

INVITED COMMENTARY

Is Vein Bypass Truly Superior to Endovascular Intervention for Tibial Disease With “Severe” Limb Ischaemia?

L. Harris

Buffalo General Medical Center, Kaleida Health, 100 High St, Buffalo, NY 14203, USA

Dr Popplewell and colleagues present a subgroup analysis of BASIL¹ (Bypass versus Angioplasty in Severe Ischaemia of the Leg), a controversial, underpowered trial. They suggest from their analysis that vein bypass is superior to balloon angioplasty for infra-popliteal disease, despite the data in their study not achieving statistical significance.

Criticisms of BASIL that must be considered for this study as well include: enrolling only 30% of potentially eligible patients, and lack of standard follow-up surveillance, with those having undergone bypass thought to have had closer follow-up. These limitations can clearly impact on outcomes. BASIL was not designed to look at patients particularly with critical limb ischaemia, but a subgroup with “severe limb ischaemia” is what has been analysed here. SLI (severe limb ischaemia) is not typically an accepted category for PAD (peripheral arterial disease) analysis, which makes comparisons with other studies more difficult. The vast majority of patients underwent PBA (plain balloon angioplasty) of one vessel (85%) alone for tibial disease for SLI, which is not the standard today with tissue loss and infrageniculate disease. Endovascular techniques rapidly evolve, and the interventions from this study do not reflect the current “real world” environment, either with ability to traverse lesions, or methods of treating lesions.

Patients with infrageniculate occlusive disease tend to have worse outcomes than those with more proximal disease with regards to life expectancy. While open bypasses to tibial and pedal vessels can have excellent patency results and, clearly are still good operations, the alteration in quality of life must be considered when advocating for one method of revascularisation over the other. Life expectancy with CLI (critical limb ischaemia) is generally very poor, with about 40% mortality within 2 years.² Open surgical interventions in this frail group of

patients often leads to a decline in quality of life, because of difficulties recovering from open surgery, and alterations to ambulatory status, as opposed to endovascular interventions, which tend to be less disruptive of ambulatory status (93% maintenance of independence, 76% maintenance of ambulation at 1 year with EVI (endovascular intervention) vs. 79% independence after bypass, down from 95% pre-operatively).^{3,4} While I would agree with the authors that we should ideally have a randomised controlled trial of infrapopliteal disease to compare outcomes between endovascular and open interventions, this is unlikely to be successful as endovascular interventions continue to evolve rapidly. Therefore, by the time accrual for any prospective study is achieved, the results are already outdated. Any new studies should clearly take into account not only patency and wound healing, but also quality of life/ambulatory status and life expectancy. This paper is certainly provocative, and we must always consider our standard of open surgery when we develop new minimally invasive techniques. However, the old paradigm of analysis, which is patency and survival, clearly will not tell the entire story. From this study, we cannot conclude that open bypass is always superior to endovascular interventions for tibial disease.

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E-mail addresses: lharris@kaleidahealth.org; lharris@buffalo.edu (L. Harris).

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