Vein bypass first vs. best endovascular treatment first revascularisation strategy for chronic limbthreatening ischaemia due to infra-popliteal disease: the BASIL-2 RCT

Catherine A Moakes,^{1*} Andrew W Bradbury,^{2,3} Zainab Abdali,¹ Gareth R Bate,³ Jack Hall,¹ Hugh Jarrett,¹ Lisa Kelly,³ Jesse Kigozi,¹ Suzanne Lockyer,¹ Lewis Meecham,⁴ Smitaa Patel,¹ Matthew Popplewell,² Gemma Slinn¹ and Jonathan J Deeks¹ on behalf of the BASIL-2 Investigators

¹Institute of Applied Health Research, College of Medical and Dental Sciences,

University of Birmingham, Edgbaston, Birmingham, UK

²Institute of Cardiovascular Sciences, College of Medical and Dental Sciences,

University of Birmingham, Edgbaston, Birmingham, UK

³Department of Vascular Surgery, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

⁴Department of Vascular Surgery, University Hospital of Wales, Cardiff, UK

*Corresponding author c.a.hewitt@bham.ac.uk

Published October 2024 DOI: 10.3310/YTFV4524

Plain language summary

Vein bypass first vs. best endovascular treatment first revascularisation strategy for chronic limb-threatening ischaemia due to infra-popliteal disease: the BASIL-2 RCT

Health Technology Assessment 2024; Vol. 28: No. 65 DOI: 10.3310/YTFV4524

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Plain language summary

therosclerosis, or narrowing of the arteries, can occur as a result of smoking, high blood pressure, diabetes, or high cholesterol in the blood. Atherosclerosis can affect any artery, including those, supplying the legs, where the condition is called peripheral arterial disease. The most severe form of peripheral arterial disease is chronic limb-threatening ischaemia which can cause severe pain in the foot as well as ulcers and gangrene. Unless the blood supply to the leg and foot is improved, by a process called revascularisation, people with chronic limb-threatening ischaemia are at high risk of amputation and death. The blood supply can be improved by using a vein from the leg to bypass around the blockages (vein bypass) or by using a balloon (angioplasty) or small metal tubes (stents) to reopen the blocked arteries (best endovascular treatment). There is debate about which type of revascularisation is best in terms of preventing amputation and death, especially in people who need revascularisation of the arteries below the knee. Bypass versus Angioplasty in Severe Ischaemia of the Leg Trial-2 is the first randomised controlled trial to compare vein bypass-first and best endovascular treatment-first in this group of patients. Bypass versus Angioplasty in Severe Ischaemia of the Leg Trial-2 found that people randomised to a vein bypass-first revascularisation strategy were 35% more likely to require a major amputation or die than those randomised to a best endovascular treatment-first strategy. Most of this difference in favour of best endovascular treatment-first was due to a higher number of patients dying in the vein bypass-first group. Best endovascular treatment-first was also cheaper for the National Health Service. The results of this study suggest that in patients with chronic limb-threatening ischaemia due to peripheral arterial disease in the arteries below the knee, who are suitable for both vein bypass and best endovascular treatment and where there is uncertainty as to which is best, best endovascular treatment should be offered first rather than vein bypass.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.6

A list of Journals Library editors can be found on the NIHR Journals Library website

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 3.6 and is ranked 32nd (out of 105 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2022 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), EMBASE (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the Health Technology Assessment journal

Manuscripts are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This article

The research reported in this issue of the journal was funded by the HTA programme as award number 12/35/45. The contractual start date was in February 2014. The draft manuscript began editorial review in June 2023 and was accepted for publication in February 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the NHS, these of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Copyright © 2024 Moakes *et al.* This work was produced by Moakes *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaptation in any medium and for any purpose provided that it is properly attributed. See: https://creativecommons.org/licenses/by/4.0/. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).