

# Journal of VASCULAR SOCIETIES

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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 the aorta, 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 charitable organisation funded by members subscriptions, an annual scientific meeting, grants and donations. It has a professional structure including a permanent Secretariat, Executive Officers and Council elected by Members.

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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.

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- The Society is an associate partner of the BJS. This entitles VS members to a reduced BJS subscription
- The Society is actively supporting vascular research through the James Lind Alliance Priority Setting Partnership, Specialist Interest Groups (SIGs), funding of three RCS England Surgical Speciality Leads (SSLs), funding of Clinical Fellows (England and Scotland) and the Vascular Research UK website (<https://www.vascular-research.co.uk/>).

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**Submission deadline: 15/09/2023**



## Editor's foreword

Welcome to the August 2023 edition of the *Journal of Vascular Societies Great Britain and Ireland (JVSGBI)* which contains two highly topical editorials, four excellent original research articles, and two case reports.

The first editorial by Professor Denis Harkin who is a Consultant Vascular Surgeon in Belfast, Chair of Medical Professionalism at the Royal College of Surgeons in Ireland and Chair Elect of the VSGBI Audit and Quality Improvement Committee, brilliantly highlights some of the causes and potential solutions to the huge workforce issues currently facing vascular surgery.

The second editorial, with VERN vascular trainees as lead authors, provides an excellent overview of huge challenges presented by climate change, the plans to reduce healthcare related carbon emissions and specifically potential pathways to develop and deliver carbon neutral vascular services whilst maintaining excellent healthcare standards.

Two original articles address the topic of tissue sampling during diabetic foot surgery. The first article by Devangi *et al*, presents the results of a survey of UK Vascular surgeons undertaken to assess knowledge, training and experience. The second article by Condie *et al* presents the results of an audit of the diabetic foot theatre sampling practice. Both highlight areas of suboptimal practice and areas for improvement.

The third original article by Gordon *et al*, presents a retrospective analysis of over 4,000 patients from the Scottish Physiotherapy Amputee Research Group (SPARG) database to make crucial comparisons of surgical and rehabilitation outcomes for patients undergoing above and through knee amputations.

The fourth original article by Kaneta *et al*, presents the findings of a survey and interviews conducted to gauge opinion regarding the deliverability of a multicentre randomised trial comparing open and endovascular interventions for common femoral artery atherosclerosis.

These four original articles provide essential intelligence regarding the requirement, design and deliverability of potential high quality research – the provision of a platform for dissemination of this crucial underpinning work has always been a fundamental priority for the *JVSGBI*.

The two case reports, both written by early career trainees, provide summaries of interesting cases and hopefully will inspire the authors to continue their academic writing and development.

May I take this opportunity on behalf of the *JVSGBI* editorial board to thank reviewers for their ongoing commitment and hard work, and to encourage authors to continue to submit articles for publication.

Finally, the *JVSGBI* is two years old – where have those years gone! We are now eligible, and will be applying for Medline status, with a subsequent PubMed application in the near future.



**Ian Chetter**  
*Editor in Chief JVSGBI*  
*Vice President Elect*

## EDITORIAL

# Repairing the vascular surgery workforce: attract, recruit and retain

*Harkin DW<sup>1</sup>*

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Vascular surgery manages diseases of the arteries, veins and lymphatics, and with a growing and more aged population, both the prevalence and frequency of intervention for vascular disease is increasing.<sup>1-3</sup> Healthcare in general, and vascular surgery in particular, is experiencing acute on chronic workforce shortages which threaten the delivery of vascular services worldwide.<sup>3-5</sup> Health systems have always had to adapt to shifting workforce pressures in a constantly changing health environment; however, the global COVID-19 pandemic and post-pandemic recovery of services have placed enormous added strain on an already overburdened health system and workforce.<sup>6</sup> In addition, several fundamental factors continue to impact on our workforce, including workforce shortages, increased staff turnover, poor health and wellbeing, changing consumer expectations, increased medical regulation, rapid innovation, new technology, population growth and diversification, and globalisation.<sup>7,8</sup> In the face of these challenges, if we are to continue to provide the best vascular care to those who are most in need, then we must ensure we repair our vascular surgery workforce.<sup>9</sup> Here we discuss three main challenges facing our vascular workforce – namely, how we attract, recruit and retain the necessary workers to meet the demands of vascular disease today and for tomorrow.

**Attract the right vascular workers**

So how do we attract the brightest and the best in today's highly competitive workforce environment? Vascular surgery offers the ability to practise a broad range of medical, surgical and endovascular therapies for the benefit of patients in a specialty renowned for evidence-based practice, research and technological innovation.<sup>10</sup>

However, as a largely postgraduate specialty, we must work hard to ensure prospective and current medical students and newly qualified doctors have awareness to consider vascular surgery as a career.<sup>11</sup> Clearly, craft-based specialties remain desirable, but with increased competition from interventional medical specialties and other surgical specialties, we must work harder to ensure vascular surgery has an attractive unique selling point. Vascular surgery has been at the forefront of innovation in minimally invasive endovascular therapy, and combined with essential open surgical skills, provides a peerless range of procedural opportunities amongst surgical specialties.<sup>12</sup> Historically, surgical specialties have lacked gender diversity, especially in senior leadership positions, so we must broaden our appeal to ensure our surgical workforce reflects society's changing demographics, welcome diversity, and demonstrate equity of leadership opportunities.<sup>13,14</sup> Furthermore, surgery – and healthcare in general – has tolerated a pervasive negative culture of bullying, harassment and sexual misconduct, damaging relationships between staff and teams and risking patient safety.<sup>13,15</sup> Vascular surgery has said 'enough'. Unprofessional behaviour will no longer be tolerated within our specialty, and through a process of open disclosure and robust actions our specialty has perhaps done more than any other surgical specialty to reform.<sup>16</sup> Vascular surgery is a growing innovative procedural specialty with values of caring, fairness and inclusivity at its core, and that is what makes it attractive.

**Recruiting new talent**

So how do we recruit the new talent we require? Vascular surgery has a significant workforce

**Key words:** ageing, frailty, vascular medicine, vascular surgery

deficit, both in training and independent practice, and we need to increase recruitment at all levels.<sup>4,5</sup> Over the last decade our specialty has established selection, curriculum and competency-based training programmes, the ASPIRE educational programme, and a robust exit examination. We have embraced academic, flexible and run-through training, and through cogent appeal to commissioners, have doubled our national training numbers in the UK.<sup>3,5</sup> However, surgery is a challenging career, both physically and mentally, and if we are to attract new surgeons we must ensure we reconnect with our mission and purpose, the values that drew us to a caring profession and purpose that attracted us to surgery, our desire to do meaningful work, and to feel that our effort and sacrifice is recognised and appreciated. Clearly, we can offer purpose. We cater for an important and growing range of conditions, vascular diseases, and we have the privilege of providing treatment to alleviate some of the most disabling and life-threatening conditions. We need to ensure our new vascular surgeons have all the knowledge, skills and behaviours necessary to care for vascular patients within a supportive team environment which recognises peoples' strengths and limitations and supports them through the many different phases of a surgeon's career.<sup>9,17</sup> We must support upskilling programmes and on-the-job training opportunities to expand the care we provide whilst ensuring quality and safety is maintained for our patients with a collaborative approach to accreditation and governance.<sup>18</sup> Vascular surgeons, like the blood vessels we treat, have always criss-crossed traditional specialty boundaries for the care of their patients, and are strong proponents of the benefits of working in the multidisciplinary team.<sup>18</sup> Recognising the synergy of knowledge and skills our colleagues bring to benefit vascular patients, we have supported the development of enhanced roles for our vascular nurses, vascular technologists, vascular anaesthesiologists, vascular physicians and many more. Vascular surgery will then provide purpose, support, opportunity and a clear pathway from recruitment to practice.

### Retaining valuable recruits

So how do we retain the valuable knowledge, skills and experience of our recruits throughout a long and challenging career? Surgeons, as all healthcare workers, have a challenging and demanding job, and for many the chronic stress of their work can lead to harmful effects on their mental and physical health. We see growing numbers of surgeons reporting stress and even burnout, a state of mental and physical exhaustion, and this leads to reduced efficiency, periods of sickness leave and even causes some to exit the profession.<sup>7,8</sup> We need to do more to support workers, garner appropriate staffing, encourage and support self-care, ensure workers' voices are heard, and make sure workplace environments and work plans are safe so that our workforce remains satisfied and healthy.<sup>19</sup> In a rapidly changing and evolving healthcare environment, many – and especially those at either extreme of their career journey – can feel confused and lack confidence. We need to make sure we keep that promise of a commitment to life-long

### KEY MESSAGES

- Intervention for vascular disease is increasing
- Vascular surgery has a significant workforce deficit
- A career in vascular surgery is both challenging and rewarding

learning and ensure ample opportunity is given to attain and acquire new knowledge and skills to maintain and retain competence through education, coaching and mentorship.<sup>20</sup> Increasingly, it is recognised that vascular surgery across a long career, with lengthy complex cases, emergency care, long hours and disrupted sleep patterns, poses very specific physical and mental risks to the body. Many surgeons have reported work-related physical pain and mental distress, burnout and even post-traumatic stress disorder, and for some that is career shortening.<sup>8,21</sup> We need to recognise these demands and adjust work patterns, especially in those vulnerable and those in later career, to ensure unreasonable demands are not being made, including the release of some surgeons from on-call rotas and emergency care.<sup>22</sup> Furthermore, until recently the pension taxation regime had unintentionally penalised senior surgeons, precipitating a wave of early retirements, and we welcome recent beneficial change to that. Vascular surgery must create a supportive environment and sustainable work/life balance, recognising both individual and service needs, so staff are not only retained but can thrive throughout their career.

### Conclusion

In conclusion, the vascular surgery workforce can be repaired, but to do so it must become more attractive, more inclusive and diverse, and retain its most valuable experience. We need to advocate for better vascular services for our patients and staff at individual, organisational and community level. Together, we can address workforce supply, strengthen workforce resilience and ensure we continue to deliver the best possible vascular care to the communities we serve.

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EDITORIAL

# The journey to greener vascular surgery

*The Vascular and Endovascular Research Network,<sup>1</sup> Sandford B,<sup>2,3</sup> Garnham A<sup>3-5</sup>*

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The consequences of climate change pose a significant threat to health and healthcare systems globally. The increase in air pollution, temperatures and natural disasters along with the shift in patterns of infectious disease are leading to an increased disease burden.<sup>1,2</sup> Unless urgent action is taken to mitigate climate change, the health consequences are projected to deteriorate further.<sup>3</sup> Specific to vascular disease, the fluctuations in temperature and reduction in air quality have been associated with an increased cardiovascular morbidity and mortality.<sup>4</sup> Thus, the continued impact of climate change, along with other disease epidemics such as diabetes, has the potential to increase the vascular disease burden. With this in mind, we need to work together as a vascular community to limit our contribution to climate change whilst continuing to manage our individual patients and vascular services.

In 2020 the NHS pledged to continue tackling healthcare-related carbon emissions and achieve carbon neutrality by 2045.<sup>5</sup> Despite the significant progress that has been made, it is estimated that healthcare systems continue to contribute 4.9% of carbon emissions worldwide.<sup>6</sup> A healthcare system's carbon footprint is influenced by several components, from staff and patient travel to the resources and technologies used daily. Surgery is a major contributor to healthcare's carbon footprint, with operating theatres being responsible for up to 25% of a hospital's carbon output.<sup>7,8</sup> Operating theatres are resource-intensive environments, so to an extent this is expected. However, it is estimated that, on average, the carbon emissions generated by a single case in the UK is 173 kg CO<sub>2</sub>e, which equates to driving approximately 480 miles in a petrol-fuelled car.<sup>9</sup> If we consider the other elements of the entire patient journey from

preoperative consultations and diagnostic tests to perioperative hospital stays, the carbon emissions generated from a single case are much higher.

## How can we develop carbon-neutral vascular services?

Achieving more environmentally sustainable vascular practices will involve addressing several factors, as shown in Figure 1.

By continuing to promote vascular research and education, we can optimise public health interventions and preventative medical management strategies for patients with vascular diseases. These will reduce the burden of vascular disease and the need for extensive surgical interventions. Increased staff awareness and training in greener practices may also lead to a reduced carbon footprint, along with institutional incentives to reduce the environmental impact of hospitals.

In recent years, many vascular surgery units in the UK have developed 'one-stop' clinics. These clinics facilitate rapid patient consultations, assessments, treatment and improve patient outcomes.<sup>10,11</sup> In streamlining patient pathways, these clinics also minimise patient visits to the hospital, reducing travel and carbon emissions. One-stop clinics can also improve patient satisfaction. During the COVID-19 pandemic we witnessed changes in healthcare delivery, including the introduction of remote consultations and telephone clinics.<sup>12,13</sup> These methods proved to be a safe and effective means of consultation during lockdown and minimised patient travel to hospitals for clinic appointments.<sup>14,15</sup> Wider adoption of remote clinic pathways, as well as 'one-stop' clinics, have the potential to reduce the carbon footprint of vascular services further.

The four surgical Royal Colleges have also developed an Intercollegiate Green Theatre

**Key words:** green surgery, environmental sustainability, net zero services

**Figure 1** Flowchart demonstrating the seven early steps to low-carbon vascular services, adapted from the VSGBI's 'Striving for net zero vascular services' document



Checklist.<sup>16</sup> This checklist addresses changes which can be made at the pre-, intra- and postoperative stages to achieve more environmentally sustainable practice. Implementation of this checklist has the potential to serve as a reminder of the changes which can be made and contribute to an overall shift in practice.<sup>16</sup>

In 2021, surgical teams from different disciplines in the UK demonstrated that it is feasible to change surgical care pathways. Changes made included reduction in the use of single use surgical equipment, which accounts for a third of surgery-related emissions, reduction in the number of unnecessary preoperative investigations, utilisation of procedure rooms, which are less energy intensive to undertake procedures that do not require the formal operating theatre environment, changes to the types of anaesthesia used, and adoption of reusable personal protective equipment. These changes led to a reduction in 133 tons of CO<sub>2</sub>e, equivalent to 38 return flights from London to Hong Kong.<sup>17</sup>

#### **Where do we begin to achieve environmentally friendly vascular services?**

We know that there are many factors that affect the carbon

footprint of vascular services, and many changes which can be undertaken to make our practice greener. The COVID-19 pandemic demonstrated the ability of vascular services to adjust practice rapidly and effectively in response to a global emergency. Now that we are faced with the challenge of delivering environmentally sustainable practice, the question is not whether we would be able to make the changes, but where the best place is to start to do so.

A recent Delphi analysis focused on reducing the environmental impact of surgery shortlisted increased recycling, reduction in anaesthetic agents and greener clinical waste processing as interventions to address.<sup>6</sup> The next step is to begin to identify specific changes in these prioritised areas that are acceptable to clinicians and patients, feasible to deliver, safe to implement and contribute to achieving favourable patient outcomes.

The shift to more environmentally sustainable practice requires a national collaborative effort to drive transformation and help the NHS reach the 'net zero' target. For the vascular community to enact meaningful changes, it is paramount to first gain an understanding of current practices across vascular services,



**Figure 2** The 'Greener Vascular Surgery' survey QR Code

identify the potential improvements, and recognise the perceived obstacles to change.

Hence, the Vascular and Endovascular Research Network (VERN), in conjunction with the Vascular Society of Great Britain and Ireland (VSGBI) and the Royal College of Surgeons of Edinburgh Vascular Surgical Specialty Board (RCSEd Vascular SSB), are working together to identify the ways that vascular surgery can lessen our impact on the environment while maintaining excellent healthcare standards. The first task is to understand how individuals, spread across a wide geographical area with varying resources and patient populations, think vascular surgery can be feasibility changed to be more environmentally sustainable and establish a baseline understanding of practice in Trusts and Health Boards across the UK. The 'Greener Vascular Surgery' survey seeks to identify practical and financially viable interventions that can be implemented, whilst not compromising patient care, and seeks to uncover any potential barriers to change. We ask you all to complete this survey and join us to achieve a greener future for vascular surgery. Link to the survey:

[https://york.qualtrics.com/jfe/form/SV\\_6QLqazYZJMwwUjc](https://york.qualtrics.com/jfe/form/SV_6QLqazYZJMwwUjc)

The QR code to the survey is shown in Figure 2.

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ORIGINAL RESEARCH

# Tissue sampling technique for diabetic toe amputations: a survey of current UK practice

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## Plain English Summary

**Why we undertook the work:** Infection of the bones and soft tissue of the foot in patients with diabetes is a growing problem across the UK, which can be difficult to treat. It is important to obtain accurate samples to identify the bacteria causing the infection to help guide treatment. We wanted to assess the techniques consultant surgeons deployed to gain accurate samples and what training they had received for this important step in the patient's care. This is important because guidelines are available but are not consistent.

**What we did:** An online survey was designed to assess consultants' knowledge, experience and training in the management of patients with diabetic foot infection and to evaluate their practice. We were particularly interested in what they actually did in theatre, what samples they sent to the laboratory and how the results of these samples affected the future management of patients. The survey was emailed to individual surgeons who were members of the national UK Society of Vascular Surgeons.

**What we found:** Responses were received from 109 surgeons from 13 regions across the UK. This is a response rate of 24%. Only one in five respondents had received formal training in taking samples for diabetic foot disease and only 60% of respondents said they always or usually took samples for infected diabetic foot disease. Finally, only 29% of respondents said their unit had a formal policy guiding sampling.

**What this means:** There is huge variability across the UK in taking samples to identify bacteria in diabetic patients presenting with foot infection. Training and formal policies to guide surgeons are seriously lacking. These deficiencies probably mean patients are not receiving antibiotics targeted specifically at the causative bacteria and need addressing urgently.

## Abstract

**Background:** The management of diabetic foot disease remains a challenge for clinicians. Outcomes are improving with the development of integrated diabetic foot teams. Understanding tissue sampling/processing and a standardised evidence-based approach would help develop integrated pathways to improve patient care and outcomes. research priorities. This paper presents the results of this process.

**Aims:** In collaboration with the Vascular Research and Innovation Consortium (VaRICS), this study aimed to evaluate the knowledge base of UK vascular consultant surgeons regarding sampling and processing techniques for diabetic foot disease.

**Methodology:** An online questionnaire was designed to assess consultants' knowledge levels of surgical techniques, infection control, placement of interventions, sampling techniques and processing. This was then distributed to vascular surgery consultants via the Vascular Society of Great Britain and Ireland (VSGBI) email newsletter.

**Results:** 109 consultants participated in this study, of which 63 (58.9%) had a sub-specialist interest in diabetic foot disease. Only 21 (19.6%) consultants had received formal training in bone sampling techniques. Eighteen (62.1%) of the respondents reported having received training at the departmental level. An average of 10–20 toe amputations were performed per month in most units. In 37% of cases, samples from clean bone were always taken after wound cleaning and debridement following toe amputations. A majority of samples from toe amputations consisted of proximal bone (64.5%), pus swabs (51.4%) and tissue/toe resections (45.8%). Most of the contamination reduction measures included saline washing and changing

instruments between samples. The majority of consultants (85.6%) are unaware of the microbiology processing techniques.

**Conclusion:** This study shows that, across the nation, in the management of diabetic patients presenting with foot infection, there is huge variation in training, sampling practice/policies and management pathways. These problems need to be urgently addressed.

**Key words:** diabetic foot disease, tissue sampling, survey

## Introduction

The increase in the prevalence of diabetes mellitus and its associated complications has become a major public health issue.<sup>1,2,3</sup> Foot-related complications affect 2–2.5% of people with diabetes, equating to a point prevalence of approximately 58,000 people in England alone.<sup>3</sup>

The management of diabetic foot disease is complex, involving input from a foot protection team and a multidisciplinary team (MDT) of professionals.<sup>4</sup> Surgical debridement of infected tissue and antimicrobial therapy to manage infection are the two mainstays of therapy for acute foot infections. The surgical aspect of the management of diabetic foot disease and the importance of appropriate training for vascular surgeons has been acknowledged by the Vascular Specialty Advisory Committee and the General Medical Council. The management of fulminant diabetic foot sepsis is one of three critical conditions in the new vascular surgery syllabus, revised in August 2021.<sup>5</sup> Alongside surgical debridement, antimicrobial therapy for managing residual infection should be guided by microbiology sampling and cultures, although very few papers report on sampling and processing techniques. Culture results are dependent on sampling method, and the International Working Group on the Diabetic Foot (IWGDF) recommends obtaining samples for culture aseptically. This should be done before or close to the start of antimicrobial treatment, to enable empirical treatment to be amended appropriately.<sup>4,6,7</sup>

This study aimed to determine the training, practice and level of knowledge that UK vascular surgical consultants have regarding techniques for tissue sampling and processing in diabetic foot infection and to identify the prevalence of unit policies for managing diabetic foot infection. This is important because there are variations in the current guidelines available. For example, IWGDF recommends 6 weeks of antibiotics in patients who do not undergo complete resection of infected bone whereas, in patients in whom all infected bone has been resected, antibiotic treatment should not be needed for more than 1 week.<sup>6</sup> On the other hand, the National Institute for Health and Care Excellence (NICE) recommends offering prolonged antibiotic treatment (usually 6 weeks) according to local protocols.<sup>4</sup>

## Methodology

The steering group for this study consisted of three consultant vascular surgeons, a research fellow in methodology, a specialty

trainee and a foundation doctor. The steering group coordinated the questionnaire development, validation, distribution and analysis.

## Questionnaire development

Survey questions for each of the three domains (demographics, sampling, results interpretation) were discussed by the steering group with a focus group of vascular consultants across two tertiary referral vascular centres. All decisions required unanimous agreement amongst the focus group members. Additionally, questions were reviewed to ensure wording was succinct, clear and unambiguous by our research methodologist. The CHERRIES checklist was used to assist the designing of the questionnaire.<sup>8</sup>

## Questionnaire validation

A preliminary survey of 31 questions across the three domains, including a range of binary, multiple choice and free-text open ended questions, was designed. This was validated through two rounds of piloting across two tertiary vascular centres with 10 consultants. After round 1, major (questions removed or added) and minor alterations (wording alterations) were made based on the feedback from the consultant body. Alterations were made in alignment with recommendations from our research fellow.

## Questionnaire distribution

The online survey was disseminated using <https://www.onlinesurveys.ac.uk><sup>TM</sup> software. Demographic data collection included background information (years of consultant practice, number of procedures performed per unit, population served by unit) and the presence of a diabetic foot sampling policy within the unit (NVR submission, sampling technique policy). Participants were advised that their responses would be anonymised.

The final survey (Appendix 1 online at [www.jvsgbi.com](http://www.jvsgbi.com)) was distributed from January 2022 to April 2022 via email, inviting approximately 370 consultant members of the Vascular Society of Great Britain and Ireland (VSGBI) to participate. The study was publicised on the VSGBI, the Rouleaux Club and Vascular and Endovascular Research Network (VERN) twitter feeds to encourage all consultants to complete. Three months were allowed for responses with a reminder email circulated at 4 and 8 weeks.



## Data analysis

Data were analysed by the steering group using Microsoft Excel. Where data were missing, they were not analysed; however, the majority of questions were completed. Optional questions such as additional comments were not answered frequently within the study.

## Results

### Demographics

The survey received 109 responses, of which 63 (58.9%) declared that they had a specialist interest in diabetic foot disease. Responses were received from 13 deanery regions (Appendix 2, Graph 1, online at [www.jvsgbi.com](http://www.jvsgbi.com)). The duration of consulting experience and the unit size covered by the survey are included in Appendix 2 (Tables 1 and 2, online at [www.jvsgbi.com](http://www.jvsgbi.com)), with 58 (54.2%) stating that their units perform 10–20 minor amputations per month (Appendix 2, Table 3, online at [www.jvsgbi.com](http://www.jvsgbi.com)). A total of 23 (21.3%) respondents stated that their unit enters minor amputations on the National Vascular Registry, and 31 (29%) respondents stated that their unit does have a formal policy on diabetic foot sampling.

### Training

Only 21 (19.6%) respondents had received formal training in diabetic foot treatment (Figure 1). Of these, 18 (62.1%) reported having received training at a departmental level (see Appendix 3, Tables 1 and 2, online at [www.jvsgbi.com](http://www.jvsgbi.com)).

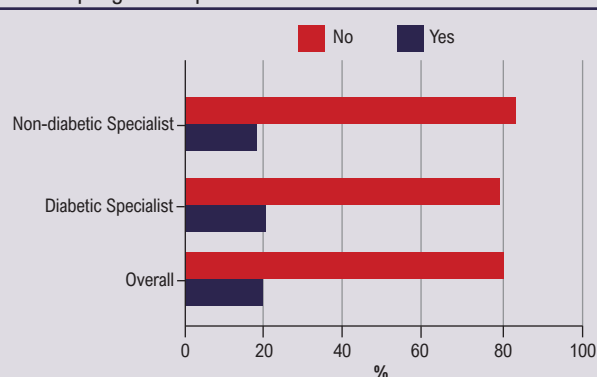
### Sampling and processing

Figure 2 shows the specimens routinely sent in theatre during toe amputations. Sixty-nine (64.5%) respondents declared they always took a proximal bone specimen. Of the respondents who sent specimens, 51 (60%) sent more than one sample at the time of sampling from each incision, with 40 (37%) stating they always clean the operative field after amputation but before sending specimens.

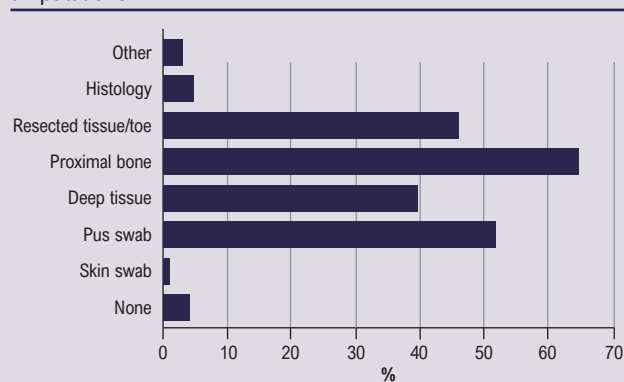
The steering group gave options on nine different techniques to reduce contamination, with the preferred technique being saline wash (58, 63.7%). The preferred technique for bone sampling reported was use of Rongeurs (71, 78.9%) with 88 (88%) reporting that they sent their samples dry. Only one respondent contacted the laboratory to inform them of the imminent arrival of a specimen, whilst 41 (39.4%) did not know how long specimens took to get to the laboratory. Fifty-one (49.1%) respondents who were informed felt their microbiological specimens were at the laboratory within 4 hours of sampling. Only five (4.7%) respondents sent specimens for histology. The majority of respondents (89, 85.6%) were unaware of the processing technique of their samples upon arrival at the laboratories and 58 (55.8%) respondents reported an expectation of a result within 49–72 hours. A further breakdown of sampling techniques is shown in Appendix 4 online at [www.jvsgbi.com](http://www.jvsgbi.com).

The majority of respondents stated that positive cultures

**Figure 1** Results of respondents who received formal training on bone sampling techniques.



**Figure 2** Specimens routinely sent in theatre during toe amputations.



change their management of the patient (Appendix 5, Table 1, online at [www.jvsgbi.com](http://www.jvsgbi.com)). Respondents had varying opinions on the impact of positive proximal bone cultures on patient management when compared with other sample types. Specifically, 88 (93.6%) respondents stated that a positive proximal bone culture would change patient management compared with 35 (36.1%) for pus swab, 62 (68.1%) for deep tissue, 36 (39.1%) for resected non-proximal bone and 16 (20.3%) for histology. In the presence of proximal bone infection, 76.5% of respondents would treat with antibiotics for 6 weeks as opposed to 6 (6.3%) if a pus swab came back positive (Appendix 5, Table 2, online at [www.jvsgbi.com](http://www.jvsgbi.com)). The differing sampling techniques, the rate of wound closure, length of hospital stay and follow-up routines are shown in Appendix 5, Tables 3–10, online at [www.jvsgbi.com](http://www.jvsgbi.com).

## Discussion

The importance of diabetic foot disease treatment development was recently highlighted in the VSGBI James Lind Alliance Priority Setting document.<sup>9</sup> It emphasised the importance of improving treatment to improve wound healing rates and prevent further amputation. Diabetic foot disease presents the clinician with

significant therapeutic challenges, with both medical and surgical approaches that can be undertaken in its management. At the point of surgical intervention, the clinician is provided with an opportunity to gather a large number of samples from various different tissues of the diabetic foot. A standard level of training is not specified in the intercollegiate surgical curriculum, and while guidance is available, it is inconsistent. This study provides evidence of the variation in sampling practice among vascular surgeons within the UK and therefore the difficulty in establishing guidelines for practice which are relevant to all to garner accurate sampling results. Particularly concerning is that 93.6% of respondents reported that positive proximal bone cultures would change their clinical management, yet only 64.5% of respondents would always take a proximal bone specimen. Evidence supporting the idea that culture from proximal bone specimens is of clinical benefit has been restricted only to small studies, and this may be because it is not part of local guidelines or protocols.<sup>10,11</sup>

The UK Standards for Microbiology Investigations acknowledges that surgery may be required in acute presentations of osteomyelitis and in chronic osteomyelitis where areas of dead bone may need resecting.<sup>9</sup> Both need to be accompanied by specific antibiotic therapy depending on culture results. For bone, bone biopsies, soft tissues and aspirates, they recommend collecting specimens into appropriate CE marked leak-proof containers and putting them in sealed plastic bags with Ringer's or saline solution and Ballotini beads (as an option) which is placed into sealed plastic bags. However, microbiology and histology specimen pots can be confused, leading to difficulties in processing samples. Specimens should be transported and processed as soon as possible. To enable timely clinical management, samples should be processed urgently. The Infectious Diseases Society of America guidelines recommend that specimens should be transported at room temperature and should be processed immediately, and within a maximum of 2 hours. If processing is delayed, refrigeration is preferable to storage at ambient temperature.<sup>12</sup>

The IWGDF advises on collecting an appropriate specimen for culture for almost all clinically infected wounds to determine the causative pathogens. For a soft tissue diabetic foot infection, a sample for culture should be obtained by aseptically collecting a tissue specimen (by curettage or biopsy) from the ulcer. During surgery to resect bone for diabetic foot osteomyelitis, obtaining a specimen of bone for culture (and if possible, histopathology) at the stump of the resected bone should be considered to identify if there is residual bone infection. If an aseptically collected culture specimen obtained during surgery grows pathogens or if the histology demonstrates osteomyelitis, appropriate antibiotics should be administered for up to 6 weeks.<sup>6</sup>

In our survey, 58.9% of responding consultants declared an interest in diabetes which remains concerning considering the epidemic proportions of the problem. This is a possible confounding factor within the results, as those with a specialist interest may be more engaged in pathway design and teaching sampling

techniques. This should be considered when reviewing the results. Few stated that they had received training and the majority (62.1%) of these were only local departmental training. 66.4% of the respondents reported the absence of a formal local policy for diabetic foot sampling, leaving surgeons to draw on their own experience. This is of concern as it suggests that vascular surgeons, diabetic specialists (clinician and podiatrists) and microbiologists providing care may not all be engaged in the process of diabetic foot management using a coherent strategy.

Antibiotic stewardship remains a problem for the NHS and can only be guided by the results gained from sampling and the knowledge level of the clinicians involved in treatment decisions. With the plethora of techniques for sampling as described above, many of which have little or no proven benefit, clinicians must deliver care based on the results they have obtained and their own experience without the confidence that the samples are reproducible or accurate enough to guide antibiotic therapy.

Heterogeneity in training levels and teaching is presently being rectified by inclusion of the management of the diabetic foot within the core competency of the vascular training curriculum UK. It is imperative that trainees are given a solid grounding in diabetic foot management to build on when they enter consultant practice.<sup>7</sup>

Since the COVID pandemic the resources of the NHS are stretched and the ability to deliver care remains a problem. The long-term consequences of diabetic foot infection lead to a protracted hospital stay, multiple returns to theatre for surgery and the cost of major limb amputations with its hospital and social care costs.<sup>13</sup> The recent NHS resolution document emphasises the importance of getting it right first time with diabetic foot infection as the costs of problems that develop are not inconsequential to the NHS and must be considered.<sup>1</sup> Establishing good practice through training in diabetic foot infection and cooperation with the MDT can limit the requirement for intervention and reduce the burden on the NHS services.

### Limitations

The survey achieved a 24% response rate from consultant members registered with VSGBI, providing a snapshot of opinions from an extensive geographical spread of UK vascular units. To help increase the response rate, an incentive was offered for completion and a reminder email was circulated at 4 and 8 weeks. Survey fatigue in general – and particularly at the end of the COVID 19 pandemic – cannot be ruled out as having an effect. This study is around an area of specific practice and therefore a level of inherent bias may have been introduced.

### Conclusions

Practice for the sampling in diabetic foot infection by vascular surgeons remains varied across the country, with local policy guidelines only being present in certain locations. Lack of formal training is highly likely to be a significant contributing factor. A large proportion of vascular surgeons state that they have an interest in

## KEY MESSAGES

- Training for diabetic foot sampling remains dependent on your specific training program and would probably benefit from standardisation
- Formal policies on diabetic foot sampling should be established within each unit to aid accuracy of diabetic foot samples.
- Deficiencies in sampling techniques means that patients are not receiving antibiotics targeted specifically at the causative bacteria. This may lead towards poor outcomes.

diabetic foot disease, and this must be drawn upon to standardise sampling techniques, develop treatment guidelines and deliver education and training going forward.

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## ORIGINAL RESEARCH

# Modern Practice of Diabetic Foot Sampling, Protocols, Pathways, Treatments and Techniques: an audit of specimen transport time from theatre to laboratory for diabetic foot tissue (MODAMP 2)

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**Plain English Summary**

**Why we undertook the work:** Patients with diabetic foot infections who undergo an amputation of a toe or leg have an increased risk of death. Treating infections that may result in an amputation promptly and effectively is essential. Guidelines state that, when patients present with infections of the bone in their lower limb, it is essential any samples taken are processed by the laboratory within 2 hours. If this target time is not met, the microbiology results from the samples taken may not be accurate. This could result in a delay in the correct antibiotics and a delayed discharge from hospital. We aimed to see if this 2-hour target time was being met within hospitals in the Vascular Research Innovation Consortium (VaRICS).

**What we did:** Four hospitals within VaRICS collected data between December 2021 and February 2022. Included in this data was information on the procedure the patient had, the time any samples were taken from the patient, the way these samples were transported and the time they were received in the laboratory.

**What we found:** The majority of patients undergoing a procedure did have samples taken. However, less than half of these samples were processed within the recommended time frame of 2 hours.

**What this means:** Increased awareness is required within theatres and by microbiology laboratory technicians regarding the importance of processing samples correctly.

**Abstract**

**Introduction:** Outcomes for patients undergoing minor or major amputations as a result of diabetic foot infections are poor. It is essential that specimens taken during investigations for osteomyelitis in these patients are processed correctly. A failure to do this may result in delays in time to start targeted antibiotic therapy and

**Methods:** Four hospitals in the West Midlands collected retrospective data on diabetic foot amputations between December 2021 and February 2022. Data on the procedure, specimen collection time, transport medium and specimen receipt time were recorded. The data were analysed to see if they met the recommended standards from the United Kingdom Standards for Microbiology Investigations, which recommends that all specimens taken during the investigation for osteomyelitis should be processed within 2 hours.

**Results:** A total of 129 procedures were performed and 94 of these had specimens taken. Twenty-one specimens (22%) reached the laboratory for processing within the 2-hour recommendation; 15 (29%) of the samples were taken 'in hours' and six (14%) were taken 'out of hours'. Fifty-seven samples had the method of transport recorded, of which 54 (95%) were transported in a dry medium.

**Conclusions:** Improvement is needed to minimise the time samples take to get from theatre to the laboratory. Increased awareness within theatres and microbiology laboratories about the importance of transporting and processing specimens quickly is required, with the result being a quicker diagnosis of osteomyelitis, accurate antibiotic treatment and overall better patient outcomes.

**Key words:** diabetic foot infection, osteomyelitis, specimen transport time

## Introduction

The number of amputations secondary to diabetic foot infections continues to rise in the UK, with more than 185 diabetes-related amputations being carried out per week.<sup>1</sup> The 5-year mortality rates of patients with diabetic foot ulceration, minor or major lower limb amputations as a result of diabetic foot infections are 30.5%, 46.2% and 56.6%, respectively.<sup>2</sup> It is essential that we treat patients who present with this condition quickly and effectively. The UK Standards for Microbiology Investigations, published by Public Health England in January 2016, recommend that, where osteomyelitis is suspected, bone or soft tissue specimens taken from diabetic foot procedures should be processed within 2 hours to maximise chances of culturing causative organisms.<sup>3</sup>

Failure to achieve accurate microbiological sampling may result in delays to starting targeted antibiotic therapy, increased risk of recurrence and spread of infection and consequent higher risk of amputation with its associated morbidity and mortality. A recent review of diabetes and lower limb complications reported that specimens were sent from 50% of diabetic foot ulcer debridements, but that only 18% of cases of processed samples influenced antibiotic therapy.<sup>4</sup> We aimed to investigate whether vascular networks within the Vascular Research Innovation Consortium (VaRICS) collected, transported and processed diabetic foot specimens within the 2-hour guideline.<sup>2</sup>

## Methods

Four vascular networks (Black Country Vascular Network, Worcestershire Acute Hospitals NHS Trust, University Hospitals Birmingham and Shrewsbury and Telford Hospital NHS Trust) in the VaRICS were involved in this audit. The aim of the audit was to compare the sample rates against the published gold standard – the UK Standards for Microbiology Investigations – published by Public Health England in January 2016.<sup>3</sup> Retrospective data on diabetic patients undergoing minor amputations between December 2021 and February 2022 were collated using an Excel proforma, with fields agreed by the leads for the data collection at the networks involved. These data were collected from paper and electronic patient notes, theatre records and electronic reporting systems. The data points collected were the date and time of the procedure, specimen collection time from theatre, specimen type (bone or tissue), transport medium and pathology receipt time. The time to processing was calculated as the time the operation ended to the time the laboratory reported receiving the specimen. The data were sent anonymously between sites using NHSmail and were analysed using descriptive statistics.

## Results

A total of 129 procedures were performed during 3 months of data collection. Specimens were sent from 94 (73%) procedures. Of the 94 specimens taken, 21 (22%) reached the laboratory for processing in <2 hours with a mean time of 10.5 hours. Fifteen (29%) samples taken 'in hours' were processed in <2 hours, with a

**Table 1** Number of specimens taken and time processed.

	Total number of specimens	Specimens processed within 2 hours	Specimens processed in over 2 hours
All hours	94	21	73
'In hours'	55	15	40
'Out of hours'	39	6	33

mean time of 7.51 hours, and six (14%) samples taken 'out of hours' were processed in <2 hours with a mean time of 14.4 hours. Table 1 shows the number of specimens taken and the time taken for processing.

The transport medium or lack of transport medium was recorded in 54 (61%) samples; 78% of bone and tissue samples were transported in no medium. In the remaining samples the transport medium was either not collected or a beaded (n=1) or amines (n=2) transport medium was used.

## Discussion

Overall, we can see that, compared with the recent report on diabetes and lower limb complications, the West Midlands theatre sampling has a higher specimen collection rate than the published literature (77% compared with 50%).<sup>4</sup> However, the number of samples processed within 2 hours is only 42%. Out of hours, this is likely due to insufficient staffing to transport the samples and receive them at the laboratory to commence processing. In hours, the gold standard remains for all samples to reach the laboratory within the 2-hour window to start processing.<sup>3</sup> This means increased awareness within theatres and by microbiology laboratory technicians about the importance of processing specimens and pre-emptively alerting the team during the theatre briefing.

The guidelines of the UK Standards for Microbiology Investigations advise that samples collected in theatres should be placed in a sterile leak-proof container with Ringer's or saline solution and then into a sealed plastic bag.<sup>3</sup> None of the samples taken in this study were processed in this way, demonstrating a need for education in this area.

To standardise this measurement of time within the study, we used the end of the operation as the specimen collection time. This is a limitation of the study design. This study was carried out in multiple networks, and it was not possible to identify storage conditions of the samples prior to transportation to the laboratory. This may affect the quality of the samples upon arrival at the laboratory, but would be an interesting avenue for further investigation. The National Institute for Health and Care Excellence (NICE) guidance states that, in patients with suspected diabetic foot infections, microbiology samples should be taken to aid with diagnosis and treatment.<sup>3</sup> We do not know exactly how taking these samples affects the duration of antibiotic treatment. This is an area of research still to be undertaken.

## KEY MESSAGES

- All patients with suspected osteomyelitis undergoing diabetic foot debridement or amputations should have samples taken in theatre and sent to the laboratory for microbiology and histology.
- Diabetic foot samples with suspected osteomyelitis taken in theatre should be transported to the laboratory within 2 hours.
- Diabetic foot samples with suspected osteomyelitis taken in theatre should be transported in a sterile leak proof container with Ringer's or saline solution.

## Conclusion

The Society of Vascular Surgery states that "In patients at high risk for diabetic foot osteomyelitis, we recommend that the diagnosis is most definitively established by the combined findings on bone culture and histology".<sup>5</sup> Ensuring our samples are processed correctly will lead to a quicker diagnosis of osteomyelitis, accurate antibiotic treatment and better patient outcomes. The recent James Lind Alliance exercise put accurate diabetic foot sampling and its consequent treatments at points 2 and 4 on its priority list,<sup>6</sup> whilst the recent NHS Resolution document emphasises the importance of getting it right first time with diabetic foot disease as the costs of problems that develop are not inconsequential to the NHS and must be considered.<sup>4</sup>

**Conflict of Interest:** None

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ORIGINAL RESEARCH

# Surgical and rehabilitation outcomes of patients undergoing through knee amputation compared with above knee amputation

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## Plain English Summary

**Why we undertook the work:** Each year in the UK, more than 5,000 people need to have their leg surgically removed (amputated). A leg amputation can have an enormous impact on a person's physical and emotional well-being. It is important that we research ways to minimise this impact. We know that people who have their leg amputated below the knee find physical and emotional recovery easier than people who have their leg amputated above the knee, but we do not know how amputation through the knee compares with amputation above the knee.

**What we did:** We used a database that holds information about amputations performed in Scotland between 2007 and 2017 and compared how people having above knee amputation and through knee amputation recovered after their surgery. We looked at how many amputations were performed above the knee and through the knee, how old the people were having an amputation, and what health conditions these people had. We looked to see if there was any difference between the two types of amputation including how long they stayed in hospital after surgery, how well their wound healed, if they were fitted for an artificial leg, and how well they could walk with their artificial leg.

**What we found:** Of the 4,197 amputation operations we looked at, over 90% were above the knee and less than 4% were through the knee, which means through the knee amputation is rarely performed in Scotland. On average, the people who had through knee amputation were a similar age to those who had above knee amputation, but a larger proportion of people in the through knee amputation group had diabetes or were obese. People who had a through knee amputation were more likely to need a second surgery because of problems with their surgical wound, but this did not mean that they needed to spend more time in hospital compared with people who had above knee amputation. The proportion of people who walked with an artificial leg was similar between the two types of amputation. Patients from centres performing larger numbers of through knee amputation were less likely to need a second operation but were also less likely to have an artificial leg fitted.

**What this means:** Hospitals in Scotland that perform relatively large numbers of through knee amputation have better results in terms of wound healing than hospitals that perform very small numbers. Through knee amputation is possibly preferred over above knee amputation in these same hospitals for patients who are unlikely to walk with an artificial leg. However, overall, people with through knee amputation were just as likely to walk with an artificial leg as those with above knee amputation, which could indicate that walking is easier with a through knee amputation. Other functional movements such as moving from bed to chair and maintaining balance when sitting in a chair are just as important as walking after amputation and should be investigated further for this patient group. As the numbers of through knee amputation in this study were much smaller than the numbers of above knee amputation, these conclusions should be investigated further with a larger group of patients.

## Abstract

**Background:** Through knee amputation (TKA) may offer benefits over above knee amputation (AKA) in patients unsuitable for below knee amputation. This retrospective analysis compared surgical and rehabilitation outcomes post TKA and AKA.

**Methods:** All TKA and AKA procedures recorded in the Scottish Physiotherapy Amputee Research Group dataset from January 2007 to December 2017 were included for analysis. All aetiologies, re-amputations and bilateral procedures were included. Demographic information, surgical outcomes (ie, further surgery, survival, and length of stay) and rehabilitation outcomes (ie, limb fitting, early rehabilitation, and mobility scores) were compared using descriptive and



inferential statistics, including Kaplan–Meier, log-rank statistics and multivariate logistic regression.

**Results:** In total, 4,197 procedures were included for analysis (3,471 initial AKA, 146 initial TKA, 580 initial below-knee or other level). Survival ( $p=0.809$ ) and length of stay ( $p=0.696$ ) were similar between groups, but TKA had significantly higher rates of further surgery ( $p<0.001$ ). Multivariable analysis showed that patients who undergo TKA at centres which perform small numbers of TKA are significantly more likely to need further surgery ( $p=0.048$ ). A significantly larger proportion of these patients had a limb fitted (25%) compared with only 12% of those from centres performing larger numbers of TKA ( $p=0.041$ ). Overall, 31% ( $n=23$ ) of those with TKA and 30% ( $n=725$ ) of those with AKA had a limb fitted ( $p=0.854$ ). All other rehabilitation outcomes were similar between groups.

**Conclusion:** High volume centres have better surgical outcomes but appear to select patients not likely to limb fit. Despite this, similar proportions of patients did subsequently limb fit between groups, which may suggest superior rehabilitation potential for TKA compared with AKA, although the numbers performed in Scotland are very small. Prospective randomised studies are urgently needed to inform clinical practice.

**Key words:** amputation, above knee amputation, through knee amputation, rehabilitation

## Introduction

Every year more than 5,000 patients undergo a major lower limb amputation in the UK.<sup>1–3</sup> Major lower limb amputation is a pivotal life-changing event which can result in significant physical and psychological impacts, depending on the person's functional ability pre-amputation, the cause of their amputation, their co-morbidities and the level of amputation.<sup>4,5</sup>

Below knee amputation (BKA) offers the greatest chance of using a prosthesis and accounts for over 50% of all major lower limb amputations performed in the UK each year.<sup>1,3,6</sup> When a BKA is not viable, above knee amputation (AKA) is routinely performed.<sup>1,3,6</sup> The removal of the knee joint, loss of the majority of the muscular insertions of the thigh, means that people with AKA face considerable challenges to achieve mobility with a prosthesis.<sup>7,8</sup> However, AKA allows for proportional prosthetic knee centres, and recent advancements in prosthetic technology such as micro-processor knees have improved mobility outcomes post AKA.<sup>9,10</sup>

Through knee amputation (TKA) is an infrequently used alternative to AKA and represents less than 4% of amputations,<sup>1,3,6</sup> despite recommendations for its use in guidelines.<sup>11,12</sup> The long, end weight-bearing residuum offers several theoretical advantages over AKA for the prosthetic and non-prosthetic user. The shape of the residuum allows for a more comfortable prosthesis and a superior method for attaching the prosthesis to the residuum than with AKA. However, healing complications following TKA are often considered too high, even though they have previously been reported to be similar to BKA.<sup>13,14</sup> Previous studies investigating outcomes of TKA have been limited by small and homogenous samples.<sup>15–18</sup> Often, rehabilitation outcomes have been overlooked and only the surgical outcomes investigated.<sup>14,19,20</sup> Comparing TKA to AKA was ranked as an important research priority in the James Lind Alliance priority research setting project.<sup>21</sup>

The aim of this study was to compare both surgical and rehabilitation outcomes for TKA and AKA.

## Methods

### Materials

This retrospective comparative cohort analysis examined data held in the Scottish Physiotherapy Amputee Research Group (SPARG) database for all patients who underwent TKA and AKA between 1 January 2007 and 31 December 2017. SPARG complete a national audit of anonymised data on every major lower limb amputation performed in Scotland. Collected data include demographic information such as age, sex, co-morbidities, the centre that performed the amputation, aetiology, need for further surgery and inpatient length of stay. Rehabilitation data comprise limb fitting outcomes: time to cast; time to fit and delivery; time to start compression therapy; type of compression therapy; time to commence early walking aid; type of early walking aid; falls; change in mobility scores; and time to complete prosthetic rehabilitation. Co-morbidities are reported and measured using the functional co-morbidities index (FCI),<sup>22</sup> which includes only co-morbidities that impact on function, with each morbidity scoring 1 point and 18 is the highest possible score. Pre- and post-amputation mobility scores are calculated using the Locomotor Capabilities Index-5 (LCI-5).<sup>23</sup> The LCI-5 is a self-reporting tool which measures perceived ability to complete activities. All data were entered locally onto the SPARG web-based database and data forms are 97.8% complete in every respect.<sup>6</sup>

### Patients

We excluded patients with BKA and through hip amputations; however, patients revised to TKA or AKA from BKA and those who had TKA or AKA and were revised to hip or pelvic levels were included. Amputations of all causes were included as were patients with bilateral amputations, whether both amputations were within the same episode, or if they already had an amputation and this episode recorded their second amputation. All types of TKA,

**Table 1** Inclusion and exclusion criteria for each stage of the analysis.

	Included	Excluded
<b>Surgical analysis</b>	<ul style="list-style-type: none"> <li>Unilateral amputations at TKA or AKA levels</li> <li>Amputations at TKA or AKA level which are part of bilateral procedures</li> </ul>	<ul style="list-style-type: none"> <li>All amputations not at TKA or AKA levels including re-amputations from and to any level other than TKA or AKA</li> <li>Amputations at TKA or AKA level which were re-amputated from a more distal level</li> </ul>
<b>Rehabilitation analysis</b>	<ul style="list-style-type: none"> <li>Patients with unilateral TKA or AKA and no re-amputation surgery</li> <li>Patients with unilateral amputation and were re-amputated to TKA or AKA level</li> </ul>	<ul style="list-style-type: none"> <li>Patients with bilateral amputations</li> <li>Patients who had TKA or AKA and were re-amputated to a level higher than AKA</li> </ul>

TKA, through knee amputations; AKA, above knee amputations

including Gritti–Stokes, were included. Each amputation was considered as a unit of analysis for surgical outcomes. Patients with bilateral amputations were excluded from analysis of rehabilitation outcomes, where the patient was used as the unit of analysis. Exclusion and inclusion criteria for each stage of the analysis are shown in Table 1.

**Statistical analysis**

Data analysis was performed using SPSS Version 25 (IBM Corp, Armonk, New York, USA). Statistical significance was set at  $p < 0.05$  for all analyses.

Descriptive statistics and surgical outcomes are presented in comparative groups of ‘initial AKA’ or ‘initial TKA’, meaning all amputations at that initial level including bilateral procedures.

Rehabilitation outcomes were analysed only in unilateral patient episodes due to complexity of rehabilitation in patients with bilateral amputation. The comparative groups are ‘final uni AKA’ or ‘final uni TKA’, meaning all patients who left the hospital with a unilateral amputation at that level.

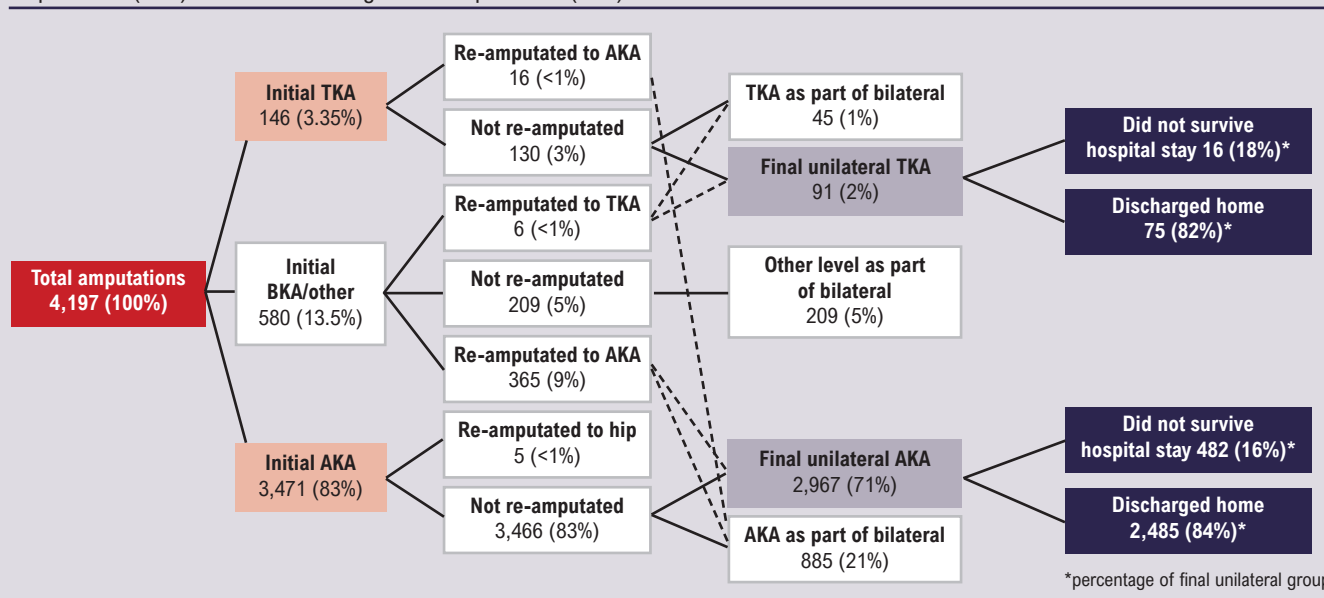
Continuous variables are expressed as mean±standard deviation (SD). All continuous data were tested for normality. If normal, hypothesis testing was with the Student’s t-test. Median and interquartile range were used for non-normally distributed data and hypothesis testing used the Mann–Whitney U test. Chi-squared tests were used for cohorts with categorical variables. Fisher’s exact test was used for variables with small sample sizes. Survival analyses and hazard analyses for further surgery to the amputated limb were assessed by Kaplan–Meier curves and log-rank statistics. Multivariate logistic regression analysis was used to identify risk factors for further surgery and mortality.

Anonymised data are entered onto the secure SPARG database by a member of the patient’s care team. Only routine clinical data are recorded for the purpose of auditing services, supporting health surveillance and clinical decision-making. No patient identifiable data were required for this study and no additional data were collected. Therefore, no additional ethical approval for this analysis was sought.

**Results**

There were 4,197 AKA or TKA surgeries performed as a primary (86%) or re-amputation (9%) procedure in Scotland between 1 January 2007 and 31 December 2017 (Figure 1). A total of 3,471

**Figure 1** Flowchart of breakdown of procedures. Of 4197 initial amputations, there were 2967 final unilateral above knee amputations (AKA) and 91 final through knee amputations (TKA).



\*percentage of final unilateral group

(83%) initial AKAs and 146 (3.5%) initial TKAs were included. Of those, 25% (n=885) of the initial AKAs and 33% (n=46) of the initial TKAs were part of bilateral procedures. Excluding revisions to a higher level of amputation and those who did not survive their hospital stay, 2,485 people with AKA and 75 people with TKA were discharged from hospital.

### Demographics

The majority of the study population were male (62%). The mean±SD population age was 69±13 years. The mean age for the AKA group was 69±13 years and for the TKA group was 67±15 years (p=0.058).

### Co-morbidities

The TKA group were significantly more likely to have a diagnosis of diabetes (p=0.034) or were obese (p=0.009) (Table 2). Median FCI scores were 3 out of 18 and were the same between groups.

### Aetiology

More than half of all amputations were due to peripheral arterial disease (PAD). Aetiology between groups was similar (Table 2). Other reasons for amputation included tumour, congenital deformity, blood-borne infection, renal disease, drug use and complex regional pain syndrome.

### Centre

Over 50% of all TKAs were performed in three out of 21 possible centres; 11 centres performed the remaining procedures and seven centres did not perform any TKA. We classified the top three centres as 'high volume' centres and the other 11 as 'low volume' centres for comparison of surgical and rehabilitation outcomes.

### Surgical outcomes

#### Further surgery

A higher proportion of patients required further surgery following TKA than following AKA (13% (19/146) vs 4% (151/3471), p<0.001). Of these, 2% of each group (57 AKA, 3 TKA) had further surgery involving only soft tissue (p=0.734). 3% (94) of AKA patients and 11% (16) of TKA patients had revision involving bone, including some which were reclassified as a higher level of amputation (p<0.001). Only 8% of TKA patients from high volume centres required further surgery compared with 19% in low volume centres (p=0.048). Having a second surgery was not associated with mortality for TKA (p=0.308) or AKA (p=0.105).

#### Length of stay

Despite more TKA patients than AKA patients requiring further surgery, their inpatient length of stay (LOS) was similar (35 (17–72) vs 42 (20–78) days, p=0.696).

#### Survival

The proportion of patients dying during their hospital admission was similar (18% AKA vs 16% TKA, p=0.870). Survival was also similar between the two groups (log-rank p=0.809) (Figure 2). In the

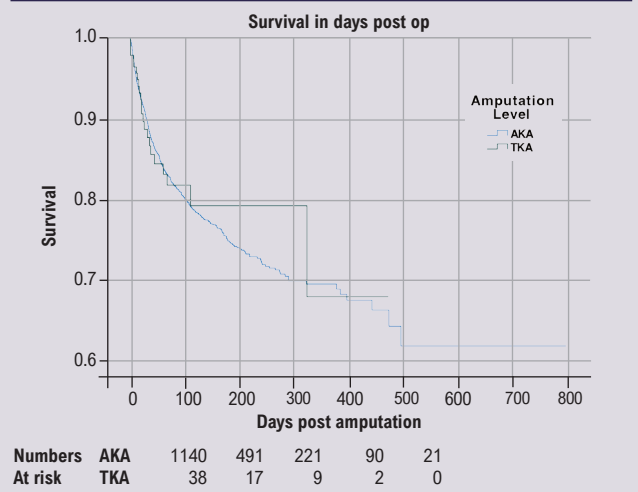
**Table 2** Past medical history and aetiology. The TKA group were significantly more likely to have a diagnosis of diabetes (p=0.034) or obesity (p=0.009). The most common cause of amputation was peripheral arterial disease (PAD) (53%).

	All, n (%)	Initial AKA, n (%)	Initial TKA, n (%)	p-value
Total	4,197	3,471	146	–
<b>Past Medical History</b>				
PAD	3,005 (78)	2,430 (77)	105 (75)	0.565
DM	1,424 (37)	1,098 (35)	61 (44)	0.034
CHF	1,114 (29)	910 (29)	31 (22)	0.085
CVA/TIA	863 (22)	711 (23)	38 (27)	0.205
Asthma	704 (18)	596 (19)	26 (19)	0.921
Obesity	449 (12)	358 (11)	26 (19)	0.012
Missing	344*	319 (9%)	6 (4%)	–
<b>Aetiology</b>				
PAD	2,223 (53)	1,869 (54)	69 (47)	0.118
DM	1,417 (34)	1,097 (32)	55 (38)	0.123
Other	557 (13)	505 (14)	22 (15)	0.862

TKA, through knee amputations; AKA, above knee amputations

\*PMH data not collected in 2007 (280 cases)

**Figure 2** Kaplan–Meier curves. Survival rates were similar between groups. The TKA group was smaller than the AKA group.



multivariable Cox regression, sex, age and history of diabetes were significant predictors of increased chance of mortality, and history of obesity significantly predicted increased chance of survival (Table 3).

### Rehabilitation outcomes

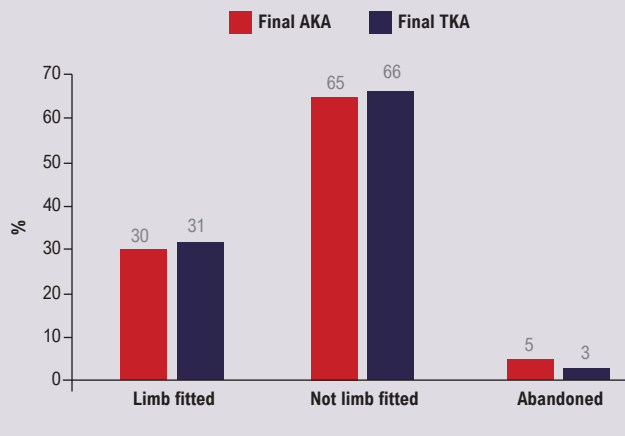
#### Limb fitting

Limb fitting outcomes were similar between those with TKA and AKA (Figure 3). Those classed as 'abandoned' commenced prosthetic rehabilitation but did not achieve independent mobility with their prosthesis. Those 'not limb fitted' were not referred for

**Table 3** Multivariable Cox regression. Sex, age and history of diabetes were significant predictors of increased chance of mortality and history of obesity significantly predicted increased chance of survival.

Variable	Hazard Ratio (95% CI)	p-value
Amputation level	0.93 (0.594 - 1.455)	0.75
Sex	1.185 (1-1.405)	0.05
Age	1.032 (1.024 - 1.039)	0
Diabetes	1.412 (1.191 - 1.673)	0
Obesity	0.623 (0.456 - 0.852)	0.003

**Figure 3** Limb fitting outcomes. Proportions of patients limb fitted were similar between groups. 30% of AKA and 31% of TKA successfully limb fitted.



prosthetic rehabilitation. Only 12% (9/77) of people with TKA from high volume centres were limb fitted compared with 25% (17/69) from low volume centres ( $p=0.041$ ).

#### Compression therapy

The median number of days between operation date and commencing compression therapy was similar between the groups (TKA 10 (7–25) vs AKA (13 (7–26),  $p=0.485$ ). Shrinker socks were the most common method of compression therapy used in all centres; 82% of those with an AKA used shrinker socks as their method of compression therapy compared with only 54% of those with a TKA; 21% used the Post Pneumatic Amputee Mobility Aid (PPAM aid), 18% used a rigid dressing and 7% used an elastic bandage.

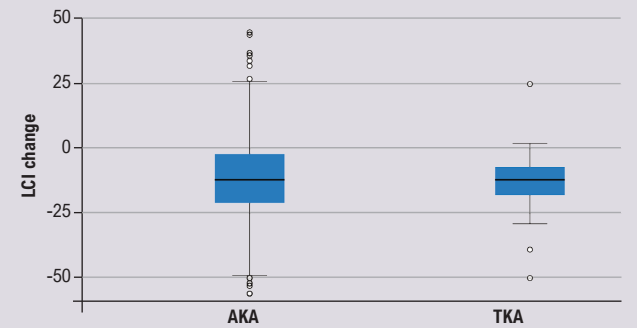
#### Early walking aids

Time to start early walking aids was similar in the TKA and AKA groups (22 and 21 days;  $p=0.426$ ). The TKA group favoured the PPAM aid (89%) over the Femurett (11%) for early walking aid, whereas 59% of the AKA group used the PPAM aid and 41% the Femurett.

#### Locomotor Capabilities Index-5

The Locomotor Capabilities Index-5 (LCI-5) was completed retrospectively for the patient's mobility six months prior to their

**Figure 4** Median change in LCI-5 scores was  $-12$  for both groups but with a larger spread in the AKA group ( $-12$  to  $-4$ ), indicating some patients in the AKA group had better mobility post amputation than the TKA group ( $-18$  to  $-7$ ), but also that some AKA patients had worse mobility after amputation compared with the TKA group



amputation and prospectively on final discharge from prosthetic rehabilitation. The difference between these two scores gives a score for their change in mobility; a positive score indicates an improvement and a negative score deterioration. The change scores for both groups are shown in Figure 4.

#### Prosthesis

The median number of days from amputation to being cast for a prosthetic limb was the same for both groups (55 days). Days from casting to receiving the finished prosthetic limb were also similar: 14 (8–21) days for those with AKA and 12 (6–16) days for those with TKA ( $p=0.084$ ).

For the 23 patients with TKA who limb fitted, it took 99 days (5–207) from inpatient discharge to complete prosthetic rehabilitation. The 725 patients with AKA who limb fitted took 133 (45–230) days ( $p=0.609$ ).

#### Discussion

This retrospective study examined demographics and outcomes from all patients who underwent TKA or AKA over an 11-year period in Scotland. Baseline characteristics (age, gender and rates of PAD and diabetes) were comparable to similar studies.<sup>16–18</sup> Similarities were observed between groups in the current study for survival, inpatient length of stay, limb fitting rates, mobility scores, and time to complete prosthetic rehabilitation, but reoperation rates in the TKA group were significantly higher.

The rates of reoperation post TKA in the current study are lower than those reported in older studies (34% and 29.9%, respectively).<sup>14,20</sup> Furthermore, this study showed that high volume centres obtain much better results, suggesting there is scope for optimisation of patient selection, operative technique and/or perioperative care.

Limb fitting rates were lower in the current study than those reported in similar studies, and were particularly low in high volume centres.<sup>17,18</sup> This may suggest that TKA is being chosen for patients



not expected to mobilise, but this cannot be determined from these data. Nijmeijer *et al* and Ten Duis *et al* reported limb fitting rates of 61% and 59%, respectively, in their TKA groups; however, only 34% and 35% of those actually achieved household mobility with their prosthesis.<sup>17,18</sup> The SPARG dataset only includes data up to the point of discharge from rehabilitation, therefore information regarding long-term prosthetic limb use at home is unavailable. It is known that up to 50% of people with AKA who limb fit stop using their prosthesis within the first year.<sup>24–26</sup> The reduced energy requirements<sup>27</sup> and superior socket comfort from a TKA prosthesis have the potential to improve long-term maintenance of prosthetic mobility. Further research is required to investigate this potential. As well as potentials in prosthetic rehabilitation, it has been claimed that TKA offers advantages for non-prosthetic rehabilitation including sitting balance and ability to transfer.<sup>28</sup> The longer lever of a TKA can, in theory, provide a more stable sitting platform, and be used as a lever and/or weight-bearing surface for standing and transferring, but these claims have not been formally tested.

The British Society of Rehabilitation Medicine (BSRM) guidelines recommend TKA for patients with existing contralateral amputation to improve bed mobility, transfer ability and leave the patient with a lap to help with carrying objects when in a wheelchair.<sup>11</sup> Despite this, 494 analysed patients underwent AKA for their second amputation compared with only 35 receiving TKA. These data suggest that considerable numbers of patients undergoing bilateral amputation are potentially missing out on significant advantages offered by TKA. The numbers of bilateral cases with one or two TKAs were too small to compare rehabilitation outcomes in this study. Inderbitzi *et al* compared outcomes of bilateral patients at different levels.<sup>29</sup> They found the higher the amputation level the worse the rehabilitation outcome and concluded that, despite the high revision rates they observed in their TKA cohort, they would still advise amputation at the most distal point possible to improve rehabilitation outcomes.

A limitation of this study is its retrospective cohort design. Missing data and unknown confounders are faults with any retrospective study; however, a strength is that the SPARG dataset was used. The dataset exists for research purposes, so efforts are made to ensure there is very little missing data (reported to be less than 3%).

Another consideration is that variations of TKA such as Gritti–Stokes are included in the TKA group, so their outcomes cannot be analysed separately. It is unknown which type of TKA is best, with several being described in the literature.<sup>28,30–34</sup> With so many techniques to choose from, surgeons may be more likely to opt for familiar AKA. Amputation surgery should only be performed by suitably experienced surgeons to ensure a good quality residuum.<sup>35,36</sup> As such small numbers of TKA are being performed, training may be an issue which limits increased utilisation of TKA. Recently, a classification system has been created to describe different types of TKA which will improve future reporting of the variations of the operation.<sup>34</sup>

## KEY MESSAGES

- Centres that perform large numbers of TKA have good wound healing outcomes, suggesting scope for optimisation of patient selection, operative technique and/or perioperative care.
- Mobility outcomes are similar between TKA and AKA despite high volume centres appearing to select patients not predicted to limb fit, suggesting superior rehabilitation potential for TKA.
- The numbers of TKA performed in Scotland are very small and prospective studies are needed to inform clinical practice.

Murakami and Murray suggest that high reoperation rates post TKA are due to poor patient selection and a lack of physiological measures used to decide the level of amputation.<sup>28</sup> The absence of defined selection criteria for each level of amputation is another limitation of this retrospective study.

Comparing TKA with AKA has always been challenging due to sample size differences. Even using 11 years of data, only 146 initial TKAs were available for analysis. Of these, only 23 were fitted with a prosthesis, making comparisons of rehabilitation outcomes difficult.

Prospective randomised studies are urgently needed to inform clinical practice with regard to deciding between TKA and AKA.

## Conclusion

This study shows that TKA remains an underused option for major lower limb amputation. High volume centres have better surgical outcomes but appear to select patients not likely to limb fit. Despite this, similar proportions of patients did subsequently limb fit between groups, which may suggest superior rehabilitation potential for TKA compared with AKA. Details of current practice and level selection need investigation to determine how best to select patients who would benefit from TKA as opposed to AKA, but with a low risk of need for reoperation. Prospective randomised studies are urgently needed to inform clinical practice.

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ORIGINAL RESEARCH

# Perception and acceptability of open versus endovascular treatment of common femoral artery disease: barriers and facilitators for randomised controlled trials

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## Plain English Summary

**Why we undertook the work:** Many patients have reduced blood supply to the legs due to narrowed or blocked blood vessels (arteries). Minimally invasive keyhole (endovascular) interventions are often used to improve the blood supply by opening up these diseased arteries. There is some controversy about whether these keyhole interventions should be used in the main artery in the groin, which is usually treated with open surgery. This study aimed to assess opinions about undertaking a trial to compare open and keyhole surgery on this main artery in the groin.

**What we did:** We conducted an online survey and face-to-face interviews with doctors who regularly use both of these treatments in patients with diseased arteries. We asked whether they thought a trial was needed, whether they would be willing to participate in such a trial, and what they considered to be the most important factors that would obstruct or facilitate such a trial.

**What we found:** Most people think a trial is needed and would be happy to participate. Several important factors were identified which would need to be addressed to ensure such a trial could be successfully delivered.

**What this means:** There is enthusiasm and a willingness to undertake a trial to compare open and keyhole surgery on this main artery in the groin. Potential obstructing or facilitating factors have been identified, which will require careful consideration and attention when designing and delivering such a trial.

## Abstract

**Introduction:** The common femoral artery (CFA) is often affected by atherosclerosis in patients with peripheral arterial disease, requiring revascularisation. Open surgical CFA endarterectomy (CFAE) remains the standard of care in this context; however, there have been multiple recent advances in endovascular CFA therapies. However, randomised controlled trials (RCTs) comparing CFA treatments have suffered from multiple pitfalls. This research aimed to assess opinions regarding potential barriers and enablers of delivering a high-quality RCT of open surgical CFAE versus endovascular CFA therapy.

**Methods:** A mixed-methods qualitative study was performed, including a structured online survey and face-to-face semi-structured interviews with healthcare professionals. Survey content and interview topic guides were developed following a literature review to identify ongoing and completed RCTs comparing CFA treatments. The data were analysed using thematic analysis.

**Results:** The online survey was completed by 121 participants, including vascular surgeons (n=75, 62%) and interventional radiologists (n=22, 18%), mostly from the UK (n=92, 76%). A total of 61 participants (51%) would be willing to take part in an RCT comparing open versus endovascular CFA revascularisation. The majority (n=89, 74%) believed that such an RCT is urgently needed. Fifteen participants were interviewed face-to-face. Five main themes emerged regarding barriers and facilitators for a high-quality RCT in this context: factors directly limiting patient recruitment; clinicians' attitudes towards equipoise between treatments; clinicians' attitudes towards endovascular therapies; attitudes towards outcomes examined in a potential RCT; and factors facilitating patient recruitment. From these, 10 sub-themes were identified.

**Conclusion:** The majority of survey respondents believed an RCT comparing open and endovascular CFA revascularisation is necessary and would participate in such a trial. Important barriers and enablers, grouped in five overarching themes, have been identified, which would require serious consideration when designing and delivering such an RCT.

**Key words:** common femoral artery, endovascular, qualitative, peripheral arterial disease, thematic analysis

## Introduction

The standard of care for the treatment of atherosclerotic disease of the common femoral artery (CFA) remains open surgical CFA endarterectomy (CFAE). Endovascular interventions, however, have become first-line therapies for atherosclerotic disease of other arterial segments. This is due to their minimally invasive nature, low rates of perioperative complications and patient preference.<sup>1-4</sup> High rates of technical success and low rates of complications with endovascular management of CFA stenosis have been reported; one small randomised controlled trial (RCT) suggests that short-term (30 days) outcomes might be better after CFA angioplasty than CFAE.<sup>1,5,6</sup> This RCT, however, was underpowered to detect differences in clinical outcomes such as amputation-free survival. Furthermore, this RCT and other similar attempts in this clinical context have suffered from low recruitment rates and limited follow-up. High-quality large-scale trials are urgently required to assess the clinical effectiveness of CFA endovascular procedures, which are now common in clinical practice.<sup>7</sup>

As previous RCTs in this area have suffered from multiple issues, the experiences of healthcare professionals need to be investigated and explored in a structured manner to understand potential barriers and enablers in RCT delivery.

This research aimed to use established qualitative methodology to understand issues surrounding RCT delivery in the context of comparing the effectiveness of surgical versus endovascular CFA revascularisation.

## Methods

### Regulatory approvals

The study was approved by the London Bromley National Health Service (NHS) Review Ethics Committee (REC) in December 2019 (reference number: 20/LO/0059). It was approved by the United Kingdom (UK) Health Research Authority (HRA) (reference number: 274726).

### Informing the content of the survey and topic guides

A systematic literature review using the Medline and Embase databases (since inception) in December 2019 (updated March 2020) was undertaken to identify all studies comparing endovascular and open surgical CFA revascularisation for atherosclerotic disease. The following terms were used: (“peripheral arterial disease” OR “peripheral artery disease”) AND “common

femoral” AND (“endovascular” OR “surgery”) - any language. The clinicaltrials.gov and ISRCT registries were also searched (December 2019) using the same terms to identify ongoing studies. We identified 39 published studies (randomised and non-randomised) relevant to CFA treatments and one ongoing RCT, which were then reviewed to identify potential barriers and facilitators in delivering randomised research. The survey content and interview topic guides were then composed. Both were reviewed by three independent vascular surgeons and two vascular interventional radiologists. A participant information sheet was prepared and sent to all those taking part, summarising the hypothesis and aims.

### Online survey

A structured online survey with both closed and open questions was developed by the two senior investigators between December 2019 and March 2020 (Appendix 1 - online at [www.jvsgbi.com](http://www.jvsgbi.com)). The survey link was disseminated via email between March and May 2020 to the membership of the Research Collaborative for Peripheral Arterial Disease (RCPAD) and the Vascular and Endovascular Research Network (VERN), representing 894 cardiovascular professionals across 53 countries. In addition, existing RCPAD and VERN social media accounts (Twitter) with a total followership of 4114 at the time of dissemination were used to further publicise the survey with weekly tweets between March and May 2020. The three authors also disseminated the survey link in their departments and professional networks during the same period. The survey could only be filled in once per Internet Protocol (IP) address requiring the practitioner to use a unique direct link, to avoid duplicate entries. Survey entries were also screened for duplicates upon completion.

### Semi-structured interviews

Semi-structured qualitative interviews were performed between January 2021 and September 2021 (face-to-face). The interviews were conducted once the analysis of the online survey had been completed so that the topic guide was written accordingly (Appendix 2 - online at [www.jvsgbi.com](http://www.jvsgbi.com)). The interview sample recruited consisted of healthcare professionals who provide primary or secondary care to patients with peripheral arterial disease and who could provide informed consent and attend the interview. They were recruited via the online survey (asked to provide their contact details) or directly by the three investigators in person, across seven



different secondary care institutions in the UK, Greece and Italy. Informed consent was obtained in all cases. We used open-ended questions framed in a locally and culturally appropriate context to encourage discussion and exploration of pertinent barriers and facilitators. Interviews were recorded (audio) and transcribed (where necessary) within 12 hours. Topic guides for future interviews were adjusted accordingly, based on prior topics explored, to ensure all barriers and facilitators were explored (iterative design).

### Analysis of data

The categorical data from the online survey were summarised in a spreadsheet. The replies to open-ended free text questions were checked for sanity and accuracy, duplicates were removed, and the text was then analysed as per the procedure described below.

For the interviews, the primary data source was the recorded audio file and (where necessary) the transcript for each interview. The text from both the online survey and transcribed interviews was coded using content analysis procedures. Transcription and coding were completed within one day of each interview. Each audio file and transcript was independently coded. A master-sheet codebook with themes and quotes was then created; the two investigators met to discuss themes after each set of interviews was analysed as quickly as possible. If the agreement in themes was less than 90%, another investigator would adjudicate accordingly. Themes were derived from a combination of pre-set questions in the topic guide as well as from data in the transcript of each interview. At this stage, the free text of the online survey was also analysed to identify emerging themes. Transcripts were then recoded using the final version of the interview and survey master-sheet/codebook. A summary of all the themes was generated; similar themes were grouped into broad and abstract categories. Qualitative data analysis software (NVivo 9, QSR International) was used to tabulate theme frequency using the master-sheet/codebook count and sort the minor themes.

## Results

### Online survey

A total of 121 individual participants from 69 vascular units completed the online survey. Most of the units were in the UK (n=92, 76%), followed by other European countries (n=13, 11%) including Italy, Germany, Greece and Belgium. Participants were mainly consultant ("attending") vascular surgeons (n=69, 57%), followed by vascular surgery trainees (n=24, 20%) and interventional radiology consultants (n=22, 18%). Most participants had more than 5 years of experience as independent practitioners (n=57, 47%) following completion of their specialist training (Table 1).

A total of 114 participants (94%) performed endovascular and hybrid vascular procedures at least once weekly; 80 participants (66%) had access to a hybrid operating theatre.

A total of 61 participants (51%) would be willing to take part in

**Table 1** Characteristics of the participants in the online survey\*

Location	
UK	92 (76%)
Mainland Europe	13 (11%)
USA	9 (7%)
Other	7 (6%)
Job title	
Consultant vascular surgeon	69 (57%)
Vascular surgery trainee	24 (20%)
Consultant radiologist	22 (18%)
Post-training fellow (vascular surgery)	6 (5%)
Years of experience	
Trainees	26 (21%)
Post-training completion	
<1	13 (11%)
1	5 (4%)
2	3 (2%)
3	6 (5%)
4	6 (5%)
5	5 (4%)
>5	57 (47%)
<b>Total</b>	<b>121 participants</b>

\*Categorical data are given as n (%).

an RCT comparing CFA stenting versus CFAE for CFA disease. The majority (n=89, 74%) believed an RCT of best endovascular therapy against best open surgery for CFA lesions is needed (Table 2).

### Semi-structured interviews

Overall, 44 healthcare professionals were invited to take part in the interviews, of which 15 participants were interviewed face-to-face, including six vascular surgeons, six radiologists and three specialist vascular nurses. All worked in secondary care (hospital) settings, had experience of treating patients with peripheral arterial disease and had recruited at least one patient in an RCT in the last two years.

Five main themes emerged regarding barriers and facilitators for an RCT comparing open versus endovascular treatments for CFA steno-occlusive disease: (1) factors limiting patient recruitment (barriers); (2) attitudes towards equipoise between treatments (arms); (3) attitudes towards endovascular therapies; (4) attitudes towards outcomes examined in a trial; and (5) factors facilitating patient recruitment. From these, 10 subthemes were identified. Saturation was reached in this analysis. A thematic map is provided in Figure 1.

### Factors limiting patient recruitment (barriers)

Local resource limitations: Limitations relating to time, space for screening, consenting, follow-up as well as completion of data collection forms were noted. With regard to time, competing clinical priorities and both academic and clinical bureaucratic workload were the most common issues. With regard to space, no availability

**Table 2** Summary of main results of the online survey\*

<b>Endovascular experience</b>	
Yes	114 (94%)
No	7 (6%)
<b>Hybrid operating theatre availability</b>	
Yes	80 (66%)
No	41 (34%)
<b>Previous use of biomimetic stents or newer generation technologies for calcified femoro-popliteal disease</b>	
Yes	94 (78%)
No	27 (22%)
<b>Would you take part in a randomised trial comparing treatments in the common femoral artery?</b>	
Yes	61 (50%)
Maybe	48 (40%)
No	12 (10%)
<b>A randomised trial in this setting (common femoral artery treatments) is necessary</b>	
Yes	89 (74%)
No	32 (26%)
<b>Total</b>	<b>121 participants</b>

\*Categorical data are given as n (%).

of rooms in the usual clinic environments or the vascular wards were noted as the main limiting factors. A further common limitation noted in all interviews was the lack of dedicated funding for research nursing time in the participants' units.

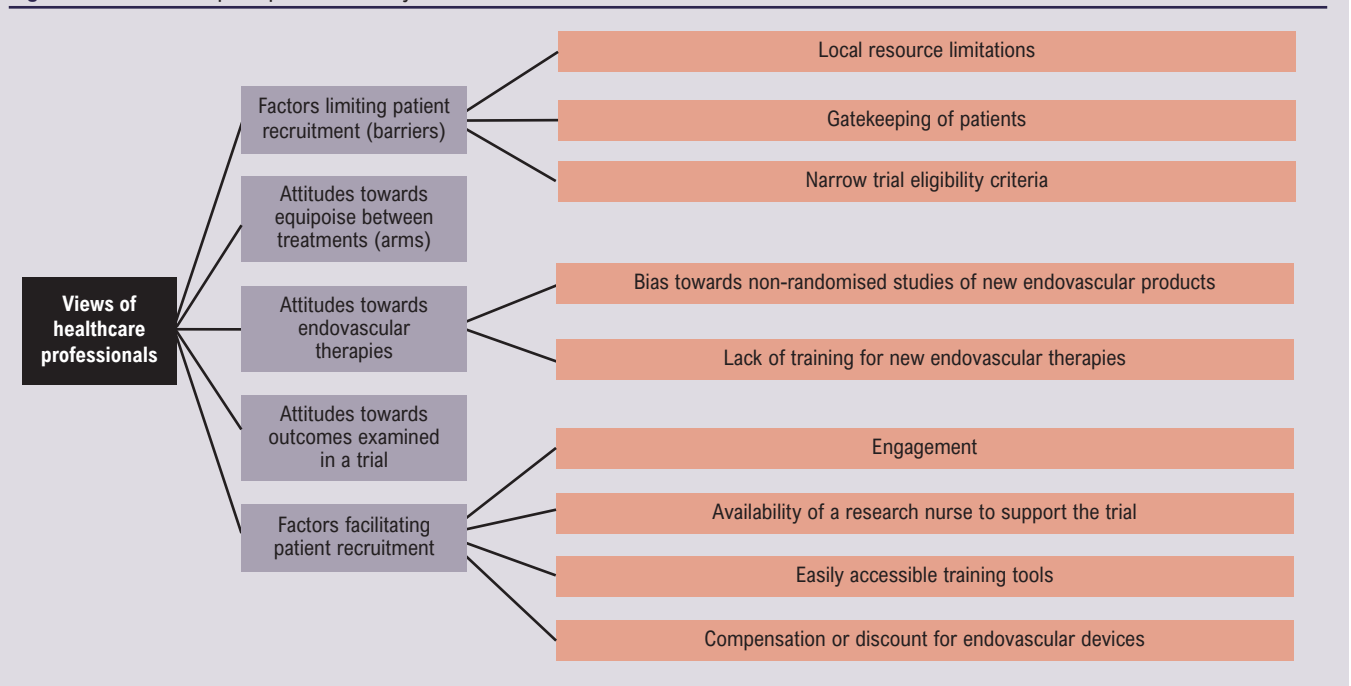
[Quotes] "... there is not time before or after my clinic to screen patients for any study, let alone something as complex as a randomised trial...", "... I have not time to discuss concepts such as randomisation during regular clinics on most days...", "... we never see any of the funds allocated to these studies come to our department, especially in the form of research nurse salary..."

Gatekeeping of patients: Some healthcare professionals noted that bias towards pre-selecting or excluding certain patients are common in this context. This included avoiding contacting patients with severe ulcerations in their lower limbs, patients with extensive disease of their arteries, those who were very immobile, and patients with potentially difficult personalities. It was noted that they would not want to recruit multi-morbid patients as they did not want to burden them with additional assessments or follow-up visits.

[Quotes] "... I wouldn't select a case where I have to do extensive endarterectomies and then stent inflow or outflow on top, as I think it would "mess" up the study results...", "... I'm not keen on talking to patients who can't walk for such a trial; I don't think these patients would do the study right as it would make the other arm look much better in the long term...", "... I really don't want to recruit patients who have several health problems or might be near the end of their life to a study which adds extra burdens such as more hospital visits; I can't see the point..."

Narrow trial eligibility criteria: Strict or very descriptive eligibility

**Figure 1** Thematic map of qualitative analysis.



criteria in terms of both symptomatology and anatomy (ie, number of arteries occluded and/or stenosed) were universally viewed as a key barrier to successful recruitment. There was clear consensus against such an approach.

[Quotes] "... *The main problem with all of the femoro-popliteal trials is always the very long list of exclusion criteria; it makes it impossible to find these patients...*", "... *This study will have to include "all-comers", otherwise no one will feel happy to take part, not patients and definitely not healthcare staff...*".

#### Attitudes towards equipoise between treatments (arms)

All healthcare professionals discussed equipoise during the interviews. Some expressed "no equipoise" between CFAS versus CFAE for CFA disease ("... there is no reason to invest in any such study as CFAE is an established technique and no one will ever randomise a patient..."). Others expressed that they view both treatments as identical ("... in the right hands, open or endo – doesn't really matter, as long as you pick the right patients and you have the experience..."). There was unanimous agreement that new therapies, especially stents, must be urgently assessed in randomised trials in terms of their role in treating CFA disease. Overall, we found that views with regard to equipoise varied widely, even though most (if not all) professionals do agree that randomised research is urgently needed in this domain. A common sub-theme which emerged was the lack of evidence specifically relating to stenting the CFA; radiologists and surgeons often expressed that they have been against using stents in this region specifically because there is no high-quality evidence assessing their use for this artery. It was found that this might be a driver towards recruitment in such a study.

#### Attitudes towards endovascular therapies

Bias towards non-randomised studies of new endovascular products: Several healthcare professionals reported strong bias towards recruiting patients in non-randomised studies (eg, registries) of new endovascular products. This was felt to be a common practice in vascular units nationally and internationally. It was felt that this stops clinicians from promoting pragmatic trials comparing treatments head-to-head, especially when this is publically funded research that does not generate considerable income. Consultant surgeons and radiologists noted that certain individuals "are only interested in their own studies" or favour "studies which generate income for the departments".

Lack of training for new endovascular therapies: Most healthcare professionals expressed concerns over a lack of uniform training amongst centres taking part in such trials. Another theme that emerged was related to the experience of the operators. Many found that this would be a source of bias when recruiting new centres and when analysing results. Finally, lack of adjudication with

regard to how the endovascular treatments have been used was another theme which often emerged as a barrier in terms of delivering a successful trial which would be translated to clinical care.

[Quote] "... *we would like to take part in such a study but we have had no formal training on how to use things like atherectomy or lithotripsy in a CFA. How are we going to be able to do the study in my department ...?*", "... *we need to ensure that all operators in the study have experience in using endovascular equipment developed for CFA disease. I think this will be very difficult to achieve...*", "... *a core-lab or some form of quality control is needed in the endovascular arm. Different people use endovascular devices in a different way. This has to be standardised or at least one has to know how the endovascular arm was treated...*".

Availability of endovascular therapies: Professionals noted that some endovascular therapies might not be available in their centre. This was seen as a key barrier to opening their site as a recruitment centre: "... there is no point discussing taking part in a study if my department does not have access to most of the endovascular tools used in endo-heavy hospitals..." or "... we need to buy the endovascular equipment first, before we take part in any trial in this area...".

#### Attitudes towards outcomes examined in a trial

The main theme emerging in this area related to the use of clinical and cost-effectiveness outcomes – namely survival, amputation and healthcare costs – as part of a primary outcome measure in a successful RCT. Interestingly, several individuals expressed a view that a successful trial would have to include patients with intermittent claudication; the main outcome of interest should be walking distance for this specific sub-population (and not amputation or patency driven). Overall, quality of life assessments were noted as a key outcome, to be included as a secondary outcome measure in any trial in this disease area, both for those with chronic limb-threatening ischaemia and those with intermittent claudication. At the same time it was noted that patient-reported outcomes relating to quality of life are not easy to use or widely validated for patients with peripheral arterial disease, especially limb-threatening ischaemia. There was a common theme against using patency of the treated lesion as the main outcome of interest, regardless of the presenting symptomatology of the trial population.

#### Factors facilitating patient recruitment

Engagement: It was deemed important for successful trial recruitment to maximise engagement/frequent interaction with sites ("... the main study site needs to keep in touch with all sites very regularly..."). This includes meetings face-to-face and remote availability most days of the week, with the lead site(s) taking part in

these activities. Regular site visits were also noted by most professionals as a key facilitator as per their experience. It was viewed, especially by the nursing staff, that the doctors must engage with the specialist and ward nurses daily to ensure patients eligible for recruitment will be identified.

Overall, this theme highlights the importance of maximising engagement, including face-to-face meetings with all interested parties and maintaining regular visits to sites.

Availability of a research nurse to support the trial: A common theme was the availability of a research nurse (or other relevant staff) on site to help with screening and study processes: "... the patients are often seen in clinic or the ward interchangeably. We need access to a dedicated nurse or some form of individual who will be chasing study procedures almost daily. This is where we keep failing with peripheral arterial disease trials ..."

Easily accessible training tools: Online rather than paper-based training was a common theme emerging with regard to trial procedures. Also, many commented that a module for the endovascular therapies should be made available remotely, as certain clinicians might not have received the same type of training for each endovascular device assessed in a potential trial.

Compensation or discount for endovascular devices: Consultant radiologists and surgeons noted that discounts for using the endovascular devices as part of such a trial by the producers would "... definitely support recruitment ..." or "... change the minds of our managers about not taking part in similar trials ...".

## Discussion

Recent advances in endovascular procedures for atherosclerotic CFA disease now allow the treatment of complex anatomies. At the same time, there is no large RCT comparing the clinical and cost-effectiveness of open versus endovascular revascularisation of the CFA. This may be due to a variety of reasons. Delivering successful RCTs to address this important clinical question necessitates an in-depth understanding of relevant barriers and facilitators.

To our knowledge, this is the first study to systematically examine the perceptions and assess the opinions of healthcare professionals to successfully delivering a high-quality RCT comparing CFAE versus CFA stenting.

This study showed that most vascular interventionists surveyed believed that such an RCT is necessary and would be willing to potentially recruit patients. At the same time, the study identified several potential barriers, and several facilitators, which require serious consideration during the design and delivery of any such future RCT.

CFAE remains the gold standard treatment for significant CFA disease because it has been proven to be safe, durable, with high technical success rates.<sup>8</sup> However, CFAE is associated with potential perioperative morbidities such as bleeding, wound infection, and re-intervention and short-term morbidity and mortality rates as high as 15% have been reported.<sup>9</sup> Of note, CFAE is mostly performed under general anaesthesia, which presents an

added risk in old frail patients.<sup>1-4</sup> Additionally, CFAE could be technically challenging in obese patients and those with previous groin surgery or radiotherapy. These factors, in addition to the minimally invasive nature of endovascular techniques and the significant advancements in this field, make CFA angioplasty with/without stenting an appealing alternative approach to treat CFA disease. However, endovascular techniques in this context are generally burdened by the added costs and the frequent need for re-interventions<sup>5,6,10,11</sup> There are no previous high-quality randomised studies which provide enough information on the performance of stents or other newer endovascular treatments in this challenging anatomical location.<sup>7</sup>

Previous attempts to conduct RCTs have encountered difficulties perhaps because they were designed and delivered without formal assessment of the perception of such trials. A small randomised study tried to address this controversy; however, recruitment was found to be a challenge (117 patients over 30-month period). Additionally, this study had strict inclusion and exclusion criteria which do not necessarily reflect the day-to-day practice of most vascular units. There was also a lack of long-term clinical outcome data such as amputation-free survival.<sup>6</sup>

Detailed exploration of research delivery in terms of barriers and enablers has been strongly recommended prior to designing and delivering successful large-scale RCTs.<sup>12,13</sup> Our study cohort reflected the diverse background of vascular interventionists treating CFA lesions, including vascular surgeons and interventional radiologists, with varying levels of expertise (79% were consultants with almost half of them having more than 5 years' experience of independent practice). Overall, 94% of those surveyed had the necessary open and endovascular skills to deliver both CFAE and CFA endovascular treatments (eg, stenting), with 66% having access to hybrid operating theatres. In particular, 78% were familiar with new devices used in the femoro-popliteal segment, including biomimetic stents. On the one hand, this shows that the necessary skill set and operating environment to deliver both treatment modalities for CFA disease are available in most vascular centres included in this study. On the other hand, almost a quarter of those surveyed indicated that further endovascular training would still be required to deliver an RCT. Although this should be considered as a potential barrier, this is a better starting position compared with other procedures at the time of their introduction to daily practice, such as endovascular aneurysm repair where initially the necessary skills were limited to certain centres prior to testing in an RCT.<sup>14</sup>

Furthermore, as part of this study, interviews were conducted with 15 healthcare professionals (surgeons, radiologists and nurses). The thematic analysis identified various barriers – for example, lack of research infrastructure in certain institutions (including research nurses or allocated research time), lack of certain endovascular devices or endovascular training, as well as the prohibitive costs of advanced endovascular tools. Extensive exclusion criteria were identified as an important factor which limits recruitment in similar trials. We have grouped the emerging themes



## KEY MESSAGES

- High-quality large-scale trials are required to assess the clinical and cost effectiveness of CFA revascularisation procedures.
- There are recurrent themes regarding facilitators and barriers to patient recruitment and trial delivery.
- Interventionists would be willing to participate in a well-designed trial taking into consideration identified themes.

into five groups with 11 sub-themes. This will help future researchers to design a trial with a much greater chance of successful delivery.

Regarding potential study facilitators, there was an agreement that obtaining the endovascular devices at a reduced cost or free of charge (as part of a costed study) would greatly facilitate recruitment. Additionally, appropriate costing for and provision of the necessary research infrastructure to support the trial (such as research nurses and clinicians' time) would also help recruitment.

In terms of study design, there was a recurring theme that the outcome measurements should include clinically relevant metrics such as amputation-free survival, limb salvage and quality of life, especially if patients with claudication were included. It was also felt that the usual outcome measures such as patency rate should not be the only endpoint for this trial. These findings should be taken into serious consideration when planning, designing and delivering an RCT in this area.

This study has some limitations. As the healthcare professionals surveyed in this study came from different countries, this might have induced heterogeneity of the feedback based on the experience from various healthcare systems with different reimbursement systems. Patients' views are not included in this comprehensive analysis as it was beyond the scope of this current study which aimed specifically to specifically explore the perceptions of healthcare staff. However, we would strongly advocate including patients when designing any form of RCT in this setting.

### Conclusion

This study showed that the majority of the surveyed healthcare professionals believe that an RCT comparing cost and clinical effectiveness of surgery versus endovascular treatments for CFA disease is necessary and the majority would be willing to recruit participants. It has also identified potential barriers and enablers which should be taken into consideration when designing and delivering such a trial.

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## CASE REPORT

# Congenital absence of splenic artery: a rare cause of upper gastrointestinal bleed

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**Key words:** congenital, absent splenic artery, gastrointestinal bleed

**Abstract**

A 21-year-old woman presented as an emergency with upper abdominal discomfort and one episode of haematemesis. Physical examination, blood results and oesophagogastroduodenoscopy (OGD) were unremarkable. The patient collapsed following a large haematemesis 24 hours later and was intubated, ventilated and resuscitated. Repeat OGD demonstrated multiple areas of gastric angiodysplasia with active bleeding. Attempted haemostasis was unsuccessful. Computed tomography angiography (CTA) demonstrated an absent splenic artery and multiple abnormal collaterals supplying the stomach, pancreas and spleen originating from a hypertrophied left gastric artery and gastro-epiploic arteries. Angiography demonstrated active bleeding from these abnormal collaterals, which were successfully embolised and haemostasis attained. On follow-up CTA, no evidence of further bleeding or infarction was noted. Congenital absence of the splenic artery is rare, with only four reported cases, and is an extremely rare cause of upper gastrointestinal bleeding.

**Case details**

A 21-year-old woman presented to the emergency department with upper abdominal discomfort and one episode of haematemesis. The patient had a previous history of haematemesis 10 years previously which was managed with medication and blood transfusion. There was no history of smoking, non-steroidal anti-inflammatory drugs or alcohol intake.

At presentation the physical examination was unremarkable. Initial blood results were pH 7.36,

haemoglobin 118 g/l, haematocrit 0.36, platelets  $326 \times 10^9/l$ , INR 1.2, albumin 31 g/l, bilirubin  $9 \mu\text{mol/l}$ , alkaline phosphatase 72 units/l, alanine aminotransferase 12 IU/l, albumin 31 g/L, amylase 74 units/l, sodium 140 mmol/l, potassium 5.1 mmol/l, urea 12.1 mmol/l, creatinine  $52 \mu\text{mol/l}$  and glomerular filtration rate  $>90 \text{ ml/min/1.73 m}^2$ . On oesophagogastroduodenoscopy (OGD), no active bleeding was seen.

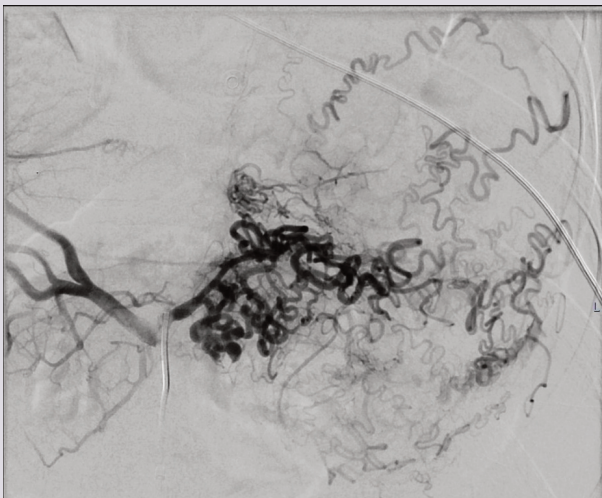
The patient collapsed with large haematemesis 24 hours later and underwent intubation, ventilation and resuscitation with packed red cells, fresh frozen plasma and platelets. She also received a proton pump inhibitor infusion, vitamin K and tranexamic acid. Repeat OGD demonstrated multiple small areas of actively bleeding gastric angiodysplasia in abnormal vascular territories. Attempted haemostasis at OGD was unsuccessful and the patient underwent computed tomography angiography (CTA) to delineate the vascular anatomy and plan treatment. CTA demonstrated an absent splenic artery, collaterals supplying the stomach, pancreas and spleen originating from a hypertrophied left gastric artery and gastro-epiploic arteries and a large volume of blood in the stomach (Figure 1).

Following transfer to the interventional radiology theatre with anaesthetic support, the right common femoral artery was accessed using an ultrasound-guided modified Seldinger technique and secured with a 35 cm 5F sheath (Cordis). The coeliac artery was accessed with a 4F Sim 1 catheter (Cordis) and 180 cm Zip wire (Boston Scientific) followed by selective catheterisation of the left gastric and gastro-epiploic arteries. Angiography with pump injection at 10 mL iodinated contrast at 5 mL/s showed active bleeding from collaterals arising from the left gastric artery and gastro-epiploic arteries.

**Figure 1** Coronal reconstruction demonstrating absence of splenic artery.



**Figure 2** Fluoroscopic angio images with absence of splenic artery, presence of multiple collaterals and spleen being supplied by short gastric arteries.

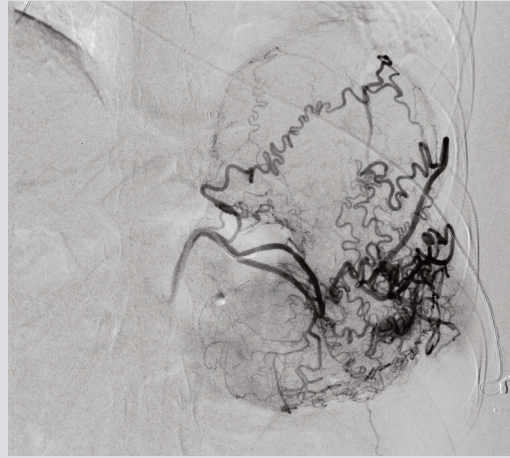


Super-selective catheterisation of the tortuous branches was performed with a 130 cm 2.7F Progreat microcatheter (Terumo) (Figure 2 & 3). The bleeding vessels were successfully coil embolised with micronester coils through the Sim 1 catheter to haemostasis (Figure 4). The patient clinically improved over her course of stay in hospital with no further bleeding. On follow-up CT, no evidence of further bleeding or infarction was noted.

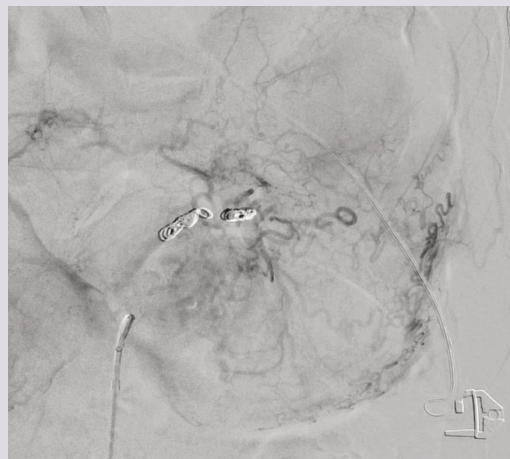
**Discussion**

Acute upper gastrointestinal bleeding is one of the most common medical emergencies in the UK with an estimated incidence of 134

**Figure 3** Fluoroscopic angio selective image with presence of blush in region of gastric rugal folds.



**Figure 4** Fluoroscopic angio selective image following embolisation with coils.



per 100,000.<sup>1</sup> Peptic ulcer disease remains the commonest cause for non-variceal upper gastrointestinal bleeding.<sup>2</sup> Endoscopy is the investigation of choice for diagnosis and targeted endoscopic treatment<sup>3</sup> after failure of conservative treatment.

Multidetector CT is a non-invasive tool for assessment of bleeding with a sensitivity of 86% and specificity of 95%.<sup>4</sup> It not only determines the site and possible cause for the bleeding, but also displays the vascular anatomy which assists in planning subsequent endovascular intervention.<sup>5</sup>

In our case, failure to secure haemostasis at endoscopy led to CTA, which demonstrated active gastric bleeding from collateral vessels derived from hypertrophic left gastric and gastro-epiploic vessels with absent splenic artery. It was thus realised that haematemesis in our patient was due to bleeding from abnormal collateral vessels.<sup>6</sup>



**Table 1** Comparison with previous case reports of congenital absence of the splenic artery with upper GI bleed.

Case	Author	Patient age and gender		Presenting feature	Findings of angiography	Treatment
1	Spriggs <sup>10</sup>	31	Male	Haematemesis	Absence of splenic artery	Drug therapy, surgery
2	Durrans <i>et al</i> <sup>6</sup>	13	Male	Haematemesis	Absence of distal half of splenic artery	Surgery
3	Shin <i>et al</i> <sup>11</sup>	61	Female	Epigastric discomfort	Not performed (CT finding: absence of splenic artery)	Drug therapy
4	Namikawa <i>et al</i> <sup>12</sup>	50	Female	Dizziness, tarry stool and haematemesis	Absence of splenic artery	Drug therapy, endoscopic coil embolisation
5	Present case	21	Female	Epigastric discomfort and haematemesis	Absence of splenic artery	Drug therapy, endoscopic coil embolisation

### KEY MESSAGES

- Congenital absence of the splenic artery and associated gastric angiodysplasia is a very rare cause of life-threatening haematemesis in young patients.
- Transcatheter embolisation is a quick, minimally invasive, effective treatment for bleeding refractory to endoscopic treatment in such cases.
- Computed tomography angiography in these cases provides a rapid diagnosis and guide to plan treatment.

Non-visualisation of the splenic artery and filling of the intrasplenic vessels through collaterals was in keeping with the absence of the splenic artery. Possible causes for splenic artery absence include atherosclerosis,<sup>7</sup> thrombosis,<sup>8</sup> surgery<sup>9</sup> and congenital absence.

Atherosclerosis is usually seen in elderly patients and rarely results in complete occlusion.<sup>7</sup> However, ischaemic changes in the spleen would be expected with splenic artery thrombosis.<sup>8</sup>

In our case there was congenital absence of the splenic artery. Only four cases of congenital absence of the splenic artery appear to have been reported, the details of which are shown in Table 1.<sup>6,10–12</sup> Congenital absence of an artery frequently results in development of collateral channels with serpentine appearance, rhythmic convolutions and uniform size.<sup>13</sup>

Transcatheter embolisation is a frequently effective treatment for acute non-variceal upper gastrointestinal bleeding refractory to endoscopy.<sup>14</sup> It is fast, effective and a minimally invasive alternative to surgery. Most commonly, the splenic artery originates from the coeliac trunk; however, it is important to appreciate anatomical variability.<sup>15</sup>

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**Patient consent to publication:** Yes

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## CASE REPORT

# Blue toe syndrome secondary to multiple spontaneous aortic thrombi following pneumonia

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**Key words:** thromboembolism, blue toe syndrome, aortic thrombus, pneumonia

**Abstract**

A 65-year-old man presented with bilateral ischaemic toes 11 days following hospital discharge for pneumonia. His initial admission was complicated by atrial fibrillation requiring rivaroxaban on discharge. A thromboembolic cause of his toe ischaemia was suspected. An echocardiogram demonstrated only moderate atherosclerosis. However, repeat echocardiogram revealed five thrombi within the descending aorta. Medical management included therapeutic enoxaparin, aspirin, atorvastatin and a five-day course of iloprost. Subsequent right 5th toe amputation was required for osteomyelitis, but otherwise the patient made a full recovery and was asymptomatic at 12 months.

**Introduction**

Blue toe syndrome is a disease of the small arteries in the foot/toes characterised by painful blue discolouration in one or more toes. The most common aetiology is distal embolic disease. If foot pulses are palpable, medical management is frequently all that is required.

**Case report**

A 65-year-old man was readmitted to hospital complaining of pain, paraesthesia and blue discolouration in his left 3rd and right 4th and 5th toes. Eleven days previously he had been discharged from hospital following treatment of a lower lobe pneumonia. During his initial presentation he was Ig-G negative for *Mycoplasma pneumoniae* but strongly Ig-G positive when readmitted 11 days later, suggesting reactivation. An antinuclear antibody (ANA) screen was weakly positive. His initial

hospital admission was complicated by the onset of rapid atrial fibrillation with resultant transfer to the cardiac care unit, where he spontaneously reverted. A transthoracic echocardiogram was functionally normal with moderate aortic atherosclerosis. He was initially discharged on rivaroxaban, doxycycline and amoxicillin (for one week).

Following discharge, the patient experienced paraesthesia and pain with purple mottling in his left 3rd and right 4th and 5th toes, which was most marked on leg elevation. On examination, peripheral pulses were palpable but both feet were cool. There was no previous history of peripheral arterial disease. He was an ex social smoker, with no personal or family history of coagulopathies. His past medical history included hypertension, paroxysmal atrial fibrillation, depression/anxiety, right total knee replacement, bilateral total hip replacements and cervical and lumbar fusions.

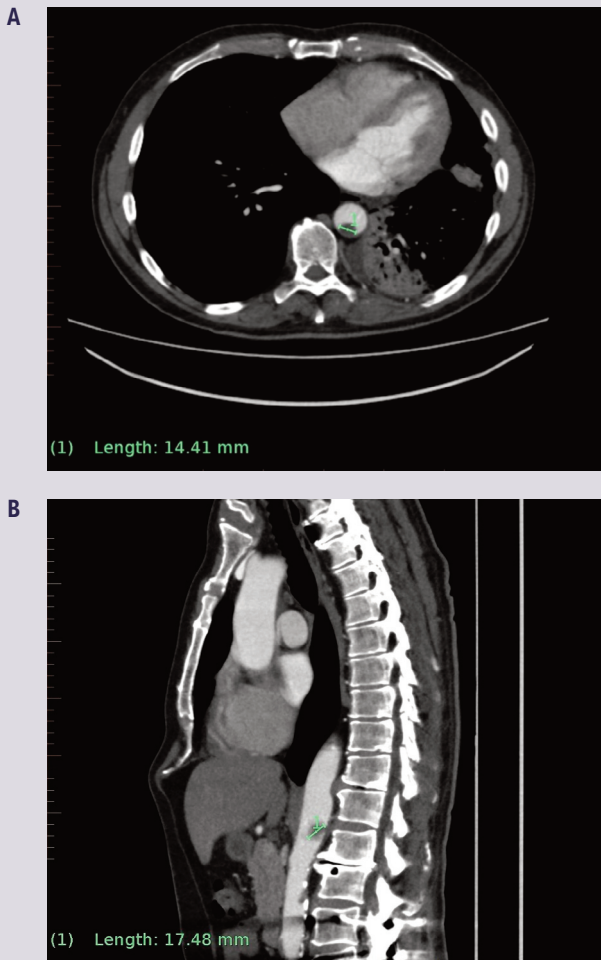
Despite recently being placed on rivaroxaban, a thromboembolic source was suspected. Thrombophilia screening was negative. The patient was reviewed by the vascular team who diagnosed blue toe syndrome, considered that there was no immediate threat to the limbs and suggested iloprost infusion for 5 days in addition to rivaroxaban.

Following a transthoracic echocardiogram which excluded a cardiac embolic source, a CT angiogram demonstrated multiple foci of protuberant soft plaque within the thoracic and abdominal aorta which were considered to be the likely source of distal emboli (Figure 1 & 2).

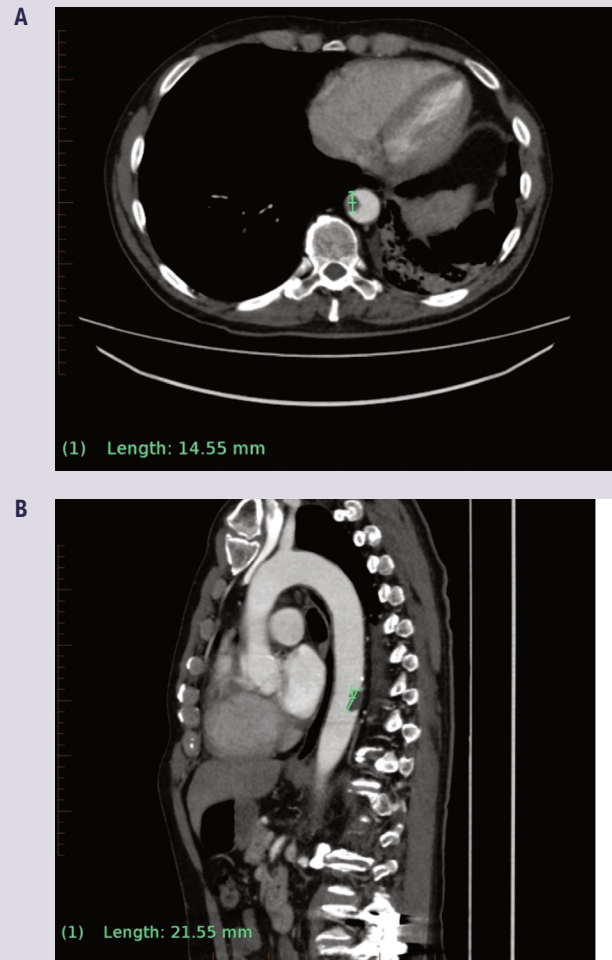
Conservative medical management was considered the most appropriate initial treatment given viable feet, palpable foot pulses, disease burden and difficulty in accessing the lesions. Haematology recommended replacing



**Figure 1** Lesion 1: CT angiogram aorta (A) axial and (B) sagittal views.



**Figure 2** Lesion 2: CT angiogram aorta (A) axial and (B) sagittal views.



rivaroxaban with therapeutic enoxaparin, and starting aspirin and atorvastatin with a view to plaque stabilisation. An outpatient PET/CT scan, given the weak ANA positivity, excluded vasculitis whilst a follow-up CT angiogram at 3 months demonstrated complete thrombus resolution. Due to established atrial fibrillation, enoxaparin was converted to rivaroxaban for ongoing therapeutic anticoagulation. The right 5th toe developed dry gangrene and osteomyelitis and was surgically amputated through the proximal phalanx at six weeks post representation. At one year follow-up the patient was asymptomatic and remained on rivaroxaban, aspirin and statin.

### Discussion

Blue toe syndrome is the acute onset of painful, ischaemic, cyanotic toes in an otherwise well perfused foot, in the absence of trauma, cold injury or generalised cyanosis. Decreased arterial flow due to digital arterial embolism is the most common aetiology. Embolic sources include cardiac (atrial fibrillation, endocarditis, myxoma, post-myocardial infarction mural thrombus) and arterial (aortic and

peripheral atherosclerotic thrombus and aneurysms). Rarer causes include in situ thrombosis (antiphospholipid syndrome, paraneoplastic syndrome), vasoconstrictive (Raynaud's syndrome) and hyperviscosity disorders (cryoglobulinaemia).

Isolated aortic thrombus as a cause as in this case is relatively rare. It is plausible that a pro-coagulable state secondary to pneumonia was a contributing factor. Arterial thrombosis post pneumonia has been attributed to activation of the coagulation cascade, in particular platelet aggregation.<sup>1</sup> *Mycoplasma pneumoniae* specifically is associated with thrombus formation in a number of case reports.<sup>2</sup> The underlying mechanism has yet to be fully elucidated, with some authors suggesting that cytokine release directly affects vascular tissue.<sup>3-5</sup> In several case reports, *Mycoplasma pneumoniae* has been detected in atherosclerotic plaque.<sup>6,7</sup>

Symptomatic treatment (analgesia), risk factor management (smoking cessation, hypertension control, management of hypercholesterolaemia) and medical management (antiplatelets, anticoagulation and vasodilatation) are frequently all that are

**KEY MESSAGES**

- Patients with blue toe syndrome due to a distal embolic event should have the potential source thoroughly investigated.
- Infection can play a role in inducing a hypercoagulable state.
- Symptomatic, medical and risk reduction management are frequently all that is required in the acute situation.

required for blue toe syndrome. Surgical or endovascular management may be required to deal with the embolic source or remove ischaemic tissue.<sup>8,9</sup>

**Conflict of Interest:** None.

**Funding:** None

**Patient consent to publication:** Yes

**Reviewer acknowledgement:** *JVSGBI* thanks the Editorial team for their contribution to the peer review of this work.

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## NEWS

## Updates from the Vascular Societies

JVSGBI is owned by the Vascular Society for Great Britain and Ireland (VSGBI), for all affiliated societies and the wider vascular community. Here's the latest society news.

### British Association of Chartered Physiotherapists in limb Absence Rehabilitation. (BACPAR)

[www.bacpar.org](http://www.bacpar.org)

@BACPAR\_official



The British Association of Chartered Physiotherapists in limb Absence Rehabilitation is celebrating its 30th year in 2023. Related presentations and articles will feature in the BACPAR programme and Autumn Journal.

Dr Miranda Asher continues to represent BACPAR on The Journal of the Vascular Societies Great Britain and Ireland editorial board as part of her role as one of BACPAR's research officers. She is also part of the BACPAR programme planning team for the VS ASM.

The Executive committee met in March 2023 and has subsequently disseminated the objectives for the current membership year including what help is needed from the membership to achieve them. Progress against which will be reported upon at the AGM in November.

Working with another Professional Network of the CSP, BACPAR will aim to deliver a webinar to support the membership in understanding Advanced Clinical Practitioner roles in limb absence rehabilitation in line with Health Education England's framework.

BACPAR's education officers are in discussion with the Vascular Society re mutually supportive education opportunities and there has been a request to BACPAR to discuss complex intervention for lower limb amputations from the VS Amputation special interest group.

Following the last Executive Committee meeting in March where we received presentations from the CSP and Diversity network representatives - BACPAR has surveyed its membership to gain an understanding of whether BACPAR should collect details on their protected characteristics and how we can best support the membership. This will be discussed at our next exec meeting in September.

There are ongoing updates of BACPAR Guidelines. Work is ongoing in updating the Pre and Post op guidelines. Volunteers from the VS and SVN have been sought to support this. The literature search has taken place and the identified papers are currently being reviewed by the update group. A survey of how the current guidelines have been used is underway and one for users is also being promoted.

The long-awaited update of the PPAM Aid Guidelines developed by SPARG are currently with external stakeholders for review (including the VS and SVN). On receipt of this feedback responses will be reviewed alongside others received and the guidelines update will be finalised.

We look forward to meeting up with the Vascular MDT in November. See you in Dublin.

*Louise Tisdale  
BACPAR Chair  
August 2023*

### Society of Vascular Nurses (SVN)

[www.svn.org.uk](http://www.svn.org.uk)

@vascularnurses



Since the last edition as junior doctors and consultants continue to strike, further nursing strikes were ruled unlawful and were therefore cut short. The nursing profession was then asked to re-vote on strike action and failing to exceed more than 50% of votes, the proposed pay rise was accepted. Nurses with extended roles and qualifications are now covering the gaps being left by the junior doctors' strike – it is important this is considered within our vascular and wider teams to ensure individuals are not reaching burnout.

In July this year the vascular nursing community lost a very dedicated and experienced nurse consultant, Wendy Hayes. Wendy was one of the first vascular nurse consultants and a SVN past president. We will be looking to honour her memory in an appropriate way, as we have with Emma Bond.

We were invited again this year to hold a joint session with the Venous Forum in London. This event was well attended by nurses and sparked a challenging debate regarding the extended role of nurses providing venous intervention. A recurring concern is the possibility of reduced training opportunities for vascular trainees. However, this has been unfounded in centres that offer nurse delivered venous intervention as these services seem to offer ample opportunity for trainees to participate and learn in a supportive environment, and indeed feedback from trainees within such centres has been positive.

At our council meeting in May we held the election for our next vice president, the successful candidate for this role was Siobhan Gorst, vascular clinical nurse specialist at Doncaster Vascular Centre. She will step into the role at conference in November.

We have positions available on the council at present and have received one application so far. We are hoping to receive more and would encourage individuals who have often thought about taking on a new challenge and wish to be involved in making positive changes for vascular patients to take a leap of faith and apply.

At conference this year the SVN will be celebrating our 30th anniversary, so please come and join us. The conference programme is almost complete and we had a record number of James Purdie Prize Presentation applications which were all of an excellent standard. This has made selection very difficult and if individuals have not been successful this time please consider re-applying next year.

*Gail Curran*  
SVN President

### The Vascular and Endovascular Research Network (VERN)

[www.vascular-research.net](http://www.vascular-research.net)  
[@VascResearchNet](#)



#### The Vascular and Endovascular Research Network Executive Committee\*

The Vascular and Endovascular Research Network continue contribute and collaborate with the wider vascular community to develop and deliver research to address the current challenges to vascular patients and their healthcare professionals.

VERN have collaborated with the Vascular Society of Great Britain and Ireland to survey current environmentally friendly practices in vascular surgery and explore how we can adapt the way we work to reduce our carbon footprint. The five minute survey is still open to responses and we

urge anyone who has not completed it yet to share their experiences. Our editorial, recently published in the Journal of the Vascular Societies of Great Britain and Ireland, explains why this is such an important topic to address now. We look forward to sharing the results of the survey during the Vice President Symposium at Vascular Societies' Annual Scientific Meeting in Dublin later this year.

The winning project from last year's Dragons' Den 'Prevention of Surgical Site Infection: A Global Pan-Surgical Survey of Practice' has had over 428 responses. The survey is comparing surgeon reported practices with guidelines from the Centre of Disease Control and Prevention, WHO and NICE to identify variation and potential reasons for deviation.

The VERN committee have been busy behind the scenes preparing to launch two new projects for the autumn. Stay tuned for updates on how to get your center involved.

The committee are delighted to announce the return of Dragons Den at this year's Vascular Societies' Annual Scientific Meeting in Dublin. Dragons' Den will be held in the main auditorium on Friday 24th November and shortlisted candidates will be invited to present their project proposal to a panel of vascular experts. The deadline for abstract submission is 15th September 2023.

#### Contact us at:

Twitter / X: [@VascResearchNet](#)

Email: [vern.arterial.disease@gmail.com](mailto:vern.arterial.disease@gmail.com)

#### Link to 'Greener Vascular Surgery Survey':

[https://york.qualtrics.com/jfe/form/SV\\_6QlqazYZJMwwUjc](https://york.qualtrics.com/jfe/form/SV_6QlqazYZJMwwUjc)

#### Link to PRESS:

[https://york.qualtrics.com/jfe/form/SV\\_0D3JS8zfbuoFVf8](https://york.qualtrics.com/jfe/form/SV_0D3JS8zfbuoFVf8)

#### Link to Dragon's Den:

<https://vascular-research.net/dragons-den/>

\*The Vascular and Endovascular Research Network Executive Committee: Louise Hitchman, Panagiota Birmpili, Aminder Singh, Brenig Gwilym, Matthew Machin, Robert Blair, Katherine Hurdall, Nina Al-Saadi, Lauren Shelmerdine, Sandip Nandhra, Ruth Benson, Sarah Onida, Nikesh Dattani, Dave Bosanquet, Joseph Shalhoub, Athanasios Saratzis, Graeme Ambler

### Society for Vascular Technology of Great Britain and Ireland (SVT)

[www.svtgbi.org.uk](http://www.svtgbi.org.uk)

[@svtgbi](#)



The SVT research committee has been working hard in the background since our last update. Our committee has more than doubled with new members bringing fresh ideas with a breadth of skills and knowledge to the team. We have attended SIG meetings, the Vascular Society research committee and trial design group meetings for future studies. Look out for these over the coming months.

Our research series published in the quarterly SVT newsletter, found on the SVT website, has continued to provide updated content on running research across the NHS. We also continue to run the successful monthly webinar series that covers everything from forming a research question through to regulation, approvals and grant applications. The webinar series is currently taking a summer break with the next one scheduled for Wednesday 6th of September, 12-1pm, which will cover training and approvals. We will be joined by guest speakers from the HSST programme and those with expertise in animal-based research. The research series and webinar series is free to SVT members but can also be accessed for a small admin fee for VS, SVN, BACPAR and BMUS members too. Make sure you register via the website to ensure you get the video link and where previous webinar recordings can be found.

We have re-booted the Bubbles section of the SVT newsletter too. For those unfamiliar, Bubbles was a snapshot of interesting papers highlighting limitations/benefits and impact on practice. SVT members will now see bubbles rebranded as SVT Bitesize Research in the summer issue of the newsletter. Each edition will focus on a particular topic with the summer publication being on historic landslide trials in Asymptomatic Carotid Disease and rounds of with the currently recruiting ECST2 and CREST2 trials.



More widely the SVT Executive Committee has run successful workshops on Thoracic Outlet with the next being on Giant Cell Arteritis on the 7th September at the RCPCH in London. Details on this are available on the SVT website where members will notice a refreshed look in parts along with new professional performance guidelines and job profiles. There are also some fantastic new resources on left-handed scanning and repetitive strain injury prevention tips.

The executive has also undertaken a major body of work with the Academy for Healthcare Science (AHCS) on equivalence mapping the SVT's Accredited Vascular Scientist training programme (AVS), as a Recognition of Prior Learning (RPL), with the Scientist Training Programme (STP). The hope is that SVT AVS members will subsequently be able to use their AVS qualification as a substantial portion of evidence for the Good Scientific Practice (GSP) learning outcomes when completing STP equivalence. More details will be made available by the President as this important work progresses through 2023.

If you would like to contact the SVT research committee you can do so via the SVT website or by emailing [research@svtgb.org.uk](mailto:research@svtgb.org.uk)

*Ms Emma Waldegrave*

*President of the SVT GB&I*

*Dr Steven Rogers*

*Vice President Elect & Research Chair  
SVT GB&I*

## The Vascular Society for Great Britain and Ireland

[www.vascularsociety.org.uk](http://www.vascularsociety.org.uk)  
[@VSGBI](https://twitter.com/VSGBI)



### Annual Society Meeting

'Early bird' registrations are open for the ASM 2023 in Dublin (22nd to 24th November). The link for registration is [VSASM 2023 - Vascular Society](#). Registrations prior to 1st October benefit

from the reduced rates so members are encouraged to book now.

### Industrial action

Industrial action by both doctors in training and consultants continues in England. The government has announced that there will be no more talks with junior doctors over pay. Junior doctors will receive pay rises of 6%, along with an additional consolidated £1,250 increase, and hospital consultants will also receive 6%. In Scotland, junior doctors have accepted a 12.4% pay rise for 2023/24. This is in addition to a wage rise of 4.5% for 2022/23. Further talks are planned to "make credible progress" towards full pay restoration to 2008 levels.

### Committee Reports

The National Vascular Registry team have drafted the 2023 "National Vascular Registry State of the Nation" report. A new NVR Board, hosted by RCS England and chaired by Professor Ian Loftus, met for the first time in July. The Audit and Quality Improvement Committee continue to work closely with NHS England (NHSE) in the development of the National Consultant Information Programme (NCIP) and the Medical Device Registry (MDR). NHSE has paused some NCIP streams, the Vascular programme is proceeding as planned.

The Education and Training committee are producing an introduction to vascular surgery for medical students. This is important as both an educational resource and to highlight a career in vascular surgery. A Superficial Venous Disease - Venous workshop, run by the VS and Venous Forum, is taking place in Dublin the Tuesday before the ASM.

[Venous Forum VS Workshop Final.pdf](#).

The research committee, and the Executive, have been frustrated by RCS Eng having not appointed any VS/RCS Eng. Research Fellows for 2023/24. There were two posts advertised with 50:50 funding from the Vascular Society and RCS Eng. The VS will be writing to RCS Eng. formally about the process and the impact on trainees looking for funding to support their research. Elected Council will look to how to use this funding to support research fellows going forward.

The workforce committee is developing a plan to train sufficient trainers for this to be a national programme. The next Conflict Resolution training course run by RCS Ed. is in September.

### Vascular Society and Circulation Foundation Websites

Five online workshops have run over the summer with our website partner (Lightmedia). Attendees have been impressed by the understanding the Lightmedia team have of our requirements. The new design concepts will work well on mobile, tablet and desktop devices.

### All-Party Parliamentary Group on Vascular and Venous Disease

The report 'Empowering Change: A Vision for Self Supported Care' was launched by the APPG on Vascular and Venous Disease in May. This report focusses on the issue of wound care. Mr Andrew Garnham, President Elect, represented the VS at the launch. The report recommends support for the National Wound Care Strategy Programmes lower limb recommendations and education on health care provision in out of hospital settings. Patients need to be supported and empowered to speak openly about the care and treatment they receive, and become equal partners in, rather than simply recipients of care.

[VVAPPG Launches Report in Parliament - Wednesday May 10th — All-Party Parliamentary Group on Vascular and Venous Disease](#)

### Other news

Miss Tatiana Martin has stepped down from her role on elected Council as co-representative for SAS/Trust Employed doctors. Tatiana's enthusiasm for this role will be missed. Both she and Ibrahim Enemosah deserve huge credit for all the work that they have done representing this group of vascular specialists.

*Marcus Brooks*

*Consultant Vascular Surgeon,  
North Bristol NHS Trust*

*Honorary Secretary, Vascular Society*



## Reviewer acknowledgement (Volume 2)

As we come to the end of our second year of publication and our eighth issue of *JVSGBI*, we would like to thank our reviewers for taking the necessary time and effort to review the manuscripts published in Volume 2. We appreciate their valuable comments and suggestions, which have helped us to improve the quality of the articles we have published online at [www.jvsgbi.com](http://www.jvsgbi.com)



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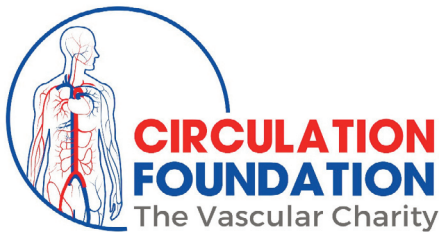
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Anyone interested in joining our team of reviewers, please email your name, place of work and your area of expertise to: [editorialoffice@jvsgbi.com](mailto:editorialoffice@jvsgbi.com)



**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 is 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.



## 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

## 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, RideLondon, Swim Serpentine or the Vitality Big Half



**THE BODY WALK**

#TheBodyWalk is a national campaign in September to raise awareness of vascular disease and for imperative funding. We are hoping everyone can get 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 Circulation Foundation. Sign up at the stand at the Vascular Societies' Annual Scientific Meeting!

To visit the Circulation Foundation Website



SCAN ME

To donate to the Circulation Foundation



SCAN ME

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](mailto:info@circulationfoundation.org.uk). Text **CIRCULATION** to **70560** to donate £10. Texts will cost the donation amount plus one standard network rate message.

[www.circulationfoundation.org.uk](http://www.circulationfoundation.org.uk)

# Annual Specialist Registrar Educational Programme (ASPIRE Digital)



The Annual Specialist Registrar Educational Programme (ASPIRE) supports the education and development of trainee vascular surgeons throughout their eight years of training, which in turn complements the national curriculum. The Vascular Society Education and Training Committee develops, manages and delivers the ASPIRE programme.

The Vascular Society GB&I continue to deliver education via the ASPIRE Digital platform. This has resulted in an overwhelming response, and provided a growing resource of education for vascular surgeons.

**Each of the recorded sessions are included on the Vascular Society members' website. Here's a list of sessions that are readily available for members of the VS website:**

- Management of the Diabetic Foot Attack
- Surgical management of CLTI
- Battle for claudication - exercise vs angioplasty
- Current Management of Acute Aortic Syndrome
- Principles of major lower limb amputation
- How to write a paper
- Strategies for Vascular Trauma
- EVAR planning
- Concept of angiosomes
- Tips and tricks for safe open AAA repair
- Renal Access
- Mesenteric ischaemia
- Carotid Disease Management - Symptomatic and Asymptomatic
- Upper limb ischaemia
- Management of the infected groin
- Managing the rupture AAA - building a team approach
- TOCS
- Why should I consider a career in academic vascular surgery?
- Management of acute / chronic deep venous disease
- Open management of complex AAA
- Options for treating superficial venous reflux
- Endovascular management of complex aortic disease v2
- Iliac intervention - How I do it
- NOTS in vascular surgery
- Radiation Safety in the Hybrid Suite
- New assessments for a new curriculum: The multi-consultant report
- A renal access MDT
- Optimisation of older vascular surgery patients
- Key aspects from the new European Venous Guidelines
- Paediatric Vascular Surgery
- Aortic MDT
- Through – knee amputation
- Thoracic Aortic Disease
- Everything you need to know about to manage AAA except how to fix them
- ASPIRE Digital Fellowships - How to get one, what to get out of it
- Management of the left subclavian artery in complex aortic interventions
- The foot in diabetic foot disease - biomechanics and operative approaches to manage clinical problems
- New Developments in Vascular Access
- Thoracic Aortic Disease
- Through Knee Amputation

## ALL YOU NEED TO KNOW

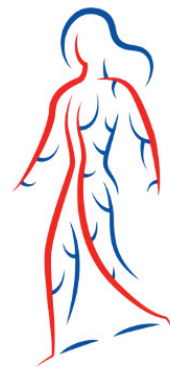
To access the above resources, visit the Education section on the Vascular Society members' website [www.vascularsociety.org.uk](http://www.vascularsociety.org.uk)





1992-2022

**CIRCULATION  
FOUNDATION**  
The Vascular Charity  
**30<sup>th</sup> Anniversary**



**THE  
BODY  
WALK**

Raising **awareness** for **vascular disease** by walking the **circulatory system** of the body

**JOIN US** this **September 2023** for  
**Vascular Awareness Month**

**Aiming to collectively achieve the 60,000 miles of the  
whole circulatory system of the body**

**Reasons we would like you to fundraise are:**

- To support vital research in to vascular disease
- To support individuals living with vascular disease
- To raise the awareness of the impact vascular disease has

We would love to see your walking, swimming, running, riding pictures on social media, and share them across our platforms.

Please tag in our social media accounts across Facebook, Twitter and Instagram and use the hashtag for this event: #TheBodyWalk

Thanks to everyone supporting the Circulation Foundation



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**www.circulationfoundation.org.uk**



# Journal of VASCULAR SOCIETIES

## GREAT BRITAIN & IRELAND

We are a peer-reviewed, open-access journal and we encourage new, relevant and interesting content to support the treatment and care of vascular patients

The *JVSGBI* is published quarterly online at

[www.jvsgbi.com](http://www.jvsgbi.com)

in February, May, August and November

## CALL FOR PAPERS

We are inviting contributions of the following article types:

**EDITORIALS** Original articles that present an important issue and conclusions that reach an advance in understanding

**ORIGINAL RESEARCH** Written by the researchers who actually undertook the study. This will include the hypothesis and purpose of the study, research method and results.

**CLINICAL TRIALS** Reports on Clinical Trials including Prospective Clinical Trials

**REVIEWS** Presents the current state of understanding on a topic.

**CLINICAL CASE STUDY** Provide an interesting insight and learning into clinical and management issues

**DEBATE** Present an argument or discussion on a relevant topic, presenting a well-argued viewpoint and represents the “pro” and “con” format

**Q&A** Submit your questions and a member of the Editorial Board will be asked to provide a solution or explanation into the question raised

SUBMIT YOUR  
ARTICLE IN

**SEPTEMBER**

AND YOUR WORK COULD  
BE INCLUDED IN THE  
NOVEMBER 2023 ISSUE  
READY FOR ASM, DUBLIN

Visit our website for  
full author instructions

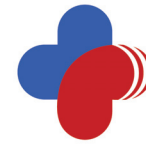
Circulation to more than 1500 healthcare professionals taking care  
of vascular patients throughout the UK

THE JVSGBI ALSO PUBLISH NEWS FROM AND ACTIVITIES FOR ITS AFFILIATED SOCIETIES



Submit your manuscripts and any enquires to: [editorialoffice@jvsgbi.com](mailto:editorialoffice@jvsgbi.com)





THE SOCIETY FOR  
VASCULAR TECHNOLOGY OF  
GREAT BRITAIN AND IRELAND

# The Vascular Societies' Annual Scientific Meeting 2023

In conjunction with the Vascular Society of Great Britain and Ireland, the British Association of Chartered Physiotherapists in limb Absence Rehabilitation, the Society of Vascular Nurses and the Society for Vascular Technology of Great Britain and Ireland

**22nd-24th November 2023**

**The Convention Centre  
Dublin**

**REGISTRATION NOW OPEN**

[https://www.vascularsociety.org.uk/asm/vsasm\\_2023.aspx](https://www.vascularsociety.org.uk/asm/vsasm_2023.aspx)

**Register before 1st October 2023 for the reduced member's rate**

**For the latest programme visit:**

[https://www.vascularsociety.org.uk/programme\\_2023.aspx](https://www.vascularsociety.org.uk/programme_2023.aspx)