Everolimus-eluting scaffold found better than angioplasty for CLTI patients with infrapopliteal artery disease

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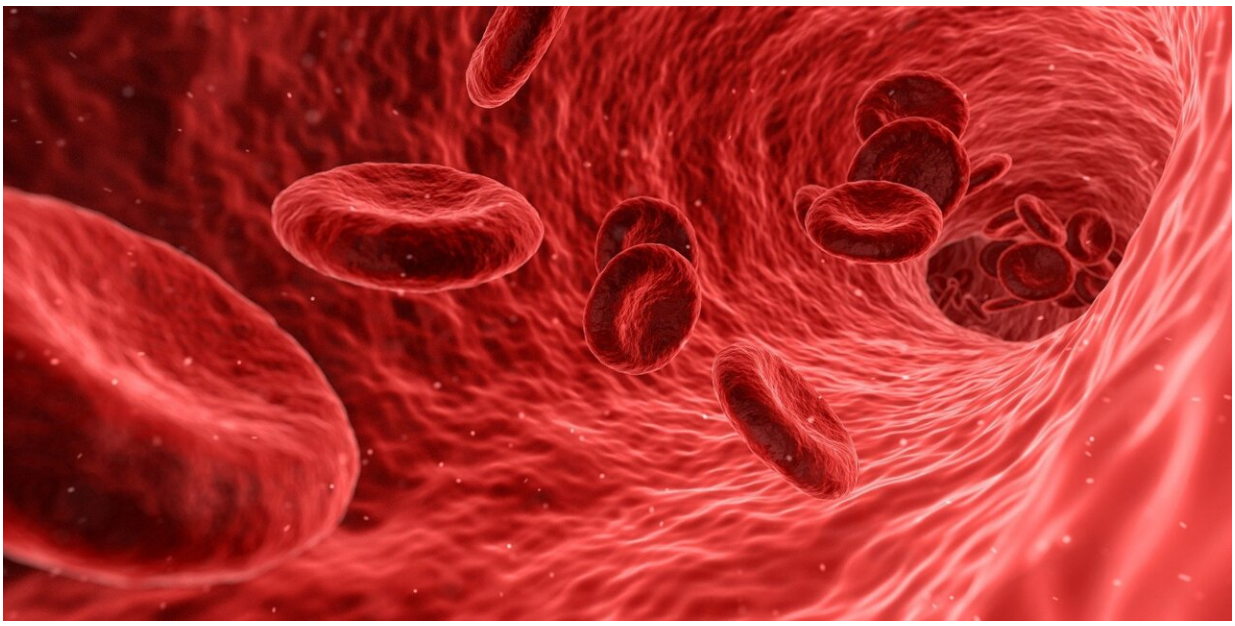

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A multi-institution study led by the Prince of Wales Hospital and University of New South Wales, Australia, has found that everolimus-eluting resorbable scaffold treatment leads to better outcomes than angioplasty for chronic limb-threatening ischemia (CLTI) with infrapopliteal artery disease.

In a paper, "Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease," published in the *New England Journal of Medicine*, researchers investigated the effectiveness and safety of using an everolimus-eluting resorbable scaffold compared to angioplasty for the treatment of chronic limb-threatening ischemia (CLTI) and infrapopliteal artery disease.

The study included 261 patients (mean age 72.6) with CLTI and infrapopliteal artery disease. Approximately 52% of patients had Rutherford–Becker class 4 disease (ischemic rest pain), and 48% had Rutherford–Becker class 5 disease (minor tissue loss). Patients were randomly assigned in a 2:1 ratio to receive either the everolimus-eluting resorbable scaffold or angioplasty.

The primary efficacy endpoint was freedom from adverse limb events at one year, such as amputation above the ankle, vessel occlusion, revascularization, and binary restenosis of the target lesion. The analysis found that the primary efficacy endpoint was achieved in 74% of patients in the scaffold group and 44% in the angioplasty group.

The primary safety endpoint was freedom from major adverse limb events at six months and perioperative death. The primary safety endpoint was met in 97% of patients in the scaffold group and 93% in the angioplasty group. Serious adverse events related to the procedure were rare in both groups, occurring in 2% of patients in the scaffold group and 3% in the angioplasty group.

CLTI is a severe condition characterized by ischemic rest pain and nonhealing ulcers or gangrene in the lower limbs. Open surgical revascularization with saphenous-vein bypass has been used for some patients, but for those with CLTI and infrapopliteal artery disease, another treatment, angioplasty, has shown promise.

The study concludes that among patients with CLTI due to infrapopliteal artery disease, using an everolimus-eluting resorbable scaffold was superior to angioplasty in achieving the primary efficacy endpoint.

The result suggests that the use of drug-eluting resorbable scaffolds may be a promising approach for treating patients with CLTI and infrapopliteal artery disease, offering better outcomes compared to traditional angioplasty.

More information: Ramon L. Varcoe et al, Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2305637