 19 2023



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New analysis of chronic limb-threatening ischemia (CLTI) treatment outcomes was presented today as late-breaking clinical research at the Society for Cardiovascular Angiography & Interventions (SCAI) 2023 Scientific Sessions.

Following the initial results of the BEST-CLI (Best Endovascular vs. Best Surgical Therapy in Patients With Critical Limb Ischemia) trial in 2022 which found [surgical intervention](#) superior to endovascular revascularization, questions remained regarding how inclusive the enrolled patient population was, how reflective the specialty of the physicians who performed the procedures are compared to the broader breakdown of U.S. specialists performing peripheral procedures, and whether outcome rates are similarly observed in [clinical practice](#) among Medicare beneficiaries.

CLTI is associated with poor long-term outcomes and a reduction in quality of life. The BEST-CLI trial compared two CLTI treatment options, endovascular revascularization and surgical bypass to understand which approach leads to better outcomes. While the study found surgical revascularization to be superior, the generalizability of this study to the clinical population with CLTI has not been evaluated.

The new study sought to analyze a broader clinical population by identifying all Medicare beneficiaries between 2016-2019 and aged 65-85 years with a diagnosis of CLTI who underwent endovascular or surgical revascularization. Revascularization was stratified by endovascular, autologous graft, and nonautologous graft. The endpoint

was a composite of major adverse limb events (MALE) and death.

66,153 patients were included in this study (10,125 autologous graft; 7,867 nonautologous graft; 48,161 endovascular). Compared to BEST-CLI Cohort 1, patients were older, more often female and had a greater burden of comorbidities. Endovascular operators for the study population versus BEST-CLI were less likely to be surgeons (55.9% vs 73.0%) and more likely to be interventional cardiologists (25.5% vs 13.0%).

The risk of death or MALE in this [cohort](#) was higher with surgery (56.6% autologous grafts vs 42.6% BEST-CLI Cohort 1; 51.6% nonautologous grafts vs 42.8% BEST-CLI Cohort 2) but similar with endovascular (58.7% real-world vs 57.4% Cohort 1; 47.0% real-world vs 47.7%). Of those receiving endovascular treatment, major interventions occurred less frequently compared to the trial (10.0% real-world vs 23.5% Cohort 1; 8.6% real-world vs 25.6% Cohort 2).

"For [critical limb ischemia](#), the key is ensuring timely access to vascular care. Although the BEST-CLI trial is important, it doesn't fully capture the full range of CLI patients, including [older patients](#) with greater comorbidities," said Eric A. Secemsky, MD, MSc, FSCAI, Director of Vascular Intervention, Beth Israel Deaconess Medical Center in Boston, Mass. and study lead. "The findings from our study point to the need to individually tailor revascularization strategies based on patient risks, benefits and preferences."

Authors note that older CLI patients may not experience the same benefit with [bypass surgery](#) as observed in BEST-CLI where at the time, fewer Medicare [patients](#) were enrolled in the trial.

More information: Conference: scai.org/scai-2023-scientific-sessions

Session Details: "Contextualizing the BEST-CLI Trial Results in Clinical Practice" [Friday, May 19, 2023, 3:40-5:10 PM MST, West 103, First Floor, Phoenix Convention Center]

Provided by Society for Cardiovascular Angiography and Interventions

Citation: New analysis of critical limb-ischemia patients places BEST-CLI trial into context within real-world setting (2023, May 19) retrieved 6 May 2024 from <https://medicalxpress.com/news/2023-05-analysis-critical-limb-ischemia-patients-best-cli.html>

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