Endovascular treatment found to be more likely to prevent amputation or death for limb-threatening artery disease

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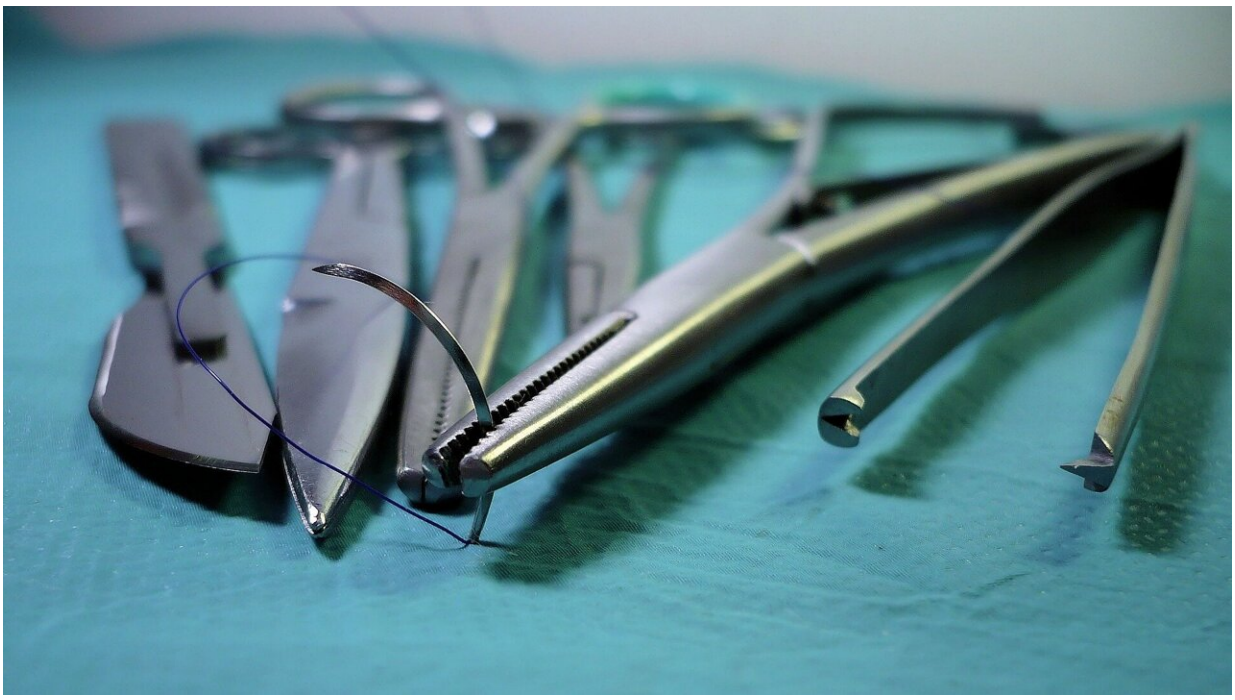

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In patients with chronic limb threatening ischemia (CLTI) due to atherosclerosis affecting the arteries below the knee, data from the first clinical trial of its kind shows that a best endovascular treatment first revascularization strategy was more likely to prevent major amputation

and death than a vein bypass first strategy.

The article, "Endovascular reperfusion strategy for infra-popliteal chronic limb threatening ischaemia" published in *The Lancet*, compared two revascularization strategies for restoring limb perfusion in patients with chronic limb-threatening ischemia (CLTI) due to atherosclerosis affecting the arteries below the knee. The two trials were the "Bypass versus Angioplasty in Severe Ischemia of the Leg Trial (BASIL-2)" and the "Best Surgical Therapy in Patients with Chronic Limb-threatening Ischemia (BEST-CLI) trial."

Patients from the U.K., Sweden and Denmark were randomly assigned to either a vein bypass (VB) first or a best endovascular treatment (BET) first revascularization strategy.

Patients who were randomized to VB first were one third more likely to require a major amputation or die during follow-up than patients who were randomized to BET, which in most cases comprised plain balloon angioplasty with selective use of stents.

Professor Andrew Bradbury, Sampson Gamgee Professor of Vascular Surgery at the University of Birmingham and chief investigator of the BASIL-2 trial said, "Patients with chronic limb-threatening ischemia generally have very poor prognosis and optimal strategies for restoring limb perfusion remain incompletely defined. BASIL-2 is only the third published RCT [randomized controlled trial] in patients with CLTI, and the only one to have specifically recruited patients who required intervention to arteries below the knee to restore blood flow to the lower leg and foot.

"There were many challenges to recruitment and follow-up, most recently due to the COVID-19 pandemic. However, BASIL-2 has now produced a statistically robust and clinically meaningful result that is

likely to have an influence on the management of CLTI worldwide."

Professor Andrew Farmer, director of NIHR's Health Technology Assessment (HTA) Program, which funded the trial, said, "The findings of this important study are likely to greatly improve treatments for patients with this life-threatening and debilitating condition. Once again NIHR-funded research is providing vital evidence to drive forward outcomes for patients and better ways of delivering care for the NHS for those who plan and deliver services."

More information: Ankur Kalra et al, Endovascular reperfusion strategy for infra-popliteal chronic limb threatening ischaemia, *The Lancet* (2023). DOI: 10.1016/S0140-6736(23)00632-3

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