Volume 1 Issue 3 May 2022

Journal of VASCULAR SOCIETIES GREAT BRITAIN & IRELAND

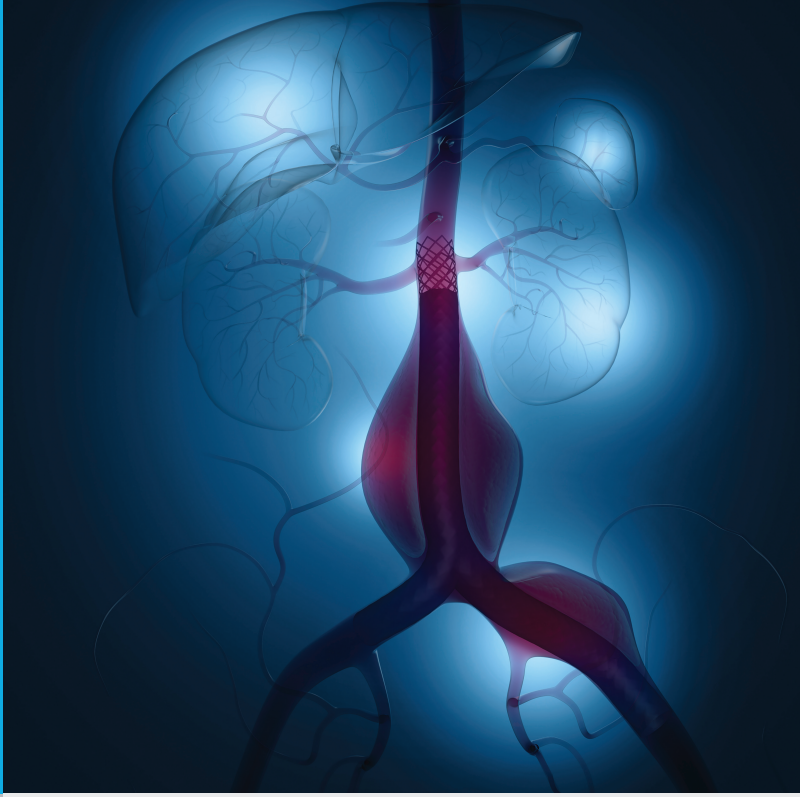
ISSN 2754-0030

The journal is owned by the Vascular Society for Great Britain and Ireland (VSGBI)

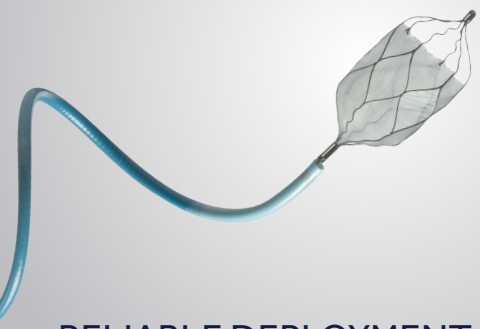
AFFILIATED SOCIETIES INCLUDE:
British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR)
British Society of Endovascular Therapy (BSET) British Society of Interventional Radiology (BSIR) Rouleaux Club
Society of Vascular Nurses (SVN) Society for Vascular Technology of Great Britain and Ireland (SVT)
Vascular Anaesthesia Society of Great Britain & Ireland (VASGBI)
Vascular and Endovascular Research Network (VERN)

www.jvsgbi.com

YOUR PARTNER FOR **EMBOLIZATION SOLUTIONS**

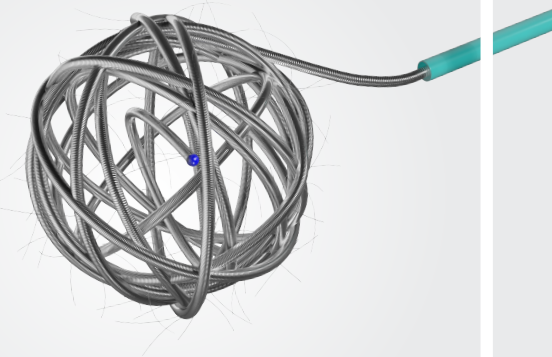


MVP™
Micro Vascular Plug System



RELIABLE DEPLOYMENT
RAPID OCCLUSION

Concerto™
3D Detachable Coil System



YOUR TRUSTED COIL
NOW IN A NEW SHAPE

Onyx™
Liquid Embolic System

THE ADVANTAGE OF TIME
THE POWER OF CONTROL

Concerto™
Helix Detachable Coil System

CONTROLLED PRECISION
RELIABLY DELIVERED

medtronic.com/apv

Medtronic
Further, Together

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

The JVSGBI is an international peer-reviewed journal which publishes relevant, high quality original research, reviews, case reports and news to support the vascular community.

ADDRESS FOR CORRESPONDENCE:
Journal of Vascular Societies GB&I
c/o Executive Business Support
Davidson Rd
Lichfield
WS14 9DZ

ARTICLE SUBMISSIONS AND GENERAL ENQUIRIES PLEASE EMAIL:
Editorialoffice@jvsgbi.com

ADVERTISING AND SALES ENQUIRIES PLEASE EMAIL:
info@jvsgbi.com

The JVSGBI is published online quarterly in Feb, May, August and November on the JVSGBI website. Articles, when finalised for publishing, will be published online, and then at the discretion of the Editor in Chief, included in the online issue and/or printed issue.

ISSN 2754-0022 (print)
ISSN 2754 0030 (online)

Printed on 100% recycled paper

JOURNAL OWNED AND PUBLISHED BY
VASCULAR SOCIETY

AFFILIATED SOCIETIES INCLUDE:
British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR)
British Society of Endovascular Therapy (BSET)
British Society of Interventional Radiology (BSIR)
Rouleaux Club
Society of Vascular Nurses (SVN)
Society for Vascular Technology of Great Britain and Ireland (SVT)
Vascular Anaesthesia Society of Great Britain & Ireland (VASGBI)
Vascular and Endovascular Research Network (VERN)

FOLLOW US ON @VSjournalGBI

VASCULAR SOCIETY

The Vascular Society for Great Britain and Ireland

About the VSGBI

The Vascular Society of Great Britain and Ireland (VSGBI) is the pre-eminent organisation in the country promoting vascular health by supporting and furthering excellence in education, training and scientific research.

The Society represents and provides professional support for over 600 members, including vascular surgeons, vascular radiologists and others involved in independent vascular practices in Great Britain and Ireland.

The Society focuses on non-cardiac vascular disease, including diseases of peripheral arteries, veins and lymphatic. Vascular specialists are trained in the diagnosis and management of conditions affecting all parts of the vascular system.

The VSGBI is a charity organisation funded principally by Members who are vascular specialists in the UK and Ireland who treat non-cardiac vascular diseases. It has a professional structure including a permanent Secretariat, Executive Officers and Council elected by Members. The aim of the VSGBI is to have an interest in the provision of diagnosis and treatment of non-cardiac vascular diseases in the UK and Ireland.

Benefits of Membership

The Society represents and provides professional support for over 600 members, including vascular surgeons, vascular radiologists and others involved in independent vascular practices in Great Britain and Ireland. Membership of the Society is widely recognised in the vascular community as a mark of professional achievement.

The advantages of membership of the Vascular Society include:

- The VSGBI **represents vascular specialists nationally** and helps drive policy through its relations with Royal Colleges, other related professional Societies (e.g. BSIR) and the Department of Health. Members have access to the Executive and Council who prepare and enable these policies.
- The VSGBI **promotes vascular training**, runs training courses and has lobbied for positions such as the post CCT Fellowships, and the Endovascular Fellowships.
- The VSGBI **organises specialist courses and meetings** delivered locally, together with an annual meeting with scientific and political updates.
- The VSGBI **publishes virtual educational resources** which are available to members.
- The VSGBI **publishes a quarterly journal,** the *Journal of the Vascular Societies Great Britain and Ireland*, which is available to its members.
- The VSGBI **publishes policy documents** and quality improvement resources which are available on its website.
- ESVS Membership. VS members can enjoy **ESVS membership at a discounted rate**, and benefit from ESVS membership benefits.
- The VSGBI together with HQIP and the clinical effectiveness unit (CEU) at the RCS London **maintains the National Vascular Registry**, the principal outcomes database for vascular interventions in the UK and Ireland (and for the NHS AAA Screening Programme).
- The Society's **Professional Standards Committee, (PSC) offers support to individuals and hospitals**. For further information visit **www.vascularsociety.org.uk** Council and Committees page. Details of the support and advice scheme are given in the Professional Standards Committee section.
- The Society is an associate partner of the BJS. This entitles VS members to a **reduced BJS subscription**
- Actively **supporting vascular research projects**

SIGN UP FOR VSGBI MEMBERSHIP

If you are not already a member, visit the VSGBI registration desk in the foyer, and find out how to apply.

ORDINARY MEMBERSHIP IS JUST £250 PER YEAR –

Applications for Ordinary membership of the Society shall normally be restricted to Specialists at a level equivalent to Consultant in independent vascular practice; of good professional standing; on the Specialist Registers of the General Medical Councils of Great Britain and Ireland; and living and working in Great Britain and Ireland. Prospective ordinary membership should be proposed by two current ordinary members of the Society who are asked to ascertain that the applicant has an established vascular practice. Nominations will be considered by the Council. Applicants satisfying the above criteria can be admitted to membership.

ASSOCIATE MEMBERSHIP IS £140 PER YEAR –

and is available to Specialists in vascular practice in non-consultant career grades, living and working in Great Britain and Ireland. Prospective associate members should be proposed by two ordinary members. Nominations will be considered by the Council. Applications satisfying the above criteria may be admitted to membership.

The Vascular Society of Great Britain & Ireland c/o Executive Business Support Ltd
City Wharf, Davidson Road, Lichfield, Staffordshire WS14 9DZ
Telephone: 02072057150 e-mail: admin@vascularsociety.org.uk

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):59
http://doi.org/10.54522/jvsgbi.2022.026

www.jvsgbi.com

Editor's foreword

Welcome to the third issue of the *Journal of Vascular Societies Great Britain and Ireland (JVSGBI)*. The journal is certainly going from strength to strength, and I hope that you find the May edition both informative and enjoyable. On behalf of the Editorial Board, thank you to all authors who have submitted articles.

This issue includes two editorials. The first is a personal journey with respect to equality, diversity and inclusion from Mr Neeraj Bhasin, a Consultant Vascular Surgeon, in West Yorkshire. The second editorial examines what the recently published Vascular PAD-QIF CQUIN, means for vascular patients, clinicians and patients. The full report is also a supplement to this issue, and can be located on the *JVSGBI* website, for easy reference.

This issue includes four original research articles, which cover a variety of research topics including: outcomes of revascularisation in elderly CLTI patients; a study of the reliability of WIfI risk stratification in the diabetic foot clinic; factors associated with delays to carotid endarterectomy in the Republic of Ireland; and a study of training in open aortic aneurysm surgery. We also have two trial protocols: the first (VENUM) aims to evaluate the provision of undergraduate vascular teaching in UK medical schools, whilst the second (WALKSTRONG) aims to test the feasibility of a novel home exercise programme for patients with intermittent claudication. Finally, this issue also contains the *JVSGBI*'s first case report and literature review – distal venous arterialisation for 'no-option' CLTI. It is particularly pleasing to see such a wide variety of study designs, research topics and our first publication from a non UK centre.

Recently, the *JVSGBI* Editorial Board took the decision to acknowledge the sterling and essential input of article reviewers. Therefore from this point forward each article will include a note of gratitude to the individual article reviewers. A list of reviewers will also be published in each November edition. Additionally, as Editor in Chief, I am proud to advise that time from article submission to on-line publication at www.jvsgbi.com is taking approximately eight weeks and that all articles have free, open access. A Twitter notification is sent out when articles are published online via @VSjournalGBI. Our Twitter following is growing – if you are not yet following us on social media please visit and follow to receive the latest news from the journal.

Finally, I hope that you enjoy reading this issue of *JVSGBI*. Please do continue to submit your work for publication, and follow us on social media.

Ian Chetter
Editor in Chief JVSGBI
VSGBI Research Committee Chair

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):60-62
http://doi.org/10.54522/jvsgbi.2022.019

www.jvsgbi.com

EDITORIAL

Neither here, nor there, but all good: my personal journey with respect to Equality, Diversity and Inclusion

Bhasin N

Consultant Vascular Surgeon, Calderdale and Huddersfield NHS Foundation Trust; Regional Clinical Director for Vascular Services across West Yorkshire, West Yorkshire Association of Acute Trusts; Chair Elect, Circulation Foundation

Corresponding author:
Neeraj Bhasin
Consultant Vascular Surgeon, Calderdale and Huddersfield NHS Foundation Trust, Huddersfield Royal Infirmary, Acre Street, Huddersfield HD3 3EA, UK
Email: neeraj.bhasin@cht.nhs.uk

Received: 16th February 2022
Accepted: 20th March 2022
Online: 5th April 2022

This invited editorial is an adapted version of a talk on Mr Bhasin's Twitter Feed originally recorded for the EDI module of the Calderdale and Huddersfield NHS Foundation Empower Leadership Programme.[1] It has also been presented at the Vascular Society of Great Britain and Ireland and Rouleaux Club Joint Symposium on Equality, Diversity and Inclusion, and at a session entitled 'Resolving Conflicts in Identity and Belonging in Second Generation British South Asians' as part of South Asian Heritage Month.

I am delighted to have been asked to write an editorial about Equality, Diversity and Inclusion (EDI). It speaks to me that attitudes are hopefully changing, with individuals and organisations making this a core priority. Across the globe we have seen high profile examples of racism, inequality and privilege. This is not right, and there is no reason my melanocytes should determine my treatment or how I am perceived. The same is true of any protected characteristic.

In writing this I have two aims. The first is to ask people to step into my shoes, think about what you are reading, how that makes people feel and hopefully become an ally, taking a proactive stance on shifting the dial. The second is to make people feel seen when they read this, embrace your journey, be proud of your diversity and experiences, see your diversity as your strength. I understand the following are my experiences, my perceptions, my thoughts, and we all have our own individual journey. That blend of gender, age, ethnicity, sexual orientation, socioeconomic background makes us all individual and aligns with the concept of intersectionality.

As I have struggled with identity and belonging for years, I have titled my journey, 'Neither here, nor there, but all good'. In terms of structuring this piece, although it is not how it is traditionally used, within our organisation we have a quality improvement methodology called the 'Three Rs'. I am going to recount stories to establish my 'Reality'. I will then describe the 'Response', which gives you the 'Result' of where I am today.

Dad came to England in 1966 after qualifying as a doctor and, as were the rules at that time, arrived with £3 in his pocket and a 20 kilogram suitcase. He aspired to be an orthopaedic surgeon and play cricket socially, but how he was treated due to his ethnicity led him to give up on his aspiration and his main hobby. Mum soon followed dad to England. Mum has a degree in English and can absolutely sound like the Queen when she is on the telephone. When Dad was working, Mum used to ring round to find accommodation for them. They had the experience of going to a house, the person opening the door, looking at them, and then just saying, "Well, you didn't sound like one of 'them' on the phone", and then just shut the door in their face.

I grew up as the youngest of three children and felt loved, secure and happy. I grew up in Huddersfield with Dad's GP surgery on the side of our house, and this is when there was the first joke about my ethnicity. The joke was that I was a 'posh Indian'; the stereotype at that time was that Asians came over, set up a corner shop and lived above their corner shop. I was a 'posh Indian' because I didn't live above a corner shop, I lived above a surgery. Occasionally Dad's parents, Dada ji and Dadi ji, came to live with us and Dadi ji would make breakfast. I would wake up to the sound of a pressure cooker and the smell of freshly made parathas. However, I was conscious because my coat was hanging on a peg near the

Key words: equality, diversity, inclusion

kitchen and I was worried about getting on the school bus smelling of Indian food, and how people would perceive that, and perceive me because of that.

I grew up badly dressed and did not own a pair of jeans until I was 16. I grew up eating Indian food, celebrating Indian ceremonies and surrounded by Indian friends. As a family we had two English language films on VHS, the 'Sound of Music' and 'Star Wars'. I can still sing every word of the songs in the 'Sound of Music', and I get a little bit over-emotional when I see an X-wing! After the school holidays, friends would describe their trips to Disneyland and the restaurants they ate in. We had driven to Germany in our car to see family members and eaten aloo gobi from a foil container in a service station by an autobahn. They were happy times, but it made me hesitant, feel isolated, like I did not fit in.

Another one of Dad's aspirations was to own a maroon Mercedes, and after an immense amount of hard work and sacrifice he achieved that. However, Dad went out in the morning to find the word 'P*ki' graffitied all the way across our garage and someone had urinated on the car. Despite that I was in a bubble, my parents never let me feel unsafe and I was happy.

I then moved to college and started to develop a racial awareness. There was a group of Asian kids at college who were only friends with other Asian kids. Due to my diverse friend group, they abused me. I was called 'coconut' or 'Bounty', meaning brown on the outside and white on the inside, insinuating I was betraying my heritage or not being true to my skin colour. I then started to socialise more widely and was almost apologetic for my 'different' name. Regularly I hear various pronunciations of my first name, such as 'knee rash', and with my surname regularly getting 'Basin' or 'Bashing'. The worst is when people say, "That's just too complicated, I'm just going to call you Bob". I will not accept that. The other question I get asked is, "Where are you from?" I'll say I'm from Huddersfield, and they respond "No, where are you really from?" I would say, "OK, I was born in Kent, but I moved to Huddersfield when I was a year old". That is clearly not the answer they are looking for.

After University in London I came back to Yorkshire and did my first SHO job in A&E. That is when I was attacked by a patient because they didn't want to be treated by a 'P*ki'. Also, for those patients who could not speak English, I tried to talk in Hindi. My white colleagues were amazed that I could do this, and those doctors that were on the ward round with me, who perhaps came from India, smirked to each other due to my accent and broken Hindi, coming back to the coconut scenario. Over the years I had the standard shouts of "Go back where you came from", getting bumped into in bars, and got threatened with a stabbing in London because I had a white girlfriend. I recount all of that as if it is normal and accepted.

These events meant I do not feel complete belonging in England, so 'neither here'.

As a young adult I went to India alone for the first time and that is when things got interesting. Although I absolutely loved it, I realised I didn't fit in there either. I stuck out because of my clothes, my approach, my accent. So, my 'Reality' is, I do not feel complete belonging or acceptance in England or in India – 'neither here, nor there'.

There will be people reading this who are thinking 'it is different now', 'things are better', I have a 'chip on my shoulder', so I thought it may be useful to outline some recent information and, for those who want to become allies who may not have been touched by this, consider how the following makes people feel about themselves and their careers:

- 95% of doctors who died from COVID-19 were from a BAME (Black, Asian and Minority Ethnic) background.[2]
- For all grades, BAME doctors are almost twice as likely as white doctors to have personally experienced discrimination at work from a manager, team leader or other colleagues.[3]
- BAME doctors are under-represented in consultant, clinical director and medical director roles.[3]
- BAME doctors were twice as likely to receive a complaint or be referred to the GMC compared to their white colleagues.[3]
- BAME staff at an NHS trust were told to use 'Western names'.[4]
- White doctors in London are six times more likely to be offered jobs than black doctors.[5]

In terms of the 'Response', my two elder siblings grew into a corporate lawyer and a fast jet fighter pilot. I did not identify them as role models, but they removed the perception of a glass ceiling, they prevented boundaries entering my head, and they showed me that there were no limits. The response was not intentional, but to overwhelm all the negativity from the 'Reality', the vast majority of people were brilliant! I made friends in college who I stood side by side with and continue to do so after 30 years; one of them asked me to be best man at his civil partnership. At university, whether it be in the accommodation, on rugby, hockey or cricket pitches, in lectures, in the bar, I never experienced any prejudice.

Groups of people made me realise it did not matter what I was. I realised that good people accepted me for who I was, and for those who did not, it was not my problem.

I joined an outdoor bootcamp for exercise. This was made up of very different people, different backgrounds, different jobs, and that made me quite conscious and anxious. It was one of the best things I ever did. That diverse group of people embraced each other, helped each other physically and mentally, built each other up and gave each other huge amounts of confidence. Then a friend asked me to be a godparent to their baby, investing more in who you are than the colour of your skin. I met more people who gave me the confidence to walk into any room and be proud of myself, be proud of my experiences and be proud of my diversity.

I then met someone who enhanced that, who gelled that pride and confidence together and brought a strength to it. Someone who embraces and respects all that is good about sharing and blending those cultures and created a family of diversity.

That is all personally, we spend a lot of time at work and those statistics I outlined earlier are work related. I had a chance meeting

with a consultant who took me under his wing as a junior doctor, he took me to the point where I was ready to be a consultant, and now works alongside me as a peer in the region. Along with certain other colleagues and consultants, I knew that if I worked hard, if I hit the expected standards, I would be fine, the colour of my skin was never a question. All that counted to these people were my professional and personal qualities.

Then I became a consultant and got to the point where I realised that the best way of changing things is from the inside, to get involved. So I applied for a role as Associate Medical Director and was given the opportunity to lead. It was at this stage I further developed that racial awareness. It developed into the fact that I was aware I had a responsibility to help others, but I was clear I did not want positive discrimination for myself or others. I wanted to be in a room because I was a right person for the job. I did not want to be in a room because I felt I was fulfilling an organisation's target. However, you cannot be what you cannot see.

These people created a 'Response' for me that was much greater than those who created the 'Reality'. I realised that my differences were a strength. If an elderly Asian lady comes into a consultation with me, I know that I can respond with the same empathy and build the same rapport as if an elderly Yorkshire gentleman comes in and starts his consultation with "Now then". My differences make me stronger.

So, is the 'Result' perfect? No, I'm still conscious when I walk into certain situations, but I take the confidence, pride and strength that has been given to me by others and I will demonstrate behaviours that give nothing to the negative people. Overall, I'm 'all good'.

Diversity makes you stronger – as an individual, profession and organisation. Our organisation's workforce has to reflect the population we care for. I hope this editorial will have helped some to step into someone else's shoes, made them curious, become an ally and move the EDI dial. It is important to challenge yourself and understand if you have privilege, how that has helped you, and how that means you have a responsibility to help others.

Peggy McIntosh described seeing her white privilege as an invisible weightless backpack of special provisions, maps, passports, codebooks, visas, clothes, tools and blank cheques.[6] Despite what I have described above, I recognise I have privilege and others continue to have a harder journey and different experiences. My surgical journey will have been easier as a male; I know I have not been conscious in certain environments where my LGBTQ friends have felt uncomfortable, I know due to my accent, clothes, interests, school and university I may be more 'accepted' in certain environments than other Asian colleagues.

So, challenge yourself, do you have privilege? Understand if you do, and help others who do not.

For those who these experiences have resonated with, and hopefully feel seen, be confident, be proud, be strong, embrace your differences, embrace your journey. Your differences are your strength; go and become a role model, go and achieve, go and excel.

Conflict of Interest: None.

Funding: None.

References

1. Bhasin N. Neither here, nor there, but all good. Calderdale and Huddersfield NHS Foundation Trust Empower Programme, EDI Module. https://www.youtube.com/watch?v=FrUnmw3V2jY
2. COVID-19: the risk to BAME doctors. The British Medical Association. 2021. https://www.bma.org.uk/advice-and-support/covid-19/your-health/covid-19-the-risk-to-bame-doctors
3. Medical Workforce Race Equality Standard (MWRES). WRES indicators for the medical workforce 2020. NHS England. July 2021. https://www.england.nhs.uk/wp-content/uploads/2021/07/MWRES-DIGITAL-2020_FINAL.pdf
4. BAME staff at NHS trust told to use 'Western names'. BBC News. 3 August 2021. https://www.bbc.co.uk/news/uk-england-58076939
5. White doctors in London are six times more likely to be offered jobs than black doctors. *BMJ* 2021;**375**:n2460. https://doi.org/10.1136/bmj.n2460
6. McIntosh P. White privilege: unpacking the invisible knapsack. https://psychology.umbc.edu/files/2016/10/White-Privilege_McIntosh-1989.pdf

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):63-64
http://doi.org/10.54522/jvsgbi.2022.018

www.jvsgbi.com

EDITORIAL

The Vascular PAD-QIF CQUIN: what is it, why is it important, what does it mean for vascular units?

Birmpili P,[1,2] Atkins E,[1,2] Boyle JR,[3] Sayers RD,[4,5] Blacker K,[6] Williams R,[7] Pherwani AD[8]

1. Clinical Effectiveness Unit, Royal College of Surgeons of England, London, UK
2. Hull York Medical School, Hull, UK
3. Cambridge Vascular Unit, Cambridge University Hospitals NHS Trust, Cambridge, UK
4. Department of Cardiovascular Sciences, University of Leicester British Heart Foundation Cardiovascular Research Centre, Leicester, UK
5. National Clinical Reference Group for Vascular Services, NHS England and Improvement, UK
6. National Specialised Commissioning Team, NHS England and Improvement, UK
7. Freeman Hospital, Newcastle upon Tyne NHS Foundation Trust, UK
8. Staffordshire & South Cheshire Vascular Network, Royal Stoke University Hospital, Stoke-on-Trent, UK

Corresponding author:
Panagiota Birmpili
Clinical Research Fellow,
Clinical Effectiveness Unit,
The Royal College of Surgeons of England, 38–43 Lincoln's Inn Fields, London WC2A 3PE, UK
Email: Panagiota.Birmpili@nhs.net

Received: 11th March 2022
Accepted: 16th March 2022
Online: 29th March 2022

The Commissioning for Quality and Innovation (CQUIN) indicators for 2022/23 were recently published by NHS England and for the first time include a vascular indicator, the "Achievement of revascularisation standards for lower limb ischaemia".[1] This is great news and will drive quality improvement for patients with chronic limb-threatening ischaemia (CLTI). In this editorial we describe what this means for English NHS organisations providing vascular services, vascular clinicians and patients.

The Prescribed Specialised Services (PSS) CQUIN framework is a pay-for-performance scheme for English NHS Trusts. It supports improvements in quality of care by linking a proportion of the healthcare providers' income to the achievement of quality improvement goals in clinical priority areas.[2] It was launched in the NHS in England in 2013 but was suspended during the pandemic. This year there are five PSS CQUIN indicators that acute Trusts must adopt. The baseline value for the CQUIN equates to 1.25% of the fixed element of the expected annual contract value, with each of the five indicators worth 0.25%. If the CQUIN target is not met, the CQUIN value will be deducted and reimbursed. For an arterial centre, this penalty is estimated at approximately £500,000 or more depending on Trust size.

The "Achievement of revascularisation standards for lower limb ischaemia" CQUIN indicator is based on the Vascular Society of Great Britain and Ireland Peripheral Arterial Disease Quality Improvement Framework (PAD-QIF) published in March 2019, which recommends a timeframe of 5 days from referral to the vascular team to revascularisation for patients admitted urgently with CLTI.[3] This indicator evaluates quality by measuring the proportion of patients with CLTI that undergo open, endovascular or hybrid revascularisation within 5 days from non-elective admission to vascular provider units.[4] Payment is determined by reference to two thresholds (upper threshold 60%, lower threshold 40%). NHS organisations will receive the full CQUIN value if 60% or more of CLTI patients who are deemed suitable for revascularisation are revascularised within 5 days from admission and no payment will be earned if this proportion is below 40%. Deductions will be graduated if performance falls between the two thresholds. Regional Specialised Commissioning teams will monitor performance of providers using Hospital Episode Statistics (HES) data and data entry to the National Vascular Registry (NVR).

The CQUIN aims to drive improved levels of data entry to NVR, which will be used to quality assure the timeliness of revascularisation and patient outcomes. This supports the Getting It Right First Time (GIRFT) recommendation that case ascertainment rates for lower limb procedures should exceed 85%.[5] Therefore, if comparison between NVR and HES data demonstrates significant under-reporting, there is the potential for commissioners, at their discretion, to withhold or reduce payment. This should ensure providers identify sufficient resources (including administrative support) for vascular services (both surgical and radiological) to meet this target level of case ascertainment to the NVR.

There has been conflicting evidence about the effectiveness of pay-for-performance schemes to improve processes and patient outcomes.[6–8] The CQUIN aims to improve quality of care by measuring clinical processes, and assumes that improvement in these metrics will result in improvement in patient outcomes and a more positive patient experience due to fewer delays. Patients treated within 5 days have been

Key words: vascular procedures, pay-for-performance, chronic limb-threatening ischaemia, peripheral arterial disease

demonstrated to have shorter postoperative and overall hospital stays in the recent NVR report,[9] and may experience fewer complications. The positive effect of interventions such as dedicated limb salvage clinics on patient outcomes such as amputation-free survival has also been demonstrated.[10] Additionally, having a vascular CQUIN indicator focuses the attention of NHS providers of vascular services and provides an opportunity for clinicians to seek resources and support from their organisational leadership, by highlighting the potential financial gains thanks to the reduced length of stay and subsequent increased bed capacity, as well as the financial incentive of the CQUIN itself.

Vascular units may need to reconfigure their pathways to prioritise patients with CLTI and expedite patient review, imaging and treatment in order to achieve the target. In this effort, they may benefit from the experience of the early adopters participating in the PAD-QIF, who have introduced a number of innovative solutions that can serve as examples for other units.[11] Vascular units are able to identify their baseline performance, published in the 2021 NVR report.[9]

The PAD-QIF timeframes are challenging and achieving them is likely to require additional resources and a change in the delivery of vascular services. However, we hope that the inclusion of the CLTI indicator in the CQUIN framework will raise the profile of peripheral arterial disease with NHS Executive teams. Furthermore, by highlighting CLTI as a clinical priority, the CQUIN will encourage the adoption of the 5-day target into clinical practice and lead to improved patient outcomes and reduced amputation rates.

Conflict of Interest: PB, KB, ADP, JRB and RDS contributed to the development of the vascular CQUIN application. RDS, JRB and ADP are members of the National Clinical Reference Group for Vascular Services. JRB and ADP are members of the VSGBI Executive Council and RDS is the VSGBI representative at the RCS England Council.

Funding: EA is supported by a Royal College of Surgeons/Circulation Foundation clinical research fellowship. PB is supported by a VSGBI/BSIR/Circulation Foundation clinical research fellowship.

Acknowledgments: We would like to acknowledge the contribution of the NVR team, and especially Professor David Cromwell and Mr Sam Waton, in the development of the vascular CQUIN. We would also like to thank Mr Michael Wilson, Programme Director for Specialised Commissioning in NHS England, for his input and support in the development of this CQUIN.

References

1. NHS England and NHS Improvement. Commissioning for Quality and Innovation (CQUIN): 2022/23 Guidance. January 2022. Available from: https://www.england.nhs.uk/nhs-standard-contract/cquin/2022-23-cquin/
2. Feng Y, Kristensen SR, Lorgelly P, *et al.* Pay for performance for specialised care in England: strengths and weaknesses. *Health Policy* 2019;**123**(11): 1036–41. https://doi.org/10.1016/j.healthpol.2019.07.007
3. Vascular Society of Great Britain and Ireland. A Best Practice Clinical Care Pathway for Peripheral Arterial Disease. Available from: https://www.vascular-society.org.uk/_userfiles/pages/files/Document%20Library/PAD%20QIF%20March%202019%20v2.pdf
4. NHS England and NHS Improvement. Commissioning for Quality and Innovation (CQUIN) 2022/23 Annex: Indicator specifications. January 2022. Available from: https://www.england.nhs.uk/publication/combined-ccg-icb-and-pss-commissioning-for-quality-and-innovation-cquin-indicator-specification/
5. Horrocks M. Vascular Surgery GIRFT Programme National Specialty Report. Available from: https://gettingitrightfirsttime.co.uk/wp-content/uploads/2018/02/GIRFT_Vascular_Surgery_Report-March_2018.pdf
6. Mendelson A, Kondo K, Damberg C, *et al*. The effects of pay-for-performance programs on health, health care use, and processes of care. *Ann Intern Med* 2017;**166**(5):341–53. https://doi.org/10.7326/M16-1881
7. Milstein R, Schreyoegg J. Pay for performance in the inpatient sector: a review of 34 P4P programs in 14 OECD countries. *Health Policy* 2016;**120**(10): 1125–40. https://doi.org/10.1016/j.healthpol.2016.08.009
8. Ogundeji YK, Bland JM, Sheldon TA. The effectiveness of payment for performance in health care: a meta-analysis and exploration of variation in outcomes. *Health Policy* 2016;**120**(10):1141–50. https://doi.org/10.1016/j.healthpol.2016.09.002
9. Waton S, Johal A, Birmpili P, *et al*. National Vascular Registry: 2021 Annual Report. London: The Royal College of Surgeons of England, November 2021. Available from: https://www.vsqip.org.uk/content/uploads/2021/11/NVR-2021-Annual-Report-Main-Report.pdf
10. Nickinson ATO, Dimitrova J, Houghton JSM, *et al*. Does the introduction of a vascular limb salvage service improve one year amputation outcomes for patients with chronic limb-threatening ischaemia? *Eur J Vasc Endovasc Surg* 2021;**61**(4):612–19. https://doi.org/10.1016/j.ejvs.2020.12.007
11. Peripheral Arterial Disease Quality Improvement Programme. Lessons learnt from the PAD QIP early adopters. August 2021. Available from: https://www.vascularsociety.org.uk/_userfiles/pages/files/Resources/26_08_21%20Summary%20of%20changes%20PAD%20QIP.pdf

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):65-70
http://doi.org/10.54522/jvsgbi.2022.021

www.jvsgbi.com

ORIGINAL RESEARCH

Outcomes of vascular interventions for chronic limb-threatening ischaemia in nonagenarians

Atkins E,[1] Stather P,[1] Burrows M,[1] Singh A,[2] Medagoda A,[1] Ezzarghani A,[1] Al-Jundi W,[1] Mughal NA[2]

1. Department of Vascular and Endovascular Surgery, Norfolk and Norwich University Hospital, UK
2. Department of Vascular Surgery, Cambridge University Hospitals NHS Trust, UK

Corresponding author:
Dr Eleanor Atkins
Vascular Surgery Registrar, Department of Vascular and Endovascular Surgery, Norfolk and Norwich University Hospitals NHS Trust, NR4 7UY, UK
Email: Eleanor.atkins@nhs.net

Received: 14th December 2021
Accepted: 5th April 2022
Online: 3rd May 2022

Plain English Summary

Why we undertook the work: People in the UK are living longer with lots of medical conditions. This means people aged over 90 are more likely to need vascular surgery for lack of blood supply to the legs. We wanted to know what the results of surgery or keyhole procedures to improve blood supply are in these people.

What we did: We looked at people aged 90 and older who were admitted to one hospital with a severe lack of blood supply to the leg, and had a surgical or keyhole procedure to improve it to try to save the leg. People admitted between January 2010 and December 2017 had their medical records reviewed, and we looked at how many of them were alive 30 days, 90 days and 1 year after their first procedure.

What we found: We looked back at the medical records of 99 patients. Their average age was 92. The 99 patients had 117 procedures between them, with 15 legs needing more than one procedure; 5.1% of people died in the first 30 days after their procedure, 18.2% died in the 90 days after and 44.4% died in the year after. If people came to hospital as an emergency, they were less likely to be alive at 1 year than someone coming in as a planned admission

What this means: There is a high chance of someone aged 90 or older dying in the first year after a procedure for a severe lack of blood supply to the leg, about the same as for patients who have an operation for a broken hip. Our operations provide pain relief and an ability to retain independence, so we should continue to consider them in people of this age.

Abstract

Background: With increasing age of the population, more patients over 90 years old are being referred to vascular surgery with increasingly complex comorbidity. There are minimal data on undertaking revascularisation at this extreme of age. This study therefore aims to evaluate the outcomes of nonagenarians who underwent vascular surgical procedures for chronic limb-threatening ischaemia.

Methods: A retrospective clinical record review was carried out of all patients aged 90 and older with chronic limb-threatening ischaemia who presented to a tertiary centre between January 2010 and December 2017 and underwent vascular surgical intervention. Primary outcomes were mortality at 30 days, 90 days and 1 year.

Results: Ninety-nine patients were included. The median age was 92 years (IQR 90–94) and median follow-up was 15 months (IQR 4–32). A total of 117 limbs were treated, with 15 limbs requiring multiple procedures. Of the patients' first procedures, 76 (76.8%) were endovascular, 14 (14.1%) open and 9 (9.1%) were major limb amputations. The 30-day, 90-day and 1-year procedural mortality rates were 5.1%, 18.2% and 44.4%, respectively, with higher mortality for emergency cases at 1 year (p=0.045).

Conclusions: Mortality for these procedures in patients aged over 90 is high, similar to patients who undergo surgery for hip fracture. Given similar benefits for treatment in terms of pain relief and ability to retain independence, patients in this age group should be considered for limb salvage procedures.

Key words: vascular surgery, frailty, care of the elderly, open vascular surgery, emergency vascular surgery

Introduction

The ageing population is growing. In 2020 there were 609,503 UK residents aged 90 and over, an increase of more than 2.5 times in the past 30 years.[1] Cardiovascular disease is a large contributor to morbidity and mortality in this age group,[2] and consequently older patients are being referred for vascular surgery evaluation.[3] Given increasing comorbidities,[3] decision making in this population becomes difficult. Risk stratifying scores such as V-POSSUM (Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity) and V-POSSUM Cambridge scores have not been validated in elderly patients.[4] This population carries an increased perioperative and postoperative mortality for vascular procedures, with a study by Saarinen *et al* evaluating outcomes in patients with either chronic limb-threatening ischaemia or acute limb ischaemia highlighting a 1-year survival rate of 50%.[5] It is important that an accurate picture of risk is discussed with patients and their advocates prior to any procedures carried out, as well as their potential benefits.

Current guidance from the Vascular Society of Great Britain and Ireland recommends early revascularisation for presentations of chronic limb-threatening ischaemia in order to prevent limb loss.[6] The Global Vascular Guidelines recommend offering revascularisation to patients after taking into account their surgical risk, level of ischaemia and how threatened their limb is.[7] Surgical risk is difficult to assess. Average-risk and high-risk patients are defined by estimated procedural and 2-year all-cause mortality, with the list of predictors including age, chronic kidney disease, coronary artery disease, congestive heart failure, diabetes mellitus, smoking, cerebrovascular disease, tissue loss, body mass index, dementia and functional status. However, the Global Vascular Guidelines recommend no particular model to assess surgical risk.

The aim of this study was to evaluate outcomes of vascular surgery for chronic limb-threatening ischaemia in nonagenarians, to compare elective and emergency surgery, and open and endovascular procedures. As the ageing population grows, this information will help guide decision making, consent discussions and risk stratification.

Methods

A retrospective notes review of patients aged 90 and older who underwent revascularisation or major amputation following a presentation with chronic limb-threatening ischaemia at one tertiary vascular unit in the UK was carried out, with reporting according to STROBE guidelines.[8] The study was registered with the local Norfolk and Norwich University Hospital institutional audit department to ensure all data collection was in line with local committee ethical standards and, after review by the local R&D department, the study was deemed exempt from ethical approval owing to the minimal risk and non-identifiable nature of the study. Patients were de-identified and analysed anonymously.

Patients admitted between January 2010 and December 2017 were included and the demographics and comorbidities of the cohort were captured. These included age, sex, diabetes, hypertension, chronic kidney disease, chronic obstructive pulmonary disease, ischaemic heart disease, having had vascular surgery in the past, stroke, heart failure and smoking history. Chronic limb-threatening ischaemia was defined as rest pain or tissue loss. The frailty score and Rutherford classification were also calculated. Patients were identified through both surgical and interventional radiology procedural databases and cross-referenced with departmental governance data. Case notes, discharge summaries and clinic notes were used for data collection. Deaths were identified from patient records. Follow-up was completed in April 2021.

The type of procedure was recorded and grouped as to whether it was elective or emergency (defined as an outpatient or inpatient pathway), and open or endovascular. Data were also collected on their discharge destination and whether they returned to the address from which they were admitted to hospital within 3 months. This was retrieved from the Trust's Patient Administration System. A 'nursing home' was defined as a care destination which always has a qualified nurse on site whereas a 'care home' has trained care assistants. Patients who require a nursing home have increased care needs compared with those who require a care home.

The decision to treat a patient in their 90s who presented with chronic limb-threatening ischaemia was made by the admitting vascular surgeon. An opinion from a consultant vascular anaesthetist was sought prior to any open vascular surgical procedure. Patients on an elective pathway were discussed at weekly vascular multidisciplinary team (MDT) meetings; however, MDT discussion for emergency admissions were variable depending on day of admission. Patients who were deemed too high risk for any procedure were managed conservatively. Input from geriatricians was not routinely sought.

The primary outcome measured was mortality at 1 year. Secondary outcomes included discharge destination, re-interventions, amputation, and mortality at 30 and 90 days.

Data analysis

Statistical analysis was carried out using Kaplan–Meier curves to calculate mortality, statistical significance being calculated using Mantel–Cox log rank test and Fisher's exact test or χ^2 test depending on raw numbers. Descriptive statistics were documented as percentages. For patients who had more than one procedure in the follow-up period, the first procedure only was used in mortality calculations. Statistical significance was defined as $p<0.05$.

Study size was based on the number of cases undergoing the procedure during the study duration and was not a calculated sample size. Missing data were reported as such and statistical analyses based on the number with data obtained. No matching of cases or sensitivity analyses were possible due to the nature of the study and sample size.

Table 1 Study population demographics, comorbidities and medications.

Demographics	n (%) (N=99)
Female	55 (55.6)
Diabetes	23 (23.2)
Hypertension	56 (56.6)
Cardiac disease (including myocardial infarction, heart failure and atrial fibrillation)	56 (56.6)
Stroke/transient ischaemic attack	15 (15.2)
Previous vascular surgery	28 (28.3)
Peripheral arterial disease	39 (39.4)
Smoking history	19 (19.2)
Statin	43 (45.3)
Antihypertensive	62 (65.3)
Antiplatelet	65 (68.4)
Warfarin	16 (16.8)
No antiplatelet/anticoagulant	15 (15.8)

Table 2 Mortality at 30 days, 90 days and 1 year post-procedure.

	30-day mortality Frequency (%)	90-day mortality Frequency (%)	1-year mortality Frequency (%)
Combined	5 (5.05)	18 (18.2)	44 (44.4)
Admission pathway			
Elective	0 (0)	2 (6.06)	10 (30.3)
Emergency	5 (7.58)	16 (24.2)	34 (51.5)
P value	0.17	**0.029**	**0.045**
Revascularisation procedure			
Endovascular	5 (6.58)	14 (18.4)	32 (42.1)
Open	0 (0)	4 (28.6)	9 (64.2)
P value	1	0.47	0.13

Results

Ninety-nine patients (44.4% male) who underwent 117 procedures were identified. The median age was 92.4 years (IQR 90.9–94.6) with a median follow-up of 1.24 years (IQR 0.37–3.17). A total of 101 limbs were treated, 67.5% of which were treated following emergency admission. Patient comorbidities and medications are shown in Table 1 and were commensurate with standard vascular risk factors. Twenty-eight patients (28.3%) had previously undergone vascular intervention. The Rutherford classification was known for 94 patients: 43.6% had Rutherford stage 6, 41.5% had stage 5, 10.6% stage 4 and 4.3% stage 3. Clinical frailty scores were also calculated for 85 patients, with 15.3% scoring 7, 20.0% scoring 6, 23.5% scoring 5, 28.2% scoring 4, 11.8% scoring 3 and 1.2% scoring 2.

Eighty-four limbs underwent a single intervention and 15 limbs underwent a secondary procedure with one limb undergoing three procedures. Primary procedures included 78 angioplasties, nine femoral endarterectomies±angioplasty, five lower limb bypasses and nine major limb amputations (above or below knee). Secondary procedures included nine major limb amputations following angioplasty, five repeat angioplasties, one femoral endarterectomy post-angioplasty and one redo femoral endarterectomy.

The 30-day, 90-day and 1-year procedural mortality rates for all patients were 5.1%, 18.2% and 44.4%, respectively (Table 2). Median survival time was 1.23 (IQR 0.37–3.17) years. One-year mortality rates for patients undergoing open surgical revascularisation and angioplasty (excluding amputation) were 64.2% and 42.1%, respectively (p=0.13). These differences were also non-significant at 30 and 90 days post-procedure (Table 2).

Median survival was higher following endovascular procedures than open surgery (1.29 years (IQR 0.37–3.17) vs 0.93 years (IQR 0.38–2.98)), but no significant difference between Kaplan–Meier curves (Figure 1) was demonstrated on the Mantel–Cox log rank test (p=0.9).

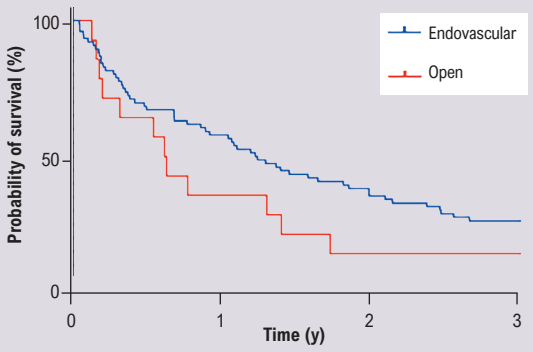
Mortality at 1 year following emergency cases was 51.5% whilst that following elective cases was 30.3% (p=0.045). Table 2 shows that the differences in mortality were not significant at 30 days post-procedure but were significant at 90 days post-procedure (p=0.029) and at 1 year. Median survival was higher following elective procedures than following emergency surgery (2.04 years (IQR 0.90–3.43) vs 0.86 years (IQR 0.29–3.08)), but no significant difference between Kaplan–Meier curves (Figure 2) was demonstrated on the Mantel–Cox log rank test (p=0.16).

Prior to the first admission, 13.1% of patients lived in a care home, 77.8% in their own home, 2.0% in a nursing home and 7.1% in sheltered housing. Three months following discharge 87 patients were alive, of which 17.2% were in a care home, 71.3% in their own home, 4.0% in a nursing home, 5.1% in sheltered housing and 1.0% in a hospice. This resulted in 94.3% of surviving patients maintaining their preoperative level of independence at 3 months.

Of the 77 patients who were admitted to hospital from their own home, all survived to discharge. Discharge destination was their own home for 68 patients (88.3%), a care home for four patients (5.19%), a rehabilitation placement for three patients (3.90%) and a nursing home for two patients (2.60%). Seventy patients (90.9%) were alive at 12 weeks, 66 (94.3%) of whom had returned to their own home, three (4.29%) were living in a care home and one patient (1.43%) was in a hospice.

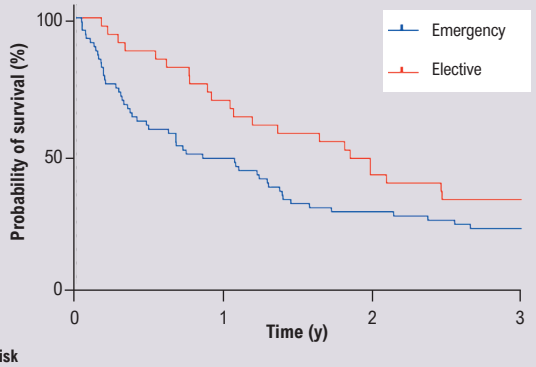
Clinical frailty was analysed to determine whether increasing frailty was associated with long-term survival. Kaplan–Meier analysis and log-rank test showed a significant association between increasing frailty scores and poorer survival (p=0.0005, Figure 3).

Figure 1 Kaplan–Meier curve showing survival for endovascular versus open vascular surgical procedures.



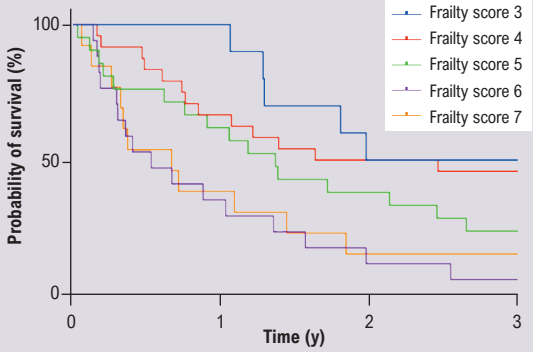
Numbers at risk				
Endovascular	76	44	27	20
Open	14	5	3	3

Figure 2 Kaplan–Meier curve showing survival for elective versus emergency vascular surgical procedures.



Numbers at risk				
Emergency	66	33	20	15
Elective	33	23	14	12

Figure 3 Kaplan–Meier curve showing survival depending on clinical frailty score.



Numbers at risk				
Frailty score 3	10	10	6	6
Frailty score 4	24	17	13	12
Frailty score 5	21	14	8	5
Frailty score 6	17	6	3	2
Frailty score 7	13	6	3	3

Discussion

These data highlight the fact that patients at the extremes of age are able to undergo vascular intervention, with the majority of patients able to maintain their pre-existing level of independence. With careful patient selection, patients over the age of 90 can return to independent living with revascularisation and should not be turned down for intervention based on age, but the risks and benefits of intervention should be appropriately discussed.

As the number of nonagenarian patients referred to vascular surgeons increases, it is important to identify those who would benefit most from invasive vascular surgical procedures, which often have significant risk attached. This assessment and identification is challenging and requires close working with the surgeon, anaesthetist and care of the elderly physician to optimise patients perioperatively. Patient frailty is an independent risk factor for poor outcomes in vascular surgery,[9] which is in accordance with the findings of this study. Many tools to assess frailty exist, and not all are validated in the surgical population. In addition, not all patients with increased surgical risk will be frail and there is no evidence to decline surgery based on a frailty score alone.[9]

The overall 30-day mortality rate for vascular surgery procedures in nonagenarians, combining elective and emergency operations over the study period, was 5.1%. This is comparable to the literature on general surgery for patients aged 90 years or older, with a 30-day mortality rate of 8.4% reported by Hosking *et al*[10] and 6.2% reported by Sudlow *et al*.[11] In the literature on vascular surgery, the 30-day mortality rate for patients aged over 90 following combined elective and emergency procedures ranges from 6.2% to 12.7%.[12]

Mortality in our study cohort was not significantly increased at 30 days for emergency procedures compared with elective procedures, but was at 90 days and one year. The lack of an early significant difference is likely due to all of these cases having chronic limb-threatening ischaemia and therefore undergoing intervention within a short period of time from referral regardless of mode of presentation. At 1 year, mortality reached 51.5% in emergency cases and 30.3% in elective cases. These outcomes are worse than in a younger cohort,[13] and as such underline the importance of frank and honest conversations about expected outcomes with patients and their advocates when making the decision to perform a surgical intervention.

When comparing open procedures to endovascular procedures, there was a higher mortality at 1 year for those undergoing open surgery, which was not significant. It is also important to note that all cases of open surgery had no endovascular option, and as such it is not a like-for-like comparison. These data suggest that an 'endovascular first' strategy may be beneficial in the over-90s, especially with recent and ongoing advances in what can be achieved via endovascular methods, although clearly this is not possible in all cases. The mortality of 44.4% in all those undergoing interventions for chronic limb-threatening ischaemia at 1 year is comparable to patients

undergoing surgery for hip fracture, which has an associated 1-year mortality rate of 25–50% in this age group.[14,15] Given the similarities in these patient cohorts, including poor functional status, pain and reduced quality of life, a similar approach to treatment could be considered as the benefits of limb salvage, mobility and pain relief in both scenarios are considerable, so open surgery should remain an option in selected patients.

It is exceedingly difficult to determine how much benefit one individual will derive from a vascular surgical procedure, especially in the context of high risk of harm. A woman aged 90 in England is expected to live a further 4.61 years and a man 4.09 years,[16] and by the age of 92 (the median age of our study cohort), the life expectancy is 3.94 further years for women and 3.5 for men. Our results show a median life expectancy of 1.19 years for nonagenarians fit enough to undergo vascular intervention, and the decision-making process should thus take into account the limited life expectancy for patients of this age.

It is evident from this study that the majority of patients over the age of 90 were treated as an emergency. This may be due to a reluctance of healthcare professionals to make a referral to tertiary providers for patients in this age group, but it may also be due to the perspective that vascular surgeons may adopt a more conservative approach to patients in this age group when seen in clinic compared with younger patients. In the context of emergency presentation, particularly if the patient has intolerable pain or significant tissue loss, the patient and their advocates may be willing to accept a higher level of risk. There may also be corresponding pressure on the surgeon to 'do something' when faced by a patient in extremis.

Fewer than half of the study cohort were taking a statin and over a quarter were not taking any antiplatelet or anticoagulant medication. Previous research on best medical therapy in vascular surgery patients has shown similarly limited cardiovascular risk factor modification.[17] This leads to an increased perioperative cardiovascular risk, especially in the population with peripheral vascular disease,[18] and may have contributed to the high mortality we have described. The harms of overprescribing have been a recent focus of the UK Department of Health and Social Care, with a review of the topic being commissioned in 2018.[19] Whilst there is no standardised definition of polypharmacy, its prevalence is increasing in older adults, along with its negative associations.[20] A meta-analysis of de-prescribing in older adults has shown that mortality is not affected,[21] but a specific subgroup analysis of patients with peripheral vascular disease has not been carried out. Clinician education on the benefits of secondary prevention in peripheral vascular disease could be a potential solution to ensure patients with cardiovascular risk factors are on appropriate secondary prevention medications.

This study has several limitations. Data on those patients who did not undergo intervention has not been obtained to provide a comparative analysis, and this will likely include those with the lowest preoperative functional status and worse outcomes.

KEY MESSAGES

- Patients aged 90 or older who undergo vascular surgery procedures for chronic limb-threatening ischaemia have reasonable short-term outcomes.
- At one year there is a high mortality of >40% for these patients, which is comparable to those in this age group treated for hip fracture.
- Appropriate risk/benefit conversations must take place with patients at the time of decision to treat.
- Both endovascular and open revascularisation should be considered.

Information on pre- or post-morbid functional status or quality of life was also not available, although discharge destination was used as the next best outcome measure. The study period is long and encompasses many advances in endovascular technology. These may lead to better outcomes for endovascular procedures in the current environment than we have described.

Conclusions

Mortality following vascular surgical interventions for chronic limb-threatening ischaemia in patients aged 90 or over is high, with a mortality rate of 44.4% at 1 year and a median life expectancy of 1.19 years in those deemed fit enough to undergo intervention. These data are similar to those for patients over the age of 90 undergoing surgical interventions for hip fractures. Considering the benefits of vascular surgery – including pain relief, retention of functional status and ability to maintain independence – these patients should be considered for limb salvage with both endovascular and open revascularisation in appropriate patients.

Conflict of Interest: The authors declare no conflicts of interest.

Funding: None to declare.

Reviewer acknowledgement: JVSGBI thanks Andrew Nickinson & Andy Garnham for their contribution to the peer review of this work.

References

1. Office for National Statistics, September 2019. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/ageing/bulletins/estimatesoftheveryoldincludingcentenarians/2002to2020 (accessed 1 March 2022).
2. Niederlaender E. Causes of death in the EU. Eurostat-Statistics in Focus. 2006; Issue number 10/2006: 1–12.
3. Diehm C, Schuster A, Allenbery JR, *et al.* High prevalence of peripheral arterial disease and co-morbidity in 6880 primary care patients: cross-sectional study. *Atherosclerosis* 2004;**172**(1):95–105. https://doi.org/10.1016/s0021-9150(03)00204-1
4. Teixeira IM, Teles AR, Castro JM, Azevedo LF, Mourao JB. Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity (POSSUM) system for outcome prediction in elderly patients undergoing major vascular surgery. *J Cardiothorac Vasc Anesth* 2018;**32**(2):960–7. https://doi.org/10.1053/j.jvca.2017.08.036
5. Saarinen E, Vuorisalo S, Kauhanen P, Alback A, Venermo M. The benefit of revascularization in nonagenarians with lower limb ischemia is limited by high mortality. *Eur J Vasc Endovasc Surg* 2015;**49**(4):420–5. https://doi.org/10.1016/j.ejvs.2014.12.027

6. Vascular Society of Great Britain and Ireland. A Best Practice Clinical Care Pathway for Peripheral Arterial Disease. March 2022. *J Vasc Soc GB Irel* 2022;**1**(Supp3):S1–S13. http://doi.org/10.54522/jvsgbi.2022.017
7. European Society for Vascular Surgery. Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischaemia. *Eur J Vasc Endovasc Surg* 2019;**58**:S1–S109.e33. https://doi.org/10.1016/j.ejvs.2019.05.006
8. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**:806. https://doi.org/10.1136/bmj.39335.541782.AD
9. Houghton JSM, Nickinson ATO, Morton AJ, *et al.* Frailty factors and outcomes in vascular surgery patients: a systematic review and meta-analysis. *Ann Surg* 2020;**272**(2):266–76. https://doi.org/10.1097/sla.0000000000003642
10. Hosking MP, Warner MA, Obdell CM, Offord KP, Melton LJ. Outcomes of surgery in patients 90 years of age and older. *JAMA* 1989;**261**:1909–15.
11. Sudlow A, Tuffaha H, Stearns AT, Shaikh IA. Outcomes of surgery in patients aged ⩾90 years in the general surgical setting. *Ann R Coll Surg Engl* 2018; **100**(3):172–7. https://doi.org/10.1308/rcsann.2017.0203
12. Wheatley BJ, Gorsuch JM, Mansour AM, *et al.* Vascular procedures in nonagenarians and centenarians are safe. *Am J Surg* 2011;**201**(3):301–4. https://doi.org/10.1016/j.amjsurg.2010.09.016
13. de Donato G, Benedetto F, Stilo F, *et al*. Evaluation of clinical outcomes after revascularization in patients with chronic limb-threatening ischemia: results from a prospective national cohort study (RIVALUTANDO). *Angiology* 2021; **72**(5):480–9. https://doi.org/10.1177/0003319720980619
14. Ridge C, Kearns S, Cahill K, *et al.* Morbidity and mortality following hip fracture in the over 90s: a cohort study. *Orthop Proc* 2018;**87**-B:Suppl 3.
15. Kadowaki M, Kono M, Nishiguchi K, Kakimaru H, Uchio Y. Mortality in patients with hip fracture aged over 90 years: a report from a progressively ageing island. *Arch Gerontol Geriatr* 2012;**54**(2):e113–7. https://doi.org/10.1016/j.archger.2011.10.003
16. Office of National Statistics. Single-year life tables – England. 25 September 2019. https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesenglandreferencetables/current
17. Saratzis A, Dattani N, Brown A, *et al*. Multi-centre study on cardiovascular risk management on patients undergoing AAA surveillance. *Eur J Vasc Endovasc Surg* 2017;**54**(1):116–22. https://doi.org/10.1016/j.ejvs.2017.04.009
18. Antithrombotic Trialists' Collaboration. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. *BMJ* 2002;**324**(7329):71–86. Erratum in: *BMJ* 2002;**324**(7330):141. https://doi.org/10.1136/bmj.324.7329.71
19. Matt Hancock orders review into overprescribing in the NHS, 8 December 2018. www.gov.uk/governemnet/news/matt-hancock-orders-review-into-over-prescribing-in-the-nhs (accessed 13 June 2020)
20. Wastesson JW, Morin L, Tan ECK, Johnell K. An update on the clinical consequences of polypharmacy in older adults: a narrative review. *Expert Opin Drug Saf* 2018;**17(**12):1185–96. https://doi.org/10.1080/14740338.2018.1546841
21. Page AT, Clifford RM, Potter K, Schwartz D, Etherton-Beer CD. The feasibility and effect of deprescribing in older adults on mortality and health: a systematic review and meta-analysis. *Br J Clin Pharmacol* 2016;**82**(3):583–623. https://doi.org/10.1111/bcp.12975

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):71-76
http://doi.org/10.54522/jvsgbi.2022.020

www.jvsgbi.com

ORIGINAL RESEARCH

WIfI scoring: a reliable tool for risk stratification in the diabetic foot clinic

Williams P,[1] Bakewell Z,[1] Akinlade B,[1] Russell DA[1,2]

1. Leeds Vascular Institute, Leeds General infirmary, Leeds, UK
2. Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, UK

Corresponding author:
Mr Paul Williams
Leeds Vascular Institute, Leeds General infirmary, Great George Street, Leeds LS1 3EX, UK
Email: Paul.williams27@nhs.net

Received: 19th December 2021
Accepted: 20th March 2022
Online: 25th April 2022

Plain English Summary

Why we undertook the work: Diabetes is estimated to affect over 5 million adults in the UK with a quarter developing a foot ulcer in their lifetime. 80% of people having their foot or leg amputated do so due to progressing diabetic foot ulcers. The associated cost to the NHS is around £1 billion per year. There are currently several scoring systems to help identify patients with the highest risk of amputation, the most commonly used being the Site, Ischaemia, Neuropathy, Bacterial infection and Depth (SINBAD) score. We compared a newer staging system (Wound, Ischaemia, foot Infection; WIfI) with the SINBAD to see if it more accurately predicts outcomes including amputation.

What we did: We reviewed the notes of patients who had been seen in our diabetic foot clinic over the 2 years from 2016 to 2018. People who had had a blood pressure measurement taken in the toe on the foot of their foot ulcer were eligible. We compared their eventual outcomes with their SINBAD score and their WIfI stage.

What we found: We found that WIfI stage 1–4 correlated better with time to healing, with stage 1 having the shortest time and stage 4 having the longest time. This was not the case with SINBAD severity. We found that a higher WIfI stage showed increased risk of foot/leg amputation at 1 year, whereas this did not change with SINBAD severity.

What this means: The WIfI stage more accurately predicted time to healing and gave a better idea of which patients will succumb to amputation at 1 year. This will help in several ways; it will allow patients to better understand their disease as well as providing a common language for future research to discuss different types of ulcers and their treatment.

Abstract

Background: The prevalence of diabetes is estimated to be over 5 million adults in the UK. Diabetic foot care is estimated to cost the NHS ~£1 billion per annum, meaning that diabetic foot ulcers (DFUs) are an increasing topic of discussion. It is estimated that reducing the prevalence of DFUs by a third could save the NHS up to £250 million annually. The Society of Vascular Surgery Wound, Ischaemia, foot Infection (WIfI) stage stratifies the risk of amputation and benefit of revascularisation in patients with threatened lower limbs and has been extensively validated in patients with chronic limb-threatening ischaemia, yet data on cohorts with diabetic foot ulcers in the UK remain scarce. The aim of this project was to compare the WIfI stage with the currently used Site, Ischaemia, Neuropathy, Bacterial infection and Depth (SINBAD) score in order to stratify risk in patients with DFUs.

Methods: The electronic case record (ECR) of eligible cases was reviewed retrospectively between February 2016 and March 2018. All patients with a recorded opening toe pressure were included. SINBAD score was taken from an ECR proforma and WIfI stage was calculated from ECR notes. The patients were followed up using electronic case notes.

Results: 119 patients with 129 foot wounds were included. WIfI stages predicted time to ulcer healing (p=0.04) whereas the trend for SINBAD severity did not reach significance (p=0.08). WIfI stages correlated with the proportion of patients with any minor/major ipsilateral lower limb amputation at 1 year (p=0.03) and minor amputation at 1 year (p=0.04), whilst SINBAD severity did not (p=0.95 and p=0.90, respectively).

Conclusions: WIfI more accurately predicts time to healing than SINBAD severity. WIfI predicted amputation risk at 1 year but SINBAD did not. WIfI more accurately predicts risk of minor amputation.

Key words: DFU, foot ulcer, diabetes mellitus, amputation, WIfI

Introduction

Diabetic foot ulcers (DFUs) are a common complication of diabetes, preceding over 80% of lower limb amputations in the UK.[1] It is estimated that by 2025 more than 5 million people will have diabetes in the UK, with DFUs estimated to affect 25% of this population.[1,2]

There are several validated DFU classification systems that aim to provide risk stratification and enable comparisons of outcomes between groups of patients.[3] Some systems address ischaemia to varying degrees as a contributing factor to amputations but are poor in reflecting other components that increase the risk of amputation.[3,4] Currently, the SINBAD (Site, Ischaemia, Neuropathy, Bacterial infection and Depth) score is the most widely used in the UK and is a key component of the National Diabetes Foot Care Audit (NDFA), and has been well validated for wound healing and risk of amputation.[3,5]

The Society for Vascular Surgery Wound, Ischaemia, foot Infection (WIfI) classification system was designed to assist stratification of amputation risk and benefit from revascularisation in patients with a threatened lower extremity.[4] The WIfI system uses wound, ischaemia and foot infection analogous to the tumour, node, metastasis (TNM) staging system in cancer and has since been established in several studies to correlate with wound healing time and amputation in patients with chronic limb-threatening ischaemia (CLTI),[6–8] but its validity in cohorts of patients with DFUs is less well established.[3,9,10]

Background

Why are DFUs a problem?

Diabetic foot care is estimated to cost the NHS £1 billion per annum.[11] Further research has revealed the mean cost of managing a single DFU over 12 months from initial presentation is £7,800, rising to £8,800 per unhealed DFU and £16,900 per amputated ulcer. DFUs significantly impact quality of life and survival. Data published by Diabetes UK suggest that four in 10 people who have a foot ulcer will die within 5 years and around half of those that experience a major amputation will die within 2 years.[1] Improvements in wound care and lowering amputation rates significantly reduces the disease burden on the NHS. It is estimated that reducing the prevalence of DFUs by a third could save the NHS up to £250 million annually.[12] This highlights clear clinical and economic benefits in improving outcomes.

Common DFU classification systems used in the UK include: The University of Texas Diabetic Foot Ulcer classification system (UT); PEDIS (Perfusion, Extent, Depth, Infection and Sensation) and SINBAD, the latter of which is the most widely used in the UK.[3,4] More recently, WIfI has been introduced which may better quantify risk of amputation and also guide need for revascularisation.

The SINBAD score is used in the NDFA in the UK and has been shown to correlate well with wound healing time in UK populations.[5,13] The SINBAD score is calculated as shown in Table 1.

Table 1 The Site, Ischaemia, Neuropathy, Bacterial infection and Depth (SINBAD) system for classifying foot ulcers

Category	Definition	SINBAD score
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischaemia	Pedal blood flow intact: at least one palpable foot pulse	0
	Clinical evidence of reduced pedal blood flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	None	0
	Present	1
Area	Ulcer <1cm	0
	Ulcer ≥ 1cm	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
Total score		/6

This table shows the SINBAD classification system adapted from Ince *et al*.[5]

A score of ≥3 signifies a high-risk ulcer. In a worldwide population, risk stratification of ulcers is correlated with healing time.[5] However, the SINBAD score does not give weight to the major factors affecting limb loss and revascularisation. SINBAD fails to account for the complex relationship between infection, ischaemia and wound healing.

The WIfI scoring system was initially developed for CLTI, specifically in the diabetic patient.[4,7] It aimed to move away from CLTI being defined by perfusion pressures alone.[10] WIfI also aimed to treat the ischaemic aspect of foot ulcers as a continuum.[10] It is calculated as shown in Table 2.

This then calculates a clinical stage which correlates to major amputation risk and revascularisation benefit as shown in Table 3.[7–10]

Given the limited data to validate WIfI in people with DFU, particularly in the UK, this project aimed to compare healing time, risk of amputation at 1 year and time free from amputation between both the SINBAD and WIfI systems.

Objectives

The objective of this study was to compare the SINBAD and WIfI classification systems in the risk stratification of DFUs. The primary outcomes were comparison of the proportion of patients undergoing amputation at 1 year between WIfI stages and high-risk and low-risk severity groups for the SINBAD score, and comparison of ulcer healing time between WIfI stages and SINBAD severity groups. The secondary outcome measure was the proportion of patients undergoing minor amputation between SINBAD severity groups and WIfI stages.

Methods

The study was performed in a tertiary referral diabetes limb salvage service (DLSS) at Leeds Teaching Hospitals NHS Trust. The study

Table 2 Wound, Ischaemia, foot Infection (WIfI) scoring classification system

Wound		
Ulcer	Gangrene	score
No ulcer	None	0
Small shallow (subcutaneous)	None	1
Deeper (tendon or muscle)	Gangrenous changes to limited digits	2
Extensive (extending to bone)	Extensive gangrene	3

Ischaemia			
ABPI	Toe pressure	Ankle systolic pressure	score
≥0.8	≥60 mmHg	>100 mmHg	0
0.79–0.6	40–50 mmHg	70–100 mmHg	1
0.59–0.4	30–39 mmHg	50–70 mmHg	2
≤0.39	<30 mmHg	<50 mmHg	3

Foot infection	
Ulcer	score
No signs or symptoms of infection	0
Local infection involving skin and subcutaneous tissue only (<2 cm erythema)	1
Local infection involving deeper structures or with >2 cm erythema (ie, osteomyelitis)	2
As above with SIRS response	3

This table shows the WIfI classification scoring system derived from Mills *et al.*[4]

Table 3 Wound, Ischaemia, foot Infection (WIfI) clinical stage associated with amputation risk and revascularisation benefit

Stage	Major amputation risk at 1 year (estimated %)	Revascularisation benefit score
1	2–3	Very low
2	8–9	Low
3	25	Moderate
4	50	High

This table shows the clinical stages calculated from the WIfI system and how the stages are associated with amputation risk and revascularisation benefit.

Table 4 Inclusion and exclusion criteria

Inclusion criteria (all patients attending foot clinic with)	Exclusion criteria
Validated toe pressure	Death/loss to follow-up before meeting one of the study end points
Complete healing at any duration	Non-diabetic foot pathology identified at first contact
	Need for minor/major amputation at first visit to clinic

was registered and approved by the local Caldicott guardian. All patients with DFUs in the referral territory of the hospital are encouraged to be referred to the DLSS service for assessment and management. A DFU was defined as a break of the skin that involves the epidermis and part of the dermis below the level of the malleoli.[14] At the time of the study, all patients were assessed with pulse palpation and audible handheld Doppler signal at first visit, along with 10G monofilament testing for neuropathy and ulcer assessment. Patients with palpable pulses or multiphasic handheld Doppler signals were deemed neuropathic and did not receive perfusion assessment. Further vascular assessment with toe pressures was only performed in the presence of peripheral artery disease detected with pulse and handheld Doppler assessment, or where the ulcer failed to reach a healing trajectory at 4 weeks. Toe pressures were performed using a commercially available device (Huntleigh, Dopplex ATP). The technique of toe pressure assessment has been well validated in other research so was not validated further in this study. Thus, the patients included in this study are 'harder to heal' than all comers attending the DLSS clinic. All ulcers were managed with ulcer bed debridement, dressings, offloading footwear and management of infection if present. Healing was defined as complete epithelialisation without discharge maintained[15] as determined by the DLSS clinical team.

All patients with an opening toe pressure, diabetes and a foot ulcer for more than 4 weeks duration presenting between February 2016 and March 2018 were retrospectively analysed using electronic case notes. The inclusion and exclusion criteria are shown in Table 4.

The SINBAD score was taken from the NDFA proforma of the case notes and the WIfI stage was calculated from data in the clinical records.

Statistics

The SPSS statistical package IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp, Armonk, New York, USA) was used to perform all analyses. Differences in proportions were performed using a χ^2 test, as were the comparisons for any amputation at 1 year and minor amputation. Due to the small number of major amputations, Fisher's exact test was used to compare proportions. HbA_{1c} was normally distributed and compared using one-way ANOVA. Time to event analyses were created using Kaplan–Meier survival curves with Cox regression. Time to event analyses followed patients up to 120 weeks for wound healing.

Risk stratification

In order to allow effective comparison between the two scoring systems and address the small number of patients within the higher number of groupings in the SINBAD score, we stratified the population into high severity and low severity groups based on their SINBAD score.[5] Scores of 0–2 were defined as low severity and scores of 3–6 were defined as high severity. With respect to WIfI stage, patients were grouped based on their stage at presentation.

Table 5 Patient demographics and co-morbidities

Variable	Overall n=129	WIfI 1 n=43	WIfI 2 n=13	WIfI 3 n=41	WIfI 4 n=32	P value
Male	79 (66%)	30 (70%)	6 (46%)	23 (58%)	20 (61%)	NS
IHD	56 (47%)	24 (56%)	4 (31%)	15 (37.5%)	13 (39%)	NS
CVA	19 (16%)	6 (14%)	2 (15%)	6 (15%)	5 (15%)	NS
HTN	63 (53%)	21 (49%)	7 (54%)	20 (50%)	15 (45%)	NS
CKD	21 (18%)	6 (14%)	3 (23%)	8 (20%)	4 (12%)	NS
PAD	38 (32%)	9 (21%)	3 (23%)	12 (30%)	14 (42%)	NS
Smoking history	78 (66%)	26 (60%)	5 (38%)	24 (60%)	23 (70%)	NS
Mean±SE HbA_{1c} (≤3)	64.8±1.9	68.3±3.2	56.4±6.3	60.7±3	67.1±4.1	NS

CKD, chronic kidney disease; CVA, cerebrovascular accident; HTN, hypertension; IHD, ischaemic heart disease; PAD, peripheral artery disease; WIfI, Wound, Ischaemia, foot Infection.

Figure 1 Time to ulcer healing with Wound, Ischaemia, foot Infection (WIfI) stage.

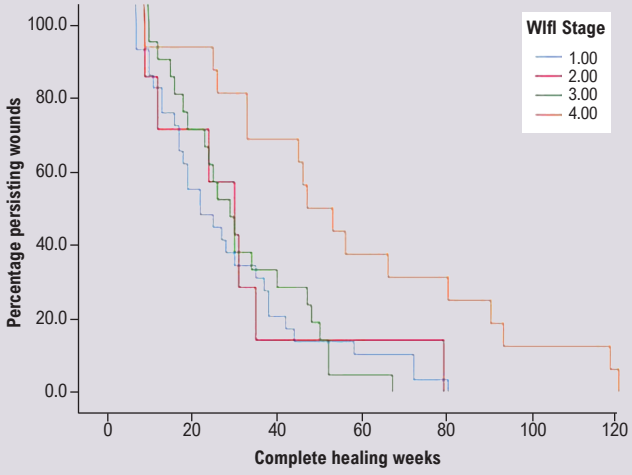
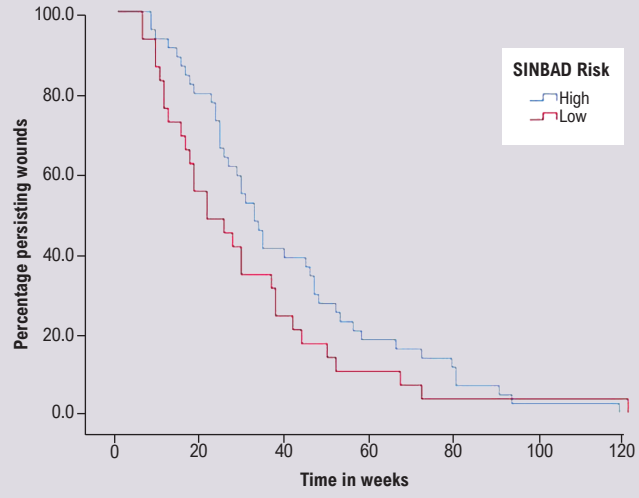


Figure 2 Time to ulcer healing with Site, Ischaemia, Neuropathy, Bacterial infection and Depth (SINBAD) severity.



Results

The study included 119 patients with 129 DFUs, with a mean age of 72±12 years and a male to female distribution of 66% vs 34%; 33% (n=43) of ulcers were WIfI stage 1, 10% (n=13) stage 2, 32% (n=41) stage 3 and 25% (n=32) stage 4 at presentation. The SINBAD score put 3% (n=4) in stage 0, 6% (n=8) in stage 1, 31% (n=40) in stage 2, 38% (n=50) in stage 3, 14% (n=18) in stage 4 and 7% (n=9) in stage 5.

The rates of ischaemic heart disease, cerebrovascular accident, hypertension, chronic kidney disease and HbA_{1c} levels were evenly distributed between WIfI stages (Table 5).

Time to ulcer healing

WIfI stage was associated with a significant increase in time to ulcer healing from stage 1 to stage 4 (p=0.04; Figure 1). Whilst a similar trend was seen with SINBAD severity, this did not reach significance (p=0.08; Figure 2).

Amputation at 1 year

There were 30 amputations during the 1-year period with seven being major, defined as any amputation at a level higher than the ankle. The remaining 23 were minor amputations. For the analysis on any (combined major or minor) amputation at 1 year, patients undergoing major and minor amputation on the same limb were considered as one amputation event.

There was an increasing proportion of patients undergoing any amputation within 1 year with increasing WIfI stage (p=0.03) whilst there was no correlation with SINBAD (p=0.095). There was a trend towards an increased rate of major amputation with increased WIfI stage which failed to reach statistical significance (p=0.09), whilst the increase in proportion of patients undergoing minor amputation with increase in WIfI stage was significant (p=0.04). There was no clear differentiation of any category of amputation with change in SINBAD severity (Table 6; Figures 3 and 4).

Discussion

The Society for Vascular Surgery WIfI stage has been shown to correlate well with healing time and amputation risk in a mixed cohort of patients with CLTI. It has previously been shown to correlate well with time to ulcer healing in a homogenous DFU population in the USA.[9] Here we report the first UK-based data to show that WIfI stage both correlates with time to wound healing and predicts amputation at 1 year in a DFU population. This is in keeping with the wider literature when applied to more heterogeneous populations.

The major amputation rate for our institution was 0% for both stage 1 and 2, 8% at stage 3 and 12% at stage 4. This is in contrast to the initial WIfI study in 2015 where a considerably wider

Table 6 Proportion of amputations

	WIfI 1 n=43	WIfI 2 n=13	WIfI 3 n=40	WIfI 4 n=33	Low-risk SINBAD (0–2) n=52	High-risk SINBAD (3–6) n=77
Combined major/minor amputations	4 (9%)	2 (15%)	9 (23%)	12 (36%)	11 (21%)	16 (21%)
Major amputations	0 (0%)	0 (0%)	3 (8%)	4 (12%)	3 (6%)	4 (5%)
Minor amputations	4 (9%)	2 (15%)	6 (15%)	11 (33%)	9 (17%)	14 (18%)

SINBAD, Site, Ischaemia, Neuropathy, Bacterial infection and Depth; WIfI, Wound, Ischaemia, foot Infection.

Figure 3 Time free from any amputation with Wound, Ischaemia, foot Infection (WIfI) stage.

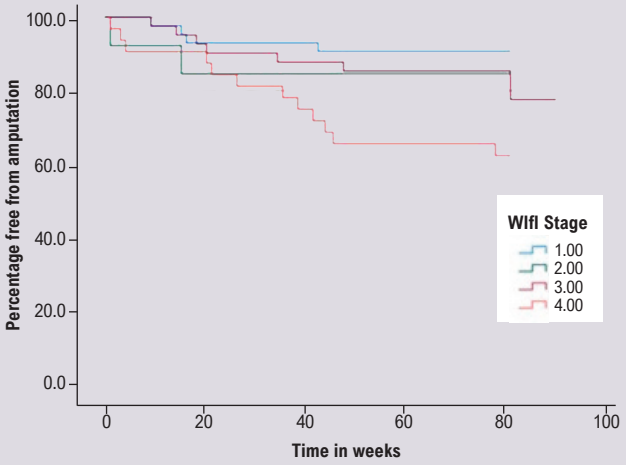
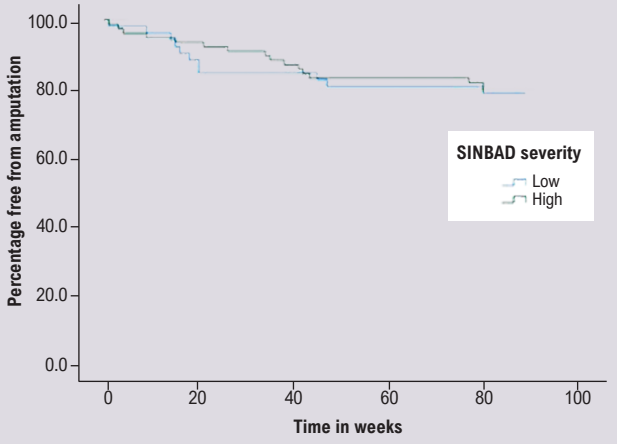


Figure 4 Time free from any amputation with Site, Ischaemia, Neuropathy, Bacterial infection and Depth (SINBAD) severity.



variation in amputation rates was seen across WIfI scores (from 0% at stage 1 to 64% at stage 4).[9] Earlier studies have found amputation rates up to 90% in stage 4 patients.[7] Our findings are more in keeping with Robinson *et al* who studied a pure DFU cohort.[8] The difference in results is likely due to a combination of two factors: differences in patient population and the ethos of the DLSS. Firstly, Zhan *et al* studied patients with CTLI which is a narrower and more severe spectrum of presentation than the data presented in this study. All of their patients were considered to have threatened limbs whilst our population included less severe disease. This would account for their higher rate of major amputation, especially in the highest risk groups. Second, the DLSS at our institution uses a multidisciplinary team approach to address not just the ulcer at hand but other systemic exacerbating or causative factors. Internationally this approach has been shown to reduce numbers of major amputations in DFU populations compared with care being delivered by vascular surgeons alone.[9]

Although we did not report a significant difference in major amputation rates between WIfI stages, there was a trend towards major amputation in the higher stages. Taking this in the context of the wider literature,[8,9] this likely represents type 2 error given the small number of major amputations taking place in this cohort. We also report a significant correlation between WIfI score and minor amputation at any time (p=0.04). This is the first time this has been observed using the WIfI score in a DFU population, with the low-risk group having an 11% risk whilst the high-risk group had a 30% risk. For the purpose of this study, we defined minor amputation as any amputation below the ankle. These data could act as a baseline measurement for community teams trying to reduce the morbidity caused by DFUs in future studies.

We took the opportunity to compare the WIfI staging against the SINBAD score, which is currently the most widely used classification in the UK. Our findings would suggest that the WIfI stage is valid in a pure DFU cohort but, further to this, it is better at predicting outcomes than the SINBAD score in a cohort of patients with hard to heal DFUs in a specialist clinic. However, it should be recognised that 69% of ulcers in this study were evenly distributed between SINBAD scores 2 and 3, and the lack of a wide distribution of the ulcers across the range of SINBAD scores may in part account for the reduced differentiation in clinical outcomes associated with SINBAD severity in this study. The SINBAD score has proved to be a useful tool in evaluating DFUs, but where regular and consistent access to expert DLSS exists, the more objective measures required for WIfI should be undertaken to give better and more reliable prognostic information to patients and to better identify those patients who would benefit from early revascularisation.

There are limitations to this study. It is retrospective and therefore at risk of selection and observer bias. The study only includes those patients who had an objective measure of perfusion pressure and has therefore sub-selected a population who are likely to have harder to heal ulcers than the general population attending

KEY MESSAGES

- In a cohort of patients with DFU, WIfI stage correlates with risk of any amputation at 1 year whilst SINBAD severity does not.
- WIfI stage correlates with minor amputations over time whilst SINBAD severity does not.
- WIfI stage shows better correlation with time to ulcer healing than SINBAD severity.

our clinic. Therefore, there needs to be some caution about the generalisability of these data, although it would be expected that the differentiation between low- and high-risk patients would be greater for both classification systems in a full patient cohort which would have a higher proportion of low-risk ulcers and better associated outcomes. There is inter-rater variability in WIfI and SINBAD in that the former was recorded retrospectively and the latter calculated prospectively by different clinicians using retrospective data. The absolute number of major amputations was small (n=7), which could affect the reliability of the measurements. However, our outcome is in keeping with the wider literature.[9]

Conclusion

This is the first study in a UK diabetic foot cohort to show that WIfI stage correlates with increased risk of amputation at 1 year. It also shows that WIfI better predicts time to healing than the SINBAD score. Despite the limitations of this study, it has shown the WIfI stage to be a valid tool for risk stratification in patients with a DFU in a UK population and should be widely adopted to the benefit of patients. The next stage in research would be a larger prospective cohort study examining outcomes and correlating them with the scoring system at presentation and eventual resolution of disease.

Conflict of Interest: The authors declare no conflicts of interest.

Funding: None to declare.

Reviewer acknowledgement: JVSGBI thanks Louise Hitchman & Junaid Sultan for their contribution to the peer review of this work.

References

1. Guest JF, Fuller GW, Vowden P. Diabetic foot ulcer management in clinical practice in the UK: costs and outcomes. *Int Wound J* 2018;**15**(1):43–52. https://doi.org/10.1111/iwj.12816
2. Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. *N Engl J Med* 2017;**376**(24):2367–75. https://doi.org/10.1056/NEJMra1615439
3. Monteiro-Soares M, Boyko EJ, Jeffcoate W, *et al*. Diabetic foot ulcer classifications: a critical review. *Diabetes Metab Res Rev* 2020;**36** (Suppl 1):e3272. https://doi.org/10.1002/dmrr.3272
4. Mills JL, Conte MS, Armstrong DG, *et al*. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on Wound, Ischemia, and foot Infection (WIfI). *J Vasc Surg* 2014;**59**(1): 220–34.e1–2. http://dx.doi.org/10.1016/j.jvs.2013.08.003
5. Ince P, Abbas ZG, Lutale JK, *et al*. Use of the SINBAD classification system and score in comparing outcome of foot ulcer management on three continents. *Diabetes Care* 2008;**31**(5):964–7. https://doi.org/10.2337/dc07-2367
6. Mills J. The application of the Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIfI) classification to stratify amputation risk. *J Vasc Surg* 2017;**65**(3):591–3. http://dx.doi.org/10.1016/j.jvs.2016.12.090
7. Zhan LX, Branco BC, Armstrong DG, Mills JL Sr. The Society for Vascular Surgery lower extremity threatened limb classification system based on Wound, Ischemia, and foot Infection (WIfI) correlates with risk of major amputation and time to wound healing. J *Vasc Surg* 2015;**61**(4):939–44. http://dx.doi.org/10.1016/j.jvs.2014.11.045
8. Robinson WP, Loretz L, Hanesian C, *et al*. Society for Vascular Surgery Wound, Ischemia, foot Infection (WIfI) score correlates with the intensity of multimodal limb treatment and patient-centered outcomes in patients with threatened limbs managed in a limb preservation center. *J Vasc Surg* 2017;**66**(2): 488–98.e2. http://dx.doi.org/10.1016/j.jvs.2017.01.063
9. Mathioudakis N, Hicks CW, Canner JK. The Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIfI) classification system predicts wound healing but not major amputation in patients with diabetic foot ulcers treated in a multidisciplinary setting. *J Vasc Surg* 2017;**65**(6):1698–705.e1. http://dx.doi.org/10.1016/j.jvs.2016.12.123
10. Weaver ML, Hicks CW, Canner JK, *et al*. The Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIfI) classification system predicts wound healing better than direct angiosome perfusion in diabetic foot wounds. *J Vasc Surg* 2018;**68**(5):1473–81. https://doi.org/10.1016/j.jvs.2018.01.060
11. Kerr M, Barron E, Chadwick P, *et al*. The cost of diabetic foot ulcers and amputations to the National Health Service in England. *Diabet Med* 2019; **36**(8):995–1002. https://doi.org/10.1111/dme.13973
12. Kerr M, Rayman G, Jeffcoate WJ. Cost of diabetic foot disease to the National Health Service in England. *Diabet Med* 2014;**31**(12):1498–504. https://doi.org/10.1111/dme.12545
13. National Diabetic Foot Care Audit (NDFA). National Diabetes Foot Care Audit Fourth Annual Report. 2019. Available from: https://www.hqip.org.uk/resource/national-diabetes-foot-care-audit-fourth-annual-report/#.YkGlZijMJPY
14. van Netten JJ, Bus SA, Apelqvist J, *et al*. Definitions and criteria for diabetic foot disease. *Diabet Metab Res Rev* 2020;**36**(Suppl 1):e3268. https://doi.org/10.1002/dmrr.3268
15. Jeffcoate WJ, Bus SA, Game FL, *et al*. Reporting standards of studies and papers on the prevention and management of foot ulcers in diabetes: required details and markers of good quality. *Lancet Diabetes Endocrinol* 2016; **4**(9):781–8. http://dx.doi.org/10.1016/S2213-8587(16)30012-2

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):77-83
http://doi.org/10.54522/jvsgbi.2022.023

www.jvsgbi.com

ORIGINAL RESEARCH

Symptoms to surgery: factors associated with delays to carotid endarterectomy for symptomatic stenosis in an Irish tertiary vascular centre

Foley MP,[1] Gray C,[1] Healy D,[1] Mulkern E,[1] McDonnell CO,[1] O'Donohoe MK[1]

1. Department of Vascular Surgery, Mater Misericordiae University Hospital, Dublin 7, Ireland

Corresponding author:
Megan Power Foley
Department of Vascular Surgery, Mater Misericordiae University Hospital, Dublin 7, Ireland
Email: meganpfoley@rcsi.com

Received: 5th February 2022
Accepted: 1st April 2022
Online: 5th May 2022

Plain English Summary

Why we undertook the work: Carotid endarterectomy (CEA) is a surgery performed to reduce the risk of stroke by clearing clot-causing debris out of one of the main arteries responsible for bringing blood to the brain. The timing of CEA is critical in patients who have already had a stroke or a mini-stroke. The best evidence indicates CEA should be done within two weeks to minimise the risk of patients going on to have another, potentially larger, stroke. However, getting the surgery done inside this short window is difficult for multiple reasons.

What we did: We reviewed the electronic medical records of consecutive patients who underwent CEA at our hospital after having a stroke or a mini-stroke between January 2017 and December 2019. We looked at how many patients had their surgery within two weeks of their symptoms starting, and at the reasons why some surgeries got delayed.

What we found: One-hundred and twenty-four individual patients were included in the study. We found that just over half of all patients had their surgery within 14 days of their first symptom. Patients who experienced typical stroke signs, as described in the 'Face Arms Speech Time' (FAST) mnemonic, were more likely to have their surgery in time; this is largely because they came to hospital sooner. Furthermore, patients who came directly to our hospital, compared with smaller district hospitals without vascular surgeons, were more likely to have their surgery on time.

What this means: Our study shows the number of patients getting their CEA within 14 days at our hospital is comparable to national figures from the UK and Australia. Despite this, a significant number of patients waited over 14 days for surgery. To improve access to timely surgery, systems between hospitals need to be put in place to prioritise these patients. The 14-day target should be mandated as part of the national stroke management strategy.

Abstract

Introduction: Carotid endarterectomy (CEA) is the accepted treatment for stroke risk reduction in patients with symptomatic 50–99% carotid artery stenosis. Best practice guidelines recommend surgery be performed within 14 days of index symptoms to achieve maximum benefit; however, achieving this target can be difficult. Late presentation and presentation to hospitals without onsite vascular capabilities are two recurring reasons for delayed CEA across the literature.

Methods: All symptomatic CEAs performed between January 2017 and December 2019 were retrospectively extracted from an electronic institutional database and analysed to determine the proportion of CEAs meeting benchmark targets and to assess factors contributing to delays.

Results: A total of 124 CEAs were performed for 62 strokes and 62 transient ischaemic attacks (TIAs); 71.8% (n=89) were male and the median (range) age was 71.0 years (43–88). The median delay between initial symptom and CEA was 14 days (range 1–183). Sixty-six patients (55%) had surgery within 14 days of the index symptom. Patients presenting with 'Face Arms Speech Time' (FAST) symptoms were significantly more likely to undergo timely CEA, largely due to earlier presentation to hospital (p=0.021, OR 2.563, 95% CI 1.143 to 5.747). Presentation directly to a tertiary vascular centre was significantly associated with CEA within 14 days compared with referrals from external hospitals (p=0.002), with a median symptom-to-surgery interval of 12.0 days and 25.0 days, respectively (p=0.001)

Conclusions: Our results are comparable to UK and Australian national audits, although a significant number of CEAs fell outside the 14-day target. Protected pathways between referring hospitals and vascular centres are needed to ensure all patients have equal access to urgent CEA. Designating CEA within 14 days as a key performance indicator for stroke management will hopefully incentivise hospitals to expedite this high-risk cohort. Furthermore, re-auditing with an emphasis on patients turned down for intervention due to recurrent events while awaiting CEA may further highlight the need to prioritise symptomatic carotids.

Key words: carotid endarterectomy, symptomatic carotid stenosis, stroke management, key performance indicators

Introduction

Carotid endarterectomy (CEA) for symptomatic stenosis is most effective when performed close to the index event.[1,2] To reduce the risk of further neurological events, the best practice guidelines issued by several international vascular societies all recommend that CEA be performed within 14 days of the initial symptoms.[3,4] However, meeting this target can prove difficult without dedicated resources.[5–8] Multiple studies have shown that later presentation to an acute hospital and increased numbers of medical practitioners involved in the patient journey cause delays between symptoms and surgery.[9,10] Conversely, hospitals with streamlined referral pathways or transient ischaemic attack (TIA) clinics with protected access to diagnostic imaging and vascular surgeons consistently report shorter intervals from presentation to CEA.[11–14]

At present in Ireland there are no national guidelines enforcing the timing of CEA for symptomatic stenosis; CEA within 14 days of an ischaemic event is not an audited key performance indicator (KPI) for stroke management and vascular surgery procedural data is not recorded in a centralised database. As such, the available data on how Irish patients with symptomatic carotid disease compare with international best practice is limited. Based on published figures from two other urban vascular units, we estimate 50–67% of Irish patients with symptomatic carotid disease undergo CEA within 14 days.[15,16] This is comparable to 60% of cases meeting the target reported in the UK National Vascular Registry 2019 Annual Report and 56% in the 2018 Australasian Vascular Audit Public Report.[17,18]

We report a three-year review of all symptomatic CEAs performed at a single urban university hospital with a large catchment area for tertiary vascular referrals. The aim was to determine how many patients met the benchmark 14-day target for CEA and to determine factors contributing to delays.

Methods

This was a single-centre retrospective case series of consecutive CEAs for symptomatic stenosis at a university-affiliated tertiary referral hospital between 1 January 2017 and 31 December 2019. During the study period, 192 CEAs were performed. All asymptomatic cases (n=66) and two symptomatic cases who were inpatients at the time of the index event were excluded. In total, the study included 124 patients.

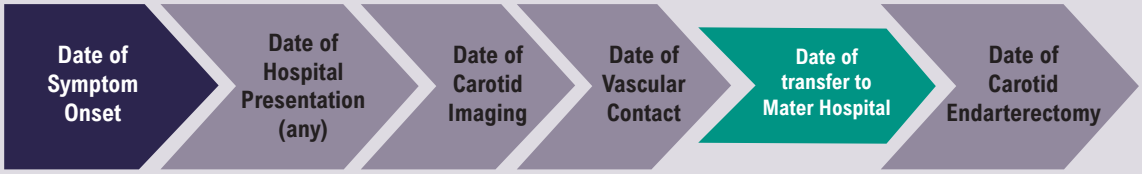
Symptomatic carotid artery stenosis has previously been defined by the Society for Vascular Surgery's reporting standards for carotid interventions.[19] The degree of stenosis was determined using the North American Symptomatic Carotid Endarterectomy Trial (NASCET) duplex criteria, where 50–99% was considered significant.[20] The decision to operate was largely based on duplex findings and preoperative CT angiograms were almost exclusively ordered by stroke physicians as part of a 'FAST Call' stroke protocol in radiology. When preoperative CT angiography was equivocal, duplex ultrasound performed by a vascular physiologist at the vascular centre was used to make the final decision. For this study, the index symptom was defined as the first neurological event, not the most recent event or the event that prompted the patient to seek medical attention.

The study centre has an immediate catchment area of approximately 185,000 urban adults. The vascular department is the dedicated referral centre for the three satellite hospitals within the hospital group. Established referral pathways for CEA include in-house consultations from the stroke service, who operate a weekday rapid-access TIA clinic; direct referral from a consultant physician within the hospital group; and indirect referral to the vascular laboratory for carotid duplex ultrasound. Further referrals were also received from the ophthalmology service, general practitioners and consultant physicians outside the hospital group. All procedures were performed at the vascular centre under general anaesthetic by one of three consultant vascular surgeons. The vast majority of cases were performed on one of the three-weekly scheduled vascular theatre lists, with occasional use of the shared emergency theatre facilities. All patients were initially recovered in the High Dependency Unit, as per local protocol.

Data collection and patient selection criteria

Creation of a local database for CEA was approved by the institution's ethics committee. All patients who underwent CEA between January 2017 and December 2019 were identified from electronic theatre logs and retrospectively entered into the database. Demographic characteristics, comorbidities, smoking status and carotid imaging were documented. Defined timepoints along the patient journey from symptom onset to surgery were recorded (see Figure 1). For patients referred from external hospitals, date of outpatient appointment and/or transfer to the

Figure 1 Graphical representation of the major clinical milestones along the patient journey from symptom onset to carotid surgery.



vascular centre were also recorded. Medical records were examined for documented causes of surgical delays.

Outcomes

Outcomes were reported as per the standards published by the Society for Vascular Surgery.[19] The primary outcome was the overall percentage of symptomatic CEAs performed within the recommended 14-day timeframe. Secondary outcomes included the median time from symptoms to surgery by referral site and 30-day mortality, stroke and morbidity rates.

Statistical analysis

All data was analysed using Statistical Package for the Social Sciences (SPSS) software Version 24.0 (IBM Corp, Armonk, New York, USA). Normally distributed continuous data was expressed as mean ± standard deviation (SD), while median (range) was used to describe abnormally distributed continuous data. Categorical variables were presented as count and percent. Time intervals were characterised using median (range) days. Chi-square tests and odds ratio were used to analyse categorical variables. The Mann–Whitney U test and Kruskal–Wallis test were used to analyse non-parametric data. The level of statistical significance for null hypothesis testing was $p<0.05$.

Results

Demographic characteristics and presenting symptoms

Demographics, risk factors, imaging and clinical symptoms are summarised in Table 1. Fifty percent (n=62) of the cohort had an acute infarct on neuroimaging. Seventy percent (n=88) had at least one presenting symptom described in the 'Face Arm Speech Time' (FAST) mnemonic. Twenty-eight patients (22.5%) presented with isolated ocular symptoms, while a further 14 patients had both amaurosis fugax and cerebral hemispheric symptoms.

Referral source to the tertiary vascular centre

The route of referral to the vascular centre is shown in Table 2. Seventy-three patients (59%) presented directly to the vascular centre, while the remaining 51 patients (41%) initially presented to an external hospital. The source of vascular surgery referral is shown in Table 3. Of the 51 external referrals, 15 patients were transferred to the vascular centre under the stroke service, who subsequently made an in-house vascular referral. The remaining

Table 1 Tabulation of patient demographics, risk factors, presenting symptoms and preoperative imaging.

	n	%
Median (range) age (years)		71.0 (43–88)
Male	89	71.8
Hypertension	93	75
Hyperlipidaemia	65	52.4
Diabetes mellitus	16	12.9
Previous TIA±CVA	25	20.2
Peripheral arterial disease	16	12.9
Smoking history (active±ex-smokers)	60±24	69.8±27.9
Neurological event		
Stroke	62	50
TIA	34	27.4
Amaurosis fugax	28	22.6
Thrombolysis for acute ischaemic stroke (n=62)	15	24.2%
Presenting Symptoms		
Any 'FAST' symptom*	88	71.0
- Limb paraesthesia/weakness/paresis	72	58.5
- Facial asymmetry	23	18.5
- Speech pathology	33	26.6
Ocular symptoms	42	33.9
Atypical	4	3.2
CT angiography carotids	77	62.1
% Stenosis symptomatic side (Duplex)		
90–99%	28	22.8
80–90%	35	28.5
70–80%	30	24.4
50–69%	30	24.4

Table 2 Tabulation of route of referral to the tertiary vascular centre, either to the emergency department or directly to the stroke or vascular service by an external hospital.

Route to referral to the tertiary vascular centre (n=124)	n	%
Self-referral to vascular centre emergency department (ED)	30	24
Referred by general practitioner to vascular centre ED	30	24
Referred by medical outpatients at vascular centre	13	11
Referred by external hospital	51	41

Table 3 Tabulation of routes of referral to vascular surgery service at the tertiary referral centre.

Source of referral to vascular service (n=124)	n	%
Inhouse consultation from stroke team	89	70
External hospital direct to vascular	22	18
Referral to vascular laboratory	7	5.5
Referral from ophthalmology service at vascular centre	6	6.5

Table 4 Breakdown of time (median days) between onset of neurological event and presentation to an acute hospital by presenting symptoms and site of referral. A Kruskall-Wallis test was used to determine statistical significance between median delays for three non-parametric variables and Mann-Whitney U tests were used to assess significance between two non-parametric variables.

Interval between symptom onset and acute hospital presentation (n=123)	n	Median (range) days	P value
Total	123	2 (0–180)	
Neurological event			
Stroke	62	0 (0–30)	<0.001
TIA	34	3 (0–66)	
Amaurosis fugax	27	21 (1–181)	
'FAST' symptoms			
Yes	88	1 (0–66)	<0.001
No	35	11 (0–180)	
Ocular symptoms			
Yes	41	13 (0–180)	<0.001
No	82	1 (0–38)	

Table 5 Tabulation of documented reasons for delay to surgery. Of note, some patients had multiple reasons for delayed intervention. The initial cause for significant delay is reflected here.

Reason for delay (n=58)	%
Initial presentation to medical services >14 days after symptom onset	25
Patient abroad at time of symptom onset	2
Patient attending stroke rehabilitation	3
Patient DNA to clinic or initially declined surgery	3
TIA not initially suspected	3
Initial imaging incongruous/suggestive of occlusion	3
Delay in referral to vascular surgery	3
Delay in transferring patient/admission to vascular centre	10
Waiting for next available vascular list	6

36 external patients were referred directly to the vascular service by an outside hospital.

Symptoms to CEA: meeting the 14-day target

Time from index symptom to surgery was available for 123 patients. Fifty-four percent (n=66/123) of patients had their CEA within the 14-day target period, 78% (n=96/123) had surgery within 14 days of presentation to any hospital and 84% (n=103/123) within 14 days of review by a vascular surgeon. However, 27.6% (n=34/123) waited at least 28 days between the index event and CEA. The median interval between symptom onset and CEA was 14 days (range 2–183).

Delays between symptom onset and acute hospital presentation

The median delay between symptom onset and hospital presentation was 2 days (range 0–180). Forty-six patients (37.4%) sought medical attention on the day of the index symptom. Table 4 shows how symptom type impacted pre-hospital delays. Patients with 'FAST' symptoms were significantly more likely to present to an acute hospital in a timely fashion (p<0.001). There was no significant difference in time from symptoms to hospital presentation between internal and external referrals (p=0.165).

Delays between hospital admission and surgery

The hospital to which patients initially presented significantly impacted the timing of CEA. Almost two-thirds of patients (62.5%, n=55/88) who presented directly to the vascular centre underwent CEA within 14 days compared with 31% of patients (n=11/35) referred from external hospitals (OR 3.63, 95% CI 1.58 to 8.37, p=0.002). The median symptoms-to-surgery interval was 12 days for vascular centre presentations and 25 days for presentations to external hospitals (p=0.001). Figure 2 demonstrates how external referrals persistently encountered significantly longer delays at various discrete milestones along the journey from symptoms to surgery. The median wait between vascular centre admission to CEA was 5 days (range 0–19). The majority of CEAs were scheduled on an elective vascular list (n=115, 93.5%). Table 5 outlines the primary cause for delayed CEA across the cohort.

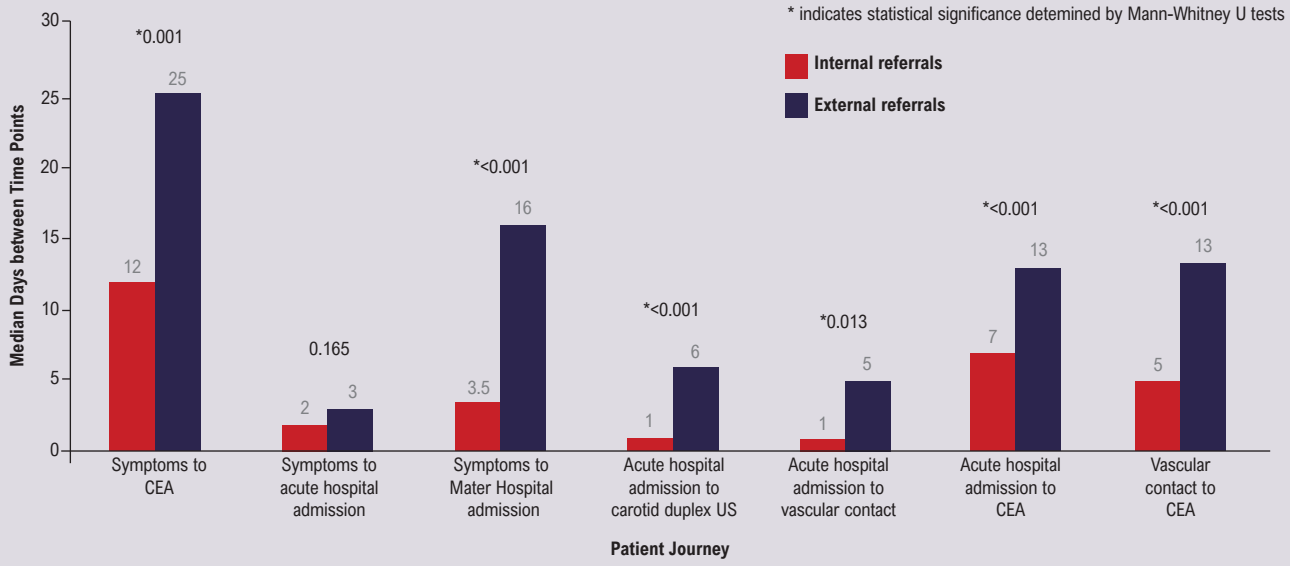
Perioperative complications and mortality

The 30-day stroke and mortality rates were 4.0% (n=5) and 1.6% (n=2), respectively. Both deaths were due to major perioperative strokes and occurred on the third postoperative day. Four patients (3.2%) had postoperative neck haematomas requiring re-exploration in theatre. Six patients (4.8%) had a transient nerve palsy postoperatively, including two recurrent laryngeal and four hypoglossal traction injuries.

Discussion

Best practice guidelines clearly recommend that CEA for symptomatic carotid artery stenosis be performed within 14 days of

Figure 2 Graphical representation of delays (median days) between discrete time periods along the patient journey from symptoms to CEA, broken down into internal (from within the Mater Hospital) and external (from external hospitals) referrals to the vascular service.



the initial ischaemic event, when the risk of further cerebrovascular accident is highest.[21] Over three years in our unit, 54% (n=66/123) of symptomatic carotids met this target. Although outside the scope of this paper, general advice is that CEA within 48 hours of TIA is safe.[22] In our cohort only one of 62 CEAs (1.6%) met this target; however, only eight patients presented to hospital expediently enough for TIA within 48 hours to be feasible. While this study treads on well-travelled ground by investigating delays to CEA, the specific strengths and weaknesses of the Irish healthcare system in managing this high-risk patient cohort have not been fully explored or addressed.

Pre-hospital delays

Consistent with the existing literature, the two main factors contributing to delays identified in this paper were late presentation to hospital by patients and the protracted referral process between external hospitals and the vascular centre.[7,8] The speed of presentation was affected by symptom type. 'FAST positive' patients had a significantly shorter interval between symptom onset and hospital presentation than patients with ocular symptoms (1 vs 12 days, p<0.001).[5,6,14,23,24] Similarly, the initial site of presentation was pivotal to achieving timely CEA. Direct presentation to a tertiary hospital with onsite diagnostic and surgical facilities – a 'one-stop stroke shop' – was significantly associated with a shorter symptoms-to-CEA interval compared with patients referred in from an outpatient setting or from satellite hospitals without a vascular capability.[6,10–12,14,24–29] In our cohort, 62% (n=55/89) of patients who presented directly to the vascular centre underwent CEA within 14 days compared with 31% (n=11/35) of patients who initially presented to an external hospital (p=0.002).

External referrals encountered significant hospital-dependent delays

The median delay from symptoms to CEA was 9 days for direct presentations to the vascular centre compared with 25 days for external referrals (p=0.001). There was no significant difference in pre-hospital delays between the two cohorts (p=0.165). However, the limited access to diagnostic imaging in external hospitals has the knock-on effect of delayed identification of suitable candidates for CEA, thereby delaying vascular consultation. Patients subsequently deemed appropriate for surgical intervention had an additional wait for transfer to the vascular centre. Bed availability and local infection control policies often obstructed expeditated transfer between hospitals, reflected by a median delay of 8 days (range 0–27) between external hospital presentation and vascular centre admission. Once admitted to the vascular centre, theatre logistics accounted for 10% (n=6/58) of delays. As the vast majority of cases (92.7%, n=115) were performed on elective lists with a dedicated vascular anaesthetist, CEAs were competing against similarly urgent aortic and lower limb cases and could not always be prioritised.

'Symptoms to surgery' as key performance indicator for stroke management

The sources of delay identified in our study are not unique to the Irish setting. To drive sustained improvement, accurate national data on the current state of service provision and active participation from all the relevant stakeholders is necessary. To achieve these goals, the 14-day target from symptoms to CEA should be formalised as a KPI for stroke management across all Irish hospitals and a national carotid registry should be established

to facilitate regular audit of all participating vascular units. These steps are essential to creating streamlined referral pathways to adequately resourced tertiary vascular units. Further lessons can be learnt from the management of hip fractures in Ireland, a comparable time-critical surgical pathology. Repair within 48 hours for all medically fit patients is an evidence-based Health Service Executive-mandated KPI, and the Irish Hip Fracture Standards are audited annually through the Irish Hip Fracture Database.[30] To facilitate these meeting this target, a number of hospitals have created multi-disciplinary 'hip fracture pathways' with dedicated beds. A similar approach to symptomatic carotids is needed, with ring-fenced beds in receiving vascular centres and prioritised theatre access with weekly protected 'vascular emergency' sessions separate from elective lists.

Challenges with delayed diagnostic imaging for external referrals

As the decision to proceed with CEA at our centre was largely based on duplex ultrasound, ensuring the findings are reliable is paramount. We noted that obtaining a carotid duplex took significantly longer in external hospitals, with a median wait of 6 days between presentation and imaging. The scarcity of qualified personnel to perform specialist carotid imaging creates a critical bottleneck in the referral chain and presents a challenging resource management issue. There are not enough vascular physiologists nor is there sufficient workload to create a post in every hospital. To navigate this, one hospital within the group funds a vascular physiologist in our laboratory in exchange for expediated access; however, the workload generated by a tertiary vascular centre is too significant to extend this facility to all hospitals within the referral group. In centres without a vascular laboratory, vascular ultrasound can be performed by consultant radiologists. However, this requires the radiologist to be comfortable reporting carotid duplexes and consistent in their findings. Interestingly, having a CT angiogram made no difference in time to vascular contact or time to CEA for external referrals, as such introducing cross-sectional imaging for all cases of suspected carotid stenosis as a means of reducing delays would likely be an inefficient use of resources, as well as unnecessarily exposing patients to radiation. Potentially, a solution to reduce delays is to support radiologists and sonographers to perform carotid duplex locally though training and an initial period of performing a second quality assurance duplex at the vascular centre to corroborate the findings. It will be interesting to re-audit this target in a post-COVID landscape as the restrictions in patient movement between centres created by the pandemic have pushed hospitals to become more self-sufficient.

Limitations of study

The main limitation of this study is its retrospective nature. In particular, we noticed that the occurrence of further neurological symptoms while awaiting CEA was poorly documented. The only readily accessible objective records of subsequent embolic events for review were requests for further neurological imaging on the shared National Integrated Medical Imaging System (NIMIS). However, this likely would not capture TIAs and thus underestimates the number of patients having recurrent events. Furthermore, as the data was drawn from theatre records and not electronic consult requests, we were unable to capture patients who were potentially referred for CEA but ultimately turned down for surgery. Admittedly, these limitations weaken the impetus to drive service improvement as there is insufficient data to demonstrate that the reported delays had a negative impact on patient outcomes. Certainly, expanding a second prospective audit cycle to encompass outcomes from all patients referred to the vascular service for consideration of CEA would provide valuable additional data.

KEY MESSAGES

- A retrospective audit was undertaken of 124 consecutive symptomatic CEAs performed between January 2017 and December 2019 at an Irish urban university hospital.
- 54% (n=66) of patients underwent CEA within 14 days of the initial embolic event.
- Consistent with the existing literature, delayed patient presentation to an acute hospital and initial presentation to an external hospital without vascular capabilities were the main causes of delayed CEA.
- We believe mandating the 14-day target for symptomatic CEA as a national key performance indicator for stroke management is needed to secure adequate resources for this time-sensitive pathology.

Conclusions

Just over half the patients referred to our vascular unit with symptomatic carotid disease underwent surgery within the recommended 14-day timeframe. Delays in patient presentation and delays associated with inter-hospital referrals were the two most significant factors associated with missing this target. Specific pathways between satellite hospitals and vascular centres need to be developed to expediate the treatment of symptomatic carotids, in particular expanding access to local diagnostics and protected theatre space. While the scope of this review did not include patients referred for CEA who ultimately did not undergo surgery, it highlights the need for further research in this area of stroke care provision in Ireland.

Conflict of Interest: The authors declare a minor conflict of interest, wherein one of our senior editors is also a member of the JVSGBI board of editors.

Funding: The authors received no external or internal funding for this research.

Reviewer acknowledgement: JVSGBI thanks Ganesh Kuhan & Dominic Howard for their contribution to the peer review of this work.

References

1. Tsantilas P, Kuhnl A, Kallmayer M, *et al.* Stroke risk in the early period after carotid related symptoms: a systematic review. *J Cardiovasc Surg (Torino)* 2015;**56**(6):845–52.
2. Coelho A, Peixoto J, Mansilha A, Naylor AR, de Borst GJ. Timing of carotid intervention in symptomatic carotid artery stenosis: a systematic review and meta-analysis. *Eur J Vasc Endovasc Surg* 2022;**63**(1):3–23. https://doi.org/10.1016/j.ejvs.2021.08.021
3. Naylor AR, Ricco JB, de Borst GJ, *et al*. Management of atherosclerotic carotid and vertebral artery disease: 2017 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg* 2018;**55**(1):3–81. https://doi.org/10.1016/j.ejvs.2017.06.021
4. AbuRahma AF, Avgerinos ED, Chang RW, *et al*. Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease. *J Vasc Surg* 2022;**75**(1S):4S–22S. https://doi.org/10.1016/j.jvs.2021.04.073
5. Charbonneau P, Bonaventure PL, Drudi LM, Beaudoin N, Blair JF, Elkouri S. An institutional study of time delays for symptomatic carotid endarterectomy. *J Vasc Surg* 2016;**64**(6):1726–33. https://doi.org/10.1016/j.jvs.2016.06.100
6. Jetty P, Husereau D, Kubelik D, *et al.* Wait times among patients with symptomatic carotid artery stenosis requiring carotid endarterectomy for stroke prevention. *J Vasc Surg* 2012;**56**(3):661–7.e1–2. https://doi.org/10.1016/j.jvs.2012.03.001
7. Kjorstad KE, Baksaas ST, Bundgaard D, *et al.* The National Norwegian Carotid Study: time from symptom onset to surgery is too long, resulting in additional neurological events. *Eur J Vasc Endovasc Surg* 2017;**54**(4):415–22. https://doi.org/10.1016/j.ejvs.2017.07.013
8. Loftus IM, Paraskevas KI, Johal A, *et al*. Delays to surgery and procedural risks following carotid endarterectomy in the UK National Vascular Registry. *Eur J Vasc Endovasc Surg* 2016;**52**(4):438–43. https://doi.org/10.1016/j.ejvs.2016.05.031
9. Blacquiere D, Sharma M, Jetty P. Delays in carotid endarterectomy: the process is the problem. *Can J Neurol Sci* 2013;**40**(4):585–9. https://doi.org/10.1017/s0317167100014712
10. Purkayastha D, Grant SW, Smyth JV, McCollum CN. Delayed carotid surgery: what are the causes in the north west of England? *Eur J Vasc Endovasc Surg* 2012;**43**(6):637–41. https://doi.org/10.1016/j.ejvs.2012.03.016
11. den Hartog AG, Moll FL, van der Worp HB, Hoff RG, Kappelle LJ, de Borst GJ. Delay to carotid endarterectomy in patients with symptomatic carotid artery stenosis. *Eur J Vasc Endovasc Surg* 2014;**47**(3):233–9. https://doi.org/10.1016/j.ejvs.2013.12.013
12. Vikatmaa P, Sairanen T, Lindholm JM, Capraro L, Lepantalo M, Venermo M. Structure of delay in carotid surgery--an observational study. *Eur J Vasc Endovasc Surg* 2011;**42**(3):273–9. https://doi.org/10.1016/j.ejvs.2011.04.021
13. Ali M, Stephenson J, Naylor AR. Delay prior to expedited carotid endarterectomy: a prospective audit of practice. *Eur J Vasc Endovasc Surg* 2013;**46**(4):404–10. https://doi.org/10.1016/j.ejvs.2013.07.015
14. Kuhrij LS, Meershoek AJA, Karthaus EG, *et al*. Factors associated with hospital dependent delay to carotid endarterectomy in the Dutch Audit for Carotid Interventions. *Eur J Vasc Endovasc Surg* 2019;**58**(4):495–501. https://doi.org/10.1016/j.ejvs.2019.05.015
15. Hanrahan L, Canning C, Abdulrahim O, *et al*. Evolution of carotid surgical practice in the last decade. *Ir Med J* 2015;**108**(8):235–7.
16. Ng KC, Hseino H, Dowdall J, Sheehan S, Barry M. An audit of the timing of carotid endarterectomy for symptomatic carotid disease. *Eur J Vasc Endovasc Surg* 2018;**56**(5):E23. https://doi.org/10.1016/j.ejvs.2018.06.021
17. Australian and New Zealand Society for Vascular Surgery. Australasian Vascular Audit Public Report – 2018. 2019. Available from: https://www.anzsvs.org.au/wp-content/uploads/2019/05/RPT-2018_AVA-Public-Report.pdf
18. Royal College of Surgeons. National Vascular Registry: 2019 Annual Report. 2019. Available from: https://www.vsqip.org.uk/content/uploads/2019/12/NVR-2019-Annual-Report.pdf
19. Timaran CH, McKinsey JF, Schneider PA, Littooy F. Reporting standards for carotid interventions from the Society for Vascular Surgery. *J Vasc Surg* 2011; **53**(6):1679–95. https://doi.org/10.1016/j.jvs.2010.11.122
20. Moneta GL, Edwards JM, Chitwood RW, *et al*. Correlation of North American Symptomatic Carotid Endarterectomy Trial (NASCET) angiographic definition of 70% to 99% internal carotid artery stenosis with duplex scanning. *J Vasc Surg* 1993;**17**(1):152–7; discussion 7–9. https://doi.org/10.1067/mva.1993.42888
21. Giles MF, Rothwell PM. Risk of stroke early after transient ischaemic attack: a systematic review and meta-analysis. *Lancet Neurol* 2007;**6**(12):1063–72. https://doi.org/10.1016/S1474-4422(07)70274-0
22. Paraskevas KI, Loftus IM. Safety of carotid revascularization within 48 hours of symptomatic presentation. *J Cardiovasc Surg (Torino)* 2017;**58**(2):139–42. https://doi.org/10.23736/S0021-9509.16.09743-3
23. Noronen K, Vikatmaa P, Sairanen T, Lepantalo M, Venermo M. Decreasing the delay to carotid endarterectomy in symptomatic patients with carotid stenosis--outcome of an intervention. *Eur J Vasc Endovasc Surg* 2012;**44**(3):261–6. https://doi.org/10.1016/j.ejvs.2012.06.014
24. Meyer D, Karreman E, Kopriva D. Factors associated with delay in carotid endarterectomy for patients with symptomatic severe internal carotid artery stenosis: a case-control study. *CMAJ Open* 2018;**6**(2):E211–7. https://doi.org/10.9778/cmajo.20170060
25. Gaba KA, Syed MJ, Raza Z. Reducing the delay for carotid endarterectomy in South-East Scotland. *Surgeon* 2014;**12**(1):11–6. https://doi.org/10.1016/j.surge.2013.09.008
26. Rudarakanchana N, Halliday AW, Kamugasha D, *et al*. Current practice of carotid endarterectomy in the UK. *Br J Surg* 2012;**99**(2):209–16. https://doi.org/10.1002/bjs.7810
27. Lim ETA, Laws PE, Beresford TP, Khanafer AMA, Roake JA. Timeliness and outcomes of carotid endarterectomy for symptomatic carotid artery stenosis: a single centre audit. *ANZ J Surg* 2020;**90**(3):345–9. https://doi.org/10.1111/ans.15757
28. Fairhead JF, Mehta Z, Rothwell PM. Population-based study of delays in carotid imaging and surgery and the risk of recurrent stroke. *Neurology* 2005;**65**(3): 371–5. https://doi.org/10.1212/01.wnl.0000170368.82460.b4
29. Gladstone DJ, Oh J, Fang J, *et al*. Urgency of carotid endarterectomy for secondary stroke prevention: results from the Registry of the Canadian Stroke Network. *Stroke* 2009;**40**(8):2776–82. https://doi.org/10.1161/STROKEAHA.109.547497
30. National Office of Clinical Audit. Irish Hip Fracture Database National Report 2019. Dublin: National Office of Clinical Audit, 2020. Report No. ISSN 2565-5388. Available from: http://s3-eu-west-1.amazonaws.com/noca-uploads/general/Irish_Hip_Fracture_Database_National_Report_2019_10.11.2020.pdf

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):84-88
http://doi.org/10.54522/jvsgbi.2022.022

www.jvsgbi.com

ORIGINAL RESEARCH

Open aortic surgical training with trainees as primary operator: a retrospective single-centre analysis

Nortley MC,[1] Dixon F,[1] Sharma I,[1] Lawson JA,[2] Rodriguez DU,[1] Perkins JMT,[1] Wilton E[1]

1. Thames Valley Vascular Network, Vascular Surgery Department, Oxford University Hospitals NHS Foundation Trust, John Radcliffe Hospital, Headley Way, Oxfordshire, UK
2. St Mary's Hospital Paddington London, Imperial College NHS Trust London, Vascular Surgery Department, London, UK

Corresponding author:
Ms Mei Nortley
Thames Valley Vascular Network. Vascular Surgery Department, Oxford University Hospitals NHS Foundation Trust, John Radcliffe Hospital, Headley Way, Oxfordshire OX3 9DU, UK
Email: mei.norltey2@nhs.net

Received: 16th February 2022
Accepted: 20th March 2022
Online: 9th May 2022

Plain English Summary

Why we undertook the work: The UK National Institute for Health and Care Excellence published guidance for unruptured abdominal aortic aneurysms (AAA) recommending vascular specialists "offer open surgical repair unless it is contraindicated because of their abdominal co-pathology and/or medical comorbidities". Uptake of open AAA repair has since increased in the UK. This has been preceded by over a decade of worldwide endovascular enthusiasm.

What we did: This study reviewed safety outcomes of open aortic surgeries with vascular surgical trainees as the primary operator using retrospective analysis of prospectively accrued data.

What we found: We demonstrate that open aortic surgical training can be provided safely with trainees as primary operator.

What this means: This is paramount for preserving open aortic surgical skills for the vascular surgeons of the future.

Abstract

Objective: To review safety outcomes of open aortic surgeries with vascular surgical trainees as the primary operator.

Methods: A retrospective analysis of prospectively accrued data was performed using our departmental database, electronic patient records and the National Vascular Registry for all elective open abdominal aortic aneurysms (AAA) (juxtarenal and infrarenal) repairs over 2 years between 1 January 2017 and 31 December 2018. Data on primary operator, training level, number of surgeons, assistant training level, operation time, duration of ITU and hospital stay, 30-day mortality, 1-year mortality and complications were obtained.

Results: During the study period 83 elective open AAA repairs were carried out. The primary operator was a trainee in 46% (n=38) and a consultant in 54% (n=45). For trainees and consultants, median operation time was 178 min vs 215 min (p=0.036), duration of ITU stay was 1.5 days vs 2 days (p=0.270), duration of hospital stay was 5.6 days vs 6.8 days (p=0.037), 30-day mortality was 0.0% vs 2.2% (p=0.932) and 1-year mortality was 0.0% vs 2.2% (p=0.932), respectively.

Conclusions: Safe surgical outcomes for open AAA repair can be achieved with vascular surgical trainees as primary operators.

Key words: abdominal aortic aneurysm; open aortic repair; endovascular repair

Introduction

Over the last two decades the popularity of endovascular abdominal aortic aneurysm (AAA) repair (EVAR) has meant that vascular units have begun to express concerns regarding the ability of vascular trainees to acquire open aortic surgical skills. In the USA, EVAR usage has been reported to be >80% in some units.[1,2] Trainees' exposure to open AAA repair has fallen and providing training for open repair is a particular challenge.[1–4] UK, US and European data show a worryingly low level of exposure to open repair – in some instances rates of open repair have dropped by 80% during the last decade.[5] In the UK, a 2016 survey of vascular trainees showed only 5% of respondents had performed >15 open repairs per year and 50% had done <5 open repairs per year.[3] This is echoed by predictive

modelling using US national databases which demonstrate a dramatic decline in exposure to open repair amongst vascular trainees.[2]

In the last few years the vascular community has been presented with compelling evidence regarding the failure of Endovascular Aneurysm Sealing System and the inferior long-term durability of EVAR versus open repair. In the UK, the publication of the National Institute for Health and Care Excellence (NICE) guidance on unruptured AAA is strongly weighted towards open repair.

In the UK, National Vascular Registry (NVR) annual reports show that concerns over the durability of EVAR may be coming to fruition; percentages of EVAR and open surgery for elective AAA repair were 68% and 32% in 2017 but changed to 63% and 37% in 2018 respectively. This indicates a potential increasing need for surgeons with open aortic skills.

Regardless of local practices, acquisition and future retention of open aortic skills is paramount for the vascular community worldwide. Simulation training for EVAR is widely available and effective, but realistic simulation for open repair is more difficult to provide with any proven transference of skills to the operating theatre. Exposure to live cases likely remains the best training available and each opportunity should be maximised with safety as a priority. This is perhaps best achieved in specialist centres, since a recent international observational study of open repairs showed that an annual centre volume of 13–16 open repairs is associated with the most significant mortality risk reduction.[6]

We present data which examines whether vascular trainees can safely perform supervised open AAA repair as the primary operator. Outcomes are compared against cases where consultant surgeons were the primary operator.

Methods

All elective open juxtarenal and infrarenal AAA repairs performed at Oxford University Hospitals NHS Foundation Trust between 1 January 2017 and 31 December 2018 were identified from three prospective databases. These were a local departmental database, a hospital-wide electronic patient record database and the NVR – a national clinic audit commissioned by the Health Quality Improvement Partnership. All patients gave prospective consent to be included in the local departmental database and the NVR.

Research ethics committee approval was not required for this study as per the UK Health Research Authority Decision tool.[7] The local Clinical Research and Trials Governance study classification meeting panel additionally classified this study under service review activity.

Case identification and data analysis was performed retrospectively. For each case the following data points were collected: primary operator (consultant surgeon vs vascular trainee), 30-day mortality, 1-year mortality, major complications, operation time, duration of ITU and hospital stay, number of consultant surgeons present, additional non-consultant assistant present, American Society of Anaesthesiology (ASA) grade and baseline co-morbidities.

The surgeon, consultant or trainee was labelled 'primary operator' if they performed a minimum of the exposure of the aorta and the proximal aortic anastomosis. This information was recorded prospectively on the local departmental database according to a locally agreed protocol. Cases with a consultant surgeon as the primary operator were compared with cases where a trainee surgeon was the primary operator. Primary outcome measures were taken as 30-day mortality and 1-year mortality. Secondary outcome measures were duration of ITU stay, duration of hospital stay, major complication rate and operation time.

For categorical data (30-day mortality, 1-year mortality, major complications), a χ^2 test was used to perform statistical analysis. For non-categorical data (duration of ITU stay, duration of hospital stay, operation time), a Shapiro–Wilk test was used to assess if data were normally distributed. All non-categorical data were non-normally distributed so a Mann–Whitney U test was used for analysis. A statistical significance level of $p<0.05$ was used. The statistical software used was OriginPro (OriginLab, 2016).

Using the Clavien–Dindo classification, any complication between grade II (complication requiring pharmacological treatment e.g. pneumonia) and grade V (life-threatening complications) was included as a 'major complication'.

Baseline co-morbidities were recorded as per NVR categories: none, diabetes, hypertension, ischaemic heart disease (IHD), chronic lung disease, chronic heart failure (CHF), stroke, cancer, chronic renal disease and lower limb arterial disease. These were then subclassified into cardio-respiratory disease (IHD, lung disease or CHF) and hypertension, and the presence or absence of these were compared. Additionally, ASA grade was recorded and compared for each group.

Results

Baseline characteristics

There was no significant difference in age, gender, baseline co-morbidities or ASA grade between patients operated on by a consultant surgeon and those with a vascular trainee as primary operator (Table 1).

Study results

Of 83 elective open AAA repairs, the primary operator was a consultant in 54% (n=45) and a trainee in 46% (n=38). The study centre had an adjusted in-hospital mortality rate for elective AAA repair of 1.4% for the year 2017 and of 1.3% for 2018. This was lower than the national average published rates of in-hospital mortality, which was 3.2% in 2017 and 2018 according to the NVR Annual Report 2018/2019.[8,9]

Primary outcome measures

There was no statistical difference in 30-day mortality or 1-year

Table 1 Baseline characteristics: age, sex, co-morbidities and ASA grade.

	Consultant surgeon as primary operator (n=45)	Vascular trainee as primary operator (n=38)	P value
Age, years (median)	70.7	71.2	0.896
Sex, M/F (%)	43/45 (94/6%)	33/38 (87/13%)	0.302
Co-morbidities			
Cardiorespiratory, n (%) (excluding hypertension)	23/45 (51%)	18/38 (47%)	0.810
Hypertension, n (%)	33/45 (73%)	29/38 (76%)	0.635
ASA grade			0.859
1	2	2	
2	9	7	
3	32	28	
4	2	1	

ASA, American Society of Anaesthesiology.

Table 2 Primary and secondary outcome measures.

	Consultant surgeon as primary operator (n=45)	Vascular trainee as primary operator (n=38)	P value
Primary outcome measures			
30-day mortality (%)	2.2%	0.0%	0.932
1-year mortality (%)	2.2%	0.0%	0.932
Secondary outcome measures			
Major complications, n (%)	7 (15.6%)	0 (0%)	0.032
Mean operation time, (min), n (range)	215 (60–375)	178 (90–270)	0.036
Mean duration of ITU, stay (days), n (range)	2 (1–17)	1.5 (1–3)	0.270
Mean duration of hospital stay (days), n (range)	6.8 (3–25)	5.6 (3–11)	0.037

mortality for patients operated on by a consultant surgeon or a trainee surgeon (2.2% and 0.0%, respectively, p=0.9), as shown in Table 2.

Secondary outcome measures

Mean operation time was shorter for cases performed by a trainee surgeon (178 min) than for those performed by a consultant surgeon (215 min) (p=0.036). The rate of major complications was higher in patients who had a consultant as primary operator than in those who had a trainee as primary operator (15.6% vs 0.0%, p=0.03). There was no difference in the duration of ITU stay but overall hospital stay was longer in patients who had a consultant surgeon perform their surgery (6.8 days vs 5.6 days, p=0.002), as shown in Table 2.

Table 3 Further characteristics: complexity.

	Consultant surgeon as primary operator (n=45)	Vascular trainee as primary operator (n=38)	P value
Additional consultant surgeon present, n/N	12/45	0/38	0.002
Additional trainee present, n/N (%)	23/45 (51%)	15/38 (39%)	0.401
Juxtarenal AAA, n/N (%)	11/34 (24%)	5/33 (13%)	0.212
Straight tube graft/ bifurcated graft	32/13	29/9	0.490

AAA, abdominal aortic aneurysm.

Table 4 Dual consultant operations.

<2 years' experience as a consultant surgeon	3 juxtarenal AAAs
2–5 years' experience as a consultant surgeon	2× semi-urgent large >8 cm juxtarenal AAAs 2× inflammatory juxtarenal AAAs
10–15 years' experience as a consultant surgeon	1× aortoiliac aneurysm 1× juxtarenal AAA 1× patient request to have surgery against MDT advice outcome
>15 years' experience as a consultant surgeon	1× complex aneurysmal disease in young Marfan's patient 1× juxtarenal AAA

AAA, abdominal aortic aneurysm.

Further characteristics and complexity

Out of a total of 83 elective open repairs, 12 (14%) had two consultant surgeons present with a consultant surgeon as primary operator. Where a trainee surgeon was the primary operator (46%), they were uniformly supervised by a single consultant surgeon. As shown in Table 3, there was no difference in the frequency at which an additional trainee was present for either group. There was no apparent difference in the frequency of juxtarenal repairs or bifurcated graft repairs in the consultant group compared with the trainee group.

Of the 12 open repairs with two consultant surgeons present, these were examined in more detail regarding case complexity and attending seniority. Further details are outlined in Table 4.

Discussion

All trainees operating within this study would have completed a minimum of two 'foundation years' of training followed by two 'core

surgical training' years. In the UK, surgical trainees then progress to a 6-year specialist surgical training programme. Trainees within this study would have been within years 1–6 of specialist vascular surgical training. A consultant surgeon was always present – either scrubbed into the operation or in the same theatre room. The level of independence was tailored to the seniority and experience of the trainee and at the discretion of the supervising consultant surgeon. All operative planning and intraoperative decision making were discussed with the supervising consultant surgeon.

Our results suggest that open repair can safely be performed by trainees as primary operator when cases are selected carefully and appropriately. Primary outcome measures of 30-day and 1-year mortality were comparable. All complications occurred within the consultant group. This and a shorter operation time and duration of hospital stay in the trainee group may reflect selection of the easier cases assigned to the trainees. However, it is likely that trainees also had the advantage of an experienced consultant surgeon assisting them throughout the open repair, which likely reduces operative time. Whilst the results did not reach statistical significance, consultants performed more juxtarenal open repairs than the trainees (24% vs 13%).

It is acknowledged that this study primarily examines the technical safety of trainees being primary operator. The degree of operative planning and intraoperative decision making by the trainee is difficult to define and measure within the realms of this study, and will have varied with the seniority of the trainee.

There was a second consultant present in theatre in significantly more consultant cases (27%) than trainee cases (0%), which again reflects increased case complexity (see Table 4). All trainee cases were supervised by a single consultant surgeon.

Underlying co-morbidity does not seem to have played a part in case selection as there were no significant differences in baseline co-morbidities or ASA between the two groups. The number of tube versus bifurcated graft repairs was the same between the trainee and consultant groups.

A recent US study analysed data from a major US vascular centre which indicated that, whilst numbers of EVAR and fenestrated EVAR (FEVAR) had remained stable, the numbers of open repair in this major centre had increased over recent years – presumably through quaternary referrals.[9] Regardless, the same study reported that "on average, graduating vascular surgery trainees performed 23.1 open repairs before graduation (range 19–26)'' – more than the reported US national average of 1–3.2 The UK vascular training guidelines have recently changed. It was previously stipulated a minimum number of 10 open repairs performed at level 4 is required to obtain the certificate for completion of training. Level 4 was defined as "able to perform the procedure fluently and without guidance or intervention'' and "able to anticipate, avoid and/or deal with any common problems/complications". This changed in August 2021 with an outcomes-based "multi-consultant report" system for set training domains. A total of 10 open repairs are now required showing progression to a minimum of four open repairs at level 4. Level 4 has a new definition: "that expected of a new consultant" with the previous level 4 definition now defined as level 5. To achieve this, each training opportunity for open repair must be maximised.

KEY MESSAGES

- In the UK a 2016 survey of vascular trainees showed only 5% of respondents had performed > 15 open repairs per year and 50% had performed <5 open repairs per year.
- Preservation of open aortic surgical skills remains paramount for the future of vascular surgery in the UK and worldwide.
- This study demonstrates that safe surgical outcomes for open AAA repair can be achieved with vascular surgical trainees as primary operator.

The authors of the US study suggested centralisation of open repair to centres of excellence in open repair, with trainees completing specialist placements as a strategy to preserve open repair training nationally.[10] In the UK, vascular services are currently modelled on a 'hub and spoke' regional service system. The current centre is in the top third nationally in terms of volume of AAA repairs.[8,9]

An alternative approach is a training strategy where single cases are shared between trainees.[10] Indeed, in the current study centre, open repair is considered in 'training stages' whereby a trainee can incrementally progress from closure, exposure, distal anastomoses, proximal anastomosis and whole procedure. The final training stage allows the trainee to perform the whole procedure with the assistance of a more junior trainee with the attending trainer unscrubbed but within theatre. Towards the end of their training, more senior trainees are also assisted by their consultant trainers in performing open repair in stable patients with ruptured AAAs. Whilst this is not necessarily a new or unique approach to training, in recent years trainees have had increasingly limited exposure to open repair, particularly as the primary operator.[3] This strategy may help to maximise training opportunities, particularly if open training becomes centralised.

Overall, the current study demonstrates that safe surgical outcomes for open AAA repair can be achieved with vascular trainees as primary operators when cases are selected appropriately. Preservation of open aortic surgical skills remains paramount for the future of vascular surgery in the UK and worldwide. We propose trainees as primary operators for open repair as a training model, within the context of an incremental training plan, as a strategy for preserving open aortic surgical skills for the vascular surgeons of the future.

This research has been used in presentations at the Vascular Society Annual Scientific Meeting, Manchester, England, September 2021 and the 35th ESVS Hybrid Annual Meeting, Rotterdam, Netherlands, September 2021.

Conflict of Interest: The authors declare no conflicts of interest.

Funding: None.

Acknowledgements: E Sideso, P Lintott, C Darby, DPJ Howard, Professor TR Magee, Professor A Handa, A Northeast, Professor R Lee, Oxford University Hospitals NHS Foundation Trust. Professor D Atwell, University College, London.

Reviewer acknowledgement: JVSGBI thanks Shirley Jia for her contribution to the peer review of this work.

References

1. Smith ME, Andraska EA, Sutzko DC, Boniakowski AM, Coleman DM, Osborne NH. The decline of open abdominal aortic aneurysm surgery among individual training programs and vascular surgery trainees. *J Vasc Surg* 2020;**71**:1371–7. https://doi.org/10.1016/j.jvs.2019.06.204
2. Dua A, Koprowski S, Upchurch G, Lee CJ, Desai SS. Progressive shortfall in open aneurysm experience for vascular surgery trainees with the impact of fenestrated and branched endovascular technology. *J Vasc Surg* 2017;**65**: 257–61. https://doi.org/10.1016/j.jvs.2016.08.075
3. Jenkins MP, Boyle JR, Rudarakanchana N. How can we ensure vascular surgical trainees become competent in open aortic surgery in the future training environment? *Eur J Vasc Endovasc Surg* 2019;**57**:617–18. https://doi.org/10.1016/j.ejvs.2018.11.005
4. Dua A, Upchurch GR, Lee JT, Eidt J, Desai SS. Predicted shortfall in open aneurysm experience for vascular surgery trainees. *J Vasc Surg* 2014;**60**: 945–9. https://doi.org/10.1016/j.jvs.2014.04.057
5. Suckow BD, Goodney PP, Columbo JA, *et al*. National trends in open surgical, endovascular, and branched-fenestrated endovascular aortic aneurysm repair in Medicare patients. *J Vasc Surg* 2018;**67**:1690–7. https://doi.org/10.1016/j.jvs.2017.09.046
6. Scali ST, Beck A, Sedrakyan A, *et al*. Optimal threshold for the volume-outcome relationship after open AAA repair in the endovascular era: analysis of the International Consortium of Vascular Registries. *Eur J Vasc Endovasc Surg* 2021;**61**:747–55. https://doi.org/10.1016/j.ejvs.2021.02.018
7. Is my study research? Available at: http://www.hra-decisiontools.org.uk/research/ (accessed 28 November 2020).
8. Clinical Effectiveness Unit, The Royal College of Surgeons of England, Vascular Society of Great Britain and Ireland. National Vascular Registry Annual Report 2018. Available at: https://www.vsqip.org.uk/content/uploads/2019/07/2018-NVR-Annual-Report.pdf (accessed March 2022).
9. Clinical Effectiveness Unit, The Royal College of Surgeons of England, Vascular Society of Great Britain and Ireland. National Vascular Registry Annual Report 2019. Available at: https://www.vsqip.org.uk/content/uploads/2019/12/NVR-2019-Annual-Report.pdf (accessed March 2022).
10. El-Arousy H, Lim S, Batagini NC, *et al*. Open aortic surgery volume experience at a regionalized referral center and impact on Accreditation Council for Graduate Medical Education trainees. *J Vasc Surg* 2019;**70**:921–6. https://doi.org/10.1016/j.jvs.2019.02.045

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):89-92
http://doi.org/10.54522/jvsgbi.2022.025

www.jvsgbi.com

TRIAL PROTOCOL

VENUM (Vascular Education iN Undergraduate Medicine) Protocol

Sucharitkul PPJ,[1] Safdar NZ,[1] Jain K,[1] Forsyth J,[2] Bridgwood B,[3] Coughlin PA,[4] Bailey MA[2,4]

1. School of Medicine, University of Leeds, Leeds, UK
2. Leeds Institute of Cardiovascular and Metabolic Medicine, Leeds, UK
3. University of Leicester, Leicester, UK
4. Leeds Vascular Institute, Leeds General Infirmary, Leeds, UK

Corresponding author:
Ms Penelope PJ Sucharitkul
School of Medicine, University of Leeds, Woodhouse Lane, Leeds LS2 9JT, UK
Email: ll16ppjs@leeds.ac.uk

Received: 20th December 2021
Accepted: 20th March 2022
Online: 11th May 2022

Plain English Summary

Why we are undertaking the research: We currently do not know how well medical students are taught about vascular disease. This includes diseases that may cause pain on walking due to reduced blood flow to the legs (peripheral arterial disease), strokes due to narrowed artery in the neck (carotid stenosis), or even problems affecting your veins (varicose veins). This means that patients with vascular diseases could potentially be better managed by new doctors if we improve how they are taught.

What we aim to do: This study allows us to work out which areas of vascular medicine teaching require improvement, and then raise awareness of this in the vascular community and within medical schools.

Key words: education, vascular disease, undergraduate

Trial registration: MREC 21-015 - Vascular Education in Undergraduate Medicine (VENUM). Granted 7/12/12

Background

Peripheral arterial disease (PAD) is most commonly an atherosclerotic condition affecting the lower limbs, which usually manifests as muscle pain during exertion.[1] The gold standard of PAD diagnosis, an ankle brachial pressure index (ABPI) of ≤0.9, can be done at the bedside.[1] PAD affects up to 5% of patients aged 60–69 years, increasing to over 20% of those aged over 80 years, and is notoriously medically undertreated compared with other cardiovascular diseases such as myocardial infarction or stroke.[1,2] A 2018 retrospective observational cohort study of patients from The Health Improvement Network (THIN) using data from 11 million UK primary care patients found that a large proportion of PAD patients did not receive their recommended secondary prevention.[3] PAD has often been reported as a 'missed opportunity' for cardiovascular reduction, as PAD patients (n=34,160) had significantly less uptake of statins, antiplatelets and angiotensin-converting enzyme inhibitors compared with their coronary artery disease counterparts (n=9,570) in a large Danish cohort study.[4] While vascular surgery teaching encompasses not just patients with PAD, it is difficult to determine whether these findings relate to the education of medical students or beyond into postgraduate training. VENUM (Vascular Education iN Undergraduate Medicine) hopes to establish the perceptions of medical students about their vascular undergraduate curricula.

Vascular undergraduate teaching of UK medical students has been poorly evaluated.[5] A recent international scoping review identified only two UK studies: one in 2019 with only 11 participants and a grey literature abstract in 2015 which claimed that a quarter of Swansea medical students reported having no vascular teaching.[5] A single-centre study at the University of Toronto found that Canadian medical students had sub-optimal knowledge of PAD compared with coronary artery disease.[6] Another study evaluating vascular surgery education in Greek medical schools concluded that the lack of vascular surgery teaching in undergraduate medical curricula led to inadequate early diagnosis and treatment of vascular diseases in primary care.[7] The need for a vascular surgery programme as part of undergraduate teaching was asserted.[7] Currently, there are no national studies of the provision of vascular surgery education within UK medical undergraduate curricula.

Lack of exposure to the vascular surgery speciality through clinical placements, projects or clinical teaching arguably results in fewer students wishing to pursue a career in vascular surgery compared with specialties which receive greater

exposure in the undergraduate curriculum. Equally, this lack of exposure and training will also significantly impact the overall care of patients with vascular disease across many medical and surgical specialities. Indeed, there is a particular concern that primary care clinicians have very limited exposure and training in vascular surgery and its associated conditions. This is a major problem on a national scale for patient care as the responsibility for the medical care of the patients is primarily placed on primary care by National Institute for Health and Care Excellence (NICE) guidelines. For example, PAD patients presenting with intermittent claudication are expected to be treated in primary care without referral to secondary care vascular surgery.[8] Primary care clinicians often have the best opportunity to aggressively manage the risk factors that so often lead to vascular pathology. The demand for vascular surgery specialists is increasing and is entirely predictable given the rise in the burden of cardiovascular disease.[9] The Vascular Society workforce planning survey in 2018 predicted an increase in general and vascular surgery workforce requirements by 67% by 2029.[9]

Previously, vascular conditions such as PAD have not attracted much national attention compared with myocardial infarction, cerebrovascular disease or malignancies. However, vascular pathologies such as PAD have higher morbidity and mortality rates compared with patients who have coronary artery disease alone.[10]

It is therefore of paramount importance to increase the body of evidence in this area. VENUM has the potential to highlight areas for improvement in the training and education of the next generation of clinicians and surgeons who will be managing this highly challenging and co-morbid patient cohort.

Aims

- Establish the provision of undergraduate vascular teaching through the experiences of final year medical students and newly graduated doctors.
- Explore the perceived confidence of students in performing vascular examinations.
- Report student perceptions of a career in vascular surgery.
- Report student uptake of vascular research, vascular mentorship and intention to pursue vascular surgery.
- Compare vascular and cardiovascular knowledge base of students.
- Disseminate new knowledge regionally to medical schools and to the national vascular community.

Proposed methodology

During the 2021/2022 academic year, medical students in the final year of UK medical schools will be invited to complete a 10-minute survey. Foundation Year 1 (FY1) trainee doctors across the UK will also be invited to complete the survey based on their graduating medical school. The students' exposure to vascular teaching during their time in medical school will be assessed. Students not in their final year will be excluded to avoid bias introduced due to the difference in timing of vascular teaching between medical schools. Surveys will be conducted on JISC survey software under a collaborative authorship model, where medical student and doctor leads will be asked to recruit their fellow peers via social media or over email. Research leads must recruit 15 participants to be eligible for collaborative authorship status. The study design has been heavily influenced by that used by the British Urology Researchers in Surgical Training (BURST) committee in the "UroLogical tEAching in bRitish medical schools Nationally" (LEARN) study[11] and by the interventional radiologists in the "An evaluation of learning and exposure to the undergraduate Interventional Radiology curriculum" (ELIXIR) study.[12] A key difference is that our study has been ethically approved to use the methods described.

Ethical considerations

Ethical approval has been obtained from: Leeds School of Medicine Research Ethics Committee MREC 21-015 - Vascular Education in Undergraduate Medicine (VENUM). Granted 7/12/2012. University of Leeds. No monetary incentive was required for this this study. To ensure students' time is effectively spent, the answers to the multiple-choice questions have been provided where students can view the survey as a free revision resource. Furthermore, it is possible for individuals to complete the survey more than once; however, medical students will be reminded of the General Medical Council probity guidance on entry to the survey.[13]

Recruitment

The survey draft was conceived and revised by the VENUM multidisciplinary team until no further improvements could be made internally. The aim was for the survey to take no more than 10 minutes. The prototype survey will be validated on a small number of fifth year medical students at the University of Leeds. This will be predominantly done through the University's Medicine Society's mailing list (those who have previously consented to be emailed opportunities and surveys) and social media. Participants of the prototype survey will be encouraged to contact the research team if they experience any issues completing the survey or have additional feedback. The preliminary surveys will then be reviewed and any changes necessary will be made to the survey before further dissemination.

Following survey validation and refinement, medical student and foundation year doctor leads will be recruited through social media channels and through the national vascular trainee association, Rouleaux Club. Rouleaux Club has a monthly newsletter which goes out to vascular-interested medical students and doctors who have consented to receive opportunities in vascular surgery. We aim to recruit medical students from all 34 established medical schools. Medical schools with no final year students for the 2021/2022 academic year (University of Sunderland, St Andrews, Universities of Kent and Canterbury Christ Church, University of Lincoln, Edge Hill University, Brunel Medical School, Aston University Medical School and Ulster University) will be excluded. Anglia Ruskin Medical School is the exception to this rule, where students will be

surveyed in their 4th year (no final year students). These may be separated from the main results if the findings significantly differ from the final year students.

The medical student and foundation doctor leads will each have a unique code, which will identify which participants they have recruited into the vascular study. The research leads will be given certificates and PubMed indexed collaborative authorship status if they have successfully recruited more than 15 participants. A second round of dissemination of the survey may be necessary if there is a lack of responses from particular medical schools.

Surveys will be conducted by JISC software under a collaborative authorship model, where the research leads will be encouraged to send the survey link to their peers; but only if they are able to send the survey to their entire year group at once either by email or over social media. This ensures that the link is not simply sent to just vascular orientated medical students, nor that it is sent only to the research lead's peer group. The survey will be open for three months to allow two rounds of recruitment, where participants will be able to withdraw their responses two weeks after the survey closes. Thirty participants from each medical school will be recruited initially before rolling out to foundation deaneries; this would make our initial target of 1,020 participants. In total, 77 medical student leads have expressed interest in becoming a survey lead, of which all 34 medical schools are represented. From this, it is expected that the results will have complete geographical representation in the UK.

Primary outcome measure

1. The proportion of vascular topics covered by medical schools across the UK as recalled by medical students and foundation doctors.

Secondary outcome measures

1. The recalled amount of time spent on vascular surgery clinical placements.
2. The recalled amount of lecture-based teaching, practical teaching, vascular examinations and anatomical teaching.
3. The recalled number of vascular-based OCSE stations.
4. The recalled number of vascular examinations performed on patients and the number of ABPIs observed in practice.
5. The proportion of vascular research activities by medical students.
6. The proportion of vascular mentorship during medical school.
7. Student perceptions of a career in vascular surgery.
8. The confidence of foundation year doctors in managing vascular surgery patients.
9. The perceived confidence of students undertaking ABPIs, vascular histories and examinations.
10. The number of extra self-selected vascular modules undertaken by medical students.
11. The proportion of students who would consider a foundation rotation in vascular surgery or a career in vascular surgery.

Data analysis

Quantitative analysis will consist of a geospatial map of the participating 34 medical schools and a graphical analysis for each of the primary and secondary outcomes. Data will be analysed in IBM SPSS Statistics Statistical software[14] and graphs will be synthesised using Origin 2020b.[15] Qualitative analysis will consist of thematic analysis for participant perceptions of vascular surgery. The responses will be coded into themes that emerge from the data. These will then be rep-resented in an organised table with anonymous quotes from the students.

Limitations

The study has limitations which have been mitigated by critical ethical analysis. The predominant limitation of this study is survey participant bias, with those students who are most interested in vascular-related specialities being more likely to complete the survey. This may mean that non-vascular-focused students feel that the survey is irrelevant. This is a component of many speciality surveys and can only be mitigated by adequate signposting. In VENUM, students are provided the answers to the knowledge-based multiple choice questions which is aimed to help their revision, which should make the survey appealing to all students. 'Peer-group bias' has been reduced by the study design whereby research leads must send the survey link to the entire year group at once.

Recall bias is unavoidable in this student-led study but should be minimised by obtaining a large sample size from each university, hence the multiple research leads from each institution. Moreover, students are able to complete the survey more than once. However, on entering the survey, they will be reminded of their professional duty of candour to the General Medical Council.[13] This is a dis-advantage of the JISC survey software. Using a paid survey software such as 'REDCap' would overcome this, but would also require significant funding.[16] There is a minor risk of research leads fabricating responses to gain authorship, but this risk is expected to be small as research leads are only expected to collect 15 respondents. If this did occur there is a chance it could affect the validity of the data, thus the surveys will be screened for respondents who have answered chaotically, and these will be removed from the study results. Before the study period, the research leads will also be reminded of their duty of candour.[13]

Dissemination

The study results will be presented at the Vascular Societies' Annual Scientific meeting in 2022 and published in a peer-reviewed journal. Research leads may also be able to present the VENUM findings regionally at their own medical schools and relevant peer speciality conferences such as cardiology and general practice.

Potential research benefits

- Student-focused understanding of the current undergraduate vascular curricula.
- Make recommendations for medical schools to implement to enhance learning.

KEY MESSAGES

- Vascular undergraduate education has been poorly researched, with only two UK studies having been previously reported.
- We outline a protocol to establish the baseline of current vascular undergraduate education of medical students in the UK.
- We hope to highlight the issues of vascular education and make recommendations to improve vascular education, student perceptions and increase mentorship opportunities.

- Provide medical students with more vascular surgery role models.
- Better care for patients living with vascular diseases in the long term under all specialities.
- Better understanding of vascular disease across specialities in the long term by improving the curriculum.
- Improve medical students' perceptions of a career in vascular surgery by understanding their current perceptions.

Potential research risks

- Low risk study, as all aspects can be carried out remotely.
- Potential risk of adding to survey burden of medical students and foundation year doctors.
- Increases the pressure on medical schools to pool more resources in vascular disease into an already packed curriculum.

Perspectives of patients living with vascular disease

"As a patient with multi-site vascular issues, I feel that the project is absolutely necessary before real change in the collective mindset of the medical profession can happen. Hopefully, it will also draw attention of this much neglected condition to curricula compilers and course leaders. Education in PAD is important for patients, but if our GPs and emergency care doctors are not aware of our vascular problems, how can we possibly form a relationship where trust in the treatment is key?"

"One of my group ended up with an amputation after critical limb ischaemia was initially misdiagnosed in A&E and the ensuing delay made it impossible to save his foot. This was not patient ignorance, just an overworked and under-educated junior doctor."

"Thirdly, we all felt that the standard norm for PAD patients, male, over 70, overweight and smokers, leads many GPs to overlook a PAD diagnosis in people who fall outside of this norm. Education would save a lot of suffering and delay to a lot of people."

Conflict of Interest: None

Funding: No funding is required to complete this study. PPJS is funded by Heart Research UK and Leeds alumni, BB is funded by the NIHR, PAC is funded by the Circulation Foundation and MAB is funded by the British Heart Foundation.

Acknowledgements: We would like to thank the Vascular Endovascular Research Network (VERN) for accepting this abstract into VERN's Dragons Den 2021, and their ongoing support. We would also like to thank Professor Stephen Wheatcroft, senior cardiologist, for his overview of our survey questions.

Author contributions: PPJS: project conception, coordination, design, critical review, writing of ethics, writing of protocol. NZS: critical review of ethics, protocol and proposed questions. KJ: critical review of ethics, protocol and proposed questions. JF: critical review of ethics, intellectual input to proposed questions. BB: writing of ethics, review of protocol, refinement of proposed questions. PAC: project conception, intellectual input, review of protocol and co-supervisor. MAB: project conception, intellectual input, review of protocol and co-supervisor.

Reviewer acknowledgement: JVSGBI thanks Dan Carradice & Sandip Nandhra for their contribution to the peer review of this work.

References

1. Peripheral arterial disease - symptoms, diagnosis and treatment. *BMJ Best Practice* [Internet]. Cited 6 April 2021. Available from: https://bestpractice.bmj.com/topics/en-gb/431
2. Sucharitkul PPJ, Jones KL, Scott DJA, Bailey MA. Lipid optimisation in lower extremity peripheral arterial disease. *Ann Vasc Surg* 2021;**76**:542–54. https://doi.org/10.1016/j.avsg.2021.03.055
3. Cea-Soriano L, Fowkes FGR, Johansson S, Allum AM, Rodriguez LAG. Time trends in peripheral artery disease incidence, prevalence and secondary preventive therapy: a cohort study in The Health Improvement Network in the UK. *BMJ Open* 2018;**8**(1):e018184. http://dx.doi.org/10.1136/bmjopen-2017-018184
4. Subherwal S, Patel MR, Kober L, *et al*. Missed opportunities: despite improvement in use of cardioprotective medications among patients with lower-extremity peripheral artery disease, underuse remains. *Circulation* 2012; **126**(11):1345–54. https://doi.org/10.1161/CIRCULATIONAHA.112.108787.
5. Lee KS, Ng JJ, Choong AMTL. A scoping review of vascular surgery education in the medical school curriculum. *J Vasc Surg* 2021;**74**(4):1362–74.e3. https://doi.org/10.1016/j.jvs.2021.04.024
6. AlHamzah M, Eikelboom R, Hussain MA, *et al*. Knowledge gap of peripheral artery disease starts in medical school. *J Vasc Surg* 2019;**70**(1):241–245.e2. https://doi.org/10.1016/j.jvs.2018.12.042
7. Georgakarakos E, Georgiadis GS, Christopoulos DC, Lazarides MK. Vascular educational needs in the "real world" and teaching of vascular surgery in medical schools: evidence and suggestions. *Angiology* 2017;**68**(2):93–5. https://doi.org/10.1177/0003319716651753
8. National Institute for Health and Care Excellence. Peripheral arterial disease. 2019. Available from: https://cks.nice.org.uk/topics/peripheral-arterial-disease/
9. Vascular Society of Great Britain and Ireland. Vascular Surgery Workforce Survey 2018. [Internet]. Cited 23 Jun 2021. Available from: https://www.vascular-society.org.uk/_userfiles/pages/files/Document%20Library/Vascular%20Surgery%20Workforce%20Survey%20%202018%20V4_0.pdf
10. Simons PCG, Algra A, van de Laak MF, *et al*. Second manifestations of ARTerial disease (SMART) study: rationale and design. *Eur J Epidemiol* 1999;**15**(9): 773–81. https://doi.org/10.1023/a:1007621514757.
11. Ng A, Cambridge W, Jayaraajan K, *et al*. Study launch: uroLogical tEAching in bRitish medical schools Nationally (LEARN). *BJU Int* 2020;**126**(2):311–2. https://doi.org/10.1111/bju.15183
12. Osman FH, Koe JSE, Lau ESW, *et al*. Study protocol for ELIXIR: an evaluation of learning and exposure to the undergraduate interventional radiology curriculum. JSPRM 2021;2021(1):snab006. https://doi.org/10.1093/jsprm/snab006
13. General Medical Council. Good medical practice [Internet]. Cited 6 Feb 2022. Available from: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice
14. SPSS Statistics - United Kingdom. IBM [Internet]. Cited 6 Feb 2022. Available from: https://www.ibm.com/uk-en/products/spss-statistics
15. OriginLab. Origin and OriginPro. Data Analysis and Graphing Software [Internet]. Cited 3 Oct 2021. Available from: https://www.originlab.com/index.aspx?go=Products/Origin
16. Software – REDCap [Internet]. Cited 9 Feb 2022. Available from: https://projectredcap.org/software/

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):93-99
http://doi.org/10.54522/jvsgbi.2022.24

www.jvsgbi.com

TRIAL PROTOCOL

Community WALKing and home-baSed circuiT tRaining in peOple liviNG with intermittent claudication (WALK-STRONG): protocol for a randomised controlled feasibility trial

Waddell A,[1] Denton F,[1] Powell R,[1,2] Birkett S,[3] Broom D,[1] Imray C,[4] McGregor G,[1,2,5] Harwood AE[1]

1. Centre for Sport, Exercise and Life Sciences, Institute of Health and Wellbeing, Coventry University, Coventry, UK
2. Department of Cardiopulmonary Rehabilitation, Centre for Exercise & Health, University Hospitals Coventry & Warwickshire NHS Trust, Coventry, UK
3. School of Sport and Health Sciences, University of Central Lancashire, Preston, UK
4. Coventry NIHR Clinical Research Facility, University Hospitals Coventry & Warwickshire NHS Trust, Coventry, UK
5. Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK

Corresponding author:
Mr Alexander Waddell
Centre for Sport, Exercise and Life Sciences, Institute of Health and Wellbeing, Coventry University, Coventry CV1 2DS, UK
Email: alexanderjrwaddell@gmail.com

Received: 5th February 2022
Accepted: 1st April 2022
Online: 11th May 2022

Plain English Summary

Why we are undertaking the research: Peripheral artery disease is a common problem where the blood vessels in the legs are narrowed by fatty deposits. Supervised exercise programmes are recommended to help treat this condition, as they can reduce leg pain and improve fitness. However, not many people are able to access these programmes typically because of barriers including travel burdens, time constraints or other commitments. As an alternative, researchers are developing home-based programmes which do not require people to travel to centres for their sessions. In the UK and to the author's knowledge, there are not many well researched home-based programmes available for people living with peripheral artery disease.

What we aim to do: We plan to undertake a study to see how feasible our home-based programme is. People with peripheral artery disease will either be asked to continue with their normal routine or will be prescribed an exercise programme, with an activity watch to monitor physical activity. This programme will include increasing the number of steps walked each day, an exercise circuit (twice a week) and a telephone support call with a member of the research team to discuss their progress or lack of progress. Questionnaire responses, blood samples, walking ability, muscle strength and the amount of daily exercise will be compared between the two groups at the start of the 12-week programme, at the end, and 12 weeks after the programme has finished. By doing this study, we will be able to refine our home-based exercise programme so that it can be tested on a larger scale to see if it is a good option for people with peripheral artery disease who may not be able to attend a supervised exercise programme.

Key words: peripheral artery disease, intermittent claudication, home-based exercise, walking, circuit training

Trial registration: ClinicalTrials.gov, NCT05059899. Registered on 17 September 2021

Introduction

Peripheral artery disease (PAD) refers to the progressive occlusion of the arteries supplying the lower limbs[1] and affects over an estimated 236 million people worldwide.[2] Sustained ischaemia to the lower limbs, resulting in an oxygen supply/demand imbalance, can lead to a symptomatic presentation of PAD, characterised by exertional cramp-like leg pain known as intermittent claudication (IC).[3]

Current guidelines recommend supervised centre-based exercise therapy (SET) to improve walking performance and quality of life in those with IC.[4–6] UK-based guidelines suggest exercise to the point of maximal claudication pain.[4] Despite all the evidence for the effectiveness of SET, access, adherence and uptake is poor because of travel burdens, time commitments and lack of motivation.[7,8]

To improve accessibility and participation, there is a growing interest in home-based exercise programmes (HBEP). However, a recent UK-based survey found that only 48% of vascular services were able to offer SET, and of these only 30% provided any home exercise advice (alongside existing SET services), in the form of verbal recommendations, exercise booklets and pedometers.[7] This issue has been heightened during the COVID-19 pandemic, as sites delivering SET have had to provide home-based alternatives or face cancelling services completely. These services were therefore forced to quickly transition into HBEPs without the experience and a limited evidence base, highlighting the importance of developing HBEPs for UK patients.[7] A recent systematic review has shown HBEPs to be a safe option for people with IC, with an all-cause adverse event rate of one per 36,953 patient-hours.[9]

HBEP interventions vary considerably in

relation to frequency, modality, location (inside the home, outdoors in the community or in leisure centres)[10] and level of support provided. Technology used to remotely monitor progress, such as wearable activity trackers, has been shown to increase the efficacy of HBEPs, equivalent to that of SET.[11] Some programmes mimic SET in a home setting while others, including UK-based studies, aim to increase daily physical activity with step goals or generic walking advice.[12–18]

An example of a structured prescription of home-based exercise includes walking at a self-selected pace three days per week for 20–45 minutes over 12 weeks.[14] Adherence was monitored with a step activity monitor, resulting in significant improvements in walking performance. An example of a step-based programme had participants use a Fitbit to increase physical activity by 2500 steps per day over baseline for one month, increasing to 3750 and 5000 for months 2 and 3, respectively.[12] Improvements were seen in walking performance and cardiorespiratory fitness. However, simply promoting an increase in step count or physical activity is not sufficient. Results from the LITE trial showed walking performance improved more by sustained individual bouts of physical activity rather than just increased total activity.[19] Further, progressing activity with a blanket step goal for all participants (such as an additional 1000 steps) does not account for individual differences. Therefore, in addition to increasing daily activity, more structured individualised walking programmes are required.

In addition to walking, resistance training may also improve functional ability; however, to our knowledge, only one study has assessed this as part of a HBEP.[20] Incorporating resistance training into a walking programme may improve strength and balance whilst also increasing adherence by providing variety, both of which may translate to tangible functional improvements and gains in quality of life. There is therefore potential for a HBEP that utilises all three of these elements: increasing physical activity behavior with a step goal, while providing structured exercise prescription that includes walking to induce claudication pain and resistance exercises. The WALKSTRONG protocol was therefore developed taking this into consideration.

Before a definitive randomised controlled trial (RCT) can assess the clinical and cost effectiveness of our HBEP, the intervention must first be refined. Therefore, the aims of the present feasibility study are to:

1. Assess the feasibility of conducting a RCT of community walking and home-based circuit training in people with IC.
2. Measure recruitment and attrition rates.
3. Measure protocol adherence and safety.
4. Conduct semi-structured interviews with intervention completers, drop-outs and decliners to assess acceptability, facilitators and barriers.
5. Explore changes in walking performance, functional ability, quality of life and markers of systemic inflammation and vascular remodelling.

Methods

Study design

WALKSTRONG is a prospective assessor blind randomised controlled feasibility study. Thirty adults over the age of 18 years with IC will be randomly assigned to either a 12-week home-based exercise intervention or a usual care control group. This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.[21]

The study design is illustrated in Figure 1.

Study setting

The study is being undertaken at the Centre for Exercise & Health, Coventry in collaboration with University Hospitals Coventry & Warwickshire (UHCW). The study will take place from January 2022 to July 2024 and is sponsored by Coventry University. Funding to deliver the RCT is provided as part of a PhD scholarship for the principal researcher (AW) from Coventry University.

Study registration and ethical approval

Ethical approval was granted by the local research ethics committee (Coventry & Warwickshire REC: 21/WM/0208) on 14 December 2021 and the study will be conducted in accordance with the Declaration of Helsinki 1975. The study was prospectively registered on ClinicalTrials.gov (NCT05059899).

Inclusion and exclusion criteria

Participants with a confirmed diagnosis of IC will be recruited. The inclusion and exclusion criteria are listed below:

Inclusion criteria

- ≥18 years of age.
- Ankle/brachial index (ABPI) <0.9 at rest or a drop of 20 mmHg after exercise testing.
- Ability to walk independently without walking aids.
- English speaking.

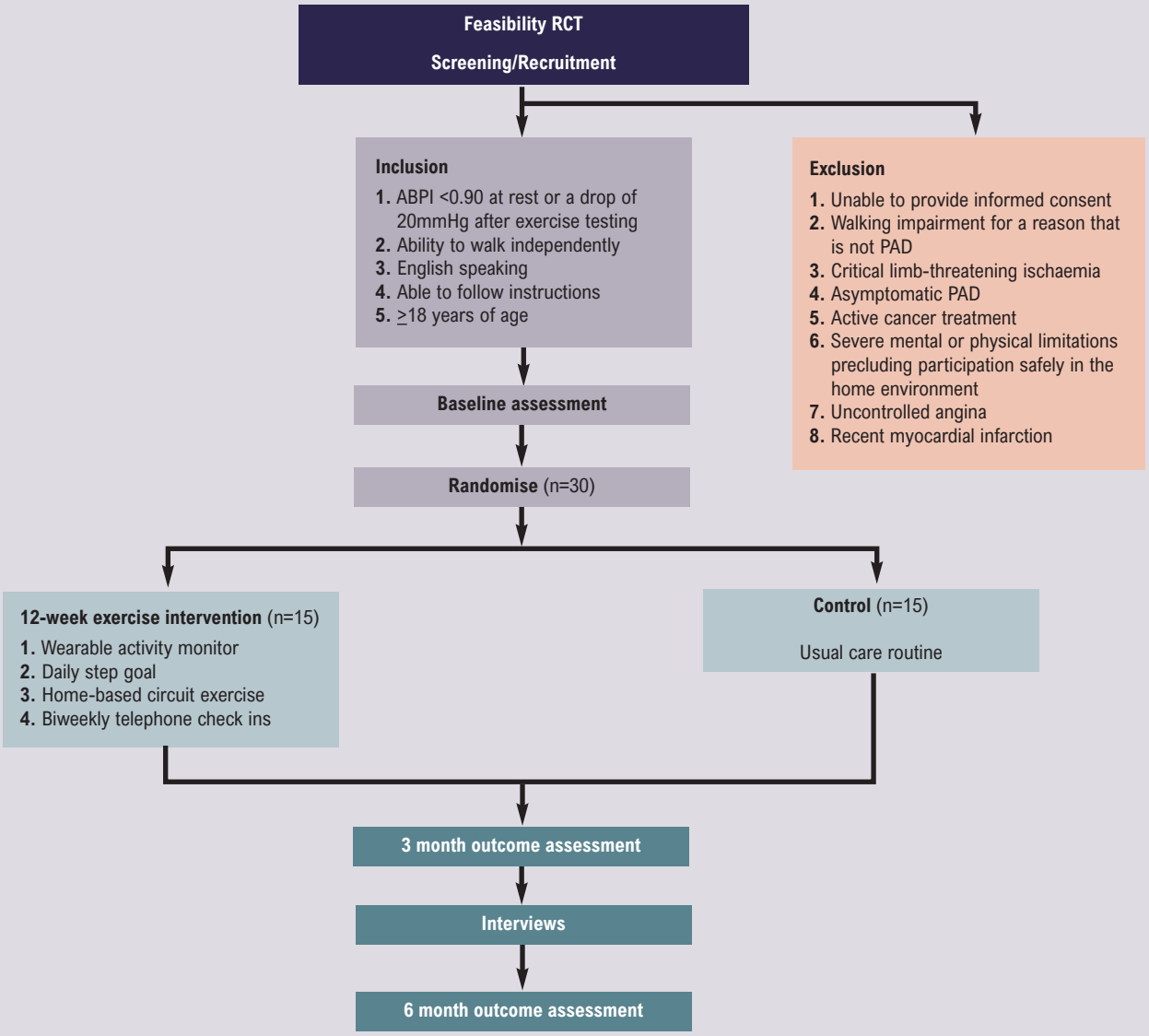
Exclusion criteria

- Unable to provide informed consent.
- Walking impairment for a reason that is not related to PAD.
- Critical limb-threatening ischaemia or asymptomatic PAD.
- Active cancer treatment.
- Severe mental or physical limitations precluding participation safely in the home environment as defined by American College of Sport Medicine.[22]
- Unstable angina.
- Recent myocardial infarction (within the previous month).

Study procedures

Patients who are potentially eligible will be referred to the research team by the clinical care team, having been initiated on best medical treatment by the referring clinician. If eligible, potential participants will be provided with a WALKSTRONG information sheet and be contacted to assess willingness to participate. Those who decide to participate will attend a baseline visit to confirm

Figure 1 Protocol flow diagram.



eligibility and provide informed consent. On completion of the baseline visit, participants will be randomised into the intervention or control group. Participants will be informed that they are free to withdraw from the trial at any time without providing a reason. If a participant's circumstances change such that they become ineligible to participate, the principal investigator reserves the right to withdraw the participant from the programme. Participants will exit the trial if they finish the intervention and complete outcome assessments at 12 and 24 weeks, or if they request to withdraw, or die.

Randomisation

Participants will be randomised in a 1:1 ratio using random permuted blocks via a secure computerised randomisation programme, maintaining allocation sequence concealment (Sealed Envelope: https://www.sealedenvelope.com). Participants will be randomised following baseline assessment. At subsequent visits, data will be collected by a different assessor who will be unaware of group allocation.

Control group

Participants allocated to the control group will not be given any intervention and will receive standard care which will include smoking cessation support and basic unstructured exercise advice by providing them with a leaflet from the British Heart Foundation. This includes information on the benefits of being physically active, what counts as activity, and how much physical activity should be undertaken each week. To ensure equity between participants, following the completion of the trial, those in the control group will be offered a Fitbit watch and the opportunity to complete the HBEP.

Exercise intervention

Participants assigned to the HBEP will be given a Fitbit Charge 4 activity monitor (https://www.fitbit.com) free of charge and will be required to download the Fitbit app using a study-specific email address provided to them. They will be asked to use the Fitbit to reach a personalised daily step goal, at their own pace, which will be determined based on baseline daily step count (measured over one week with an accelerometer). They will be initially asked to increase their daily step count by 10% above what they achieved at baseline. They will also be provided with a set of circuit exercises to be completed in their home twice per week, lasting approximately 45 minutes – as many UK centres prescribe exercise 1–2 days a week and a minimum of two resistance sessions a week is recommended.[7,23] This will involve a light warm-up period of 10 minutes including rhythmic pulse raising movements, joint mobilisation and passive stretches. This will be followed by a circuit, separated into six stations of resistance exercises. These include shoulder press, calf raise, wall press, sit-to-stand, bent over row and lunges, interspersing upper and lower body exercises. The aim is to complete two minutes at each station at 11–14 on the Borg scale of perceived exertion. Each station is separated by walking on the spot at an intensity to induce severe claudication pain for two minutes (but may be longer if severe pain is not reached in this time). The circuit will be followed by a 10-minute light cool down. Participants will be asked to record each circuit workout using an exercise logbook, noting the number or repetitions and weights used as well as leg pain during each walking bout.

The exercise intervention was designed based on current best practice guidelines for the management of PAD,[4–6] evidence from previous research[11] and informal public and patient involvement (PPI) discussions (see Appendix 1 online at www.jvsgbi.com). Findings from PPI discussions were that patients were keen to have a home-based alternative to SET, were interested in using an activity watch to visualise improvements, were happy to complete resistance exercise if given appropriate instructions and that check-ins should be biweekly.

Researchers will monitor the compliance of participants with their daily step goal by accessing their Fitbit data weekly. Every two weeks, participants will be contacted by telephone, providing an opportunity to discuss any issues or questions. Daily step count, exercise intensity and frequency will be discussed, with a mutual decision being made on progression or regression.

Outcome measures

Primary outcomes

The primary outcomes for this study are feasibility and acceptability, assessed via recruitment, attrition, adherence to the protocol, adverse events and participant feedback.

Recruitment: calculated by dividing the number of eligible candidates by the number who consent to participate.

Attrition: established as discontinuation of the intervention and loss to follow-up.

Adherence: assessed by monitoring logbook entries for the exercise sessions and recorded physical activity data will assess an individual's engagement with the intervention. This will include the percentage of step goals achieved, percentage of circuit sessions completed, partially completed and percentage completed at the required intensity. Where possible, reasons for drop out will be recorded to assess the suitability of the protocol.

Adverse events: reported in accordance with the principles of Good Clinical Practice, with the relatedness of the event to the intervention being assessed by the research team in collaboration with the clinical care team. Serious adverse events will be reported to the relevant ethics committee and sponsor. In the event of harm arising to participants as a result of study management, design or conduct, Coventry University insurance and indemnity policies will apply.

Acceptability: assessed by conducting semi-structured interviews. Participants who have completed the trial, as well as those who drop out or decline to take part, will be offered the opportunity to take part in a semi-structured interview either in person, over the telephone or via video conference with a member of the research team. With permission from participants, conversations will be audio recorded and transcribed verbatim. The interviews will be conducted using a topic guide to have consistency across all participants; however, they will be flexible to allow for discussion. Interviews will explore participants' opinions and experiences with the exercise programme, and any criticisms or factors that limited or enabled participation. Interviews will last approximately 30–60 minutes.

Secondary outcomes

Pain-free and maximal walking distance: This will be determined via a 6-minute walk test and graded treadmill test. The 6-minute walk test will be conducted in accordance with the guidelines from the American Thoracic Society.[24] This involves a 30 m course indoors, along a flat surface. The course will be marked every 3 metres with cones at each end. After the patient has rested, they will be instructed to walk as far as they can within the time limit, receiving standardised encouragement every minute. Participants can stop walking during the test for rest; however, the timer will not be stopped. Speed gates will be placed at each end of the course to measure walking speed.

The graded treadmill test (Gardner protocol) involves walking at a constant speed of 2 mph, at a 0% incline grade, which increases by 2% every 2 minutes. Participants will be instructed to indicate when claudication pain begins, giving pain-free walking distance (metres), and when claudication pain becomes too severe to continue walking, giving maximal walking distance (metres).[25] Adequate time will be provided between each test to ensure recovery.

Grip strength: Participants will be asked to hold an isometric dynamometer in their hand, with the handle being adjusted so that the base rests in the heel of their palm. Participants should be

seated, resting their arm on the chair arm. When they are ready, they will be asked to squeeze the dynamometer with maximal effort for 5 seconds. The test will be repeated three times on each hand with full recovery between each effort, recording the greatest value, as described by the Southampton protocol and American Society of Hand Therapists.[26]

Physical activity behaviour: determined by giving participants a research grade accelerometer (ActiGraph GT3X) to wear for one week. Participants will be asked to go about their normal activity and should wear the device continuously, only removing it when washing or sleeping. The ActiGraph GT3X is a reliable, gold standard accelerometer for measuring physical activity in adults under free-living conditions.[27]

Quality of life: will be recorded by assessing responses to three questionnaires. Disease-specific quality of life will be measured using the VascuQol questionnaire, a validated and standardised intermittent claudication-specific questionnaire.[28] The 36 Item Short Form survey will also be used. It is a well validated, generic health status questionnaire which provides a score on eight domains of health: bodily pain, mental health, vitality, physical and social functioning, physical and emotional roles and general health.[29] Answers to the EQ-5D-5L questionnaire will also be collected.[30,31]

Blood sampling: blood will be drawn from participants at each visit by a member of the research team trained in venepuncture using standardised operating procedures. Blood samples will be centrifuged and serum aliquoted and stored at –80°C until they are analysed. Assays will be performed by a member of the research team at Coventry University. Markers of systemic inflammation and vascular remodelling will be measured via serum C-reactive protein, interleukin-6, tumour necrosis factor-alpha and vascular endothelial growth factor using an enzyme-linked immunosorbent assay with each sample measured in duplicate.

An overview of the participant pathway through the study is shown in Table 1.

Sample size

As this is a feasibility trial, a power calculation was not completed. A general recommendation for feasibility studies is to include at least 30 participants, and it has been suggested that samples between 24 and 50 are sufficient to calculate a standard deviation of an outcome that can then be entered into a formal power calculation for a full-scale RCT.[32–34]

Data collection, storage, management and monitoring

Data will be collected by the principal investigator and other named and trained co-investigators at all time points. Data will be anonymised and given a study code. All other data will be stored securely at The Centre for Exercise and Health and/or saved on encrypted computer drives. Only members of the research team will have access to the dataset. Data will be securely archived after

Table 1 Participant schedule of enrolment, interventions and assessments

	STUDY PERIOD								
	Enrolment	Allocation	Post-allocation						Close-out
TIME POINT	−1 wk	0	2 wk	4 wk	6 wk	8 wk	10 wk	12 wk	24 wk
ENROLMENT:									
Eligibility screen	X								
Informed consent		X							
Allocation		X							
INTERVENTIONS:									
Exercise group			◆	—	—	—	—	◆	
Control group			◆	—	—	—	—	◆	
ASSESSMENTS:									
Feasibility and process measures		X						X	
Walking performance		X						X	X
Grip strength		X						X	X
Physical activity behaviour		X						X	X
Quality of life		X						X	X
Blood samples		X						X	X
Adverse events								X	
Interview								X	

study closure and stored for up to 5 years, after which it will be destroyed. All data will be stored and managed according to Coventry University's confidentiality and data protection policies. No formal data monitoring committee will be formed. The study will be regularly monitored by the research team members, led by the chief investigator (AH), throughout the study period.

Data analysis

All quantitative statistics will be presented as mean ± standard deviation (SD) unless otherwise stated. Participant data will be analysed in accordance with the intention-to-treat model, analysing according to the group to which they were randomised, regardless of the intervention they received.

Descriptive statistics will be used to describe the two groups at baseline, being assessed for normality via the Shapiro–Wilks test. To assess heterogeneity of the randomised groups, outcomes will be compared using independent t-tests or Wilcoxon signed-rank tests. All statistical analysis will be undertaken using IBM SPSS Statistics software.

Exploratory analysis

Data for walking performance, functional ability, physical activity, blood samples and quality of life will be assessed at baseline, week 12 and week 24. Presuming data are normally distributed, differences between means will be assessed using a mixed model repeated measures ANOVA with group allocation as the between-subject factor and time as the within-subject factor. Data will be analysed to assure they meet the assumptions of an ANOVA test and post hoc analysis will be undertaken on significant differences between group means. Partial eta squared will be reported as effect size. Statistical significance will be inferred if $p<0.05$. Results of all analyses will be interpreted and reported with the knowledge that the study is a feasibility trial that has not undergone a formal sample size calculation, and so is exploratory.

Qualitative data obtained during the semi-structured interviews will be managed and analysed using the qualitative software package (NVIVO). Qualitative data will be analysed using thematic analysis.[35] This is an inductive and iterative approach, in which themes will be derived from the data and agreed by the researchers following triangulation. Collection and analysis of the data will occur simultaneously.[36]

Dissemination of study findings

Trial participants will be provided with a summary of the results of the study. We will seek to publish results in reputable peer-reviewed journals and present the findings at relevant conferences. The results of the study and participant or sponsor information will not be passed on to any third party without gaining participant and sponsor consent.

Discussion

Supervised exercise alongside optimisation of best medical treatment and reduction of risk factors (ie, smoking) is currently first-line treatment for people with IC.[5] There has been a surge in research investigating the effectiveness of home-based alternatives to account for the underutilisation and lack of availability of SET in clinical practice. Typically, these programmes follow a similar structure to SET, with intermittent walking to the onset of moderate to maximal claudication pain, 3–5 days per week, progressively increasing the duration.[14,37] There is also growing interest in programmes that promote daily physical activity. To account for the lack of supervision, in-person or virtual check-ins are frequently implemented to discuss progress and alter intensity.

WALKSTRONG aims to investigate the feasibility of implementing a 12-week exercise intervention that encourages increases in physical activity behaviour and undertaking a home-based exercise circuit in people with IC. This will allow for the refinement of the protocol which can be used in a fully powered RCT to assess the effect of the programme on walking performance. The WALKSTRONG study is unique as it aims to incorporate home-based resistance training exercises with structured walking. Additionally, an increase in daily steps as a percentage of baseline rather than as a set number of steps will be implemented to promote physical activity. The programme aims to expand the ability of healthcare systems to provide a remote exercise programme to those unwilling or unable to take part in SET. A limitation is that there may be some socioeconomic bias in sample selection, as a smartphone will be needed to synchronise with the activity monitor to provide step data.

KEY MESSAGES

- Interest in home-based exercise programmes for people with PAD is growing to account for the poor utilisation of supervised exercise.
- We plan to assess the feasibility of a home-based exercise programme which involves an exercise circuit and promotes an increase in physical activity.
- This will allow us to refine the programme to investigate its effectiveness on a larger scale which, if successful, will provide an alternative option for people with PAD unable to access supervised exercise.

Trial status: Protocol version 2.0; 5 October 2021. Recruitment beginning February 2022 until required numbers are reached.

Conflict of Interest: The authors declare no conflicts of interest.

Funding: This project is being completed as part of a fully funded PhD with the Centre for Sport, Exercise and Life Sciences, Research Institute of Health and Wellbeing, Coventry University.

Authors' contributions: The protocol was written by AW with guidance from AH, DB, FD, GM and SB. All authors have approved the manuscript.

Ethical approval: Ethical approval was approved by the Coventry University Ethics Committee. Health Research Authority (HRA) approval has been obtained and Research Ethics Committee favourable opinion has been granted by the

Coventry and Warwickshire REC on 14 December 2021 (reference: 21/WM/0208). HRA and sponsor approval will be sought and documents updated in the case of any substantial amendments.

Reviewer acknowledgement: JVSGBI thanks Sean Pymer & Brian Johnson for their contribution to the peer review of this work.

References

1. Muir RL. Peripheral arterial disease: pathophysiology, risk factors, diagnosis, treatment, and prevention. *J Vasc Nurs* 2009;**27**(2):26–30.
2. Song P, Rudan D, Zhu Y, *et al*. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis. *Lancet Global Health* 2019;**7**(8):e1020–30. https://doi.org/10.1016/S2214-109X(19)30255-4
3. Rose GA. The diagnosis of ischaemic heart pain and intermittent claudication in field surveys. *Bull World Health Organ* 1962;**27**(6):645–58.
4. National Institute for Health and Care Excellence. Peripheral arterial disease: diagnosis and management. NICE guideline [CG147]. 2012. Available from: https://www.nice.org.uk/Guidance/CG147
5. Gerhard-Herman MD, Gornik HL, Barrett C, *et al*. AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2017;**69**(11):1465–508. https://doi.org/10.1016/j.jacc.2016.11.008
6. Lane R, Harwood A, Watson L, Leng GC. Exercise for intermittent claudication. *Cochrane Database Syst Rev* 2017;**12**(12):CD000990. https://doi.org/10.1002/14651858.CD000990.pub4
7. Harwood AE, Pymer S, Ibeggazene S, Ingle L, Caldow E, Birkett ST. Provision of exercise services in patients with peripheral artery disease in the United Kingdom. *Vascular* 2021;17085381211035259.
8. Harwood A-E, Smith GE, Cayton T, Broadbent E, Chetter IC. A systematic review of the uptake and adherence rates to supervised exercise programs in patients with intermittent claudication. *Ann Vasc Surg* 2016;**34**:280–9. https://doi.org/10.1016/j.avsg.2016.02.009
9. Waddell A, Seed S, Broom DR, McGregor G, Birkett ST, Harwood AE. Safety of home-based exercise for people with intermittent claudication: a systematic review. *Vasc Med* 2021 Dec 20;1358863X2110603. https://doi.org/10.1177/1358863X211060388
10. Denton F, Power S, Waddell A, *et al*. Is it really home-based? A commentary on the necessity for accurate definitions across exercise and physical activity programmes. *Int J Environ Res Public Health* 2021;**18**(17):9244. https://doi.org/10.3390/ijerph18179244
11. Pymer SA, Ibeggazene S, Palmer J, *et al*. An updated systematic review and meta-analysis of home-based exercise programmes for individuals with intermittent claudication. *J Vasc Surg* 2021;**74**(6):2076–2085.e20. https://doi.org/10.1016/j.jvs.2021.03.063
12. Duscha BD, Piner LW, Patel MP, *et al*. Effects of a 12-week mHealth program on functional capacity and physical activity in patients with peripheral artery disease. *Am J Cardiol* 2018;**122**(5):879–84. https://doi.org/10.1016/j.amjcard.2018.05.018
13. Collins TC, Lunos S, Carlson T, *et al*. Effects of a home-based walking intervention on mobility and quality of life in people with diabetes and peripheral arterial disease: a randomized controlled trial. *Diabetes Care* 2011; **34**(10):2174–9. https://doi.org/10.2337/dc10-2399
14. Gardner AW, Parker DE, Montgomery PS, Blevins SM. Step-monitored home exercise improves ambulation, vascular function, and inflammation in symptomatic patients with peripheral artery disease: a randomized controlled trial. *J Am Heart Assoc* 2014;**3**(5):e001107. https://doi.org/10.1161/JAHA.114.001107
15. McDermott MM, Liu K, Guralnik JM, *et al*. Home-based walking exercise intervention in peripheral artery disease: a randomized clinical trial. *JAMA* 2013;**310**(1):57–65. https://doi.org/10.1001/jama.2013.7231
16. Spafford C, Oakley C, Beard J. Nordic pole walking is more effective than a standard home exercise programme in improving walking distance in patients with intermittent claudication: a prospective randomised study. *Br J Surg* 2014;**101**(7):760–7. https://doi.org/10.1002/bjs.9519
17. Roberts AJ, Roberts EB, Sykes K, de Cossart L, Edwards P, Cotterrell D. Physiological and functional impact of an unsupervised but supported exercise programme for claudicants. *Eur J Vasc Endovasc Surg* 2008;**36**(3):319–24. https://doi.org/10.1016/j.ejvs.2008.04.008
18. Sandercock GR, Hodges LD, Das SK, Brodie DA. The impact of short term supervised and home-based walking programmes on heart rate variability in patients with peripheral arterial disease. *J Sports Sci Med* 2007;**6**(4):471–6.
19. Slysz JT, Rejeski WJ, Treat-Jacobson D, *et al.* Sustained physical activity in peripheral artery disease: associations with disease severity, functional performance, health-related quality of life, and subsequent serious adverse events in the LITE randomized clinical trial. *Vasc Med* 2021;**26**(5):497–506. https://doi.org/10.1177/1358863X21989430
20. Cornelis N, Buys R, Dewit T, *et al*. Satisfaction and acceptability of telemonitored home-based exercise in patients with intermittent claudication: pragmatic observational pilot study. *JMIR Rehabil Assist Technol* 2021; **8**(1):e18739. https://doi.org/10.2196/18739
21. Chan A-W, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;**158**(3):200–7. https://doi.org/10.7326/0003-4819-158-3-201302050-00583
22. Williams G. ACSM's Guidelines for Exercise Testing and Prescription. 11th ed. Lippincott Williams & Wilkins; 2020.
23. Askew CD, Parmenter B, Leicht AS, Walker PJ, Golledge J. Exercise and Sports Science Australia (ESSA) position statement on exercise prescription for patients with peripheral arterial disease and intermittent claudication. *J Sci Med Sport* 2014;**17**(6):623–9. https://doi.org/10.1016/j.jsams.2013.10.251
24. ATS Committee on Proficiency Standards for Clinical Pulmonary Functional Laboratories. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med* 2002;**166**(1):111–7. https://doi.org/10.1164/ajrccm.166.1.at1102
25. Gardner AW, Skinner JS, Cantwell BW, Smith LK. Progressive vs single-stage treadmill tests for evaluation of claudication. *Med Sci Sports Exerc* 1991; **23**(4):402–8.
26. Roberts HC, Denison HJ, Martin HJ, *et al.* A review of the measurement of grip strength in clinical and epidemiological studies: towards a standardised approach. *Age Ageing* 2011;**40**(4):423–9. https://doi.org/10.1093/ageing/afr051
27. Aadland E, Ylvisåker E. Reliability of the Actigraph GT3X+ accelerometer in adults under free-living conditions. *PLoS One* 2015;**10**(8):e0134606. https://doi.org/10.1371/journal.pone.0134606
28. Mehta T, Venkata Subramaniam A, Chetter I, McCollum P. Assessing the validity and responsiveness of disease-specific quality of life instruments in intermittent claudication. *Eur J Vasc Endovasc Surg* 2006;**31**(1):46–52. https://doi.org/10.1016/j.ejvs.2005.08.028
29. Chetter IC, Spark JI, Dolan P, Scott DJA, Kester RC. Quality of life analysis in patients with lower limb ischaemia: suggestions for European standardisation. *Eur J Vasc Endovasc Surg* 1997;**13**(6):597–604. https://doi.org/10.1016/s1078-5884(97)80070-6
30. Hernandez Alava M, Wailoo A, Grimm S, *et al*. EQ-5D-5L versus EQ-5D-3L: the impact on cost effectiveness in the United Kingdom. *Value Health* 2018; **21**(1):49–56. https://doi.org/10.1016/j.jval.2017.09.004
31. National Institute for Health and Care Excellence. Position statement on use of the EQ-5D-5L value set for England (updated October 2019). Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/technology-appraisal-guidance/eq-5d-5l
32. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;**10**(2):307–12. https://doi.org/10.1111/j..2002.384.doc.x
33. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012; **65**(3):301–8. https://doi.org/10.1016/j.jclinepi.2011.07.011
34. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res* 2016;**25**(3):1057–73. https://doi.org/10.1177/0962280215588241
35. Clarke V, Braun V. Thematic analysis. In: Encyclopedia of Critical Psychology. New York: Springer, 2014, 1947–52.
36. Attride-Stirling J. Thematic networks: an analytic tool for qualitative research. *Qual Res* 2001;**1**(3):385–405. https://doi.org/10.1177/146879410100100307
37. McDermott MM, Spring B, Berger JS, *et al.* Effect of a home-based exercise intervention of wearable technology and telephone coaching on walking performance in peripheral artery disease: the HONOR randomized clinical trial. *JAMA* 2018;**319**(16):1665–76. https://doi.org/10.1001/jama.2018.3275

Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):100-104
http://doi.org/10.54522/jvsgbi.2022.016

www.jvsgbi.com

CASE REPORT

Distal venous arterialisation for 'no-option' chronic limb-threatening ischaemia

Beck KJ,[1] Howard DPJ[2,3]

1. Medical Sciences Division, University of Oxford, Oxford, UK
2. Wolfson Centre for Prevention of Stroke and Dementia, Nuffield Department of Clinical Neurosciences, University of Oxford, UK
3. Department of Vascular Surgery, Oxford University Hospitals NHS Foundation Trust, UK

Corresponding author:
Katharina J Beck
Medical Sciences Division, University of Oxford, Oxford, OX3 9DU, UK
Email: katharina.beck@gtc.ox.ac.uk

Received: 7th December 2021
Accepted: 7th March 2022
Online: 29th March 2022

Abstract

Chronic limb-threatening ischaemia (CLTI), defined as significant peripheral arterial disease causing ischaemic rest pain and/or tissue loss, is associated with a high amputation and mortality rate. Avoiding amputation in CLTI is crucial and restoration of blood flow is usually achieved using endovascular or open surgical revascularisation. However, significant occlusion of the distal limb vasculature may result in 'no option' CLTI, where there are no available target vessels for angioplasty or bypass. An emerging procedure to treat patients with 'no option' CLTI is distal venous arterialisation (DVA). This involves using the distal venous system as a conduit for arterial blood to revascularise the lower limb. This report describes a patient presenting with 'no option' CLTI who underwent limb-saving treatment with DVA. The case highlights how worsening clinical outcomes may occur despite technical success of DVA. It also emphasises complications of the procedure. Finally, the evidence base surrounding DVA for CLTI is examined.

Key words: peripheral arterial disease, chronic limb-threatening ischaemia, distal venous arterialisation, limb salvage

Introduction

Peripheral arterial disease (PAD), which causes narrowing or occlusion of the arteries and reduced blood flow to the affected limb, affects 13% of the western population over 50 years old.[1] As PAD progresses and becomes severe, it can result in critical limb-threatening ischaemia (CLTI). This is characterised by ischaemic rest pain and/or tissue loss in the form of non-healing ulcer or gangrene.[2]

It is estimated that at 1 year following presentation with CLTI, 25% of patients will die and 30% will undergo amputation.[3] The mean 5-year care cost for patients with CLTI is estimated at 46,281€, and every above-knee amputation increases care costs by 25,692€. Therefore, the long-term care costs to the National Health Service (NHS) following CLTI are considerable.[4]

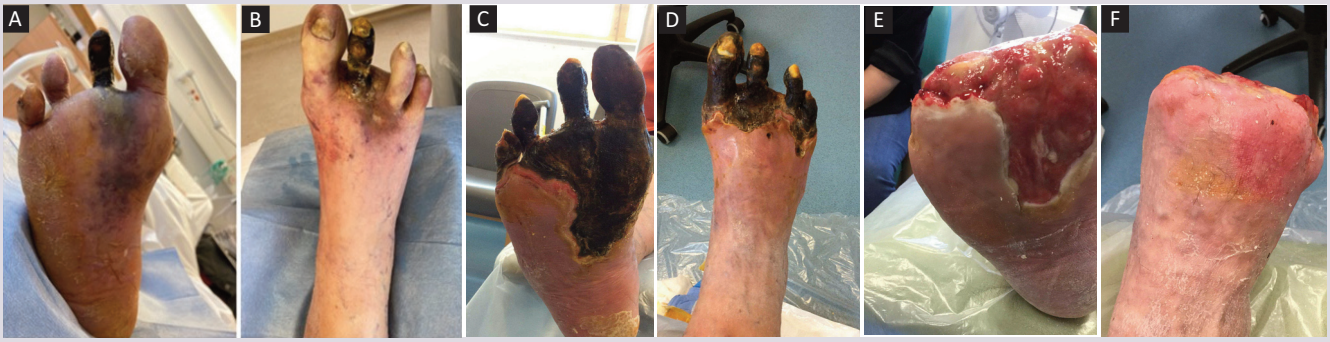
Depending on the severity at presentation, initial management of CLTI involves pain and pressure relief, antiplatelet therapy, antimicrobial therapy and wound care.[5] Revascularisation through endovascular or open approach is often urgently pursued, aiming to restore blood flow to the affected limb, improve wound healing, preserve limb function and mobility, and avoid amputation. Unfortunately, some patients exhibit severe forms of PAD, extending below the ankle with significant occlusion of the distal limb arteries. This could result in a phenomenon called 'no option' CLTI or 'desert foot', where there is no suitable vessel for endovascular angioplasty, stenting or even open bypass surgery.[6–8] It is estimated that 14–20% of patients fall into this category of 'no option' CLTI, and their prognosis is usually poor.[9]

An exciting potential option used as a last resort to restore blood flow to the foot in patients with 'no option' CLTI is distal venous arterialisation (DVA). It involves creating a connection between the tibial artery and vein, diverting arterial blood into the venous system to perfuse the distal lower limb.[7,10,11] Halstead and Vaughan first proposed using the venous bed as a conduit to perfuse the peripheries in 1912.[10] Open surgery was then first used in the 1970s, with case reports describing anastomosis of an arterialised great saphenous vein to the dorsal venous arch of the foot.[7] Since then, there has been a move to percutaneous approaches for DVA. Here we present a case of a patient who presented with 'no option' CLTI and successfully underwent limb-saving treatment with percutaneous DVA.

Case history

A 54-year-old man had an 8-month history of increasing pain on the right foot, redness of the

Figure 1 Clinical progression of the patient's right foot. (A, B) Pre-distal venous arterialisation (DVA). (C, D) Three weeks post-DVA. (E, F) Eight months post-DVA.



medial aspect of the right calf with gangrene of the right second toe. He was a previous smoker (30-pack year history) and has type 2 diabetes mellitus with diabetic retinopathy, hypertension, asthma and thalassaemia. His current medication included metformin 500 mg, atorvastatin, ramipril as well as a Clenil Modulite inhaler, and his HbA_{1c} was 5.2%. He had a long-standing history of PAD with previous right third toe amputation and multiple previous attempted angioplasties, including both antegrade femoral access and retrograde pedal access.

On examination, the right leg was cool peripherally, with pallor of the digits, and both erythema and mild pitting oedema of the forefoot and lower calf. The right second toe was necrotic and black, with dusky discolouration on the dorsal aspect of the foot (Figure 1A and B). On the right leg, the femoral and popliteal pulses were palpable. Examination of the right dorsalis pedal (DP) and posterior tibial (PT) arteries with a hand-held doppler ultrasound revealed damped monophasic waveforms. Toe pressure measurement was 18 mmHg on the right and 43 mmHg on the left. Overall, his presentation was consistent with Rutherford category 5 CLTI with a Wound, Ischaemia and foot Infection (WIfI) stage 4.

An arterial ultrasound duplex scan of the right leg demonstrated calcification and occlusion of the anterior tibial artery (ATA) and peroneal artery (PA), as well as distal stenoses in the PT artery. Initial management included continuation of his antiplatelet, antihypertensive, antidiabetic and statin therapy, with addition of antibiotics (intravenous co-amoxiclav and oral metronidazole) for right foot infection. A right leg angiogram revealed a patent superficial femoral artery and popliteal artery, but the distal ATA was heavily calcified and occluded (Figure 2A). The occluded ATA was treated with angioplasty using a 3 mm balloon. Occlusions were also found in PT and DP arteries, but these could not be traversed. On arterial ultrasound duplex, there was no distal artery that was a suitable target for open bypass surgery. Arteriovenous imaging ascertained a Global Limb Anatomic Staging System (GLASS) stage III. Because of the failure of endovascular treatment and impossibility of open bypass, the patient was considered for DVA.

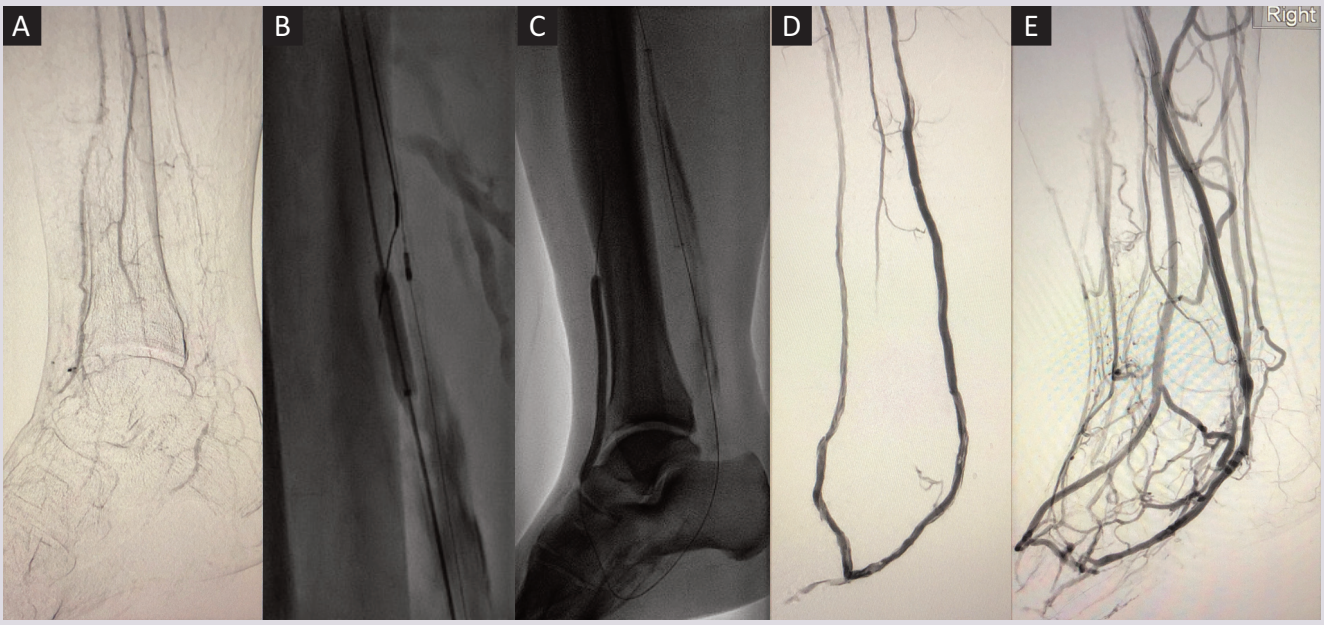
The DVA procedure was performed at the major vascular centre in our network. This procedure was pre-approved by the Trust Technologies Advisory Group Committee and was performed under anaesthetic by an experienced vascular and endovascular surgeon and interventional radiologist. Patients are carefully consented and are made aware that the procedure is novel and long-term outcomes are currently unknown. The DVA procedure was carried out as follows: the PT artery and posterior tibial vein (PTV) were cannulated. The proximal PT artery was dilated with angioplasty and an outback re-entry device was used to create a fistula from the proximal artery into the vein (Figure 2B). Stents were placed across the arteriovenous fistula (Papyrus Biotronik 4x26 mm, Viabahn 5x100 mm). The PTV was then aggressively venoplastied to optimise blood to flow into the foot (Figure 2C). All significant valves in the PTV were rendered incompetent with balloon venoplasty (standard 5x100 mm, Angiosculpt 6x100 mm balloons). During the operation thrombus formed in the stent but was removed via mechanical thrombectomy.

Postoperatively, the patient initially had no complaints of pain. On examination, the right foot was pink and warm with a strong palpable thrill present in the venous arch of the foot. Three days post-DVA, right leg arterial duplex demonstrated the PT artery to PTV fistula was patent, indicating a technically successful procedure. However, 4 days post-DVA increasing pain and erythema were noted in the patient's right leg. This resulted in further angioplasty of the fistula outflow vein with a 5 mm balloon, improving the flow of the distal arch veins seen on angiography (Figure 2D). Following this, the pain improved and the patient was discharged to his home 3 days later.

At 3-week follow-up a well demarcated spreading necrosis on the plantar surface of the right foot was observed (Figure 1C, D). The calf of the patient was erythematous and he reported tiredness. At this point the foot was still deemed at risk of ischaemia and thus below-knee amputation was still an option.

The patient was regularly followed up in a weekly multidisciplinary diabetic foot clinic, ensuring regular debridement of necrotic tissue and regular review of antibiotic therapy. A 'watch and wait' approach was adopted and, eventually, no further

Figure 2 Right leg infra-popliteal angiogram and intraoperative imaging. (A) Pedal vessels pre-distal venous arterialisation (DVA) after multiple angioplasty attempts. (B) Outback re-entry device and balloon for forming arteriovenous fistula. (C) Stent in position and venoplasty. (D) DVA 4 days post formation. (E) Matured DVA 3 months post formation.



operative procedures were needed. Over the next months the remaining toes gradually autoamputated leaving behind healthy granulation tissue (Figure 1E, F). The right PT venous pulse remained palpable with good doppler signal, and follow-up right leg arterial duplex demonstrated continued patency of the arteriovenous fistula. He reported feeling well in himself and denied significant pain in the right foot. Ultimately, the vitality of the mid and hindfoot had been preserved and below-knee amputation had successfully been avoided. This highlights that, in spite of technical success, DVA may not initially improve clinical outcomes with eventual worsening of gangrene before improvement.

In terms of functional improvement, the patient went from requiring a wheelchair for most activities to having completely independent mobility and being able to drive in a car and return to work.

The patient provided written informed consent for his case to be written up as a case study.

Discussion

The crux of a successful DVA is dedication to ensuring that excellent flow is achieved around the venous foot arch. This requires endovascular disruption of all venous valves and potentially embolisation of any large collateral veins that would divert blood away from the distal forefoot. This patient demonstrates that, if this occurs successfully, DVA can be used to avoid amputation, improve wound healing and improve quality of life in patients with 'no option' CLTI. Although this is a new and novel technique, initial subclinical deterioration in tissue loss has been recognised and we can confirm this in our case series so far. This is likely to be due to the sudden haemodynamic changes caused by the formation of the DVA. Immediately after formation the arterialised vein can potentially 'steal' blood flow from the distal forefoot and digits as it is a high-flow fistula without any maturation. As the vein arterialises and matures, the microcirculation to the foot starts to be pressurised by this new vessel with oxygenated blood being driven in reverse through the venules and arterioles. The foot often swells and looks erythematous for 3–6 weeks post intervention and then this process subsides. Nonetheless, careful use of regular multidisciplinary foot clinic review and staged debridement ensures wound healing eventually occurs.

Outcomes of systematic reviews and retrospective studies assessing DVA for CLTI

Reports of DVA as a treatment option for 'no option' CLTI have only emerged in the last two decades, mostly in the form of case reports and retrospective cohort studies. Summarising the observations of 16 retrospective cohort studies looking at a total of 768 patients undergoing DVA for CLTI, Schreve *et al* reported a mean 1-year limb salvage rate of 75% (95% CI 70% to 80%).[11] Limb salvage is defined as the percentage of subjects free from above ankle amputation of the affected limb. Other outcomes included 30-day hospital mortality, which ranged from 0% to 10%, and overall survival, ranging from 54% to 100%. The post-surgery patency of venous arterialisations, usually measured using duplex ultrasound in the days following surgery, has been reported as 66–72%.[11] More recently, the largest retrospective cohort study to date

assessed 32 patients with Rutherford category 5 or 6 'no option' CLTI receiving DVA with a Limflow device.[12] It reported a 97% technical success rate, with limb salvage rates 86.8% at 6 months, 79.8% at 12 months and 79.8% at 24 months. Notably, there was also a statistically significant increase in transcutaneous oxygen pressure ($TcPO_2$) from 14.5±12.7 mm Hg before surgery to 56.1±11.9 mm Hg 2 years after DVA. $TcPO_2$ measurements demonstrate perfusion status in the microvasculature of the foot and are a direct predictor of wound healing.[13,14]

Complications of DVA identified in retrospective studies include postoperative oedema, thrombosis (as was the case in this patient's surgery), major cardiac events, bleeding and infection.[12,15] Perhaps the most significant flaw of DVA is the loss of DVA primary patency. Lu *et al* reported that, in 144 patients undergoing DVA, after 1 year DVA patency was only 46% (95% CI 39% to 53%).[15] Likewise, others report a reintervention rate due to loss of primary patency of 65%.[12] Furthermore, whilst major amputation occurrence is reduced through DVA intervention, notably among those going on to require amputation, angiography demonstrates no occlusion of the DVA in 75% of cases.[12] Duplex imaging of the DVA every 6–8 weeks for the first 6 months post procedure is important due to the risk of developing venous valve stenoses or neointimal hyperplasia at the distal stent transition which may require expedited reintervention to maintain DVA patency.

Limitations of retrospective cohort studies assessing DVA for CLTI

Since only retrospective observational cohort studies are currently available to assess DVA for CLTI, publication bias is a major issue in the field as positive results following DVA are more likely to be published. Given how rarely DVA is performed, the numbers of participants reported in individual studies are very low. There is a lack of randomised controlled trials comparing DVA with other limb-saving procedures for CLTI (endovascular and bypass surgery) due to the 'last resort' nature of the procedure. Designing a randomised controlled trial to ascertain the success of DVA is complicated; given its novelty and associated learning curve, it is difficult to accurately compare it with established procedures for CLTI – namely, surgical bypass and endovascular intervention. Other experimental non-surgical treatment options for 'no option' CLTI patients exist – for example, spinal cord stimulation, lumbar sympathectomy, pharmacotherapy (prostanoids, vasoactive drugs) or stem cell therapy.[5] Future studies could aim to compare DVA with these approaches. Alternatively, one could compare patients having DVA with those who go on to have amputation without consideration for DVA using outcomes such as survival, physical function and quality of life.

In addition, there is a lack of standardisation among cohort studies in terms of outcome measures: many studies fail to report on one or more of patient reported outcomes such as subjective rest pain resolution or improvement in carrying out activities of daily living, precise haemodynamic outcomes with measurements such as ankle brachial pressure index (ABPI) or $TcPO_2$, or anatomical reporting in terms of patency seen on duplex or angiography. The outcome of 'above ankle amputation-free survival' does not take into account varying degrees of amputation above the ankle, which could vary in impact on the patient's quality of life. Given in our case there was often a discrepancy between patient reports of pain, the technical success of DVA formation shown on angiography and the assessment level of necrosis visible on the foot, we suggest a detailed assessment of outcomes following DVA should be undertaken to include subjective (patient reported pain and other symptoms), haemodynamic and anatomical outcomes. A validated recommended core outcome set for CLTI studies would be invaluable.

Furthermore, patients who undergo DVA for CLTI are heterogeneous. It is difficult to undertake a nuanced subgroup analysis factoring in, for example, the extent of diabetes management or WIfI and GLASS classification, all of which influence amputation-free survival and overall mortality, given the small number of patients undergoing the procedure. As DVA becomes more routine, more evidence will emerge to facilitate a refined understanding of exactly which categories of CLTI DVA is most effective for.

Future directions

The PROMISE II trial (ClinicalTrials.gov identifier NCT03970538) is currently assessing the safety and efficacy of DVA using the LimFlow device for 'no option' CLTI in 120 participants based in the USA.[16] Outcomes include major amputation-free survival, primary and secondary patency and wound healing. Of note, the incidence of contrast-induced nephropathy will also be assessed, which is missing from most reports.[11,12,15] The technique used in our centre is similar to the LimFlow device, but potentially cost saving as it is performed with standard endovascular access, wires and devices.

In order to effectively provide a robust evidence base for DVA, ideally PROMISE II will address several limitations of the existing literature. Firstly, it should report multiple outcomes such as subjective patient-reported measures, functional assessment of patient mobility as well as precise haemodynamic measures such as ABPI and $TcPO_2$. Furthermore, patients in the trial should be followed up with regular arteriovenous imaging to determine DVA patency and determine which factors could be linked to re-occlusion and loss of patency, as this appears to be the main drawback of the procedure.[17,18] Finally, trials could account for subject heterogeneity by stratifying patients into different subgroups. Assessing these subgroups separately will enable the creation of a model that predicts for whom DVA would be most effective and appropriate. The PREVENT III risk score has already been established for estimating amputation-free survival in patients with CLTI undergoing infrainguinal bypass – a similar risk score could be established here.[17]

We propose that, in conjunction with PROMISE II, centres performing DVA should carefully monitor the incidence of

KEY MESSAGES

- DVA is a promising intervention for patients with 'no option' CLTI improving wound healing, avoiding amputation and improving patient mobility.
- Complications of DVA include thrombus formation within the DVA as well as a loss of patency in the graft requiring re-intervention.
- Initial worsening necrosis may be observed despite DVA graft patency, but given regular multidisciplinary foot clinic review with debridement, healing will occur.

intraoperative complications, follow up long-term patency and link these to functional assessments of patient mobility and quality of life (eg, using SF-36 questionnaires). This will facilitate a holistic assessment of the role of DVA in improving the lives of a complex group of patients with multiple co-morbidities.

Conclusion

For patients with 'no option' CLTI, amputation has traditionally been likely. Ultimately, this patient demonstrates that DVA is a promising option for patients with 'no option' CLTI, avoiding amputation, improving wound healing and patient mobility. Notably, this case highlights two important complications of DVA: thrombus formation and re-intervention to maintain patency. These are key areas that need to be addressed in this continuously developing area of vascular surgery. Furthermore, initial temporary extension of forefoot necrosis is often observed after successful DVA formation. With off-loading, regular foot clinic review and staged debridement we have found this stabilises and excellent granulation tissue formation and wound healing eventually occurs. Our case suggests that, in patients in whom a DVA remains patent for at least 8–12 weeks, healing and avoidance of major amputation is possible.

Conflict of Interest: None.

Funding: None.

Acknowledgements: The author(s) thank all clinical professionals involved in this patient's care.

Reviewer acknowledgement: JVSGBI thanks Paddy Coughlin & Thanos Saratzis for their contribution to the peer review of this work.

References

1. Morley RL, Sharma A, Horsch AD, Hinchliffe RJ. Peripheral artery disease. *BMJ* 2018;**360**:j5842. https://doi.org/10.1136/bmj.j5842
2. Hiatt WR, Brass EP. Pathophysiology of peripheral artery disease, intermittent claudication, and critical limb ischemia. In: *Vascular Medicine: A Companion to Braunwald's Heart Disease*. W B Saunders, 2013, 223–30.
3. Davies MG. Critical limb ischemia: epidemiology. *Methodist DeBakey Cardiovasc J* 2012;**8**(4):10–14. https://doi.org/10.14797/mdcj-8-4-10
4. Luengo-Fernandez R, Howard DP, Nichol KG, Dobell E, Rothwell PM. Hospital and institutionalisation care costs after limb and visceral ischaemia benchmarked against stroke: long-term results of a population based cohort study. *Eur J Vasc Endovasc Surg* 2018;**56**(2):271–81. https://doi.org/10.1016/j.ejvs.2018.03.007
5. Conte MS, Bradbury AW, Kolh P, *et al*. Global vascular guidelines on the management of chronic limb-threatening ischemia. *Eur J Vasc Endovasc Surg* 2019;**58**(1):S1–S109.e33. https://doi.org/10.1016/j.ejvs.2019.05.006
6. Almasri J, Adusumalli J, Asi N, *et al*. A systematic review and meta-analysis of revascularization outcomes of infrainguinal chronic limb-threatening ischemia. *J Vasc Surg* 2019;**69**(6S):126S–136S. https://doi.org/10.1016/j.jvs.2018.01.071
7. Sheil AG. Treatment of critical ischaemia of the lower limb by venous arterialization: an interim report. *Br J Surg* 1977;**64**(3):197–9. https://doi.org/10.1002/bjs.1800640314
8. Ferraresi R, Mauri G, Losurdo F, *et al*. BAD transmission and SAD distribution: a new scenario for critical limb ischemia. *J Cardiovasc Surg* 2018;**59**(5): 655–64. https://doi.org/10.23736/S0021-9509.18.10572-6
9. Wolfe JH. Defining the outcome of critical ischemia: a one year prospective study. *Br J Surg* 1986;**73**:321.
10. Halstead AE, Vaughan RT. Arteriovenous anastomosis in the treatment of gangrene of the extremities. *Surg Gynecol Obstet* 1912;**14**(1):1–9.
11. Schreve MA, Vos CG, Vahl AC, *et al*. Venous arterialisation for salvage of critically ischaemic limbs: a systematic review and meta-analysis. *Eur J Vasc Endovasc Surg* 2017;**53**(3):387–402. https://doi.org/10.1016/j.ejvs.2016.11.007
12. Schmidt A, Schreve MA, Huizing E, *et al*. Midterm outcomes of percutaneous deep venous arterialization with a dedicated system for patients with no-option chronic limb-threatening ischemia: the ALPS multicenter study. *J Endovasc Ther* 2020;**27**(4):658–65. https://doi.org/10.1177/1526602820922179
13. Rother U, Lang W. Noninvasive measurements of tissue perfusion in critical limb ischemia. *Gefässchirurgie* 2018;**23**(Suppl 1):8–12. https://doi.org/10.1007/s00772-018-0368-x
14. Wang Z, Hasan R, Firwana B *et al*. A systematic review and meta-analysis of tests to predict wound healing in diabetic foot. *J Vasc Surg* 2016;**63**(2 Suppl): 29S–36S.e1–2. https://doi.org/10.1016/j.jvs.2015.10.004
15. Lu XW, Idu MM, Ubbink DT, Legemate DA. Meta-analysis of the clinical effectiveness of venous arterialization for salvage of critically ischaemic limbs. *Eur J Vasc Endovasc Surg* 2006;**31**(5):493–9. https://doi.org/10.1016/j.ejvs.2005.12.017
16. The PROMISE II Trial, Percutaneous Deep Vein Arterialization for the Treatment of Late-Stage Chronic Limb-Threatening Ischemia (PROMISE). Retrieved from https://CLTInicaltrials.gov/ct2/show/NCT03970538 (Identification No. NCT03970538)
17. Schanzer A, Goodney PP, Li Y, *et al*. Validation of the PIII CLI risk score for the prediction of amputation-free survival in patients undergoing infrainguinal autogenous vein bypass for critical limb ischemia. *J Vasc Surg* 2009;**50**(4): 769–75. https://doi.org/10.1016/j.jvs.2009.05.055
18. Ysa A. Commentary: Percutaneous venous arterialization: should we contain our enthusiasm? *J Endovasc Ther* 2020;**27**(4):666–8. https://doi.org/10.1177/1526602820923059

CIRCULATION FOUNDATION
The Vascular Charity

Our Vision:- is a society free of vascular disease, and its associated suffering.

Our Mission:- is to promote awareness into Vascular conditions and to support vital research.

Established in 1992 by vascular surgeons, the Circulation Foundation is the only UK Vascular charity, dedicated to vascular health. It is the charitable foundation of the Vascular Society of Great Britain and Ireland, run by a committee which are accountable to the Trustees of the Vascular Society of Great Britain and Ireland.

Research

The Circulation Foundation makes three major awards per year to fund vascular research. The value of research funds awarded is currently approximately £1/4 million per year. Like a seed bed, we fund primary research which often goes on to large scale, life transforming studies. In the last four years the Circulation Foundation has awarded over £500,000 in funds for research, pushing the boundaries in the treatment of vascular disease. Get involved and help us save more lives and limbs through our evolving research programme.

Getting involved

- Donations
- In memory and gift in your will
- Corporate support
- Ambassador Scheme
- Events – create your own personal event, or sign up for a challenge e.g. London Marathon, Great North Run, Swim the Serpentine or ride the Vitality Big Half!

Become a Foundation Ambassador

The Circulation Foundation's goal is to establish a Circulation Foundation Network by having an Ambassador in each Arterial Centre and patient representatives across the UK. We would then be able to work together to increase awareness of vascular conditions, share and repeat fundraising success, increase our research grants and make the Circulation Foundation the support centre for patients.

- Make a real difference to the lives of people who are affected by vascular disease.
- Help to raise awareness of vascular disease.
- Continue to use expertise and knowledge.
- Learn new skills.
- Be able to network with like-minded people.
- Give something back to the vascular community.
- Be part of a professional and committed charity and a valued member of the team.
- Recognition on social media, newsletter and on the website.
- Special recognitions at the Annual Scientific Meeting.

THE BODY WALK

#TheBodyWalk is a national campaign to raise awareness of vascular disease and for imperative funding. We are hoping everyone can get involved to collectively achieve the 60,000 miles that make up the circulatory system! Walk, run, cycle, swim ... it is up to you!

Join us to reach the 60,000 miles and raise funds for the Circulation Foundation.

Help support the Circulation Foundation today!

Text CIRCULATION to 70560 to donate £10

Texts will cost the donation amount plus one standard network message.

To discuss getting involved in the Circulation Foundation by fundraising, legacy donations, becoming an ambassador or corporate support, please call 020 7205 7151 or email info@circulationfoundation.org.uk

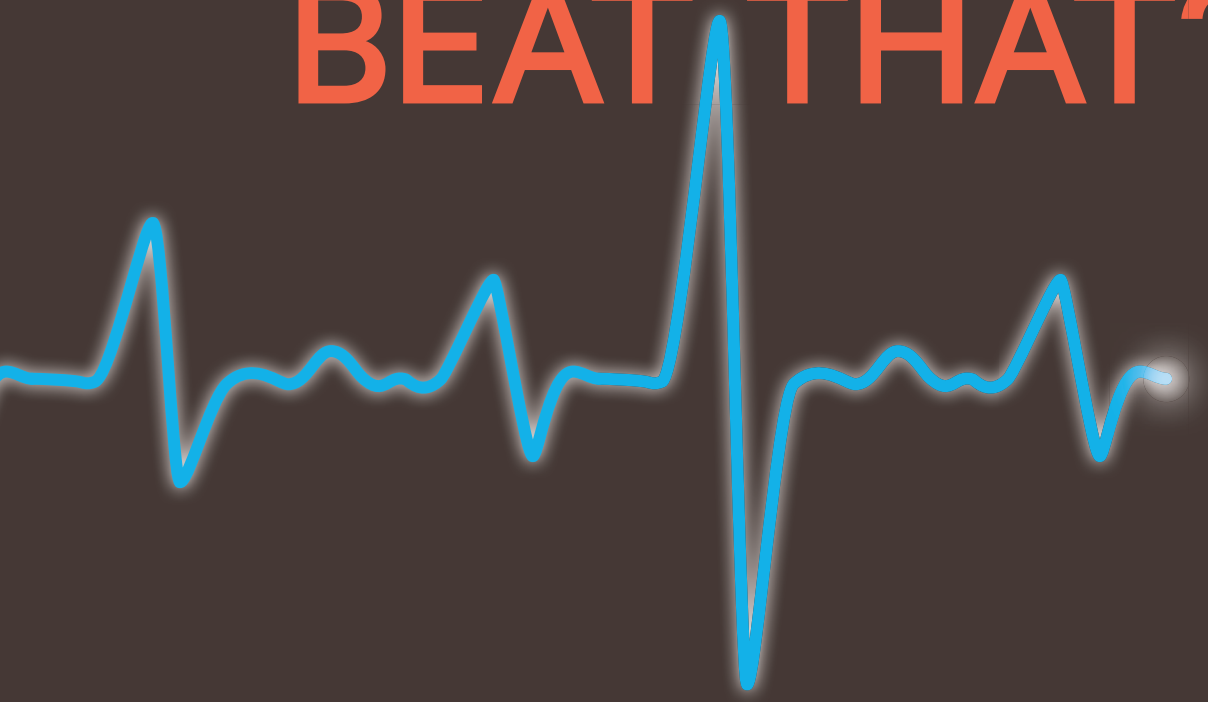
www.circulationfoundation.org.uk

Charity Number: 1102769

Bentley

OUR DELIVERY RELIABILITY IS 98.5%

CAN YOUR COVERED STENT SUPPLIER BEAT THAT?



At Bentley, we strive for the highest possible delivery reliability. In 2020, we had a score of an outstanding 98.5%. We calculate our delivery reliability based on the orders that we receive and which are available in our warehouse. But what does that actually mean for you? It means that you can be sure that we deliver our products to you on time as agreed, and that is what we call: **reliable.**

For more information, please contact us via email info@bentley.global or visit our website www.bentley.global