# Journal of VASCULAR SOCIETIES

### **GREAT BRITAIN & IRELAND**

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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.

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- The VSGBI publishes virtual educational resources which are available to members.
- The VSGBI publishes a quarterly journal, the *Journal of the Vascular Societies Great Britain and Ireland*, which is available to its members.
- The VSGBI publishes policy documents and quality improvement resources which are available on its website.
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- The VSGBI together with HQIP and the clinical effectiveness unit (CEU) at the RCS England maintains the National Vascular Registry. NVR is the principal outcomes registry for the UK and for the AAA Screening Programmes (England, Wales, Scotland and Northern Ireland).
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# Journal of VASCULAR SOCIETIES

## **GREAT BRITAIN & IRELAND**

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#### **Editor's foreword**

Welcome to the November 2025 edition of the JVSGBI.

We have two editorials in this issue, the first editorial is the second in a series by Long and co-authors outlining the principles of, and evidence for, mentorship. This editorial details mentorship in practice - how to build a successful mentorship program and relationship.

The second editorial by Ninkovic-Hall *et al* discusses why the UK is yet to embrace robotic assisted vascular surgery and proposes a structured and evidence-led way forward to correct this and facilitate this exciting evolution.

We include three protocols: The first - *Surgical Site Infections in Major Lower Limb*Amputation – *Transmetatarsal Extension (SIMBA-T)* an international multicentre audit by

Alawattegama on behalf of the SIMBA-T Study Group. The second - *Protocol for the Physical*Activity after Cardiovascular Screening (PACS) study in women aged 60–69 years; a

prospective observational cohort study by Messeder *et al.* The third is a systematic review

protocol of *The use of non-steroidal anti-inflammatory drugs for the prevention and reduction*of pain following superficial venous incompetence treatment by Vedanayagam *et al.* 

The three case reports we have chosen for this issue we hope you will find of interest, two of which cover rare vascular complications and the third presents the first confirmed case of a mycotic aortic aneurysm due to *Dermabacter Vaginalis*.

JVSGBI are happy to publish the prize wining abstracts from the Vascular Society Annual Scientific Meeting in Brighton last year and the top scoring abstracts from the VASGBI Annual Scientific Meeting in London this year. Also the two winning entries from this year's Rouleaux Club Essay Competition.

Finally the issue finishes with news from some of the Vascular Societies.

We are excited to have reached our 5th year of publication, to ensure the *JVSGBI* continues to thrive and grow please submit your papers for publication via email to: editorialoffice@jvsgbi.com.



lan Chetter
Editor in Chief JVSGBI
Vascular Society GBI President





**FDITORIAL** 

# Mentorship in practice: what to expect and how to build a successful mentoring relationship

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#### Introduction

Following the first editorial in the August issue of *JVSGBI*, which outlined the value of structured mentorship in vascular surgery, this second editorial highlights what participants can expect from a mentorship programme and the core principles of starting an effective mentoring relationship, using the VSGBI mentorship programme as an example.

#### Mentorship programme structure

The design of the mentorship programme should balance structure with flexibility, providing a supportive framework that guides mentoring relationships without being prescriptive. The aim is to allow mentor and mentee to develop a partnership that reflects their individual needs, goals and aspirations.

Matching and Development Day: Mentors and mentees should be matched based on interests and goals. An in-person Development Day led by mentorship experts facilitates description of the process outline and introduces reflective practice, communication skills, boundaries and core mentoring principles.

Ongoing meetings and support: Pairs are encouraged to commit a minimum of 6 hours over 12 months, with additional informal contact as needed. VSGBI will also conduct checkpoints throughout to help maintain momentum.

Programme evaluation: Feedback is essential to identify and overcome barriers. Evaluation is planned for the VSGBI mentorship programme at three key stages: a post-matching check-in to confirm initial meetings have taken place and clarify any further support requirements; a midpoint survey at 5–6 months to assess

progress and impact; and a final survey at 12 months on completion to evaluate overall value, outcomes and impact, to help inform next steps.

#### Establishing trust and building rapport

Trust is the foundation of any mentoring relationship. Early conversations should focus on getting to know one another, exploring backgrounds and motivations and agreeing communication preferences and boundaries. The NIHR Mentorship Scheme<sup>2</sup> highlights that early rapport is critical for open, honest and constructive dialogue.

The Development Day plays a key role in helping pairs establish rapport. Mentees are then encouraged to take ownership by arranging the first meeting. Many pairs benefit from creating a short mentoring agreement covering expectations, confidentiality, meeting format and practical arrangements. Taking brief notes after each session helps track learning and progress.

#### Setting direction and agreeing goals

Once rapport and trust are established, mentoring pairs should focus on setting a clear direction for their relationship. Early conversations provide an opportunity to explore the mentee's motivations, whether developing leadership skills, navigating complex clinical decisions, building confidence, supporting wellbeing or planning career progression. Clarifying these aims helps ensure both parties are aligned and that the mentor's experience can be applied most effectively.

From these discussions, the pair can agree on a small number of realistic goals to guide the first 6–12 months. These goals provide focus for future meetings and a framework to track

Key words: early-career consultants, mentorship, professional development

Action	Purpose/guidance	
Preparation	Reviewing preparatory guidance before starting the relationship. This ensures both mentor and mentee begin with a shared understanding of expectations and core principles.	
Mentee-led initiation	The mentee makes first contact and arranges the initial meeting. This reinforces mentee ownership and sets the tone for an active engaged partnership.	
Focus on rapport	Using the first one or two meetings to explore backgrounds, experiences and motivations. This builds trust and establishes the relational foundation needed for open constructive dialogue.	
Discuss expectations	Clarifying confidentiality, boundaries, communication preferences, meeting format and frequency. This creates psychological safety and supports productive well-structured conversations.	
Mentoring agreement	Creating a brief agreement that outlines expectations, responsibilities and early objectives. This provides clarity, shared understanding and confidence for both participants.	
Capturing progress	Taking brief notes after each session to record key themes and learning points. This supports continuity, reflection and tracking of development over time.	

progress. Importantly, goals are not static and revisiting them periodically allows the relationship to adapt to the mentee's evolving needs and priorities.

Reflection is central throughout the process. Considering what is working well, identifying challenges and defining what success looks like helps both mentor and mentee shape a purposeful, dynamic and impactful partnership.

#### Launching a meaningful mentoring journey

Effective mentorship begins with trust, rapport and clear goals. By investing in the early stages of the relationship and engaging fully in the process, mentoring pairs can create productive goal-focused partnerships.

Action	Purpose/guidance
Clarify motivations	Discussing why the mentee has sought mentoring and what they hope to achieve. This ensures early alignment around purpose, challenges and developmental priorities.
Set clear goals	Agreeing on 2–4 specific realistic goals for the first 6–12 months. This provides focus, direction and a structured basis for reviewing progress.
Align expectations	Checking that the mentee's goals match the mentor's experience and capacity. This supports a well-matched partnership and ensures meaningful, relevant guidance.
Use reflective questions	Incorporating prompts such as "What would success look like?" or "What changes do you hope to see?" This deepens reflection and helps refine priorities and intentions.
Review regularly	Revisiting goals every few meetings and adapting them as needs evolve. This keeps the relationship relevant, responsive and aligned with the mentee's development.

As the first VSGBI mentorship cohort begins their mentoring journey, the programme represents an investment in strong productive partnerships that offer both guidance and professional growth. We look forward to seeing how these mentor–mentee pairs develop and make the most of the opportunities ahead.

Conflict of Interest: None.

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#### References

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**FDITORIAL** 

# Robotic assisted vascular surgery adoption in the UK: future-proofing with prudence

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#### Introduction

Robotic assisted surgery is no longer a novel frontier, but the operating reality for a growing proportion of surgical disciplines. Robotic systems filter out natural hand tremor and scales movement, allowing enhanced accuracy. A three-dimensional (3D) high-definition camera gives a magnified view of deep or narrow anatomical spaces that are difficult to reach in open surgery. It therefore offers greater precision, ergonomics and minimally invasive access to reduce patient trauma, recovery time and surgeon fatigue, and is supported by NHS England and Getting It Right First Time (GIRFT).<sup>1</sup>

Yet within vascular surgery in the UK, clinical and educational adoption remains non-existent, with no UK centres offering robotic open vascular surgery and only Imperial College Healthcare NHS Trust offering clinical experience with robotic endovascular procedures.<sup>2</sup> While most surgical fields have integrated robotics into mainstream NHS practice, vascular surgery stands alone at a crossroads.

Is this current position in the field of robotics one of prudence – or paralysis? Why has UK vascular surgery not embraced robotics or considered how it could be utilised in vascular practice?

#### What is robotic assisted vascular surgery?

Robotic assisted vascular surgery (RAVS) uses platforms such as the da Vinci system to perform open vascular procedures through minimally invasive console control. It differs from robotic endovascular systems (Magellan (Hansen Medical, Mountain View, California, USA), CorPath GRX (Corindus Vascular Robotics/Siemens Healthineers, Waltham,

Massachusetts, USA/Erlangen, Germany)) that steer intraluminal devices to reduce operator radiation exposure and improve precision.<sup>3</sup>

In RAVS, the surgeon may perform standard open techniques robotically, including dissection, vessel control and suturing, but with the advantages of enhanced dexterity, visualisation and precision enabled by wristed instruments, tremor filtration and 3D high-definition optics. This has the advantage of allowing access to anatomically challenging regions with minimal tissue disruption.<sup>4</sup>

Crucially, RAVS is not confined to replicating traditional open procedures. One of its most compelling applications lies in hybrid procedures, where robotic exposure, dissection or conduit formation is combined with endovascular intervention in a single operative setting.

#### The surgical innovation divide

Robotic platforms such as the da Vinci Xi (Intuitive Surgical, Sunnyvale, California, USA), Versius (CMR Surgical, Cambridge, UK) and Hugo (Medtronic, Dublin, Ireland) systems are now standard in operating theatres across the UK. In urology, colorectal and gynaecology, robotics has moved from innovation to infrastructure, underpinned by national simulation hubs and structured training pathways. NHS England's 2025 GIRFT report advocates shared access and national pathways.<sup>1</sup>

Vascular surgery, however, remains largely absent from this momentum. There are currently no defined robotic competencies in the Joint Committee on Surgical Training (JCST) vascular curriculum, and no formal vascular-specific robotic training centres within the UK. A recent Royal College of Surgeons (RCS) England

Key words: robotic assisted vascular surgery (RAVS), surgical innovation, future-proofing

Multi-Specialty Robotic Surgery Training Roundtable, established to shape national robotic training standards, has further highlighted this vacuum.

This hesitancy is particularly striking given that robotic procedures involving major blood vessels are already being performed in the UK and internationally across other surgical disciplines. These include robotic coronary artery bypass grafting, nephrectomy with inferior vena cava tumour thrombectomy, renal and iliac vein reconstructions, renal transplants, fobotic first rib resections and now also cardiac transplants. These operations demonstrate that robotic handling of arteries and veins is not only theoretically feasible but is already being done – just not by vascular surgeons. Without a clear strategic plan, vascular surgery within the UK is being left behind in what is rapidly becoming the dominant paradigm for minimally invasive high-precision surgery.

#### From feasibility to functionality: what the evidence shows

Over the past decade, international experience has moved beyond isolated case reports to a consistent series to demonstrate that robotic assistance can be applied safely and effectively to aorto-iliac reconstruction, ilio-femoral and aorto-femoral bypass, type 2 endoleak branch ligation, renal/visceral artery revascularisation and major venous reconstruction including renal vein transposition and inferior vena cava tumour thrombectomy – with acceptable perioperative outcomes when delivered by experienced teams. <sup>6–10</sup>

The largest single-centre RAVS experience to date, from Prague, reports 668 RAVS operations for occlusive and aneurysmal disease and post-endovascular aneurysm repair endoleak, of which 96% were completed robotically with 3.6% conversions and a 0.45% 30-day mortality. These data illustrate the feasibility, reproducibility and safety of RAVS once the learning curve is achieved. Technical advancements such as sutureless anastomotic adjuncts and single-port architectures further improve access and ergonomics and are likely to lower barriers to wider adoption. 10,12

Despite this progress, widespread uptake remains low. Systematic reviews estimate only ~2000–5000 RAVS procedures have been performed worldwide since inception, 10,13 a vanishingly small fraction of the >14 million da Vinci procedures performed globally by >76,000 surgeons.4 Much of the vessel-intense robotic work is currently undertaken by cardiac, urological or transplant teams, highlighting a gap in infrastructure and pathways – platform access, training routes, proctoring and governance – within the vascular specialty, rather than any limitation in surgeon skill or technology.6

The experiences gleaned from these approaches in other specialities may be harnessed and adapted for specific vascular procedures. Port strategies, workflow, credentialling and hybrid lists design from cardiac, urology and transplant programmes are readily transferable to vascular surgery and offer a pragmatic starting point for UK pilot work.<sup>5,6</sup>

## From consensus to capability: a targeted UK implementation plan

Integration of RAVS into UK practice requires a coordinated national strategy. Key steps include development of pilot centres, defined training and credentialing pathways, strict governance and evaluation, and incremental scaling tied to performance outcomes. Above all, the goal is not one of replication of open surgery but reimagining precision, access and tissue handling in anatomically complex or high-risk cases where robotics can genuinely add value.

This five-phase pathway mirrors established UK robotic rollout in other specialities and aligns with the Idea, Development, Exploration, Assessment, Long-term study (IDEAL) framework for surgical innovation, the RCS England RAS Guide and the NHS England/GIRFT implementation plan – each emphasising proctoring, simulation, staged case complexity and prospective registry evaluation.<sup>1,14,15</sup>

- 1. Pilot centre: Early adoption should be limited to a small number of large high-volume centres, each nominating 2–3 early adopters and committing to a staged five-year rollout.
- Credentialing: This approach should translate the UK panspecialty Delphi consensus on training and credentialing – covering simulation, modular skills, objective metrics – into vascular practice. This embeds the accepted minimum standards for robotic proficiency and aligns with General Medicines Council (GMC) credentialling principles and NHS England/GIRFT policy on cross-specialty collaboration and evaluation. 1,14,16
- Governance: This must be endorsed from case one; CEcompliant indications, novel-tech consent, multidisciplinary
  team case selection and a rehearsed bailout protocol (including
  the following: pre-marked conversion incision, open instruments
  in theatre, endovascular balloon occlusion available, rapid
  undock drill).
- Evaluation: All cases should enter a prospective registry with predefined Key Performance Indicators such as conversion <10%, Clavien–Dindo III–V <5%, length of stay reduction versus open, downward trends in console time and routine reporting to GIRFT.
- Scaling: Progress to ring-fenced sessions, business case growth and ultimately a curriculum-defined competency and fellowship pathway should be contingent on meeting safety and value thresholds

Early adoption should focus on hybrid 'starter' cases – for example, robotic-assisted first rib resections and aorto-iliac exposure/ anastomosis – delivered on shared da Vinci sessions rather than dedicated lists, while guaranteeing simulator access, including out-of-hours, for trainees. Cases should be proctored, including cross-specialty proctors, and should explicitly support reverse mentorship; this sits alongside a metrics-based credentialling pathway (simulation benchmarks, mentored cases,

video/console-metric review) before independent practice. 6,14,16 In robotics, seniority in service does not necessarily equate to seniority in skill. Many UK vascular trainees already have console exposure via thoracic/ urology/colorectal rotations; formal reverse mentorship should be normalised so trainees support consultants during early adoption. This must sit within a credentialled pathway – simulation benchmarks, mentored/live cases and objective metrics – aligned to UK guidance and pan-specialty consensus. 14,16,17

#### Why has vascular hesitated?

Reluctance within UK vascular surgery reflects structural and practical constraints rather than potential ability. Since separating from general surgery in 2012, the specialty lacked the early robotic exposure available to peers in other training pathways. This has denied consultants the progression from non-arterial robotic work (soft tissue/retroperitoneal/first rib/lymphatic) to robotic assisted arterial reconstruction. Added barriers include the absence of defined robotic competencies, uncertain trust-level credentialling/medico-legal pathways, and limited access to robotic platforms already saturated by other services. 1.14

Cost and access remain a critical constraint. NHS freedom of information (FOI) shows annual maintenance contracts in the region of £110k–£170k per robot, with per-procedure costs rising steeply at low volume. Centres performing fewer than 200 cases/year typically exceed £3000 per case (before staff/theatre overheads), making business cases hard to justify without shared platforms and cross-specialty throughput. 18-20

A real clinical anxiety among robotically assisted surgeons is the 'red-out' – referring to uncontrolled bleeding in a closed insufflated field – but this is protocol-manageable with rehearsed rapid undocking, a pre-marked bailout incision, open vascular instruments on the table, pre-planned proximal/distal control (including endovascular balloon occlusion) and explicit conversion thresholds. Centres crossing the learning curve report high completion, low conversion and low 30-day mortality. 6.13

Finally, while the technology is mainstream in the NHS and NICE has now listed da Vinci X/Xi/SP, Hugo, Senhance (Asensus Surgical, Durham, North Carolina, USA) and Versius for use during evidence generation, vascular-led evidence remains sparse. Demonstrating tangible patient benefits including reduced blood loss, reduced length of stay and improved recovery through UK registry outcomes is essential.<sup>21</sup>

#### Conclusion

RAVS complements rather than replaces traditional open or endovascular practice. It is an opportunity to expand and fill the procedural gaps between them. It offers an opportunity to enhance precision and expand treatment options for complex anatomy. The prudent path forward is structured, evidence-led adoption – starting small, evaluating rigorously and scaling responsibly. Our specialty has an exciting opportunity to think

#### **KEY MESSAGES**

- Vascular surgery in the UK lags other specialties in robotics due to service-level constraints (access, pathways, credentialling, theatre allocation), not surgeon skill.
- Adoption should be targeted, not universal, limited to high-volume centres with 2–3 early adopters, shared platform access and staged rollout over ~5 years.
- Safety in the early phase relies on cross-specialty proctoring, reverse mentorship, simulation and a rehearsed bailout protocol.
- The aim is not to replicate open surgery one-to-one but to re-imagine precision, access and tissue handling in anatomically challenging/high-risk cases – start small, evaluate rigorously, scale responsibly.

differently, keep an open mind and begin preparing ourselves for the next stage in the evolution of vascular surgery.

Conflict of Interest: None.

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**PROTOCOL** 

## Surgical Site Infections in Major Lower Limb Amputation – Transmetatarsal Extension (SIMBA-T): an international multicentre audit: study protocol

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#### Plain English Summary

Why we are undertaking this research: Nearly 2,000 people needed an amputation of their foot in England in 2022–23. This meant that they lost all the toes of that foot, but they will still be able to walk. This is most likely due to either poorly-controlled diabetes or blocked or very narrow arteries in their legs. Following amputation, infection in the wound is common. Infection may be treated with simple antibiotics, require more surgery or, at their most severe, result in sepsis, loss of a leg or even death. Unfortunately, we do not really know how common infection after foot amputation is, what makes people at higher risk of getting infection and the result of having infection in the wound. The main concern with infection after a foot amputation is that it might require further amputation higher up the leg (usually below the knee joint) to treat the infection. This means people will stay in hospital for longer and may have to walk with an artificial leg. The purpose of this work is to better understand the causes and consequences of infection in foot amputations so that we can prevent further amputations, shorten hospital stays and ultimately improve patients' quality of life.

What we aim to do: To find out more about wound infection rates and how to reduce them, we have designed a large study involving multiple centres across the UK and across the world. This will be called the Surgical Site Infections in Major Lower Limb Amputation – Transmetatarsal Extension (SIMBA-T) audit. We will record data for as many patients as possible having foot amputation surgery over a 6-month period from March to September 2025. Normal care of patients will not be affected by taking part in the SIMBA-T project as we are simply recording what normally happens to patients before, during and after their foot amputation surgery.

#### **Abstract**

Introduction: A total of 1,872 transmetatarsal amputations (TMAs) were performed in England in 2022–23. TMA allows management of serious infection or removal of gangrenous digits in patients suffering from chronic limb threatening ischaemia or diabetes-related foot complications. Following amputation, surgical site infection (SSI) is common. Unfortunately, the incidence, predisposing factors and outcomes for SSIs in patients who have undergone TMA is not clearly defined, with pooled SSI rates ranging from 16.7% to 24.0%. An SSI following a TMA may lead to ongoing difficulties leading to a proximal revision or a major lower limb amputation. SSIs are often associated with prolonged hospital stay with increased morbidity, mortality and healthcare costs.

Methods: To address the current lack of evidence and understanding of the current management and outcomes in patients undergoing TMA, we proposed an international, multicentre, prospective collaborative audit using the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) Lower Limb Amputation Report as a framework, in consecutive patients undergoing TMA over a 6-month period. Our objectives include the incidence and risk factors of SSI and wound breakdown, the surgical revision rate at 30 days and sequelae of complications associated with SSI, with the intention of capturing 30-day and 1-year post-TMA outcomes.

**Discussion:** This prospective audit will document the rate of SSI following TMA in patients from multiple centres across the world. It will be the first of its kind to do so in a large population, with current studies limited to single centres and relatively low volumes of patients. The study

will build on the global links built as part of the original SIMBA study, delivering high quality trainee-led research to improve patient outcomes and awareness for this challenging population.

Key words: transmetatarsal amputation, diabetes, surgical site infection, chronic limb threatening ischaemia

#### Introduction

#### Background and rationale

In patients with chronic limb threatening ischaemia (CLTI) or diabetes related foot complications, transmetatarsal amputation (TMA) is often required to treat serious infection or remove gangrenous digits to promote a healing wound. This is often accompanied by an attempt at revascularisation of the limb. TMA preserves limb length as well as a functioning ankle joint, allowing patients to walk unaided with lower energy expenditure (compared with a major lower limb amputation (MLLA) with a prosthesis). 1–3

Following amputation of a limb, surgical site infection (SSI) is common. We have recently reported the pooled incidence of SSI following MLLA, which is estimated at 7.2%.<sup>4</sup> The Vascular Society of Great Britain and Ireland (VSGBI)<sup>5</sup> and the National Institute for Health and Care Excellence (NICE)<sup>6</sup> have published guidelines with the aim of improving outcomes following MLLA surgery. Unfortunately, the incidence, predisposing factors and outcomes for SSIs in patients who have undergone TMA is less clear. SSIs following TMA may lead to revision to a more proximal MLLA, which is associated with prolonged hospital stay and increased morbidity and mortality and healthcare costs.<sup>1,2,7</sup>

Although less common than MLLA, there were 1,872 TMAs performed in England in 2022–23.8 Despite this, the reporting of outcomes following TMA are poor. Members of our study group recently performed a systematic review and determined that the pooled SSI rate following TMA was 24.0% using data from one randomised controlled trial and four observational studies.9 However, this was only based on 233 patients with heterogeneous reporting methods and a high risk of bias. Another systematic review, which focused on healing rates and outcomes following closed TMAs, reported a random effects pooled postoperative infection rate of 16.7% (range 3.0–30.7%) and a random effects pooled dehiscence rate of 28.8%.<sup>10</sup> In the UK, the National Vascular Registry (NVR)<sup>11</sup> records the number of TMAs performed nationally, but the outcomes are not routinely reported due to low case ascertainment compared with Hospital Episode Statistics data. For example, there was an average of 273 single digit amputations and TMAs (grouped together) in 2022–23 recorded on the NVR. Although the revision rate to higher levels of amputation should be recorded by proxy, SSI is not a well recorded outcome.

To address the deficiencies in reporting and outcomes following MLLA, the Surgical Site Infections in Major Lower Limb Amputation (SIMBA) audit<sup>12</sup> has recently completed data collection, providing outcome data on approximately 1,300 patients who had MLLA (not

yet published). Building on SIMBA, we aim to use the same platform to deliver the Surgical Site Infections in Major Lower Limb Amputation – Transmetatarsal Extension (SIMBA-T) audit, which will address the current lack of evidence, and understand the current management and outcomes in patients undergoing TMA.

#### Objectives

- To capture centre-specific data regarding pathways and policies for patients undergoing TMA
- To calculate the 30-day incidence of SSI post-TMA
- To calculate the 30-day incidence of wound breakdown post-TMA
- To identify the cause of wound breakdown post-TMA (eg, ischaemia or haematoma)
- To calculate the 30-day incidence of revision surgery post-TMA (to the same or higher level)
- To identify the patient and surgical risk factors associated with post-TMA SSI using the NCEPOD Lower Limb Amputation Report as a framework<sup>13</sup>
- To calculate the incidence of complications related to SSI including sepsis, acute kidney infection, mortality, increased length of stay or admission to critical care
- To capture 1-year outcome data for these patients (mortality, amputation revision, ambulation status) and assess the impact of SSI on these outcomes.

#### Project design

- SIMBA-T is an international multicentre audit of current practice disseminated via the Vascular and Endovascular Research Network (VERN).
- SIMBA-T is observational, and only routinely collected data will be used.

#### Methods

#### Participants, interventions and outcomes

#### Project setting

SIMBA-T is an international multicentre audit of practice disseminated via the Vascular and Endovascular Research Network (VERN: https://vascular-research.net). VERN is a trainee-led national research collaborative that is run by, and engages with, research-active vascular trainees and allied health professionals, and has expertise in running national and international audits of practice.

Hospitals providing emergency and/or elective TMA surgery in the UK and abroad will be recruited via VERN. TMA surgery can be performed within a vascular surgery department, orthopaedic department or other appropriate department. Based on current interest, at least 50 units are expected to be enrolled. Whilst the best practice policies are based on UK documents, SIMBA-T will also capture how non-UK centres practice aligns to these guidelines.

#### Eligibility criteria

The audit will capture data on consecutive patients undergoing TMA. Any patients undergoing TMA due to complications of peripheral arterial disease, diabetes mellitus, trauma and other reasons are eligible for enrolment if they meet the specified criteria below. Eligible patients will be identified by screening data available to the clinical team; patients will not be approached/contacted during any part of SIMBA-T, and there should be no change to any patient care during the course of the audit. In patients undergoing TMA of both limbs during the duration of SIMBA-T data capture, so long as the patient is eligible, both sides will be included (as separate case records). Inclusion criteria:

- Patients >18 years of age
- Patients undergoing transmetatarsal forefoot amputation (including guillotine TMA) with the intention of primary/delayed primary closure, partial closure (including leaving drain in situ) or secondary closure (at a later date or healing by secondary intention).
- Emergency or elective TMA

#### Interventions

The study is observational and low risk. There are no interventions and only routinely collected data will be used. All patients will receive standard routine care, and what this entails will be collected as part of the audit.

#### **Outcomes**

Data from consecutive patients undergoing TMA meeting the eligibility criteria will be collected prospectively. Data will be captured for each participant until 30 days following surgery, as well as 1-year data outcomes.

Outcomes are a modified version of the short-term core outcome set for MLLA, including problems with amputation healing and infection, mortality, requirement for re-admission, re-operation or further specialist treatment for complications. <sup>14</sup> The 30-day postoperative morbidity grade will be recorded as per the Clavien–Dindo scale. <sup>15</sup>

Outcomes will include compliance with NICE guidelines on SSI prevention. The Centres for Disease Control and Prevention (CDC) definition will be used to identify SSI within 30 days of TMA. However, if a bone/deep tissue sample taken intraoperatively during the TMA is positive on culture, this will be considered an incompletely debrided infection rather than a SSI. SSI will be limited

to those apparent to the treating vascular clinicians within 30 days of surgery. It is recognised that this audit may not capture milder infections treated in the community; this will be accounted for in the analysis and dissemination.

Outcomes that will be captured for individual patients are shown in Appendix 1 online at www.jvsgbi.com. Preoperative variables will encompass modifiable and non-modifiable risk factors related to the development of SSI postoperatively, including age, sex, body mass index, preoperative haemoglobin, albumin and glomerular filtration rate, presence of diabetes, smoking status, comorbidities, preoperative perfusion status of the limb, existence of open wound(s), concurrent infection and history of prior vascular or endovascular intervention on the ipsilateral limb. Perioperative data will include severity of limb threat using the Wlfl (Wound, Ischaemia, foot Infection) classification, grade of operating surgeon and anaesthetist, operative time, estimated blood loss, closure technique, drain placement and type of dressings. Postoperative outcomes include length of hospital stay, postoperative haemoglobin, incidence and management of postoperative SSI and wound breakdown within 30 days, and subsequent outcomes of patients diagnosed with SSI including development of sepsis, critical care admission, readmission secondary to SSI within 30 days, additional interventions needed and mortality rates.

#### Participant timeline

Centres will be permitted to open for data collection once all approvals are in place. Centres may open and close at any point within the time window for recruitment as prescribed above. It will obviously be the intention for centres to be open for the maximum time possible to maximise recruitment. Key dates are presented in Table 1.

Table 1 Key dates for SIMBA-T audit.	
SIMBA-T launch; new site enrolment	1 March 2025
Close of SIMBA-T to new site enrolment	1 June 2025
Return of outcome data for recruited patients so far	1 July 2025
End of new patient identification	1 Sept 2025
End of 30-day data capture	1 Oct 2025
End of 30-day data validation	1 Nov 2025
End of 1-year outcome data capture	1 Sept 2026
End of 1-year outcome data validation	1 Oct 2026

#### Sample size

Sample size will depend on enrolled unit activity and case volume.

#### Recruitment

SIMBA-T is required to be registered with each participating centre prospectively, prior to data collection. This is typically with the audit

department or the Research and Development department. Participating centres outside the UK must comply with local regulations prior to commencement. The audit is open to all centres that undertake elective and/or emergency TMA. In the case of UK vascular units, often they comprise of a Hub and Spoke type model. A registered Hub site may be able to undertake data collection for the Spoke sites without registering the Spoke site separately.

Each centre will require the support of a named supervising consultant/attending (or equivalent), who will act as guarantor of all activity undertaken at that centre, and a data collection team. The local audit team will be responsible for data collection and data validation. This team will comprise a maximum of a supervising consultant/attending and a further four individuals and can include medical trainees or allied healthcare professionals.

On enrolment to SIMBA-T, each centre will be asked to complete a baseline unit survey. This will collect data on individual centres' clinical care pathways and policies surrounding TMA.

Local Information Technology (IT) systems, theatre lists and inpatient lists will be used to screen for eligible patients.

#### Data collection, management and analysis

#### Data collection methods

Key demographic data, baseline variables and intraoperative data should be collected as early as possible following TMA surgery, ideally at the completion of the operation. Once eligibility is confirmed, the baseline Data Collection Tool (DCT) should be completed. When the data are uploaded onto the SIMBA-T Research Electronic Data Capture (REDCap) database, a unique REDCap identifier will be allocated to the patient. This unique study number will be used in all correspondence between the SIMBA-T study office and the site. Linkage between the REDCap ID and patient should be maintained securely at the hospital site.

Postoperative sequelae data points will be collected up until 30 days following surgery. In the case of SSI development, further details will be required regarding extent of infection and subsequent patient outcomes. Data will be obtained using patient notes and electronic records, preoperative assessment, clinic letters, theatre IT systems, discharge summary and Accident & Emergency and General Practice records (where available). No changes to normal follow-up will be made and the patient will not be contacted to enquire about SSI unless this is standard in centre-specific care. SSI will be defined as per the 2024 CDC criteria. <sup>16</sup>

#### Project organisation

Similar to the previous SIMBA study,  $^{\rm 12}$  the SIMBA-T audit is also partially funded by the ROSSINI platform.

The study is coordinated by the Birmingham Centre for Observational and Prospective Studies (BiCOPS) at the University of Birmingham. BiCOPS provides both methodological support and the infrastructure for the delivery of non-randomised prospective research. BiCOPS has established expertise in the design,

coordination and analysis of large-scale national and international cohort studies across a range of clinical specialties. All BiCOPS projects are conducted in compliance with the UK Policy Framework for Health and Social Care Research, the Data Protection Act 2018<sup>17</sup> and the Principles of Good Clinical Practice (GCP). BiCOPS enables the successful delivery of adopted projects through active interaction with national and international networks and collaborative groups.

The SIMBA-T Study Management Group (SMG) comprises individuals who have created this protocol and those who will be responsible for the day-to-day running and management of the study. This will include the project leads, SIMBA-T operations staff, statistician and lead clinicians. The group will meet via regular teleconference to review ongoing progress. The role of the SMG is to monitor all aspects of the conduct and progress of the study, ensure that the protocol is adhered to and take appropriate action to safeguard the quality of the study itself.

In addition to the SMG meetings, the project leads and the BiCOPS staff located within the University of Birmingham will convene monthly for ongoing and continual review of study and progress.

#### Data management

Data will be collected at the following times:

- · At the time of TMA
- At 30 days postoperatively

Funding will be sought to keep the REDCap database open and permit the follow-up of patients 1 year after their TMA. This will be to assess the impact of SSIs on longer-term outcomes after TMA. Data on mortality, ambulation status and need for revision surgery will be collected. If this is feasible, one more team member can be added to the existing team to support the return of 1-year data. It is expected that the overseeing consultant/attending will not change.

Source data will be electronically uploaded directly onto the SIMBA-T REDCap database (https://www.bistc.redcap.bham. ac.uk) by study collaborators at participating hospital sites. REDCap<sup>18,19</sup> is a secure web-based software platform designed to support data capture of single and multi-site studies. It is encouraged that data be uploaded directly to REDCap as close to the time of surgery as possible. Paper DCTs will be provided to centres to facilitate data capture when direct upload to REDCap is not possible at the time of surgery. No patient-identifiable data will be transferred to REDCap.

Each local centre will hold a secure database with a minimum of three patient identifiers and a three-digit pseudo-anonymised number used to link perioperative and postoperative data. A template document will be sent to centres on enrolment to be overseen by the local lead, who will be responsible for ensuring this file is stored only on-site, is done so securely, and is disposed of appropriately following upload of all follow-up data to REDCap.

#### Data validation

Data completeness will be quantified following the initial data

collection. Any data points left blank will be considered incomplete. Data points recorded as 'unknown' will count as complete data. Cases with <90% data completeness will be returned to the local centre for completion. If this is not possible, these cases will be excluded from the analysis, as is standard within international collaborative audits.<sup>20</sup> Individual patient records with less than 90% completeness of mandatory data points will be returned for completion; if this is not possible the patient will be excluded from the analysis. All centres will be required to validate data accuracy in 20% of their uploaded cases (randomly selected); 25% of data points (randomly selected) per case will be validated, equating to 5% of total data points captured. Any centre reporting accuracy of less than 90% will be required to validate a further 20% of their cases and the lead team member will be asked to investigate and report back to the SIMBA-T Management Group. Data validation will be undertaken independently by a team member not involved in the initial data collection.

The online database has been designed to allow sites to securely access an individual patient's data for all DCTs throughout the study period. This means that any missing or erroneous data can be altered by the local investigators whilst the data collection period is ongoing. In order to maximise data completion and emphasise its importance to collaborators, participating centres with >5% missing data in mandatory fields (ie, <95% data completeness) will be excluded from the study, as is standard within international collaborative audits.<sup>20</sup>

#### Statistical methods

The statistical analysis of this audit will be undertaken by our statisticians based within the Department of Applied Health Sciences at the University of Birmingham. The report of the audit will be prepared in accordance with the guidelines as set by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement.

Continuous variables will be summarised with means and standard deviations; frequencies and percentages will be used for categorical variables. Univariate and multivariate analyses will be assessed by appropriate statistical techniques. Multilevel-logistic regression models will be used to allow for clustering at a centre or a country level. A p value of <0.05 will be considered significant for all statistical methods used and the analysis will be completed using appropriate statistical software. The performance of individual hospitals will not be disclosed, and all subgroup analyses will include large patient cohorts to protect patient anonymity. No surgeon- or hospital-specific comparisons will be performed in the final dataset.

#### Monitoring

#### Data monitoring

Data validation will be performed for confirmation of case ascertainment and data accuracy. At the close of the data capture timeframe, centres will be asked to review theatre logs to ensure

that all patients undergoing TMA during the data collection timeframe were entered. Any patients not included will be added retrospectively; it is appreciated that not all data may be available retrospectively, but the SIMBA-T team will account for this during analysis and dissemination.

SIMBA-T is an international prospective audit and, thus, a data monitoring committee is not formally required.

#### Harms

As SIMBA-T is not an interventional study and is only concerned with events related to routine clinical practice, reporting of adverse events and other unintended effects is not required.

#### **Ethics and dissemination**

#### Research ethics approval

SIMBA-T does not require research ethics approval from the NHS Research Committee as the methodology does not meet the criteria for research as defined by the Healthcare Research Authority (see Appendix 2 online at www.jvsgbi.com). Every participating centre will register the audit locally prior to data collection (audit and service provision registration at all NHS sites involved). Centres outside the UK should comply with local regulations.

#### Protocol amendments

Any protocol amendment will be communicated immediately to each site directly. This version and any future versions of this protocol will be uploaded to the VERN website (https://vascular-research.net), which is widely available to all sites.

#### Consent or assent

SIMBA-T is a multicentre international audit of practice centred around routine care, and therefore individual patient consent is not required. All data entry into REDCap will be completely anonymised, as stated in the Data Management section.

#### Confidentiality

Patient identifiable information will not be collected in this study. All participant data held at the University of Birmingham will be anonymised.

All data collected will be strictly confidential and will be identified using a unique SIMBA-T study number (REDCap ID) only. Only the central research team will have access to the complete dataset. All data will be handled in accordance with the principles of the Data Protection Act 2018 and General Data Protection Regulations.<sup>17</sup>

#### Access to data

The final SIMBA-T dataset will be available to members of the core SMG listed in this protocol. Those outside of the study group may access the dataset on reasonable request. The data will be available following publication of the initial SIMBA-T findings. Data

will be stored and accessed in accordance with the principles of Good Clinical Practice (GCP).

#### Dissemination policy

All publications and presentations using data from this audit will be submitted to the SMG for review and authorisation. The results of SIMBA-T will be submitted for presentation at both national and international meetings. Manuscript(s) from the resultant data will be submitted for publication in a peer-reviewed scientific journal. A writing team, including those involved with design, implementation and dissemination of the audit and those contributing to data analysis will be responsible for both presentation(s) and publication(s). For both, a collaborative authorship model will be used, with a list of contributors clearly listed at the end of the manuscript.

To qualify for PubMed-citable collaborative co-authorship, individuals must have either:

 Had a significant role in the set-up and management of the study, including audit department registration, creation of a data collection team and engagement with the SIMBA-T team to ensure timely upload of data (with validation) and completion of the questionnaire

#### OR

Captured sufficient data to warrant authorship – this would be
the equivalent of collecting baseline and follow-up data on
approximately 10 patients, although it is appreciated individuals
may participate in only baseline data collection or only follow-up
data capture. This will be reviewed during the study period
dependent on case ascertainment at each unit. Data collection
is expected to be complete (>90% variables completed) and
submitted in a timely manner

#### OR

 (For consultants/attendings) provided oversight and support as detailed in the 'Recruitment' section.

#### OR

• Captured sufficient 1-year outcome data to warrant authorship.

The local lead at each centre will be responsible for ensuring that the SMG has the names and contact details of all collaborators who qualify for collaborative co-authorship at their centre. All collaborators will be given the opportunity to review draft paper(s) prior to submission. Whilst the SIMBA-T team appreciates the importance of this step, the team are also keen to ensure this stage does not add to significant delays in submission. All collaborators should inform the team of any changes in email addresses. Unless there are major issues or questions identified, collaborators will be given a single opportunity to comment on the paper before it is returned to the writing group for further review within 72 hours. The writing group will make a final decision regarding the comments and edits made during this process.

Plain language summaries will be created and distributed to national amputation charities and key stakeholders.

#### **KEY MESSAGES**

- The incidence, predisposing factors and outcomes for surgical site infections (SSIs) in patients who have undergone transmetatarsal amputation (TMA) is not clearly defined, with pooled SSI rates ranging from 16.7% to 24.0%.
- Post-TMA SSI may lead to a more proximal revision or major lower limb amputation, which is associated with increased morbidity and mortality.
- This audit aims to calculate the incidence and risk factors of SSI and wound breakdown in TMAs, the surgical revision rate at 30 days and sequelae of complications associated with SSI.

#### Discussion

The published literature on the rate of SSI in TMA is small compared with other procedures. This multicentre audit will allow us to interrogate present practice and garner a greater understanding of the incidence and risk factors of SSI and wound dehiscence in patients undergoing TMA. The strengths of this audit will lie in its use of contemporaneous data collection from numerous hospitals and the in-depth data collection focusing primarily on TMA SSI. It is anticipated that the audit will provide impactful data for future comparisons with global practice and support the design of robust and meaningful studies.

Limitations of the audit will include its inability to define specific causative associations between factors and the incidence of SSI. Therefore, focus will be placed on factors either known to contribute to SSI or areas with limited evidence. Although the VERN collaborative has experience of data collection from previous studies, it will be impossible to confirm reliable consecutive patient recruitment. Finally, the data will be limited to SSIs that are severe enough to prompt review or referral to secondary care.

If you would like to know more about SIMBA-T, please contact us by email at: simbat.amputation@gmail.com

**Conflict of Interest:** IC is Editor of *JVSGBI*, the rest of the SIMBA-T Study Group have no conflicts of interest to declare.

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**PROTOCOL** 

# Protocol for the Physical Activity after Cardiovascular Screening (PACS) study in women aged 60–69 years: a prospective observational cohort study

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#### **Plain English Summary**

Why we are undertaking this work: Women are more likely than men to be misdiagnosed or receive poorer treatment for cardiovascular disease. Two key conditions – elevated blood pressure (BP) and peripheral artery disease (PAD) – are often missed in women. Both conditions are serious risk factors for heart disease and stroke. Screening and lifestyle advice, especially around exercise, can help reduce risk. This study was launched to find out if screening women for PAD and BP, and giving them tailored advice, could improve physical activity and health outcomes.

What we will do: We will invite women aged 60–69 years from Leicestershire to attend screening for PAD and high BP. Two hundred of these women will be invited to wear an activity tracker for 7 days at the time of screening and again 6 months later. One hundred women who are not being screened will be invited as a comparison. The goal is to track changes in physical activity levels and examine any lifestyle improvements after screening and receiving health advice.

What we expect to find: We expect to find that women who are diagnosed with PAD or high BP will increase their physical activity levels the most. This is compared with women who screen negative or who are not screened. We are also collecting information such as smoking and alcohol use and weight to see if the screening helps encourage broader health changes.

What this means: If our findings support the idea that screening leads to increased activity and healthier behaviours, it could justify rolling out targeted screening for women across the UK. This may help close the gender gap in cardiovascular care, promote healthier lifestyles and reduce the risk of heart attacks and strokes in women.

#### **Abstract**

Introduction: Women with cardiovascular disease receive a poorer standard of care than men; they are more likely to be misdiagnosed and undertreated. Individuals with peripheral artery disease (PAD) and/or elevated blood pressure (BP) have a similar cardiovascular risk as those with established ischaemic heart disease. As part of a National Institute for Health and Care Research (NIHR) programme, we are screening women for PAD and elevated BP. The primary objective is to determine key performance metrics for a screening programme: attendance and disease prevalence. There is, however, an opportunity to undertake a more detailed process evaluation of PAD+BP screening in women to help address this sex-based health inequality. We aim to assess whether screening and/or the identification of PAD/elevated BP, along with patient education in the form of leaflets and face-to-face advice, results in positive changes in physical activity.

Methods and analysis: The Physical Activity after Cardiovascular Screening (PACS) study is funded by the British Heart Foundation (FS/CRTF/23/24452) and is a sub-study of the NIHR PHAST-F study, an observational cross-sectional multicentre feasibility study (NIHR200601; UK's Clinical Study Registry Registration ISRCTN17320335). Women in Leicestershire aged 60–69 years will be invited to attend for PAD+BP screening. Two hundred consenting participants (100 positive for PAD/or elevated BP and 100 negative) will undergo assessment of physical activity using accelerometers and complete the International Physical Activity Questionnaire Short Form, the EQ-5D-5L, Generalised Anxiety Disorder Questionnaire and the

Edinburgh Claudication Questionnaire. Follow-up assessments will include accelerometers, questionnaires and GP data obtained at 6 months. An unscreened cohort of 100 women will also be recruited to evaluate the broader impact of screening.

Ethics and dissemination: The study has received ethical approval from the Sub-Committee of the North of Scotland Research Ethics Committee (reference 21/NS/0147). The results will be disseminated through research presentations, papers and social media.

Key words: peripheral artery disease; hypertension; screening; physical activity; health inequalities

#### Introduction

Women with cardiovascular disease receive a poorer standard of care than men; they are more likely to be misdiagnosed and undertreated. Contributing factors include failure to recognise the importance of secondary prevention, sex-related differences in clinical presentation, delays in seeking care and misperceptions about cardiovascular disease in women. These issues also contribute to elevated blood pressure (BP) and peripheral artery disease (PAD) being underdiagnosed and understudied in women.

The pathophysiology of PAD is similar to coronary artery disease.<sup>3,4</sup> Studies of asymptomatic individuals with PAD demonstrate a 5-year cardiovascular risk of around 20%.<sup>5,6</sup> UK primary care data records the prevalence of diagnosed PAD at around 3%;<sup>7</sup> however, large empirical population studies estimate the true prevalence to be between 13% and 18%.<sup>8–10</sup> A lack of public awareness contributes to this under-diagnosis. In a recent small study of population screening for PAD, Davies *et al.*<sup>11</sup> found that most individuals with PAD do not recognise their symptoms or present to health services.

Elevated BP is also often underdiagnosed due to its asymptomatic nature. It is estimated that up to 6–8 million adults within the UK could have undiagnosed or uncontrolled elevated BP. This is significant as it is one of the most important risk factors for cardiovascular disease and death. In fact, a linear relationship between BP and mortality from both ischaemic heart disease and stroke exists. Mortality from ischaemic heart disease and stroke doubles for every 20 mmHg systolic or 10 mmHg diastolic increase in BP. 13

Physical activity is an important modifiable risk factor for both PAD and elevated BP, improving pain-free walking distance as well as overall cardiorespiratory fitness. <sup>2,14,15</sup> Higher levels of physical activity are also associated with a lower risk of cardiovascular disease and reduction in all-cause mortality over the medium and long term. <sup>15</sup> Exercise is a subset of physical activity that is planned, structured and repetitive with the aim of improving or maintaining physical fitness. <sup>16</sup> In individuals with hypertension, exercise is as effective as antihypertensive medication in reducing systolic BP. <sup>17</sup> A supervised exercise programme is the primary clinical management strategy for individuals with PAD. <sup>13,14,18</sup> However, a recent audit <sup>19</sup> showed that only 36% of UK vascular centres were able to offer supervised exercise therapy for PAD. Additionally, of those that did,

only 6.8% were fully compliant with current National Institute for Health and Care Excellence (NICE) guidelines.<sup>14</sup>

#### **Existing evidence**

The Viborg vascular trial (VIVA),<sup>20</sup> a Danish study that assessed the efficacy and cost-effectiveness of combined screening for PAD, BP and abdominal aortic aneurysm (AAA) in men aged 65–74 years, showed a significant reduction in all-cause mortality compared with no screening. The trial, however, did not assess objective physical activity levels and was unable to assess the impact that screening and clinical management had on physical exercise. A small population screening study from South Wales<sup>11</sup> invited men aged 45 and women over 55 with cardiovascular risk factors for PAD screening. Similar to VIVA, this study did not assess the impact on physical activity levels.

Currently within the UK individuals aged 40–74 years with no pre-existing cardiovascular disease are invited for a free NHS Health Check every five years. During this appointment, individuals receive an assessment for BP, hypercholesterolaemia and body mass index as well as general cardiovascular advice focused on smoking cessation, physical activity and maintaining a healthy lifestyle. In 2023, only 40% of individuals invited for an NHS Health Check attended. In recent years there has been a trend towards lower rates of attendance, therefore more needs to be done to maximise cardiovascular health screening at every clinical encounter.

#### PHAST-F Study

The Peripheral arterial disease, High blood pressure and Aneurysm Screening Trial (PHAST) is a multicentre £2.4 million NIHR-funded programme examining the feasibility and effectiveness of screening men for PAD and elevated BP at the same time as screening for AAA (NIHR200601, Chief Investigator: Bown). As there is no AAA screening programme for women, the overall PHAST approach potentially exacerbates the sex-based inequality in preventative cardiovascular medicine highlighted above. To directly address this inequality, the PHAST programme includes a limited feasibility study of isolated BP and PAD screening for women (PHAST-F). This feasibility study is focused on determining attendance for screening and disease prevalence but is a good opportunity to undertake a more detailed evaluation of responses to PAD+BP screening in this population. The European Society for Vascular Surgery guidelines

recommend the consideration of screening for PAD in individuals aged  $\geq$ 70 years or 45–69 years with cardiovascular risk factors. <sup>22</sup> The current National AAA Screening Programme invites men on the year of their 65th birthday. Therefore, women aged 60–69 years are invited to take part in this feasibility study to align closely with these two considerations.

#### Ongoing studies

A search of the clinicaltrials.gov, International Standard Randomised Controlled Trials Number and EU Clinical Trials registries identified no ongoing population screening trials in this area (PAD or elevated BP). We have not identified any ongoing trials of population screening for PAD or elevated BP funded by the NIHR or other UK institutions.

#### Why is this research needed now?

The PACS study supports the 10 Year Health Plan for England<sup>23</sup> by preventing heart attacks and strokes, and aligns with the Department of Health and Social Care's prioritisation<sup>24</sup> for prevention medicine. In 2019 the National Cardiovascular Disease Prevention System Leadership Forum launched its cardiovascular disease prevention programme. Additionally, the *Lancet* has commissioned a global report on cardiovascular disease in women to tackle the inequality in cardiovascular health by 2030.<sup>25</sup> This research is therefore timely as well as relevant. This study aims to assess if PAD+BP screening and providing women with information on disease pathology and treatment will ultimately increase physical activity levels and overall cardiovascular health.

#### Research hypothesis

Women who screen negative for PAD/elevated BP will have a greater level of physical activity at initial screening than women who screen positive. Women who screen positive for PAD/elevated BP will have a greater increase in physical activity levels from initial screening to 6 months than women who screen negative.

#### **Outcomes**

#### Primary outcome

Change in average daily milligravities (mg) of physical activity (measured using GENEActiv accelerometer (acceleration/steps)) and MVPA (defined as time accumulated above an average acceleration of 100 mg in bouts of at least 1 minute)<sup>26</sup> from screening to 6 months.

#### Secondary outcomes

- Average daily mg of physical activity and moderate to vigorous physical activity (MVPA) in women aged 60–69 years
- Comparison of physical activity and MVPA at screening of women who screen negative for PAD/and or elevated BP and women who screen positive
- Comparison of average daily mg of physical activity and MVPA

- at screening for women who screen negative for PAD/and or elevated BP and women who screen positive
- Change in smoking, alcohol consumption, weight and subjectively documented physical activity levels in individuals who screen positive for elevated BP/and or PAD
- Time spent in 24 hours of physical behaviour intensities (inactive time, light physical activity, moderate physical activity and sleep) amongst all groups

#### **Objectives**

#### Primary objectives

To assess the average change in accelerometer-assessed physical activity/steps immediately after initial PAD+BP screening to 6 months in women.

#### Secondary objectives

- To determine the 'normal' physical activity levels of women aged 60–69 years
- To determine whether women who screen positive for elevated BP/PAD have lower baseline levels of physical activity than those who screen negative
- To determine whether women who screen positive for elevated BP/and or PAD have a greater increase in physical activity levels at 6 months than women who screen negative
- To determine whether elevated BP/and or PAD at screening results in a positive change in health behaviour

#### Methods and analysis

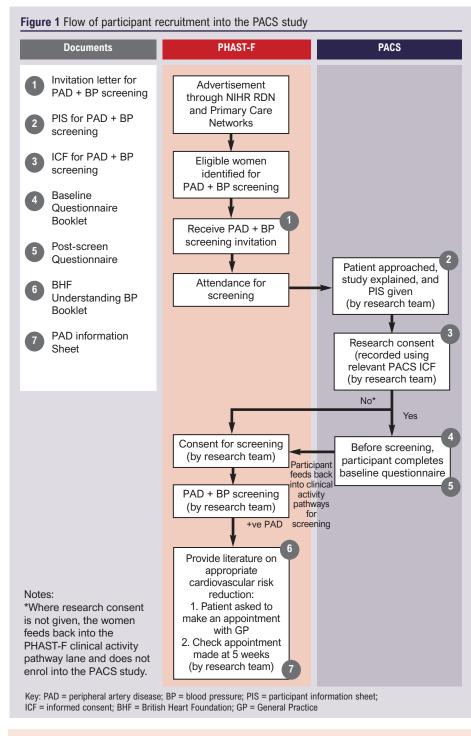
#### Study design

The Standard Protocol Items: Recommendations for Intervention Trials<sup>27</sup> and the Strengthening the Reporting of Observational Studies in Epidemiology<sup>28</sup> statements were followed in the development of this study. The Physical Activity after Cardiovascular Screening (PACS) study is a prospective observational cohort study to determine if screening for hypertension and PAD results in an increase in physical activity levels from baseline to 6 months after screening. PACS is funded by the British Heart Foundation (FS/CRTF/23/24452). It is a sub-study of the PHAST-F study, which is an observational cross-sectional multicentre feasibility study funded by the NIHR Programme Grants for Applied Research scheme (NIHR200601) (Figure 1).

#### Study setting

Women attending for PAD+BP screening as part of the PHAST-F study will be invited to participate in PACS. The NIHR Research Delivery Network will support the recruitment of Leicestershire general practices to take part in PHAST-F. In addition, individual general practices based in Leicestershire will be directly approached by members of the trial team.

Women aged 60-69 years registered with participating general



practices will then be invited to attend for PAD+BP screening. Letters of invitation will be sent via post with patients asked to contact the department, either by telephone or email, to book a screening appointment at a convenient time for them. All letters will also include a PAD screening information leaflet (see Appendix 1 Supplementary file online at www.jvsgbi.com) and a local map.

Leicestershire has been chosen as the study location because it is a 'plural city' with no single ethnic majority. The wider Leicestershire area serves individuals from diverse socioeconomic and ethnic backgrounds across rural and urban areas.

#### Eligibility criteria

The target population for this study are women aged 60–69 years registered with a Leicestershire General Practice and attending the PHAST-F programme for PAD+BP screening. Patients will be eligible for the study if they fulfil the inclusion and exclusion criteria shown in Table 1.

#### Recruitment

Upon arrival at the screening clinic, women attending for PAD+BP screening will receive a participant information sheet (see Appendix 1 Supplementary file online at www.jvsqbi.com). Patients will be pre-screened by a member of the clinical team and approached to ask if they wish to speak to a member of the research team. It will be emphasised that declining participation in PACS will not affect their clinical care, and screening will proceed as planned. Patients who express interest will be directed to a member of the research team, who will confirm eligibility and obtain informed consent prior to screening.

#### Data collection

The following data will be collected at baseline and at 6 months:

 Demographics: age, sex, ethnicity, height, weight, smoking and alcohol use, occupation status (or previous occupation where retired)

#### Table 1 Inclusion and exclusion criteria.

An ability to understand verbal and written English

Inclusion criteria

Exclusion criteria

Willing and able to provide informed consent

Women unable to provide consent

Women aged 60–69 years and registered at a
Leicestershire General Practice

Co-morbidity that the research team consider to be a contraindication to the study

Serious illness with life expectancy <6 months

- Cardiovascular history: hypertension, PAD, diabetes, hypercholesterolaemia, angina, myocardial infarction, stroke/transient ischaemia attack, cardiac arrhythmia, operation for coronary arteriosclerosis
- Medication history
- Patient-reported outcomes: European Quality of Life 5
   Dimensions 5-level (EQ-5D-5L), Generalised Anxiety Disorder
   Questionnaire (GAD-7), Edinburgh Claudication Questionnaire
   (ECQ) and International Physical Activity Questionnaire Short
   Form (IPAQ-SF)
- Health utilisation (for health economics analysis): Accident and Emergency attendance, hospital admissions, hospital outpatient appointments, primary care services accessed

#### Intervention: PAD+BP screening

A systematic review of the diagnostic accuracy of automated and semi-automated ankle-brachial pressure index (ABPI)/toe pressure devices and a consensus conference to determine real-world usability was previously undertaken to determine the most suitable device for PHAST-F.<sup>29</sup> Trained healthcare professionals will perform the ABPI using the MESI-ABPI-MD device.<sup>30</sup> Measurements will be obtained after a period of rest in the supine position. Systolic BP will be measured simultaneously in one arm (brachial artery) and both ankles (posterior tibial arteries). The test is then repeated using the alternate arm. The ABPI is automatically calculated by the MESI-ABPI-MD device and the reading will be verified by healthcare professionals. The ABPI reading will be the lowest of the two readings. All results obtained during screening will be sent to the patients' general practitioner.

Elevated BP will be defined as either a systolic BP of >140 mmHg or a diastolic BP of >90 mmHg and individuals will receive a British Heart Foundation (BHF) 'Understanding Blood Pressure' booklet.<sup>31</sup> The BHF booklet provides advice on physical activity with suggested guidance on how to increase levels. PAD will be defined as an ABPI of <0.9, as per NICE Guidelines.<sup>14</sup> Individuals diagnosed with PAD will receive a PAD Information Sheet (see Appendix 1 Supplementary file online at www.jvsgbi.com). The PAD Information Sheet also provides advice on physical activity. All patients diagnosed with elevated BP and/or PAD will be asked to make an appointment with their GP to discuss their results further and undergo further investigations, if required. For all individuals who screen positive, the research team will make a follow-up telephone call appointment at 5 weeks to discuss what health behaviour changes (cessation of smoking, reduction in alcohol consumption, maintenance of a healthy weight and increase in subjectively documented physical activity levels), if any, have been adopted.

#### Follow-up

Follow-up will be conducted remotely and will take place at 6 months. The data collection mentioned above will be collected via post. Participants who do not return 6-month GENEActiv results will be contacted by telephone. GP data and routinely collected data will

also be obtained throughout the follow-up period. Data collected will include: date of GP appointment, BP at GP attendance, result of home BP diary, changes in medication, diagnosis of other cardiovascular-related risk factors (hypercholesterolaemia, stroke/transient ischaemic attack, angina, myocardial infarction, diabetes, major limb amputation, intervention for PAD), referral to secondary care services and associated outcomes. These data will be obtained to examine uptake and adherence to cardiovascular risk management following self-made GP appointments for those who screen positive for PAD/and or elevated BP.

#### Accelerometer

The accelerometer used will be the GENEActiv device. This device has been used in a wide range of clinical trials and is a well-recognised validated device for research in physical activity. Participants will provide consent to wear a GENEActiv accelerometer on their non-dominant wrist (defined as their non-writing wrist) 24 hours a day for 7 days. The GENEActiv will be initialised to begin recording at 00:01 hours at 100 Hz. Participants will be encouraged to go to bed wearing the device the evening of their screening appointment. They will also complete a self-reported diary stating the time they went to bed, estimated time they went to sleep, when they woke up in the morning and when they physically got out of bed. These results will be analysed in conjunction with the accelerometer results. Follow-up GENEActiv devices will be sent out to participants at 6 months via postal services along with the above questionnaires.

#### Unscreened group

We recognise that recruiting women for PACS who are attending for PAD+BP screening may influence baseline physical activity levels. We will invite women from the same population and age range as those invited for PAD+BP screening. To facilitate this, participants will be recruited through the Extended Cohort for E-health, Environment, and DNA (EXCEED) study. The EXCEED protocol has been described previously.<sup>32</sup> Briefly, EXCEED is a longitudinal health study assessing the impact of genetics and lifestyle on long-term health conditions. The EXCEED study team were approached to help with recruitment into the unscreened 'control' group. A data access proposal form was approved by the core group in EXCEED with changes approved by the Sub-Committee of the North of Scotland Research Ethics Committee (Reference 21/NS/0147). Participants enrolled in the EXCEED study who have agreed to be contacted for future research will be invited to participate in PACS. Email invitations will be sent out from the EXCEED team until 100 women aged 60-69 years living in Leicestershire have enrolled into the PACS study. Consent will be obtained using one of the following methods, depending on participant preference and logistical feasibility: e-signature, email response, email attachment, postal consent, verbal consent (documented by the researcher), or written in-person consent. The unscreened group will wear a GENEActiv accelerometer and complete questionnaires, as described above.

#### Statistical analysis and plan

#### Sample size

We know that an increase of 1000 steps or 10 minutes of brisk walking corresponds to an increase of roughly 2 mg of average acceleration. Previous data regarding accelerometers corresponds to initial activity levels rather than degree of change. Therefore, our power calculation is based on the outcome of mg at 6 months. A sample size of 200 participants (100 positive for PAD/or elevated BP and 100 negative) would provide >80% power to detect a difference of 4 mg (roughly 2000 steps or 20 minutes of brisk walking). This would be at the 5% significance level, providing more than 61% of participants reached the 6-month time point (based on a standard deviation of  $\pm 7.8$  mg). PAD and elevated BP outcomes will be analysed together as exercise is the primary treatment for both cardiovascular diseases. We will also undertake a sub-group analysis between women who are positive for PAD and women who are positive for elevated BP.

#### Unscreened group

We will aim for an attendance of 100 participants as a baseline convenience sample to compare physical activity levels of women who undergo PAD+BP screening with those who do not receive PAD+BP screening.

#### Accelerometer processing

The GENEActiv data will be uploaded using GENEActiv PC software version 3.3 and analysed using the latest version of the R-package GGIR version in R (http://cran.r-project.org). The approach for GENEActiv analysis has been described previously.  $^{34-37}$  Briefly, local gravity will be used as a reference for autocalibration,  $^{35}$  sustained abnormally high values will be detected and the average magnitude of dynamic acceleration will be calculated (corrected for gravity and expressed as Euclidean Norm Minus One (ENMO) in mg averaged over 5 s epochs). Participants will be excluded if their accelerometer files show a post-calibration error of >0.01 g (10 mg), <3 days of valid wear (defined as >16 hours per day), or wear data are not present for each 15 min period of the 24 hour cycle.  $^{36}$  The default non-wear setting in GGIR will be used, which imputes invalid data by the average at similar timepoints on different days of the week.  $^{36}$ 

The following measures will be generated and averaged across all valid days:

- Average acceleration used as a proxy measure of overall volume of physical activity (24-hour day). Higher levels of average acceleration correspond to higher levels of physical activity. The minimum clinically important difference is an increase in average acceleration by 1 mg a day<sup>38</sup> (equivalent to a 5-minute brisk walk; 15-minute slow walk; or 500 daily steps).<sup>33</sup>
- 2. The intensity gradient used to describe the distribution of physical activity intensity across the day.<sup>37</sup> The intensity

- gradient is helpful to describe an individual's activity profile. The steeper the gradient, the less time spent at higher levels of acceleration. Thus, the intensity gradient is always negative.
- MVPA defined as the time accumulated above an average acceleration of 100 mg in bouts of at least 1 minute (ie, moderate physical activity as described below).<sup>26</sup>
- 4. Time spent in different physical behaviour intensities across 24 hours:<sup>39</sup>
  - Inactive time (defined as time accumulated below 40 mg)<sup>39</sup>
  - Light physical activity (defined as time accumulated 40–99 mg)
  - Moderate physical activity (defined as time accumulated 100–399 mg)
  - Vigorous physical activity (defined as time accumulated >400 mg)

#### Data analysis

Categorical data will be presented as absolute values and proportions (%) with a  $\chi^2$  test used to compare proportions between groups. Where data are paired, McNemar's test will be used (ie, baseline to 6 months) or Fisher's exact test if the sample size is less than five. Where more than two categories are present (never smoker; previous smoker; current smoker), then a  $\chi^2$  test will be used.

Continuous variables will be examined for normality using histograms, skewness and kurtosis. Normally distributed variables will be reported as mean (± standard deviation) with a t-test (independent, ie, screen negative vs screen positive group) or a paired t-test (paired, ie, baseline to 6 months) used to compare within or between groups. For non-normally distributed variables, median (interquartile range) with a Wilcoxon rank-sum test (independent) or a Wilcoxon signed-rank test (paired) will be used to compare differences between groups. Where comparisons are undertaken across more than two groups (ie, control vs screen negative vs screen positive), ANOVA (normally distributed) or a Kruskal-Wallis test (non-normally distributed) will be used. All analyses will be performed using R Core Team (Version 4.4.1; 2024; R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

#### Data management

Data will be recorded directly into the paper case report form (source data) and then transcribed into the electronic case report form. Original copies of the participant consent form and information sheet will be filed in the Investigator Site with copies placed in the participant's hospital notes. Data entry will be conducted by the site research team and the Leicester Clinical Trials Unit (LCTU). Participant contact details will be securely collected and retained to enable send out of follow-up questionnaires by post. Data management will be through MACRO, a validated web-based data entry system and database.

#### **KEY MESSAGES**

- This is a multicentre study recruiting women from primary care services across rural and urban areas, increasing the representativeness of the study population.
- Recruitment will include women from varied socioeconomic and ethnic backgrounds, enhancing the generalisability of the findings.
- The study uses both objective (accelerometery) and subjective (validated questionnaires) methods to assess physical activity, health status and symptoms.
- The study will determine whether PAD+BP screening alone is sufficient for improving the overall physical activity level and thus overall cardiovascular health in women
- The outcome of the study will inform the future NIHR Health Technology Assessment Programme to see if physical activity monitoring can be used as an outcome for cardiovascular screening.
- As a feasibility sub-study with a relatively small sample size and short follow-up, the study may not capture longer-term or less pronounced behavioural changes.

#### Study management

The management of PACS will be undertaken by SJM, a British Heart Foundation Clinical Training Fellow. The management of PHAST-F will be undertaken by the LCTU, a fully registered UK Clinical Research Collaboration Clinical Trials Unit (UKCRC no.43) in collaboration with the Investigators and the Trial Management Group. The LCTU will be responsible for site set-up, project management, statistical expertise and provision of MACRO databases. Serious adverse events are not expected. The study intervention consists of PAD and BP screening, which are known to be safe with no long-term physical consequences.

#### Dissemination

We will disseminate and present our results at national UK conferences such as the Vascular Societies' Annual Scientific Meeting. The results of this will be published in a peer-reviewed academic journal as it will be relevant for other researchers in cardiovascular medicine, psychology, epidemiology, public health and vascular surgery. It will inform these future researchers if physical activity levels could be used as a measurable outcome in screening. It will also inform the design of our future NIHR Health Technology Assessment Programme to see if physical activity monitoring can be used as an outcome for cardiovascular screening.

We will also publish outputs on social media in lay format and use existing PAD and diabetes patient groups to involve patients in dissemination, as well as our PPI group. This will improve patient education and ultimately cardiovascular health. For those involved in PACS, it represents an opportunity to discuss cardiovascular risk

factor modification. The encouragement of a healthy lifestyle and exercise will lead to improved cardiovascular risk management and be of direct benefit to patients.

**Conflict of Interest:** AS has received consultancy and lecture fees/honoraria from Shockwave Ltd, Abbott Ltd, BD Medical, General Electric Healthcare and Medyria GmBH. He has also received research funding from Shockwave Ltd, Abbott Ltd, Boston Scientific Ltd and educational fees from Cook Medical.

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**Author contributions:** SJM, MJB and AS were involved in conception and design of the PACS study. SEB obtained ethics approval. SB and AVR provided statistical expertise in clinical trial design and SJM is conducting the primary statistical analysis. All authors edited, revised, and approved the final manuscript. MJB is the Chief Investigator for PHAST-F and SJM is the NIHR Associate Principal Investigator.

Ethics approval: PACS has received ethical approval as part of a substantial amendment to the PHAST-F Programme (Sub-Committee of the North of Scotland Research Ethics Committee; Reference 21/NS/0147). PHAST-F is registered on The UK's Clinical Study Registry (Registration ISRCTN17320335). The study protocol v.2.0 dated 8 August 2023 has been reviewed by the Sub-Committee of the North of Scotland Research Ethics Committee (Reference 21/NS/0147) and was approved on 18 October 2023.

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**PROTOCOL** 

## The use of non-steroidal anti-inflammatory drugs for the prevention and reduction of pain following superficial venous incompetence treatment: a systematic review protocol

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#### **Plain English Summary**

Why we are undertaking this research: Enlarged and twisted veins just under the skin in the legs (varicose veins) are common and often cause problems such as pain, swelling, itching and wounds that are hard to heal (ulcers). The most common treatment for varicose veins is to use heat or chemicals to seal the veins shut. Approximately 30% of patients report prolonged pain after such treatments. Reducing this pain would improve patients' quality of life and reduce associated healthcare costs. A short course of painkillers following treatment may minimise the pain, but this is not currently routine. Non-steroidal anti-inflammatory drugs (NSAIDs) are a group of painkillers which can be bought commonly over-the-counter and include ibuprofen and aspirin. We want to know if a routine short course of NSAIDS reduces the pain patients experience after treatment for varicose veins.

What we aim to do: To investigate the effect of NSAIDs on pain following treatment for varicose veins, we are going to do a systematic review. A systematic review is a way of bringing together the results from existing studies to decide if a treatment is effective or not. This paper describes how we will bring together all existing studies on painkillers after varicose vein treatments to determine whether they should be used in routine practice..

What this means: The results from this review will tell us if NSAIDs should be used in routine practice to reduce or prevent pain after varicose vein treatment, or if more research is needed. It will also allow other researchers to repeat the systematic review if they wish.

#### **Abstract**

Introduction: Post-procedural pain is a common complication following interventional treatments for patients with superficial venous incompetence (SVI). Currently, analgesia is not routinely prescribed following treatment. Simple analgesia in the form of non-steroidal anti-inflammatory drugs (NSAIDs) can be administered. This is a protocol for a systematic review of the studies on the use of NSAIDs following SVI treatment for post-procedural pain.

Methods: A systematic review will be conducted on the use of NSAIDs for post-procedural pain following SVI treatment in accordance with PRISMA guidelines. A search of Ovid MEDLINE, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) databases will be carried out to search for terms including 'varicose veins', 'non-steroidal anti-inflammatory', 'ibuprofen' and 'post-procedural pain'. The primary outcome of the review will be post-procedural pain, defined as pain occurring within the first six weeks following SVI treatment. The secondary outcomes will be patient adherence to NSAID treatment, reported complications from NSAID treatment and mean time to return to normal daily activities/work. All prospective and retrospective studies considering the use of NSAIDs to reduce and prevent pain following SVI treatments will be included. The Covidence systematic review software will be used for the screening and selection of studies. Data extraction will be performed using a dedicated Excel spreadsheet. The risk of bias of included studies will be assessed using tools recommended by Cochrane for both randomised and non-randomised studies. The GRADE tool will be used to assess the quality of the evidence.

**Conclusion:** This systematic review aims to assess and summarise the evidence for the use of NSAIDs for pain following SVI treatment. The findings will inform us whether NSAIDs should be used routinely or whether further research is needed.

**Key words:** superficial venous incompetence (SVI), varicose veins, post-procedural pain, non-steroidal anti-inflammatory drugs (NSAIDs)

#### Introduction

Superficial venous incompetence (SVI) is among the most common chronic diseases in adults. Approximately one-third of the general population is affected, with the main risk factors being older age, parity, obesity and family history. 1-3 The disease commonly manifests as varicose veins, which are tortuous and dilated superficial veins in the lower extremities. It also leads to symptoms in the lower limbs such as pain, itching, swelling and heaviness. 4.5 Clinical assessment is performed using the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification, with varicose veins being at the C2 Clinical stage and active venous ulceration being the highest Clinical class (C6). 6 Other serious complications include bleeding, eczema, phlebitis and venous thromboembolism. 7-9 SVI symptoms negatively impact the physical, social and psychological aspects of a patient's quality of life (QoL), and international guidelines recommend treating all patients with symptomatic SVI. 10

Interventional treatments of SVI include thermal and non-thermal minimally invasive approaches as well as open surgery. These procedures are effective at relieving symptoms, improving QoL and reducing disease complications. <sup>11,12</sup> However, they are associated with recognised post-procedural complications. Major but rare complications include deep vein thrombosis and pulmonary embolism. <sup>13,14</sup> Nearly all patients experience early post-procedural pain and discomfort, which resolves within 1–2 weeks. <sup>15,16</sup> However, persistent post-procedural pain is experienced by up to 30% of patients following SVI treatment, and this can last up to 6 weeks and is likely associated with inflammation of residual thrombosed varicose tributaries. <sup>17</sup> Early post-procedural pain is an appropriate response to the procedural insult; however, prolonged post-procedural pain and tenderness are pathological, and attempts should be made to minimise this phenomenon.

Most patients undergoing SVI treatment are working adults who are otherwise fit, and, therefore, a delay in post-procedural recovery of 6 weeks represents a significant illness. <sup>18</sup> Moreover, prolonged pain can result in a significant socioeconomic impact as it prevents the return to normal daily activities such as exercise or work. This, in turn, causes distress and leads to unplanned visits to health professionals and additional strain on stretched healthcare services. The reported frequency of this phenomenon and its impact on patients warrant an assessment of the literature to find strategies to address it.

Administration of non-steroidal anti-inflammatory drugs (NSAIDs) is therefore a potential solution to this persistent pain. NSAIDs have dual activity, providing analgesia as well as reducing

the body's inflammatory response. This may reduce the severity of symptoms, allowing patients to return to normal daily activities. Additionally, early administration may also prevent the activation of this persistent pain cascade by reducing inflammation. There is evidence for the use of NSAIDs to treat similar short/medium-term inflammatory processes such as musculoskeletal pain and in other surgical and non-surgical settings. <sup>19-21</sup> Therefore, a systematic review of the literature to ascertain the effect of NSAID use on post-procedural pain and patient recovery following SVI treatment is warranted.

#### Methods

This systematic review protocol is written in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines and is registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42024598078). A systematic review of the literature will be conducted in line with Cochrane's recommendations for performing systematic reviews of interventions. The objective of the systematic review is to identify and synthesise the literature on whether NSAIDs reduce pain following SVI treatment.

#### Study eligibility criteria

All randomised controlled trials (RCTs), prospective and retrospective studies evaluating the use of NSAIDs in reducing post-procedural pain in patients with SVI of either sex following interventional treatment are eligible for inclusion. The study population are symptomatic patients undergoing interventional treatment for SVI. Only invasive interventional treatments recommended by international bodies such as the European Society for Vascular Surgery (ESVS) for SVI will be eligible for inclusion, such as endovenous laser and radiofrequency ablation, foam sclerotherapy, cyanoacrylate adhesive ablation, mechanochemical ablation and varicose vein surgical stripping. Compression therapy and lifestyle advice will not be included as they are considered non-invasive.

The study intervention will consist of the administration of NSAID medication shortly after SVI treatment. All NSAID types and formulations are acceptable interventions. NSAIDs given before SVI treatment will not be eligible for inclusion. The duration of the course of NSAID treatment will be no less than 1 week and not longer than 8 weeks. Acceptable comparators include the use of analgesia other than NSAIDs or not offering any systemic analgesic

medication. Comparison of types of NSAIDs is also acceptable.

Studies to be included must be peer-reviewed English language studies. The language restriction is because we do not have the resources to translate manuscripts. Book chapters and conference abstracts will be excluded. No date restrictions will be applied. Unpublished data that meet the inclusion criteria are acceptable to be included. Studies assessing pain before and after SVI treatment for the aim of assessing symptom resolution are not eligible for inclusion.

#### Outcomes

Post-procedural pain, specifically in the first 6 weeks following SVI treatment, will be the primary outcome. There is no consensus on the duration of post-procedural pain; thus, a window of 6 weeks was chosen pragmatically in order to maximise eligible data but not capture pain that may be deemed as chronic. Pain must be measured using validated patient subjective pain scores such as the 100 mm Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Verbal Rating Scale (VRS), FACES Pain Rating Scale or other conventional and accepted pain measurement tools. 24-27 Studies that report post-procedural pain >6 weeks following varicose veins treatment will be excluded unless they also report pain in the first 6 weeks.

The secondary outcomes will be patient adherence to NSAID treatment, reported complications from NSAID treatment (including but not limited to abdominal pain, indigestion, cough, nausea, shortness of breath and headache), and mean time to return to normal daily activities/work.

#### Search strategy

Searches will be conducted on Ovid MEDLINE, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) electronic databases from inception to December 2024. Literature searches will be performed under the supervision of qualified medical librarians (DC, TS). References of studies included in the review will be examined for additional eligible studies that may have been missed from the literature searches.

The databases will be searched for studies reporting the use of NSAIDs following SVI interventional treatment using keywords, equivalent words and Medical Subject Headings (MeSH) terms to maximise search sensitivity. Search terms will include but are not limited to 'non-steroidal anti-inflammatory', 'ibuprofen', 'varicose veins' and 'postprocedural pain'.

An example search strategy for the search on Ovid MEDLINE is outlined in Table 1. A similar approach will be employed for other databases, taking into account variations in acceptable search terms between databases.

In addition to the databases, clinical trial registers such as clinicaltrials.gov will be searched for ongoing studies. If any abstracts of ongoing clinical trials or unpublished data meet the inclusion criteria, then the authors will be contacted for results, if available. Grey literature will not be searched in this review.

1.	Varicose vein/
2.	varicose vein*.mp.
3.	venous incompetence.mp.
4.	venous reflux.mp.
5.	venous insufficiency.mp.
6.	endothermal ablation.mp.
7.	endovenous ablation.mp.
8.	radiofrequency.mp.
9.	sclerotherapy.mp.
10.	laser ablation.mp.
11.	phlebectomy.mp.
12.	microphlebectomy.mp.
13.	Cyanoacrylate.mp.
14.	mechanochemical ablation.mp.
15.	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16.	Pain, Postoperative/
17.	pain.mp.
18.	postprocedural pain.mp.
19.	post-procedural pain.mp.
20.	post procedural pain.mp.
21.	16 or 17 or 18 or 19 or 20
22.	Anti-Inflammatory Agents, Non-Steroidal/
23.	non-steroidal anti-inflammatory.mp.
24.	ibuprofen.mp.
25.	diclofenac.mp.
26.	aspirin.mp.
27.	etoricoxib.mp.
28.	naproxen.mp.
29.	22 or 23 or 24 or 25 or 26 or 27 or 28
30.	15 and 21 and 29

#### Study selection

The Covidence systematic review software (2024, Veritas Health Innovation, www.covidence.org) will be used for study screening and selection. The search results will be uploaded to Covidence, followed by automatic duplicate identification and removal. Two assessors will independently review the literature search results and screen studies that meet the inclusion criteria based on the title and abstract. If studies are deemed eligible, they will be screened further using a full-text review by the same two independent reviewers. The reviewers will be blinded to each other's decisions. Any discrepancies will be resolved by consensus between the two reviewers or arbitration of a third reviewer.

A PRISMA flow diagram will be produced to convey information such as the number of search hits, the number of duplicates automatically removed, the number of titles, abstracts and full texts reviewed, the number of studies excluded following full-text review with the reasons for exclusion displayed and ultimately the number of studies included in the systematic review.

#### Data collection and synthesis

Two reviewers will independently extract data from the studies identified onto two separate Microsoft Excel spreadsheets (Microsoft® Corporation, 2024) using specifically designed data extraction forms. Once the extraction has been completed, the reviewers will compare the results. If there are any discrepancies, these will be resolved again through consensus. If any clarification is needed, it will be resolved by obtaining and confirming data from investigators and inputting it into the final form.

Data will be collected on study characteristics including study design and sample size, participant demographics including age, sex and comorbidities, a description of the intervention(s) and comparators, if any, adverse events, length of follow-up and findings related to primary and secondary outcome data. Data on study characteristics will include information to make a judgement on the quality of the study. If available, conflicts of interest, funding for the study and other potential sources of bias will be reported. RCTs and non-randomised studies will be reported separately. For each study included, a table will be provided outlining the key characteristics and findings.

Quantitative outcome data analysis will be conducted using Cochrane's RevMan software program.<sup>28</sup> First, the clinical heterogeneity will be reviewed, specifically the patient demographics, comorbidities, types of interventions, follow-up duration and outcomes. If the criteria for clinical homogeneity are satisfied, then statistical heterogeneity will be assessed using  $\chi^2$ and I<sup>2</sup> tests and associated p values.  $\chi^2$  represents the estimate of the variance of true treatment effects between the trials. I2 is an estimate of the proportion of variability that is due to trial heterogeneity. Data from different interventional treatments of SVI will be analysed separately. Meta-analyses will be performed for studies that are deemed clinically homogenous. Dichotomous outcomes will be presented in a forest plot with risk ratios and 95% CI, whereas continuous outcomes will be presented as mean difference (MD) or standardised mean difference (SMD) with 95% CI. Data from homogeneous single-arm cohort studies will be combined and presented as a mean with a 95% CI for continuous outcomes or proportion with a 95% CI for categorical outcomes, or a hazard ratio with a 95% CI for time-to-event data. Data from RCTs will be presented separately from observational studies. A narrative synthesis will be provided for any included studies that cannot be included in quantitative data analysis.

#### Bias risk assessment

For RCTs, two independent reviewers will assess the risk of bias

#### **KEY MESSAGES**

- Prolonged post-procedural pain is a common complication following superficial venous incompetence (SVI) treatment.
- Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used analgesics which may help relieve this pain.
- This review aims to explore all the current available evidence on the use of NSAIDs in the treatment of post-procedural pain following SVI treatment.

using Cochrane's risk-of-bias tool for randomised trials (RoB-2).<sup>29</sup> It assesses the risk of bias across five domains, including bias arising from the randomisation process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in the measurement of outcome and bias in the selection of the reported result. Within each domain there is a series of signalling questions, and the responses are combined to make a final judgement about the risk of bias for each domain. If there are any discrepancies between the two reviewers, this will be resolved by a consensus or arbitration with a third reviewer. A Microsoft Excel table will be used to implement the RoB-2. Any studies with an outcome of high risk of bias will be excluded from quantitative data analysis and synthesis.

The risk of bias in non-randomised studies will be assessed using the modified Downs and Black checklist, which assesses different components of the methodology.<sup>30</sup> It comprises 27 questions which can be answered using a 'yes', which equates to 1 point, 'no' or 'unable to determine', each of which is 0 points. The maximum score is 28 points, with a higher score indicating better quality.

The presence of publication bias and selective outcome reporting will be explored further using funnel plots.

The overall quality of the evidence will be assessed by using the Grading of Recommendations, Assessments, Development and Evaluations (GRADE) tool.<sup>31</sup> First, the study design will be considered. Then the evidence will be downgraded or upgraded based on five categories: the risk of bias, inconsistency, indirectness, imprecision and publication bias. The evidence can be rated 'high', 'moderate', 'low' or 'very low'.

#### Discussion

This protocol outlines a systematic review that aims to identify and summarise the evidence base for and safety of NSAIDs in relieving pain following SVI treatment. The findings will be used to inform current practice or the design of future studies to investigate how NSAIDs can be best utilised to optimise patient recovery following SVI treatment. The NHS in England performs approximately 35,000 procedures to treat SVI each year. <sup>18</sup> Most of these patients are working-age adults for whom delays in recovery impact

employment and care duties. Currently, post-procedural care and pharmacotherapy are guided by clinician preferences, and potentially a third of patients are negatively impacted by this practice. <sup>17</sup> Data from this review and subsequent studies will provide evidence to support a standardised care package to optimise recovery post-SVI treatment.

**Conflict of Interest:** IC is the Editor of *JVSGBI*. The rest of the authors declare that there are no conflicts of interest

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CASE REPORT

# Spinal cord infarction due to immune thrombocytopenic purpura following aorto-bifemoral bypass surgery: a rare complication

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#### **Abstract**

Spinal cord infarction is a rare but devastating complication following aorto-bifemoral bypass surgery, particularly in patients without typical risk factors. We report a unique case of a 68vear-old female who developed acute spinal cord infarction in the setting of newly diagnosed immune thrombocytopenic purpura (ITP) after undergoing elective aorto-bifemoral bypass surgery for chronic aorto-occlusive disease. Despite an initially uncomplicated procedure, the patient developed significant postoperative thrombocytopenia followed by profound neurological deficits. MRI revealed spinal cord infarction at the T11–L1 level. Haematological investigations suggested a paradoxical thrombotic event associated with ITP. This case highlights the need for heightened vigilance regarding thromboembolic risks in patients with ITP, even in the postoperative setting where bleeding complications are typically prioritised. Awareness of this potential complication is crucial for timely diagnosis and management.

**Key words:** immune thrombocytopenic purpura (ITP), spinal cord infarction, aorto-bifemoral bypass, paradoxical thrombosis, aorto-occlusive disease

#### Introduction

Immune thrombocytopenic purpura (ITP) is an autoimmune disorder characterised by the production of autoantibodies, commonly IgG, that target platelet surface glycoproteins (eg, GPIIb/IIIa), leading to platelet destruction primarily in the spleen. In some cases it also impairs platelet production in the bone marrow. Paradoxically, ITP can also be associated with thromboembolic events, including spinal cord

ischaemia or infarction. <sup>1,2</sup> Potential triggers for ITP include infections, autoimmune diseases, medications and post-trauma or post-surgery.

Aorto-bifemoral bypass surgery is a major procedure typically performed for aorto-occlusive disease. There is a paucity of reports describing spinal cord ischaemia in the context of ITP following this type of surgery.3 In aorto-occlusive disease, chronic stenosis or obstruction of the aorta and its branches leads to the development of collateral circulation to maintain blood supply to vital structures, including the spinal cord. However, these collaterals may be insufficient during acute occlusion, perioperative hypoperfusion or surgical disruption, potentially leading to spinal cord ischaemia. Spinal cord ischaemia has more commonly been associated with aneurysmal disease related to aortic aneurysm rupture and systemic hypotension.<sup>4,5</sup>

#### **Case presentation**

### Patient demographics and preoperative details

A 68-year-old female, ex-smoker, with a background of peripheral arterial disease, previous femoral-femoral crossover bypass, hypertension and hypercholesterolaemia, presented with bilateral rest pain, worse on the left. Duplex and 3D CT imaging revealed occlusion of her previous graft. Visceral branches and bilateral internal iliac arteries were patient. Preoperative cardiac assessments showed adequate function with an ejection fraction >50% and 90% stenosis of the right coronary artery with stable angina. Preoperative platelet counts were normal, and she was deemed fit for aorto-bifemoral bypass surgery.

Figure 1 Sagittal view of T2 Turbo Spin Echo (TSE) sequence of lower thoracic and lumbar spine. The arrow points to a hyperdense signal within the spinal cord at levels T11 to L1.



#### Surgical details

The patient underwent an uncomplicated aorto-bifemoral bypass via transverse laparotomy and bilateral vertical groin incisions using a 14×7 rifampicin-soaked Dacron graft. The proximal aortic clamp was placed infrarenally. The proximal anastomosis was done in an end-to-end fashion and was completed in approximately 25 minutes. Blood loss was approximately 1 L, and the minimum systolic blood pressure during surgery was 100 mmHg. The surgery lasted 5 hours and 45 minutes, reflecting the time required for careful aortic exposure through a transverse laparotomy and bilateral re-do common femoral artery dissection. Bilateral pedal pulses were restored postoperatively. Prior to surgery the patient received a spinal local anaesthetic block.

#### Postoperative complications

The patient remained intubated and sedated until postoperative day 2. Upon extubation she was confused (Glasgow Coma Score 14/15), and this confusion persisted for 2 weeks. Platelet counts significantly deteriorated over the first 4 postoperative days to a nadir of 18×10<sup>9</sup>/L. Sepsis was ruled out (afebrile, negative blood cultures) and heparin-induced thrombocytopaenia was excluded with haematology input.

**Figure 2** Sagittal view of T2 Turbo Spin Echo (TSE) and STIR (Short Tau Inversion Recovery) sequence of lower thoracic and lumbar spine. The arrow points to a hyperdense signal within the spinal cord at levels T11 to L1.



On postoperative day 4, new bilateral foot drop was noted. Neurological examination showed complete loss of power (0/5) and sensation in both lower limbs, absent reflexes and faecal incontinence. MRI on postoperative day 4 revealed acute spinal cord infarction from T11 to L1 involving the conus medullaris. This can be seen in figure 1 and figure 2. No haematoma was identified.

The neurology and haematology teams hypothesised that the spinal cord infarction was due to a paradoxical thromboembolic event in the setting of acute ITP.

#### Management and outcomes

The patient was treated with high-dose methylprednisolone for 5 days. She engaged in intensive rehabilitation. After a 3-month inpatient stay she had partial sensory and motor recovery but remained non-ambulatory. She was referred to a national rehabilitation unit.

#### Discussion

Spinal cord infarction is a devastating but rare complication of aortic surgery, more commonly associated with aneurysmal disease due to hypotension or extensive clamping.<sup>4,5</sup> In occlusive disease,

#### **KEY MESSAGES**

- Spinal cord infarction can occur as a paradoxical thrombotic event in immune thrombocytopenic purpura (ITP), even though ITP is classically associated with bleeding.
- Patients with ITP undergoing major aortic surgery require close postoperative monitoring for both haemorrhagic and thromboembolic complications.
- Early recognition and multidisciplinary management of new neurological deficits are essential to minimise long-term morbidity from spinal cord infarction.

collateral circulation often provides protection, making spinal cord infarction after aorto-bifemoral bypass rare.

The spinal cord's vascular supply includes the anterior spinal artery (supplying the anterior two-thirds) and two posterior spinal arteries. The artery of Adamkiewicz, usually arising between T8 and L4, plays a crucial role.<sup>6,7</sup> Disruption to this artery or its collaterals increases the risk of infarction, particularly during high aortic clamping or compromised internal iliac flow.<sup>8,9</sup> Typically, anterior spinal artery syndrome presents with motor deficits, urinary and faecal incontinence, while vibration and proprioception remain intact. MRI is the gold standard investigation. Management is supportive with rehabilitation.

Previous literature reports a very low incidence of spinal cord ischaemia after occlusive disease repair (approximately 0.3%).<sup>10</sup> Spinal cord ischaemia after aneurysmal repair is more frequent.

Concerning ITP, while typically associated with bleeding, studies have shown increased thromboembolic risks. <sup>1,2</sup> This paradox is believed to stem from platelet microparticles and immune-mediated endothelial activation.

To our knowledge, this is the first reported case of spinal cord infarction secondary to ITP following aorto-bifemoral bypass. The temporal association of sudden platelet drop, platelet transfusion and spinal cord infarction suggests a paradoxical thromboembolic phenomenon.

Other operative factors were considered but were unlikely, given the short clamp time, absence of significant hypotension and adequate systemic heparinisation.

#### Conclusion

This case highlights the need for heightened vigilance for thrombotic complications in patients with ITP, even after non-aneurysmal aortic surgery. Although rare, spinal cord infarction is a catastrophic event that must be recognised early. Understanding the thrombotic potential in patients with ITP can guide closer monitoring and early intervention.

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**Patient consent to publication:** Informed consent was obtained from the patient for this publication.

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CASE REPORT

# The first confirmed isolation of *Dermabacter vaginalis* from a mycotic abdominal aortic aneurysm

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#### **Abstract**

Dermabacter vaginalis is a recently identified extremely rare bacterial species not previously implicated as an agent in any disease process. This report covers the first recorded case of D. vaginalis isolated from periaortic fluid during surgical repair of a mycotic abdominal aortic aneurysm. The patient was successfully treated with a surgical approach combined with an antibiotic regimen tailored to the sensitivities of D. vaginalis.

**Key words:** mycotic abdominal aortic aneurysm, *Dermabacter vaginalis*, opportunistic infection

#### Introduction

Bacteria of the genus Dermabacter are considered skin colonisers. Dermabacter hominis, the first species characterised, has been isolated from a variety of clinical specimens including blood, suggesting its potential as an opportunistic pathogen.1 Dermabacter vaginalis was first isolated in 2016 from the vaginal fluid of a woman in Korea.<sup>2</sup> Subsequently, the genome of D. vaginalis has been sequenced,3 along with the identification of unique metabolites that it produces.<sup>4</sup> Following its initial discovery, this strain has not been isolated from another human source, and thus no role in pathogenicity has been described to date for D. vaginalis. We report the isolation of *D. vaginalis* following surgical repair of a mycotic aortic aneurysm.

#### **Case presentation**

A 74-year-old man presented to the emergency department in January 2025 with a two-day history of severe abdominal pain which had worsened overnight and had radiated to the back. He had also vomited once but displayed no other

symptoms. These features were deemed suggestive of a mycotic abdominal aortic aneurysm. He had recovered from a cold 10 days earlier and had several vascular risk factors including hypertension, diabetes mellitus, previous stroke and myocardial infarction. His white cell count was 14×109/L and a CT scan confirmed the presence of a 3.7 cm diameter infrarenal aneurysm with evidence of aortitis. An initial strategy of IV antibiotic therapy without surgical intervention was commenced. However, the following morning the patient complained of worsening abdominal pain with ongoing fever overnight. Repeat CT angiography revealed rapid expansion of the aortic aneurysm to 4.2 cm with worsening fat stranding confirmed (Figure 1). The patient was therefore counselled for emergency open aneurysm repair.

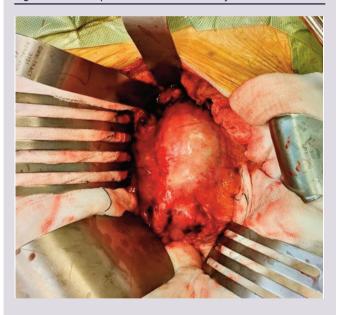
A standard midline laparotomy incision was made and the retroperitoneum opened. Collateral and lumbar vessels were ligated and the renal and common iliac arteries were isolated. The aorta was clamped above the left and below the right renal artery. Extensive inflammation of the aortic aneurysm and the surrounding tissues was visible (Figure 2). The repair was completed using a silver impregnated Dacron tube graft and took a total of 4 hours and 50 minutes.

Postoperatively the patient recovered well with minimal complications. Periaortic fluid samples cultured *D. vaginalis*, which was reported as susceptible to higher doses of penicillin, tetracycline, linezolid, rifampicin, vancomycin and resistant to ciprofloxacin. Blood cultures were negative after five days. He was treated with six weeks of IV ceftriaxone 2 g once daily via a peripherally inserted central catheter followed by long-term oral doxycycline 100 mg twice daily, as guided by input from infectious diseases. The

**Figure 1** CT angiogram showing the aneurysm at 4.2 cm diameter.



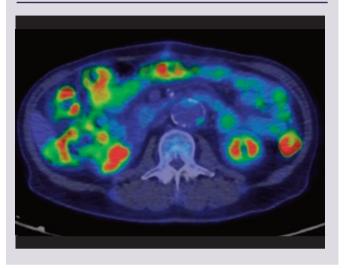
Figure 2 An intraoperative view of the aneurysm.



patient was discharged nine days postoperatively with safetynetting advice in place and follow-up arranged with both vascular and infectious diseases specialists.

An interval PET-CT scan (Figure 3) was performed around 12 weeks after surgical repair which showed patchy uptake within the aortic graft, likely to represent postoperative changes post-intervention. Clinic review five months after surgery was reassuring with the patient recovering well and tolerating oral doxycycline along with normal blood tests. The agreed plan was for a further interval PET-CT scan at 10 months after surgery (November 2025) with subsequent review and discussion in clinic regarding whether to continue or stop antibiotic suppression at that point.

Figure 3 Interval PET-CT scan of the aneurysm 12 weeks after repair.



#### **KEY MESSAGES**

- Dermabacter vaginalis is a rare pathogen and few cases of it causing disease in humans have been documented.
- This is the first recorded case of *D. vaginalis* being isolated from a mycotic aneurysm.
- Data from future cases may be useful in determining if D. vaginalis will have a continuing role in human disease.

#### Discussion

Mycotic aneurysms are rare, causing as few as 0.6–2% of abdominal aortic aneurysms, with evidence consistently showing *Staphylococcus aureus* to be the most commonly involved pathogen in high-income settings. <sup>5,6</sup> Several other bacterial species – and more rarely some fungal agents – have been shown to cause mycotic aortic aneurysms, but *D. vaginalis* represents a potential novel player in aneurysm pathology. Given the relatively recent discovery of *D. vaginalis* and the low global incidence of mycotic aneurysms, it is unsurprising that no such cases have been described previously. Data from future cases may help determine if *D. vaginalis* is likely to have an ongoing role in human pathology moving forward.

Interestingly, just prior to developing his mycotic aneurysm this patient had returned from a trip to Japan, which included some rural areas, and while there he had suffered from a flu-like illness causing a cough and generalised joint aches. It seems plausible that these symptoms could represent the early stages of infection by *D. vaginalis*. Alternatively, an acute viral infection may have made the patient more susceptible to opportunistic infection by *D. vaginalis*.

#### Conclusion

This case represents the first reported instance of *D. vaginalis* as a potential causative agent in a mycotic abdominal aortic aneurysm. Isolation of this bacteria from clinical specimens should be reported to aid our understanding of its potential pathogenic role in opportunistic infections.

Conflict of Interest: None.

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Patient consent to publication: Informed consent was obtained from the patient for this publication.

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CASE REPORT

# Rare vascular complication of total hip arthroplasty: common femoral artery perforation diagnosed two months postoperatively

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#### **Abstract**

Background: Vascular injuries complicating total hip arthroplasty (THA) are uncommon, with reported incidences between 0.2% and 0.42%. When they occur, they can threaten both the patient's life and functional prognosis of the limb.

Case report: We describe a 38-year-old woman with tuberculous coxitis who underwent THA. Two months later she presented with acute back and groin pain associated with severe anaemia. Exploration revealed a perforation of the common femoral artery (CFA). Reconstruction using reversed saphenous vein bypass and profunda femoris reimplantation resulted in successful recovery.

Conclusion: CFA perforation after THA is exceedingly rare and may present late. Any unexplained groin symptoms or anaemia following THA should trigger urgent vascular evaluation.

**Key words:** hip arthroplasty, vascular injury, common femoral artery, pseudo-aneurysm, vascular surgery

#### Introduction

Arterial complications following total hip arthroplasty (THA) are rare but potentially devastating, with incidence estimated between 0.2% and 0.42%.<sup>1,2</sup> Mechanisms include penetrating trauma from retractors or screws, traction injury during dislocation, perforation during acetabular preparation, or delayed vessel erosion leading to pseudoaneurysm formation.<sup>3</sup> Revision surgery, dysplasia and pelvic fractures are established risk factors.<sup>4</sup>

We report an exceptional case of delayed common femoral artery (CFA) perforation two months after primary uncomplicated THA for tuberculous coxitis, highlighting the need for vigilance beyond the immediate postoperative period.

#### Case report

#### Preoperative assessment

A 38-year-old woman with treated pulmonary tuberculosis presented with an 18-month history of right hip pain and limping. Examination revealed restricted flexion without vascular or neurological deficits. A pelvic radiograph demonstrated destruction of the femoral head and acetabular changes consistent with chronic coxitis (Figure 1). A CT scan confirmed chronic right-sided coxitis with muscular atrophy (Figure 2). Bone biopsy verified tuberculous infection. After multidisciplinary review she underwent THA using the Hardinge lateral approach. Intraoperative fluoroscopy was satisfactory and the early postoperative course was uneventful (Figure 3), with postoperative haemoglobin 9.6 g/dL.

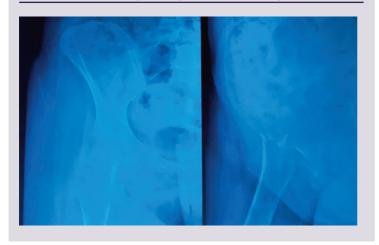
#### Postoperative presentation

Two months later the patient developed sudden low back and groin pain radiating to the thigh. The hip was held in flexion; distal pulses remained palpable. Laboratory results showed severe anaemia (haemoglobin 4 g/dL). Because she was haemodynamically stable, surgical exploration was performed without preoperative angiography.

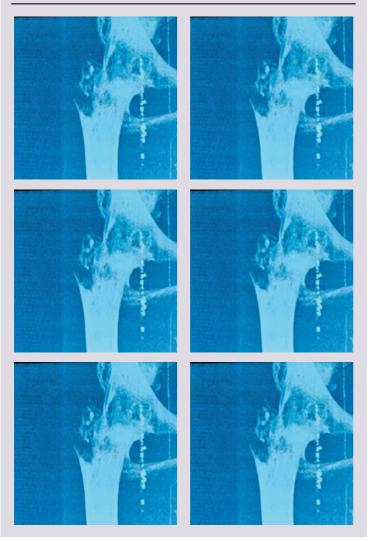
#### Operative findings and management

A large haematoma was evacuated, revealing active arterial bleeding at the femoral bifurcation. The vascular team was called. After proximal and distal control, a transfixing perforation of the CFA was identified (Figures 4 and 5). The damaged

**Figure 1** Preoperative pelvic radiograph showing a deformed right femoral head with osteolysis and joint space narrowing.



**Figure 2** CT scan images of the right hip demonstrating chronic coxitis and acetabular destruction.



**Figure 3** Postoperative pelvic radiograph after total hip arthroplasty.



**Figure 4** Intraoperative photograph showing the common femoral artery perforation at the femoral bifurcation.

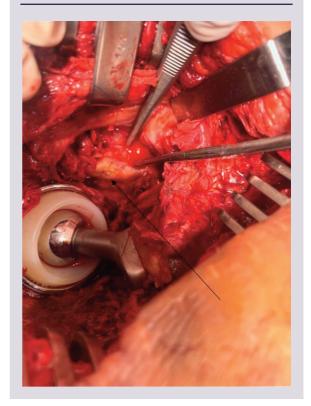
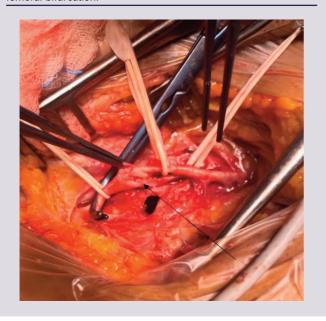
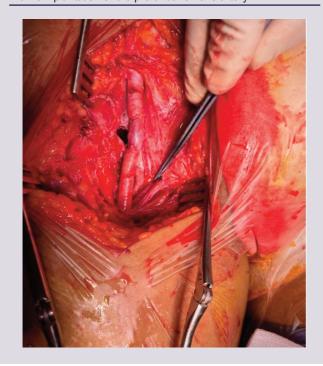


Figure 5 Intraoperative photograph showing control of the femoral bifurcation.



**Figure 6** Intraoperative photograph of the venous bypass graft with reimplantation of the profunda femoris artery.



segment was excised and continuity restored with a reversed autologous saphenous vein graft from the CFA to the superficial femoral artery, with profunda femoris re-implanted into the graft (Figure 6). The patient recovered uneventfully with preserved limb perfusion.

#### **KEY MESSAGES**

- Vascular injury following THA is rare but serious.
   Published series report a 0.2–0.42% incidence of arterial injury. Low incidence contributes to delayed recognition.
- Delayed presentation is possible. CFA perforation or pseudoaneurysm may present weeks or months after surgery with groin pain, anaemia or neurological symptoms even when distal pulses are preserved.
- Maintain a high index of suspicion. Any unexplained groin, thigh or back pain, swelling or drop in haemoglobin after THA should trigger vascular evaluation.
- Early multidisciplinary management saves limbs.
   Prompt recognition and collaboration between orthopaedic and vascular surgeons allow timely repair and minimise morbidity.
- Meticulous surgical technique and preoperative planning reduce risk. Awareness of anatomical variations, careful placement of retractors and screws, and avoidance of excessive traction or torsion are essential preventive measures.

#### Discussion

Vascular injury during THA remains rare yet potentially catastrophic. Reported incidence ranges between 0.2% and 0.42%. The external iliac and common femoral arteries are most often involved because of their proximity to the acetabulum and femoral canal. Early recognition is crucial, since delayed diagnosis can lead to limb loss or death.

Mechanisms include direct trauma from retractors, drills or acetabular screws; thermal damage from bone cement; traction-related intimal disruption; and delayed perforation from pseudoaneurysm erosion. 4.5 Our patient lacked traditional risk factors – no revision surgery, dysplasia, pelvic fracture or fibrosis – emphasising that even technically uncomplicated primary THA can produce vascular complications.

Delayed presentations, such as pseudoaneurysm rupture months after surgery, are diagnostically challenging. Collateral circulation may maintain distal pulses, masking acute ischaemia. Therefore, persistent groin pain, thigh swelling, neurological deficit or unexplained anaemia after THA should raise suspicion for vascular injury. CT angiography remains the diagnostic modality of choice when haemodynamic stability allows.

Management depends on lesion type and location. Endovascular therapy is increasingly preferred for contained perforations or pseudoaneurysms in anatomically suitable sites. However, open reconstruction remains essential when the femoral bifurcation is involved, when infection is possible, or when prosthetic artefacts limit imaging accuracy. Autologous saphenous vein provides durable infection-resistant reconstruction, as illustrated in this case.

This experience underlines the necessity of continued postoperative vigilance and close collaboration between orthopaedic and vascular teams. Even in primary THA, awareness of vascular anatomy, meticulous technique and prompt multidisciplinary action are vital to preventing devastating outcomes.

#### Conclusion

Common femoral artery perforation following THA is exceptionally rare but potentially life-threatening. Delayed presentation, as in this case, complicates diagnosis and management. Persistent groin pain, anaemia or neurological symptoms after hip arthroplasty should always prompt vascular evaluation. Early diagnosis and multidisciplinary collaboration between orthopaedic and vascular teams remain vital for limb salvage and survival. Preventive strategies include meticulous surgical technique, respect for anatomic variations and careful postoperative vigilance.

Conflict of Interest: None.

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Patient consent to publication: Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

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**ABSTRACTS** 

### VS ASM 2024 prize winning Abstracts

The Vascular Societies' Annual Scientific Meeting 2024, in conjunction with the VSGBI, BACPAR, SVN and CSVS, took place at DoubleTree by Hilton, Brighton, on the 27th-29th November 2024. Here are the 2024 prize winning abstracts.

#### **VS - Sol Cohen Founders Prize**

The Natural History of Splenic Artery Aneurysms: A Decade's Experience of Surveillance and Management at a Large Tertiary Vascular Unit

Mr. Robert Leatherby<sup>1</sup>, Mr. David Li<sup>1</sup>, Mr. James Budge<sup>1</sup>, Dr Adelola Oseni<sup>2</sup>, Dr Rose Howroyd<sup>2</sup>, Professor Peter Holt<sup>1</sup>, Mr. lain Roy<sup>1</sup>

1St George's Vascular Institute - St George's University Hospital NHS Foundation Trust / St George's University of London, UK,

2 Interventional Radiology Department, St George's University Hospital NHS Foundation Trust, London, UK

#### Background

Splenic artery aneurysms (SAAs) are the commonest visceral artery aneurysm. Their natural history is poorly defined and guidelines for their surveillance and management provide weak recommendations based on moderate quality evidence. We present one of the largest retrospective SAA series.

#### Methods

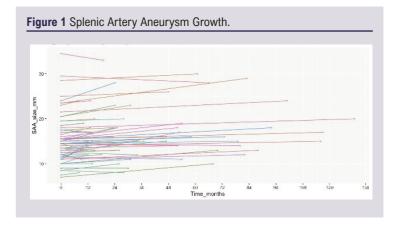
All patients reported to have a SAA between 2012 and 2021 inclusive at a single centre were identified through a search of radiology records. These data were combined with clinical electronic patient records and follow-up scans to determine a natural history.

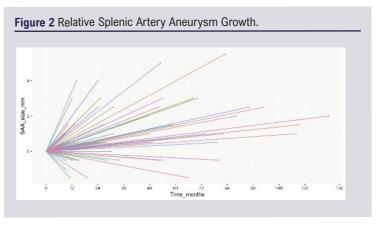
#### Results

162 patients with SAA were identified, 73% female with a mean age of 71 years (SD 14) at index scan. The mean maximal SAA diameter in any plane was 15.7mm (range 6-62mm), 88% were calcified, 1% pseudo-aneurysmal. The morphology for 88% was saccular, 4% fusiform and 8% indeterminate.

Sixty-five patients underwent further imaging, 20 within a formal SAA surveillance programme. The mean time between index and final scan was 3 years and 5 months with a mean SAA growth of 0.33 mm/year (Figure 1&2).

Five SAAs underwent intervention, 1 under surveillance, 4 de-novo: 2 for rupture. Four underwent coil embolisation (1 requiring repeat embolisation with N-butyl-cyanoacrylate) and one underwent splenectomy. There were only 2 ruptures in the cohort, neither under surveillance, both were treated successfully. There were no SAA related deaths.





#### Conclusion

SAAs predominate in an elderly female cohort, rarely rupture and demonstrate a slow rate of growth at 0.33mm per year. Consideration should be given to lengthening the surveillance interval in stable SAAs to 3-5 years.

#### **VS - BJS Prize**

#### Surgical Site Infections in Major Lower Limb Amputation: An International Multicentre Audit (SIMBA).

Miss Ismay Fabre<sup>1</sup>, The SIMBA Collaborative

<sup>1</sup>South East Vascular Network, Cardiff, United Kingdom

#### Introduction

Surgical Site Infection (SSI) after major lower limb amputation (MLLA) significantly affects function, mobility, morbidity and mortality alongside broader impacts on healthcare services. Limited data exists on incidence, prevention and management. Improving clinical outcomes and wound healing have been identified as research priorities for MLLA patients.

#### Methods

SIMBA is an international, prospective, collaborative audit. Data were collected for consecutive patients undergoing MLLA over 8 months, with 30-day follow-up. Outcomes included comparing

current practice against published recommendations, incidence of SSI, wound dehiscence, revision, mortality, adjunct use, and SSI predictors.

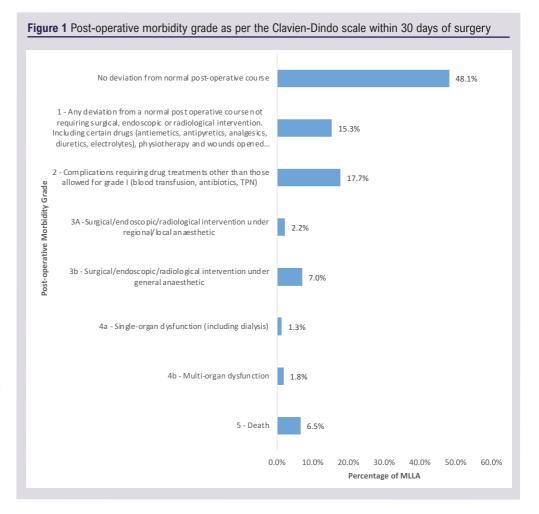
#### Results

Validated data for 940 MLLA from 33 centres (UK (24), Europe (7), Australasia (1) and Asia (1)) were collected, comprising 48.0% above-knee, 3.2% through-knee and 48.6% below-knee amputations. The indications for amoutation included ischaemia (52.8%), uncontrolled infection (24.1%), breakdown of previous amputation (6.4%), extensive tissue loss (13.3%) and other (3.2%). 66.2% received prophylactic post-operative antibiotics, with a mean duration of 5.8 days. The incidence of SSI and wound breakdown were 10.0% and 14.7%, respectively. Within those who developed SSI(n=94); 31.6% resulted in sepsis, and 15.8% required critical care. In total, only 48.1%

of MLLA experienced no deviation from normal post-operative course, with 9.2% requiring further intervention. 30-day mortality was 6.5% (Figure 1).

#### Conclusion

SSI and wound breakdown after MLLA are frequent complications with significant sequelae, resulting in high rates of re-intervention, increased morbidity and mortality. SIMBA, which to our knowledge is the largest international collaborative study of its kind, highlights the need for strategies to minimise the incidence of SSI, to improve patient outcomes and reduce burden on healthcare systems.



#### **VS - Poster Prize**

#### The incidence of surgical site infection following major lower limb amputation: A systematic review

Miss Nina Al-Saadi<sup>1</sup>, Mr. Khalid Al-Hashimi<sup>2</sup>, Mr. Matthew Popplewell<sup>1</sup>, Miss Ismay Fabre<sup>3</sup>, Mr. Brenig Gwilym<sup>3</sup>, Miss Louise Hitchman<sup>4</sup>, Professor Ian Chetter<sup>4</sup>, Mr. David Bosanquet<sup>3</sup>, Mr. Michael Wall<sup>1</sup>

<sup>1</sup>Black Country Vascular Network, <sup>2</sup>Colchester Hospital, <sup>3</sup>South East Wales Vascular Network, <sup>4</sup>Hull York Medical School

#### Introduction

Surgical site infections (SSIs) following major lower limb amputation (MLLA) in vascular patients are a major source of morbidity. The objective of this systematic review was to determine the incidence of SSI following MLLA in vascular patients.

#### Method

This review was prospectively registered with the International Prospective Register of Systematic Reviews (CRD42023460645). Databases were searched without date restriction using a predefined search strategy.

#### Results

The search identified 1427 articles. Four RCTs and 21 observational studies, reporting on 50 370 MLLAs, were included. Overall SSI incidence per MLLA incision was 7.2% (3628/50370).

The incidence of SSI in patients undergoing through-knee amputation (12.9%) and below-knee amputation (7.5%) was higher than the incidence of SSI in patients undergoing above-knee amputation, (3.9%), p<0.001. The incidence of SSI in studies focusing on patients with peripheral arterial disease (PAD), diabetes or including patients with both was 8.9%, 6.8% and 7.2%, respectively.

#### Conclusion

SSI is a common complication following MLLA in vascular patients. There is a higher incidence of SSI associated with more distal amputation levels. The reported SSI incidence is similar between patients with underlying PAD and diabetes. Further studies are needed to understand the exact incidence of SSI in vascular patients and the factors which influence this.

#### **VS - The Richard Wood Memorial Prize**

Anxiety levels in men in Abdominal Aortic Aneurysm (AAA) surveillance: a cross-sectional survey to investigate the prevalence of psychosocial consequences of AAA in men in surveillance.

Ms. Jane Hughes<sup>1</sup>, Mr. Akhtar Nasim<sup>2</sup>, Mr. Alan Elstone<sup>4</sup>, Dr Jo Hall<sup>3</sup>, Mrs Elizabeth Lumley<sup>1</sup>, Mr. Niall Macgregor-Smith<sup>1</sup>, Professor Jonathan Michaels<sup>1</sup>, Mr. Stephen Radley<sup>2</sup>, Dr Phil Shackley<sup>1</sup>, Professor Gerry Stansby<sup>5</sup>, Dr Emily Wood<sup>1</sup>, Professor Alicia O'Cathain<sup>1</sup> 

<sup>1</sup>University of Sheffield, United Kingdom; <sup>2</sup>Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, United Kingdom; 

<sup>3</sup>Derbyshire Community Health Services NHS Foundation Trust, Bakewell, United Kingdom, <sup>4</sup>University Hospitals Plymouth NHS Trust, Plymouth, United Kingdom, <sup>5</sup>The Newcastle Upon Tyne University Hospitals NHS Foundation Trust, Newcastle Upon Tyne, United Kingdom

#### Introduction

Abdominal Aortic Aneurysm (AAA) is a potentially fatal condition. There are approximately 3500 deaths annually in England and Wales following AAA rupture. The NHS AAA Screening Programme undertakes surveillance on men with small AAA's. There are potential harms as well as benefits associated with screening. This study investigates the prevalence of the psychosocial consequences of AAA in men in surveillance, and how these consequences vary by characteristics of men, their AAA and their screening frequency, using generic and AAA-specific measures of quality of life.

#### Methods

We conducted a cross-sectional postal survey of 1161 men in surveillance with five providers in England. The survey comprised the ePAQ-AAA, the Psychological Consequences of Screening Questionnaire (PCSQ), the EQ-5D-5L, socio-demographic questions and a free text section.

#### Results

The response rate was 64% (734/1161). Anxiety levels related to AAA varied by size, rate of growth, screening frequency and men's characteristics. For example, mean scores for the ePAQ-AAA scale measuring anxiety ranged from 15.1 for a small AAA (3.0 - 4.0cm) to 28.1 for a AAA over 5.0cm in diameter (p<0.001). Men with fast growing AAA's had higher mean scores than those with slow or non-growing AAA's (40.7 vs 13.1) (p<0.001). Men from the most socially deprived areas had higher anxiety scores than those in the least deprived areas (25.1 v 17.3) (p<0.001).

#### Conclusion

Any intervention aimed at managing anxiety can be targeted at men in three monthly surveillance or with fast growing AAA's and must be acceptable to men from socially deprived areas.

#### **VS - Venous Prize**

### Characterising variations in venous thromboembolism prophylaxis practice in orthopaedic surgery: a cross-sectional survey

Mr. Shahaab Shameem, Dr Francesca Siracusa, Mr. Joseph Shalhoub, Professor Alun Davies *Imperial College London, United Kingdom,* 

Orthopaedic surgery can predispose patients to venous thromboembolism, however literature highlights the limited prescribing of guideline-appropriate thromboprophylaxis. <sup>1-7</sup> Differing physician opinions and controversies in evidence creates variation in guidance, potentially challenging unified prescribing. This study aims to characterise variability in thromboprophylaxis prescribing within orthopaedics.

A scenario-based survey was designed on Qualtrics.com, comprising five total knee arthroplasty (TKA) scenarios and five knee arthroscopy scenarios. The survey was distributed to surgeons and haematologists via professional associations to elicit routine thromboprophylaxis practices. Responses were collated over six weeks. Descriptive statistics and Fisher's exact tests evaluated the impact of risk factors on thromboprophylaxis strategy.

30 responses were analysed. Most respondents prescribed mechanical prophylaxis for TKA (83.3%, n=25) and knee arthroscopy (70.4%, n=19), with variability in the type and duration selected. Pharmacoprophylaxis use varied in knee arthroscopy, with further debate regarding the duration selected. In TKA, respondents were more likely to modify thromboprophylaxis for a history of deep vein thrombosis (DVT) or low platelet count than for other risk factors (p<0.05). In knee arthroscopy, thromboprophylaxis changes were more likely for a history of DVT (p<0.01).

Variation in the type and duration of thromboprophylaxis was documented, which may be associated with the conflicting evidence supporting certain prophylactic agents.<sup>8–15</sup>

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		TKA	Knee Arthroscopy
	Question	Scenario 1 of 5: No additional risk factors n,(%)	Scenario 1 of 5: No additional risk factors n,(%)
Mechanical Pro	phylaxis  No Mechanical Prophyakis  Prophylaxis Until Patient is Ambulating  Prophylaxis Until Discharge  Inpatient Prophylaxis and Post-Discharge	5 (16.7) 7 (23.3) 12 (40.0) 6 (20.0)	8 (29.6) 8 (29.6) 10 (37.0) 1 (3.7)
	Total Responses	30	27
Type?	Anti-Embolism Stockings Intermittent Pneumatic Compression Device Foot Impulse Device Other Total (more than one option could be chosen)	17 (51.5) 15 (45.5) 1 (3.0) - - 33	12 (54.5) 10 (45.5) - - 22
Time of Initiation?	rotat (more trial one option could be chosen)	33	22
	Pre-Operatively Intra-Operatively Post-Operatively Total Responses	13 (52.0) 8 (32.0) 4 (16.0) 25	12 (63.2) 6 (31.6) 1 (5.3) 19
Pharmacologic	al Prophylaxis		
	No Pharmacological Prophylaxis Aspirin Low Molecular Weight Heparin Fondaprinux Rivaroxaban Apixaban Dabigatran	7 (23.3) 19 (63.3) - 3 (10.0) -	16 (59.3) 3 (11.1) 8 (29.6) - - - -
	Other	1 (3.3)	-
Time of Initiation?	Total Responses	30	27
	Pre-Operatively 1-5 Hours Post-Operatively 6-12 Hours Post-Operatively 13-24 Hours Post-Operatively >24 Hours Post-Operatively Total Responses	1 (3.3) 2 (6.7) 26 (86.6) 1 (3.3)	1 (9.1) 10 (90.9) - - 11
Duration?		30	
	Until Patient is Ambulating Duration of Inpatient Stay 7 Days Post-Operatively 14 Days Post-Operatively 28 Days Post-Operatively Other Total Responses	1 (3.3) - - 24 (80.0) 4 (13.3) 1 (3.3) 30	2 (18.2) 3 (27.3) - 4 (36.4) 2 (18.2) - 11
Post-Discharge Age			
(Those that selected 7, 14 or 28 days post-op duration)		11 (39.3) 5 (17.9) - 9 (32.1) 3 (10.7) - 28	3 (50.0) 2 (33.3) - 1 (16.7) - - - 6

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#### VS - Medical Student Prize

#### Using Thromboelastography to compare post-operative anticoagulation: Rivaroxaban and Apixaban demonstrate similar clot strengths in Peripheral Arterial Disease patients.

Miss Aaliya Ashik<sup>1,2</sup>, Miss Lois Owolabi<sup>2,3</sup>, Dr Adriana Rodriguez<sup>2</sup>, Mr. Shiv Patel<sup>2</sup>, Dr Isabella Cieri<sup>2</sup>, Dr Leela Morena<sup>2</sup>, Mr. Mohit Manchella<sup>2,3</sup>, Miss Enya Wang<sup>2,4</sup>, Dr Anahita Dua<sup>2</sup>

<sup>1</sup>University Of Manchester, Manchester, United Kingdom; <sup>2</sup>Massachusetts General Hospital, Boston, United States of America; <sup>3</sup>Harvard Medical School, Boston, United States of America; <sup>4</sup>University of Rochester School of Medicine and Dentistry, Rochester, United States of America

#### Introduction

The VOYAGER trial demonstrated that adding low-dose Rivaroxaban improves peripheral arterial disease (PAD) post-revascularisation outcomes but did not study the effect of other anticoagulants. This study utilised Thromboelastography with Platelet Mapping (TEG-PM) to objectively compare the impact of Rivaroxaban and Apixaban on clot strength (MA-ADP) to determine if there was a difference between medication regimens.

#### Methods

Patients with PAD undergoing a revascularisation procedure between 2021-2023 were prospectively evaluated. TEG-PM samples taken one-month postoperatively were compared based on patient anticoagulation (Apixaban and Rivaroxaban) and antiplatelet regimen. Descriptive statistics characterised the anticoagulant groups, with Chi-square or Fisher's exact tests comparing discrete data such as demographics and co-morbidities. Mann-Whitney U testing compared MA-ADP values between groups where Gaussian distribution was not seen, and Welch's t-test was used where Gaussian distribution was seen.

#### Results

Sixty-eight samples were analysed. 32% were on Rivaroxaban, and 68% were on Apixaban. No significant difference in the MA-ADP was noted between Rivaroxaban and Apixaban groups when antiplatelet use was not controlled for (46.9mm (IQR 34.5) vs 45.1mm (IQR 34.2), p= 0.7). Similarly, no significant difference was noted between Rivaroxaban and Apixaban when patients were taking dual antiplatelet therapy (37.8mm  $\pm 16.7$  vs 42.8mm ±19, p=0.5), Aspirin monotherapy (46.4mm ±20.8 vs 44.3mm ±14.2) or Clopidogrel monotherapy (58.3mm (IQR 43.2) vs 45.9mm (IQR 42.8), p>0.9).

#### Conclusion

No significant difference was noted in clot strengths between PAD patients taking Apixaban vs Rivaroxaban. This is clinically useful when considering post-operative thromboprophylaxis prescribing, as both medications are equally efficacious.

#### Supplemental Material

Table 1: Comparison of demographics, co-morbidities and procedure type in Apixaban and Rivaroxaban patients.

Characteristic	Rivaroxaban group	Apixaban group	P value	
Characteristic	(N= 22)	(N=46)		
Age (years), median (IQR)	69 (16.3)	71 (15.3)	0.767	
Male gender, n (%)	15 (68).	36 (78)	0.369 <sup>b</sup>	
Race, n (%)				
Caucasian participants	19 (86)	37 (80)	0.549 <sup>b</sup>	
Other	3(14)	9(20)	0.549	
Medical Co-morbidities, n (%)				
Diabetes mellitus	13 (59)	30 (65)	0.624	
Hypertension	18 (82)	41 (89)	0.456	
Hyperlipidaemia	19 (86)	38 (82)	>0.999	
Renal Status (Normal)	11 (50)	15 (33)	0.167 <sup>b</sup>	
BMI, median (IQR)	26.9 (7.2)	26.0 (7.8)	0.699a	
Procedure type (Endovascular), n (%)	11 (50)	24 (52)	0.867b	

- <sup>a</sup> Statistics by Mann Whitney U test <sup>b</sup> Statistics by Pearson's Chi-squared test. <sup>c</sup> Statistics by Fisher's exact test Abbreviations used: IQR interquartile range

Table 2: Comparison of MAADP between Rivaroxaban and Apixaban patients separated by antiplatelet regimen

nti-platelet Regimen	Rivaroxaban group	Apixaban group	P value
DAPT OR MAPT, Median (IQR)	49.6 (34.5)	45.1 (34.2)	0.7438
Aspirin + Clopidogrel, mean ± SD	37.8 ± 16.7	42.8 ± 19.0	0.487b
Aspirin, mean ± SD	46.4 ± 20.8	44.3 ± 14.2	0.827b
Clopidogrel, median (IQR)	58.3 (43.2)	45.9 (42.8)	>0.999

- <sup>a</sup> Statistics by Mann Whitney U test <sup>b</sup> Statistics by Welch's t-test
- Abbreviations used: MAPT Mono antiplatelet therapy, DAPT Dual antiplatelet therapy, SD standard deviation, IQR - Interquartile ra

Table 3: Comparison of MAADP between antiplatelet regimens within Rivaroxaban and Apixaban groups

Table 3. Comparison of MA <sub>ADP</sub> values between antiplatelet regimens within Rivaroxaban and Apixaban groups.				
MAPT	DAPT	P value		
46.0 ± 20.5	37.8 ± 16.7	0.339*		
43.4 ± 17.3	42.8 ± 19.0	0.9198		
	MAPT 46.0 ± 20.5	MAPT DAPT 46.0 ± 20.5 37.8 ± 16.7		

<sup>a</sup> Statistics by Mann Whitney U test abbreviations used: MAPT – Mono antiplatelet therapy, DAPT – Dual antiplatelet therapy

#### **SVN - James Purdie Prize**

### Empowering Patients: A Project for Raising Awareness of Peripheral Arterial Disease (PAD) and the Development of the Claudication Pathway

Miss Lauren Lynch, Mrs Zoe Noakes, Mrs Ellena Smedley, Mr. Edward Lopez, Mrs Angela Iles <sup>1</sup>University Hospital Coventry and Warwickshire, Coventry, United Kingdom

This project aims to address the under diagnoses and under treatment of PAD and its associated symptom, intermittent claudication, by engaging patients, healthcare professionals, and the broader community in awareness-raising activities. Through education, patient empowerment, and advocacy, we aspire to improve early detection, management, and outcomes for individuals living with PAD.

The vision the Vascular Nursing Team had was:

- To raise awareness about PAD and its associated symptom, claudication, among both the general population and healthcare professionals.
- Establish a clear pathway for the diagnosis, management, and treatment of PAD and claudication.
- Empower patients with PAD to actively participate in their healthcare journey and advocate for improved access to resources and support.

We established areas of waste within the current service and conducted audits of the current clinic set up to identify areas of improvement. Patient forums were introduced for them to share their views and ideals. Surveys were taken and feedback was welcomed. Patient focus groups shall continue as the team recognises that patients provide valuable insights into the usability, appropriateness, and impact of the service on their experiences and outcomes.

The long-term benefits in terms of improved patient outcomes by preventing disease progression, reducing hospitalisations, and minimising the need for invasive procedures results in reduced healthcare costs. By reducing waste within the previous service, along with reducing wait times for initial appointments for patients, the clinical capacity has increased by more than 150% resulting in a financial gain of over £50,000 per year for the Trust.



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#### **SVN - Poster Prize**

### Multicomponent interventions to support adherence to guideline-recommended therapy in patients with peripheral arterial disease

Mrs Smaragda Lampridou<sup>1,2</sup>, Miss Tania Domun<sup>1</sup>, Miss Javiera Rosenberg<sup>1</sup>, Professor Alun Huw Davies<sup>1,2</sup>, Professor Mary Wells<sup>1,2</sup>, Dr Gaby Judah<sup>1</sup>

<sup>1</sup>Imperial College London, <sup>2</sup>Imperial College Healthcare NHS Trust

#### Introduction

Adherence to guideline-recommended therapies in peripheral arterial disease (PAD) patients remains low. Single-component interventions addressing either smoking, exercise or medication adherence have demonstrated some efficacy. However, given the complexity of the PAD treatment plan, multi-component interventions are essential for comprehensive patient management. This scoping review systematically synthesized information on multi-component interventions for PAD patients.

#### Methods

A systematic search was conducted in Embase, MEDLINE, Cochrane Library, APA PsycINFO, CINAHL, Web of Science Core Collection, ProQuest and Google Academic, to identify primary research describing multicomponent interventions to support treatment adherence in PAD patients, published between 2007-2024. A narrative synthesis was reported using the Template for Intervention Description and Replication (TIDieR) checklist and the Behavioural Change Techniques (BCT) Taxonomy.

#### Results

This review included 15 studies including 2,462 PAD patients (60.4% male). Only two interventions targeted all PAD therapies. Key intervention components included structured exercise (12/15) and education programmes (10/15). Most interventions were delivered by multidisciplinary teams in hospital settings over three months. Only one study reported employing behavioural theories in its development, and most interventions (14/15) focused on the BCT "instruction on how to perform a behaviour" rather than diverse BCTs. No interventions significantly increased adherence to all PAD therapies.

Conclusion Few interventions target all behaviours; with no evidence of holistic support. Not enough studies measured the intervention's impact on adherence, hindering recommendations on effective intervention characteristics. Most interventions lacked behavioural science approaches and were not designed to address specific adherence determinants. Future interventions should incorporate behavioural strategies to maximise patient benefit.

#### **CSVS - Best Scientific Abstract**

### Ultrasound based turbulence quantification can predict intimal hyperplasia development in arteriovenous fistula. Mr. Matthew Bartlett<sup>1</sup>

<sup>1</sup>Royal Free London NHS FT, London, UK, <sup>2</sup>UCL, London, UK

#### Introduction

Imaging surveillance does not offer significant improvements to long term arteriovenous fistula (AVF) patency, but the haemodynamic information obtained using Doppler ultrasound, may hold the key to developing improved monitoring techniques.

#### Objectives

- Develop a simple tool for analysing the complex haemodynamic data contained within a Doppler spectrogram and quantify the level of turbulence present.
- Validate the tool using patient specific in-silico simulations, and in-vivo trials.

#### Materials & Methods:

Patients with newly created AVF underwent duplex scanning postsurgery. Cardiac gated audio recordings of the Doppler shifted frequency spectrum were obtained and an ensemble averaging technique was employed to extract the frequencies relating to turbulent components of the flow field. Ultrasound Turbulence Intensity Ratio (USTIR) was calculated in different regions of the flow circuit and compared with distribution of oscillatory shear index (OSI) on the computational simulations, and with neointimal hyperplasia (NIH) development on the 10-week maturation scan.

#### Results & Summary

Distribution of ultrasound-based turbulence intensity ratio corresponds with regions of elevated oscillatory shear stress and accelerated NIH formation. ROC curve analysis found a USTIR >6.4 of the pre-maturation scans, could predict development of haemodynamically significant NIH at 10 weeks with a sensitivity of 87.5% and a specificity of 80%.

#### **CSVS - Best Case Study Abstract**

#### Think Zebras: Identification and Investigation of Vascular Mimics

Mr. Ben Warner-michel

Kingston Hospital NHS Foundation Trust, Kingston upon Thames, United Kingdom

Pathologies of the peripheral vascular system, especially those involving venous disease, usually present with symptoms including generalised or localised pain and oedema. When patients present with these symptoms, it is often prudent to exclude vascular pathology such as venous thrombosis or peripheral arterial disease using duplex ultrasonography.

However, there are occasions in which these phenomena are caused by other types of pathology that mimic vascular symptoms.

Vascular ultrasound operators are likely to encounter these pathologies throughout their practice, and in these instances, it can be difficult to know how best to scan and report these findings.

In this talk I will present a few such case studies from my own recent practice, and discuss how to image, assess and describe vascular mimics using sonographic terminology in order to ensure that the patient receives the most efficient and appropriate management.

#### **BACPAR - Highest scoring abstract**

### A quality improvement project to improve the provision of emotional support for patients following major lower limb amputation

Joanne Clapp<sup>1</sup>, Dr Ashlyn Firkins<sup>1</sup>, Dr Ray Owen<sup>2</sup>, Dr Stephanie Carty<sup>1</sup>

<sup>1</sup>Gloucestershire Hospitals NHS Foundation Trust, <sup>2</sup>DRO Psychological Services

Major lower limb amputation (MLLA) is a lifesaving but life-altering vascular procedure. Psychological distress is common in the acute post-operative period, but despite the documented negative impact that poor psychological functioning can have on long-term physical health outcomes, there is a lack of high-quality guidance outlining how to best support the psychological needs of individuals post-MLLA. The aim of this project was to develop a practical and feasible protocol for improving the provision of emotional support for all patients on the vascular ward post-MLLA. The protocol was adapted from the Holistic Needs Assessment framework used within oncology services to provide holistic care to their patients. The primary intervention involved developing a model for an 'emotionally supportive conversation' (ESC) which was delivered by

a dedicated member of the vascular team under the supervision of a Clinical Psychologist. During the six-month implementation phase, 27 patients received an ESC, an average of eight days post-MLLA. The secondary intervention involved in-house training for vascular ward staff, led by a Clinical Psychologist. Pre-ESC protocol and staff training implementation, 43% of patients reported receiving sufficient information from hospital staff on how they would feel post-operatively and 57% stated they had received sufficient support from staff during their stay. Post-implementation these figures increased to 86% and 71% respectively. This project represents a novel and creative way for psychological services to add value to the quality of care provided to vascular patients during the inpatient phase post-MLLA.



**ABSTRACTS** 

## VASGBI Annual Scientific Meeting 2025, London, 15-16th September, oral presentation top abstracts

Authors of the top scoring abstracts submitted were given the opportunity to give an oral presentation of their work during our free paper session.

The papers by Dr Ian Young and Dr Michael Nesbitt were joint first prize winners.

An audit of the impact of a joint surgical and anaesthetic pre-op assessment clinic for abdominal aortic aneurysms

Dr Michael Nesbitt, Dr Sneha Betkekar, Mr Andrew Batchelder, Dr Rishie Sinha, Dr David Evans, Dr Delme Luff, Dr Oliver Morgan

Nottingham University Hospitals NHS Trust - Queens Medical Centre

#### Introduction

Following recommendations made by the national abdominal aortic aneurysm quality improvement programme (AAAQIP), that we should adopt a multi-disciplinary approach to pre-op assessment, we introduced a joint surgical and anaesthetic pre-op assessment clinic for abdominal aortic aneurysms (AAA) in March 2024. In the clinic, all patients are reviewed jointly by a consultant vascular surgeon and a consultant vascular anaesthetist. The aims of this are to improve pre-op multi-disciplinary team (MDT) involvement, in keeping with AAAQIP recommendations, and also to improve the efficiency of our AAA pre-op pathway, measured by the time from referral to surgery and the proportion of patients who undergo elective AAA repair within 8 weeks of assessment.

#### Methods

We conducted a retrospective audit of the following: 1) Time from referral to review by a consultant vascular surgeon. 2) Time from referral to review by a consultant vascular anaesthetist. 3) Time from referral to surgery (open or endovascular AAA repair). We compared patients who were referred for surgery in the 6-month period after the clinic started (March – September 2024), to patients who were referred for surgery during the same 6-month period of the previous year (March – September 2023). We also accessed national vascular registry (NVR) data, to analyse our trusts performance against the 8-week target for time from assessment to surgery.

#### Results

Before clinic set-up (March – September 2023), 29 patients underwent elective AAA repair. The mean time from referral to review by a consultant vascular surgeon was 29 days, mean time from referral to review by a consultant vascular anaesthetist was 80 days, and the mean time from referral to surgery was 161 days (23 weeks). In comparison, after clinic set-up (March – September 2024), 16 patients underwent elective AAA repair. There were improvements in all 3 areas, but most significantly in the mean time from referral to review by a consultant vascular anaesthetist (21 days vs. 80 days) and the mean time from referral to surgery (63 days vs. 161 days).

Figure 1 shows the moving average of the proportion of AAA repairs performed within 8 weeks of assessment. It is clear that from the first quarter of 2024 (Q1 2024) onwards, there was a significant

**Figure 1** National vascular registry (NVR) quarterly report for Nottingham University Hospitals NHS Trust. The 1-year moving average of the proportion of elective infrarenal AAA repairs performed within 8 weeks of assessment.



improvement in this metric. By the third quarter of 2024 (Q3 2024), over 60% of AAA repairs were performed within 8 weeks, compared to only 34% in Q1 2024. This represents a significant improvement in our performance against the 8-week target.

In comparison, the national (United kingdom) performance against the 8-week target for assessment to treatment remained static during the same period (29% in Q1 2024 vs. 34% in Q3 2024).

#### Conclusion

We have demonstrated that the implementation of a joint surgical and anaesthetic pre-op assessment clinic for AAA, has resulted in substantial reductions in the time from referral to review by a consultant vascular anaesthetist, and the time from referral to surgery. The improved efficiency of our AAA pre-op pathway is reflected in our NVR data, which demonstrates a dramatic improvement in the proportion of patients who undergo surgery within the target timeframe. Ultimately, this should result in fewer AAA ruptures while patients are waiting for surgery.

### From Comorbidity to Mortality: Long-Term Outcomes Following Open Thoracoabdominal Aortic Aneurysm Repair in a National Surgical Cohort

Dr lan Young,¹ Dr Alasdair Ruthven,¹ Dr Euan McGregor,¹ Mr Aryaan Ashraf,² Mr Orwa Falah¹ ¹ The Royal Infirmary of Edinburgh; ² The University of Edinburgh

#### Introduction

Patients undergoing open thoracoabdominal aortic aneurysm (TAAA) repair frequently present with significant comorbidity. Preoperative assessment seeks to identify peri-operative risk and ensure functional fitness for surgery. However, it remains unclear whether flagged comorbidities are predictive of future cause-specific mortality, or simply descriptive features of this ageing surgical population. We aimed to examine the long-term relationship between pre-operative comorbidities and eventual causes of death.

#### Methods

We reviewed all 424 patients who underwent open TAAA repair at the Royal Infirmary of Edinburgh between 1999 and 2022. Patients completed a standardised pre-operative assessment including cardiopulmonary exercise testing, stress echocardiography, CT coronary angiography, and pulmonary function testing. Mortality data, including primary cause of death, were obtained from the Scottish mortality registry and censored in 2024. We analysed the relationship between specific pre-operative comorbidities (cardiovascular, cerebrovascular, respiratory, and renal) and actual causes of death. These were compared to age-matched mortality rates in the general Scottish population.

#### Results

By 2024, 168 patients (40%) had died. Among those with preoperative cardiovascular disease, 33% had died, but only 5.8% died from ischaemic heart disease. Of patients with respiratory comorbidity, 43% had died, but only 7.5% from respiratory causes. For those with cerebrovascular disease, 39% had died, but only 10.7% from stroke-related causes. Of those with chronic kidney disease, 32% had died, but only 2.6% from renal failure. In every comorbidity category, more patients died of a different cause than from their flagged comorbidity.

#### Discussion

Pre-operative comorbidities were not strongly predictive of cause-specific mortality. Most patients died of causes other than the comorbidity identified prior to surgery. These findings suggest that while pre-assessment effectively selects patients with adequate physiological reserve, comorbidities should be interpreted cautiously in predicting long-term outcomes. For multidisciplinary teams, this distinction is important: comorbidities that do not impair functional capacity should not be over-weighted in estimating long-term prognosis following open TAAA repair.

### Opioid Requirements Following Elective Open AAA Repair: The Analgesic Impact of Epidural and Spinal Techniques

Dr Kirsty House, 1 Dr Rishabh Sethi, 2 Dr Lisa Grimes 2

<sup>1</sup>Luton and Dunstable Hospital, Bedfordshire NHS Foundation Trust; <sup>2</sup>Addenbrookes Hospital, Cambridge University Hospitals

Effective perioperative analgesia is essential in elective open abdominal aortic aneurysm (oAAA) repair, a procedure associated with high postoperative pain and morbidity. Thoracic epidural analgesia (TEA) has demonstrated reductions in complications, long-term mortality and hospital stay, <sup>1–3</sup> lowering delirium incidence through reduced opioid use. <sup>4</sup> It is recommended by ERAS and the Society for Vascular Surgery due to benefits in pulmonary and cardiac outcomes, GI bleeds and ICU stay. <sup>5</sup>

However, TEA carries risks in vascular patients receiving perioperative anticoagulation.<sup>6,7</sup> With ERAS moving away from TEA in favour of spinal techniques in some abdominal procedures, interest has grown in the use of intrathecal analgesia (ITA) for oAAA surgery. Though less common in this setting, ITA may help reduce systemic opioid use.<sup>8</sup> This is increasingly relevant in the context of opioid-related adverse effects and the broader opioid crisis.<sup>9</sup>

We reviewed our local electronic records to evaluate analgesic strategies and postoperative systemic opioid requirements for elective oAAA cases performed between 2019–2024. Patients were classified into three groups: 1) TEA, 2) ITA, and 3) GA alone.

Oral morphine equivalent (OME) doses were calculated over the first 72 postoperative hours.

A total of 199 patients met inclusion criteria. Demographics across groups were comparable. TEA was the most frequently employed technique (n=121), with ITA (n=44) and GA (n=43) used less often. TEA patients had the lowest systemic opioid use: median 5mg OME (0-258mg). Median OME was markedly higher in both ITA (274.5 mg) and GA (283.5 mg) groups (149-589mg, 185-463mg).

TEA was associated with significantly reduced opioid consumption compared to GA (p<0.001) and ITA (p<0.001). No significant difference was observed between ITA and GA (p=0.92). There was no significant difference in length of stay across groups (p=0.79), although itshowed wide variation, likely reflecting surgical complexity and patient comorbidities.

While recent literature suggests spinal anaesthesia may match TEA in early postoperative analgesia, 10 our data show TEA remains the preferred technique in elective oAAA repair in our centre. In most ITA cases, the choice was due to contraindications or

technical failure of epidural placement.

TEA use correlated with a substantial opioid-sparing effect, reinforcing its value in multimodal analgesia for older, comorbid vascular patients, where minimising opioid exposure is critical.<sup>3</sup> Conversely, ITA did not confer a significant opioid reduction vs GA. Prior studies have reported superior early pain control with ITA, even over TEA, <sup>10</sup> which prompts interest in combined spinal-epidural (CSE) approaches.

OME was used as a proxy for pain scores. Future research should include patient-reported outcomes, such as pain scores, mobility, opioid side effects, and long-term functional recovery.

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#### Does NT-pro-BNP correlate with Cardiopulmonary Exercise Testing (CPET) variables or Clinical Frailty Score?

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NT-pro-BNP (N-terminal pro–B-type natriuretic peptide) is a biomarker that may indicate perioperative risk in high-risk patients undergoing non-cardiac surgery. 1.2 We sought to identify whether NT-pro-BNP correlated with CPET variables or Clinical Frailty Score (CFS) in our vascular surgical population being considered for abdominal aortic aneurysm (AAA) surgery.

We analysed data from 126 patients being considered for AAA surgery who underwent CPET at our institution in 2024. Variables including peak oxygen uptake (VO<sub>2</sub> peak), anaerobic threshold (AT), ventilatory equivalent for carbon dioxide (VE/VCO<sub>2</sub>), and CFS were extracted from our CPET database. NT-pro-BNP values were collected from the electronic patient record (Epic). NT-pro-BNP values were included if taken within 6 months of the CPET test and prior to surgery. A Spearman's rank correlation analysis was performed to identify whether a correlation existed between preoperative NT-pro-BNP and each variable. Statistical analysis was performed using Microsoft Excel.

A total of 126 patients underwent CPET between 1 January and 31 December 2024. Fifty-two were excluded due to unavailable NT-pro-BNP data. Seventy-four patients were analysed. Demographics: male 63/74 (85.1%), mean age 73.3 years (range 57–89 years). Median NT-pro-BNP was 185ng/L (range 25–36,772 ng/L). Mean VO<sub>2</sub> peak was 17.1 mL/kg/min (range 7.9–31.0

mL/kg/min). AT data were available for 68/74 patients, with a mean value of 12.5 mL/kg/min (range 6.9–27.3 mL/kg/min). VE/VCO<sub>2</sub> was available for 70/74 patients (mean 33.9, range 23–51). CFS was available for 72/74 patients, median score 3 (range 1–7).

Spearman's correlation coefficients (r<sub>3</sub>) were:

NT-pro-BNP vs VO<sub>2</sub> peak: -0.38

NT-pro-BNP vs AT: -0.14

NT-pro-BNP vs VE/VCO<sub>2</sub>: +0.23

NT-pro-BNP vs CFS: +0.31

This exploratory analysis suggests a moderate inverse correlation between NT-pro-BNP and VO<sub>2</sub> peak, and weaker associations with AT and VE/VCO<sub>2</sub>. A modest positive correlation was observed between NT-pro-BNP and CFS. These findings support the hypothesis that NT-pro-BNP may reflect broader physiological reserve beyond cardiac function alone. While limited by small sample size and retrospective design, this study suggests NT-pro-BNP could complement existing measures of cardiopulmonary fitness and frailty in perioperative risk stratification for AAA surgery.<sup>3</sup>

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ROULEAUX CLUB ANNUAL ESSAY COMPETITION

### **Rouleaux Club Winning Essays 2025**

The Rouleaux Club run an annual essay competition to help promote interest in vascular surgery. Entrants are asked to write 1,500 words on one of three topics selected by the RC Executive. The essays are marked by the committee and the prizes are awarded to the best essay at the annual Vascular Society meeting. There are two prize categories, one for medical students and another for junior doctors. We are delighted to publish the winning essays here.

#### STUDENT CATEGORY

How can we achieve more timely revascularisation in patients with Chronic Limb Threatening Ischaemia (CLTI)? Ryan Bloxsom, University of Oxford

Revascularisation is time-critical in Chronic limb-threatening ischaemia (CLTI), with delayed revascularisation associated with excess amputation and mortality. 1.2 From symptom onset, there are multiple, sequential delays to revascularisation, with delayed presentation, referral, Vascular review, admission, and revascularisation procedure all contributing to longer time-to-revascularisation (TTR). This essay will explore contributions from each delay to TTR, and identify actionable changes to reduce these delays, and subsequent TTR amongst patients with CLTI.

### Facilitating prompt presentation with CLTI symptoms reduces TTR

Delay between symptom onset and primary care (PC) assessment contributes to TTR, being influenced by patient factors, past PC encounters, and appointment availability.3 In a recent interviewbased study exploring delays from symptoms to first presentation for CLTI,3 19% of patients identified 'stoicism' and 19% identified the perception of the NHS being 'under pressure' contributed to their delayed presentation with CLTI symptoms.<sup>3</sup> Additionally, past experiences, including frustration with conservative management and lifestyle advice for stable peripheral arterial disease (PAD) contributed to delay in CLTI presentation.3 Patients reported poor awareness of CLTI's severity, and 25% cited difficulty accessing GP appointments as a cause of delay, highlighting patient behaviours, prior experiences, and PC accessibility influence CLTI presentation.3 Safety-netting PAD patients with stable disease, advising immediate re-presentation to PC upon onset of rest-pain, night-pain, ulceration, or tissue loss, may improve patients' relation with PC, willingness to re-present, and shorten symptom-torevascularisation time.

### Primary care requires further vascular education for timely CLTI recognition

A recent interview-based study with GPs, podiatrists, and practice-

nurses explored factors delaying revascularisation amongst CLTI presentations in PC.<sup>4</sup> Lack of knowledge of CLTI was evident; 55% self-identified they understood the meaning of CLTI, but 36% of these respondents incorrectly described CLTI when questioned.<sup>4</sup> Moreover, 71% of GPs interviewed agreed vascular teaching in PC training is 'limited', with 29% believing this impedes timely referral.<sup>4</sup> 100% of respondents reported referrals were 'time-consuming'; only 29% felt confident recognising CLTI, and 86% lacked confidence when referring to Vascular for CLTI,<sup>4</sup> highlighting a clear need for improved vascular education among PC professionals, promoting early recognition and referral for CLTI patients.

The term 'chronic' in CLTI may be unhelpful – 30% of PC professionals interviewed believed CLTI was not an 'urgent' condition. Whilst underlying atherosclerosis is chronic, CLTI onset marks a shift to rapid deterioration and subacute tissue damage. Re-branding CLTI as 'subacute limb-threatening ischaemia' ('SALTI') would be radical, but may better reflect its urgency, distinguish it from stable PAD, and reduce referral delays.

### More thorough peripheral vascular examination in PC is needed for timely CLTI identification

Thorough vascular examination, including pedal pulses (PdPs), is critical for timely recognition of CLTI. Despite this, retrospective analysis of PC data from the Clinical Practice Research Datalink identified that amongst 3,260 patients undergoing lower-limb amputation secondary to CLTI, only 7% had PdPs checked in PC in the year preceding amputation, despite a median of 19 PC consultations per patient during that period.<sup>6</sup> Moreover, only 2.3% had Doppler ultrasound of PdPs, and 0.2% had ABPI measured,<sup>6</sup> suggesting earlier identification of CLTI through vascular examination may prevent amputation. 67% of these patients were seen in PC 7-30 days prior to amputation, although the presenting complaint and discussions during these consultations were not captured.<sup>6</sup> For 2025/26, QOF only incentivises PdP-palpation for

known diabetics, but not vasculopaths;<sup>7</sup> extending QOF-incentives to non-diabetic vasculopaths (e.g. past-MI, stroke/TIA, PAD) may improve early CLTI detection, and reduce TTR.

### CLTI referrals should include key signs/symptoms to facilitate appropriate triage to reduce TTR in severe cases

The Vascular Society (VSGBI) outlines an 'admitted' pathway for CLTI with rapid progression, deep infection, or uncontrolled pain; and a 'non-admitted' pathway for CLTI patients with minor necrosis, controlled pain, or superficial infection, in their quality improvement framework (QIF),<sup>8</sup> with indicated target TTR of 5-days and 14-days, respectively.<sup>8</sup> In a recent interview-based study, 57% of GPs reported not feeling confident examining for CLTI, 86% did not feel confident referring CLTI, and only 14% suggested examination findings were used to support their decision to refer.<sup>4</sup> 71% felt Vascular referral forms were helpful, and 29% suggested referral proforma with key referral criteria supported referrals,<sup>4</sup> suggesting a standardised referral proforma may guide history and examination, identifying the presence or absence of discriminating symptoms and signs which may influence Vascular triage.

#### Daily review of referrals in secondary care reduces TTR

Once PC identifies CLTI and refers to Vascular, additional delay is encountered between electronic referral submission (eRS) to triage and outpatient assessment (OPA) by Vascular teams. In a recent study of 12 arterial centres, RRS review frequency by Vascular teams varied, from daily at 42% of centres, at least every 48-hours in 33%, and weekly in 25% of centres. Differences in hubs' eRS review frequency associated with time to OPA, with centres reviewing daily all achieving OPA within a maximum of 3-days from eRS submission, but those reviewing weekly all experienced a maximum 9-days between eRS submission and OPA, suggesting daily eRS review in hubs may reduce TTR by reducing delay to OPA.

Similarly, amongst 10 non-arterial 'spokes', daily eRS review was conducted in 20% of centres, with 40% reviewing weekly, and 20% of centres reviewing 'less-than-weekly', with only 1 spoke offering emergency, bookable, consultant-led OPAs.960% of spokes relied on overbooking emergency OPAs into fully-booked clinics, with one spoke reporting zero emergency OPA capacity.9 70% of spokes offered no 'hot clinic', which may contribute to reduced emergency capacity, although these were typically led by Vascular Specialist-Nurses.9 Delays from PC eRS to Vascular OPA could be reduced through more frequent monitoring of eRS submissions, and in spokes offering limited or no emergency capacity, automatic eRS forwarding to hubs reviewing eRS daily may reduce time to OPA and subsequently TTR, but may require patients to travel further for initial OPA and revascularisation. Additionally, if PC have the choice of submitting eRS to a hub or spoke, and both are accessible to the patient, hub referral may reduce TTR through rapid eRS triage, but at the expense of increasing hub caseload and patient travel.

### Referral to hubs is associated with shorter TTR than spokes

Delay between Vascular OPA and revascularisation was comparable for hub and spoke OPA, if revascularisation was to take place in a hub, both with a median OPA-to-revascularisation time of 13-days.<sup>10</sup> However, since delays from referral-to-OPA, and OPAto-revascularisation are sequential, total referral-to-revascularisation time is shorter for hub referrals. 10 However, if revascularisation was to occur at the spoke, OPA-to-revascularisation time was significantly greater, with a median 26-days, suggesting referral to a hub (if accessible to a patient) may reduce TTR, by reducing referral-to-OPA time, and OPA-to-revascularisation if revascularisation would have occurred in the index spoke, with more than 75% of spoke revascularisations taking longer than the recommended 14-days for revascularisation.<sup>8,10</sup> Additionally, a small number of patients presenting for OPA were admitted, discharged, and readmitted - this was associated with a median delay of 33days, 10 reinforcing the idea that discharging CLTI patients from inpatient care should be avoided to reduce TTR amongst this timecritical population.

### For patients on the 'admitted pathway', hub admissions yield shorter TTR than spokes

Amongst patients on the 'admitted pathway' for severe CLTI, Vascular contact-to-revascularisation is significantly shorter in hubs than spokes, with median admission-to-revascularisation times of 5-days and 12-days, respectively. 10 Admission to a spoke for inpatient hub-transfer was associated with significantly longer delays (median 12-days), encountering additional 7-days delay versus direct hub-admission, with 81% of patients on this 'admitted' pathway failing to meet the inpatient revascularisation within 5-days target, versus 50% for direct hub admissions. This data suggests facilitating patients' direct hub admission may reduce TTR compared to both spoke-admission for spoke-revascularisation, or spoke-admission for inpatient hub-transfer. 10 Patients admitted to either a hub or spoke, who were then discharged for re-admission for revascularisation encountered greater delay of median 20-days from index admission, suggesting patients admitted for CLTI should not be discharged from inpatient care to minimise TTR, preventing an associated 8-days additional delay.<sup>10</sup>

Additionally, pay-for-performance financial incentives may reduce TTR: a recent single-centre retrospective analysis identified the proportion of CLTI patients revascularised within 5-days via the admission pathway rose from 41% pre-incentive to 59% post-incentive, 11 with suggestions that financial incentives engage senior hospital management, 11 engendering systematic changes facilitating shorter in-hospital TTR. 11 Making these pay-for-performance targets more ambitious over time may encourage continued engagement from senior hospital management, and progressive reductions in TTR.

This essay highlights how TTR in CLTI is influenced by patient presentation, recognition of CLTI, timely referral, urgent Vascular

review, and inpatient admission, exploring strategies which could be implemented to reduce each delay and total TTR. During the early stages of CLTI, patient and clinician recognition of CLTI symptoms and urgency of the condition appear rate-limiting factors, with more thorough peripheral vascular assessment in PC essential to increase timely identification of CLTI, to permit prompt revascularisation and reduce major amputation. Delays in secondary care tended to be administrative, with delayed review of referrals and limited OPA availability significantly contributing to overall delay and TTR. Patient and clinician education, thorough vascular assessment plus examination, and streamlined Vascular referral pathways are required to facilitate more timely revascularisation in patients with CLTI.

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#### **DOCTOR CATEGORY**

How can we achieve more timely revascularisation in patients with Chronic Limb Threatening Ischaemia (CLTI)? William Jenkins, East of England

#### Introduction

Chronic limb-threatening ischaemia (CLTI) represents an end-stage manifestation of peripheral arterial disease (PAD)<sup>1</sup>; characterised by rest pain, non-healing ulcerations (>2 weeks) and/or gangrene.<sup>2</sup> CLTI impacts 11% of the 200,000,000 global population with PAD.3 Revascularisation is the mainstay of treatment and is achieved by either open surgery, endovascular intervention or hybrid approaches.4 Prompt identification and revascularisation is paramount as failure to achieve this results in an amputation incidence of ~25% and mortality rate of 25-35% at 1-year postdiagnosis.<sup>5</sup> The Vascular Society of Great Britain and Ireland's (VSGBI) Peripheral Arterial Disease Quality Improvement Framework (PADQIF) recommend revascularisation within 5 days for inpatients, and within 14 days for ambulatory outpatients<sup>6</sup> due to the significant disease sequelae associated with delayed intervention. Delays to revascularisation occur along the entire referral pathway<sup>7</sup> thus there is scope for streamlining the process with targeted interventions to achieve timelier revascularisation.

Demand for vascular services is estimated to increase owing to an ageing population and increased prevalence of diabetes.<sup>8</sup> Therefore, this review addresses a prevalent issue with solutions required to improve the significant morbidity and mortality rates associated with CLTI and reduce the ever-increasing burden on healthcare services via achieving timelier revascularisation.

#### **Identifying Community Delays to Revascularisation**

To achieve timelier revascularisation, causes of delay along the referral process must be identified and rectified. A systematic review investigating the identification, causes and outcomes of delays in CLTI management attributed delays to both patient and healthcare factors.<sup>7</sup>

Patient factors included poor health-seeking behaviours and symptom recognition; inevitably resulting in delayed vascular referral. This represents lack of lay understanding surrounding PAD and potential sequelae of delayed revascularisation in CLTI. CLTI patient cohorts and those at risk may benefit from targeted educational public health campaigns like the F.A.S.T. initiative for identifying symptoms of stroke and similar initiatives for myocardial infarction. Raising awareness of common signs and symptoms associated with CLTI and the consequences of not seeking medical attention by applying the 'time is tissue' mantra to CLTI will likely improve health-seeking behaviours and result in swifter vascular referral.

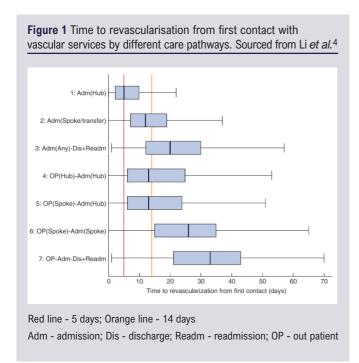
Primary and community care represents a pivotal initial role in the referral pathway for CLTI. Atkins *et al*<sup>9</sup> sought to evaluate the factors affecting primary care clinicians' referral behaviours and how these may delay CLTI care. A qualitative semi-structured interview process involving general practioners, community nurses

and podiatrists across 12 different vascular surgery units identified several themes delaying CLTI referral. Ambiguity regarding the term CLTI, its status as a distinct entity from acute limb ischaemia and diagnostic thresholds imply CLTI may benefit from a mnemonic akin to 6 P's for acute limb ischaemia which clinicians expressed more confidence in diagnosing. Another issue voiced was overreliance on ankle-brachial pressure index (ABPI) as an objective proxy of perfusion status and how this can lead to false-reassurance. Apprehension surrounding referring directly to vascular surgeons was also highlighted as a barrier to a streamlined referral process, with negative previous experiences involving 'sarcasm' and 'nervousness about speaking to a specialist' mentioned. Vascular surgeons must therefore be aware of how they are perceived and the potential repercussions of not being deemed approachable.

An overwhelming theme was how much interviewees felt they would benefit from written guidelines providing clarity on who can refer to vascular specialists. Circulating referral criteria and step-bystep guides on local referral processes to primary and community care staff within regional vascular networks would undoubtedly streamline the process; mitigating any confusion or ambiguity which otherwise may result in revascularisation delay. This was reinforced by participating podiatrists, who generally have greater exposure to CLTI cohorts, expressing more confidence in referring to vascular specialists due to familiarity using tools such as the Wound, Ischaemia, Foot Infection (Wlfl) classification<sup>10</sup> and European Society of Vascular Surgery calculators to guide referrals more objectively. If this was implemented into common practice when assessing potential CLTI patients in the community it would likely lead to more certainty in referral decisions and swifter contact with vascular specialists. This study also echoed the findings of the systematic review by Nickinson et al7 with patient unwillingness for referral acting as a major barrier to timely revascularisation. Factors contributing to this reluctance need to be identified but is likely due to lack of perceived threat concerning CLTI thus further stressing the need for lay education.

#### The Hub-and-Spoke Model – Postcode Lottery?

National Health Service (NHS) England has adopted a centralised hub-and-spoke regional model for vascular arterial surgical provision. This reconfiguration was introduced following studies which concluded there was a significant relationship between higher-volume hospitals and successful outcomes following arterial surgery. Within regional networks, the hub performs arterial surgery and complex endovascular procedures whilst spoke hospitals cater to outpatient services and appropriate day-case procedures. Patients requiring arterial surgery who have been admitted to a spoke hospital therefore need to be transferred promptly to the relevant arterial hub.



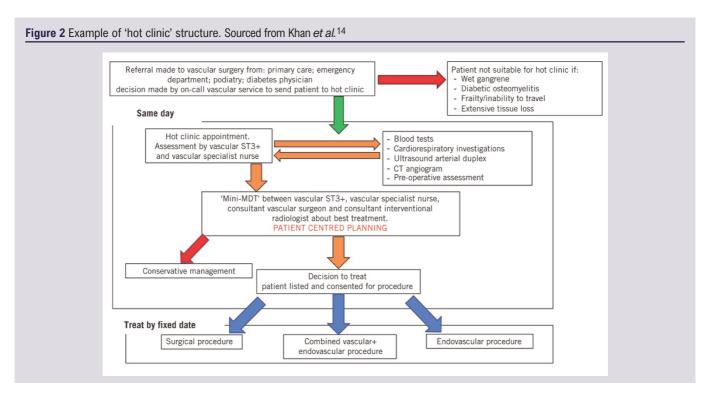
A 2022 study found CLTI patients initially presenting to a nonarterial spoke hospital waited more than twice as long for revascularisation compared to those first presenting to an arterial hub<sup>4</sup> (Figure 1). This marked discrepancy was however not maintained for those who had initial outpatient assessment at either hub or spoke, followed by admission and revascularisation at the hub hospital.<sup>4</sup> This study found that the VSGBI's PADQIF recommendations of revascularisation within 5 days for non-elective admissions was achieved in 50.3% of patients admitted directly to an arterial hub versus only 18.8% for the spoke transfer cohort.

This study identifies an inherent flaw of the hub-and-spoke model in that initial spoke presentation results in unavoidable delay as patients require transfer to the hub for intervention. 12 This logistical delay is likely further exacerbated by inpatient hub capacity constraints. Therefore, effective referral pathways within the hub-and-spoke model are paramount to negate the concept of a 'postcode-lottery' arising and ensuring timely revascularisation regardless of where a patient presents within a regional vascular network.

#### 'Hot Clinic' for Cold Limbs

One concept implemented by some vascular units to try and meet PADQIF recommendations is emergency clinics termed 'hot' clinics, whereby CLTI patients receive full clinical assessment including consultant review, laboratory and imaging studies to guide potential intervention<sup>6</sup> (Figure 2). Despite hot clinics being recommended in the 2019 Global Vascular Guidelines<sup>13</sup> and their use in other specialties being long-established, as of 2021 they were utilised by fewer than 50% of UK vascular units for urgent CLTI assessment.<sup>6</sup>

A single-centre prospective cohort study sought to compare outcome measures between cohorts of hot clinic patients versus emergency admissions. <sup>14</sup> Whilst there was no significant difference in median time from intention-to-treat to procedure between the cohorts, median time from admission to procedure was significantly lower (0 days) for the hot clinic cohort versus the comparable emergency cohort (3 days). This study also found a significant



difference in median length of hospital stay in favour of the hot clinic cohort (3 days versus 17 days) which indirectly facilitates achieving timelier revascularisation for other patients by improving inpatient bed capacity.

The potential role of hot clinics has been given further credence by an observational cohort study with historical controls concluding that 1-year amputation rates decreased from 25% to 11.1% following the establishment of a rapid access limb salvage clinic in a single UK centre. Comparison of time to revascularisation between the historical and prospective cohorts could not be directly investigated due to lack of historical data. However, these findings in the context of the implemented rapid access clinic and the established knowledge that timely revascularisation is associated with reduced major amputation incidence suggests hot clinics may well reduce delay in revascularisation and further research is certainly warranted.

The concept of utilising hot clinics to achieve timelier CLTI revascularisation has not been completely adopted nationally and has not yet undergone large-scale investigation but these studies illustrate their potential role. A potential means of further development is establishing small-scale clinics at spoke hospitals (time, personnel and financial provision allowing) with any laboratory and radiological investigations conducted before virtual review, akin to virtual fracture clinics in Trauma and Orthopaedics, by the relevant hub consultant surgeon. This would further streamline the hub-and-spoke referral pathway and reduce the preoperative assessment and decision-making upon arrival at the hub, resulting in prompt revascularisation and reduced hub burden. Further utilising spoke hospitals as sites for appropriate endovascular intervention and training surgeons to perform more endovascular procedures independently would reduce burden on not only hub hospitals but also interventional radiologists thus maximising existing resources to achieve timelier revascularisation. 15 These implementations would somewhat alleviate current issues; ensuring timely revascularisation regardless of where patients present in the hub-and-spoke model.

#### Conclusion

Delays in CLTI revascularisation are associated with significant morbidity and mortality. Considering disease prevalence is projected to increase, it is critical that methods to achieve timelier revascularisation are identified and implemented. Revascularisation delays occur along the entire referral pathway and thus improvement and education must occur in patient, community and hospital settings. This can be achieved via targeted public health initiatives to improve lay understanding, providing clarity regarding

referral criteria for community healthcare professionals, encouraging greater implementation of hot clinics and reallocating certain services to underutilised spoke hospitals.

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**NFWS** 

### **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 news from some of the societies.

#### **Rouleaux Club**

www.Rouleauxclub.com @RouleauxClub



We are delighted to continue our partnership with the RCSEd to continue to run a one day practical course "So you think you want to be a vascular surgeon?" this year held in October at the College's Regional Centre in Birmingham with a date in the diary for the Scottish iteration in the Spring (25th April 2026). Once again, it was well attended and is an excellent resource for medical students and resident doctors in the early years of training. Please encourage members of your team to attend if the haven't already.

Turning our attention to the run up to VS ASM, we have been busily preparing behind the scenes. We had a good number of high quality, fascinating video abstracts for the MDT session and had the difficult but

enjoyable task of shortlisting them. The top three have been contacted and will make an educational session for colleagues with all levels of experience.

Submissions for the second year of the Averil Mansfield Prize surpassed the strong numbers we received last year; 48 submissions were received, nominating 36 candidates. The top four nominees were interviewed by a panel consisting of three Rouleaux Executive Committee and two VS Council members and they were all an inspiration. It was a close competition but the second Trainer of the Year to receive the Averil Mansfield Prize, will be announced at VS ASM's Gala Dinner.

There are still some spaces for our "Introduction to Vascular Surgery Course", an annual highlight, held on the Wednesday morning of the conference.

We have selected our essay competition winners for both the medical student and resident doctor (pre SPR level) entries. The winner from each category will have their

essay published in JVSGBI so please look out for those and entrants receive free entry to the above course. Winners will be announced at Rouleaux's AGM held on the Wednesday evening of the ASM.

Finally our association will continue with CX/BIBA Medical regarding the now annual infographic/infomercial competition and the title has been confirmed for next year's competition, focussing on diabetic foot disease, "The Footsteps Challenge." Winners of each category win £500/£1000 respectively and entries close on the 5th January 2026.

At the upcoming ASM I hand over the responsibility of President to Mohamed Elkwafi. Mo has been Education Rep on the committee for the last two years, spearheading the Averil Mansfield Prize, so I know the society is in good hands.

Lauren Shelmerdine President

#### Society of Vascular Nurses (SVN)

www.svn.org.uk @vascularnurses



The SVN has focused on education this year both for clinicians and patients. We have offered numerous webinars hosted by legs matter, covering venous and arterial disease. The appetite for vascular education is apparent with healthy numbers signed up for all webinars. Our first SVN road show took place in Lancaster in September. It was open to all clinicians working with vascular patients, both in primary and secondary care, and was a

sell-out. We plan to offer these days at various locations around the country. We continue to work closely with our associated societies and the circulation foundation. We presented at the venous forum annual meeting in June and look forward to the joint symposiums at the vascular conference in November.

We are committed to raising awareness of vascular disease and reducing the inequalities in services for patients. We continue to liaise with the VVAPPG and were represented at the Parliamentary Drop-In, Leading Vascular Care: Fit for the Future in May this year. Through fostering meaningful dialogue between parliamentarians and sector leaders, the event created valuable opportunities to

strengthen collaboration and support the future of vascular and venous services.

The committee is keen to understand better the vascular nurse workforce within the UK. We have distributed a survey to all vascular centres and plan to present the outcome of that in Hull this year. The SVN continues to encourage members to share their research and best practice in appropriate publications, present at the national conference in the James Purdie prize symposium and offers financial support in the form of bursaries to enable members to achieve these outcomes.

Jane Todhunter President

### Vascular Anaesthesia Society of Great Britain & Ireland (VASGBI)

www.vasgbi.com @vasgbi



The Vascular Anaesthesia Society of Great Britain & Ireland

In September 2025 the Vascular Anaesthesia Society held their annual scientific meeting at the Royal Society of Medicine in London. The event was attended by over 250 delegates who enjoyed workshops, lectures and MDT discussions. Highlights included an entertaining debate on the pros and cons of a separate vascular anaesthetic on call rota for vascular surgical emergencies. Dr Maria Safar (Liverpool) argued persuasively in favour of the motion, but the audience voted in favour of her opponent's view. In line with the outcome of the debate, a separate vascular anaesthetic on call rota is unlikely to become a reality. Another highlight was the resident oral presentation session, the abstracts of which are published in this issue of the JVSGBI.

The VASGBI committee are sad that Dr Dan Taylor (GSTT) has completed his

term of office as chair; he has handed over the reins to Dr Vanessa Fludder (Brighton). We said farewell to Dr Gary Matthews (Truro), Dr Ronelle Mouton (Bristol) and Dr Manik Chandra (Leeds) who all demitted from the VASGBI committee this year; we are most grateful to them all for their many years of service and contribution to the work of VASGBI. We welcome 3 new committee members: Dr Rhys Ridian (Bristol), Dr Louisa Shovel (Royal Free) and Grant Harris (Chester) and well as resident reps Dr Leonie Murphy (KSS) and Michael McCann (Belfast).

We are very much looking forward to the joint meeting of the Vascular Societies in Liverpool in 2026. This will be the first conference where Vascular Anaesthetists and Vascular Surgeons have collaborated for a joint ASM. We hope this will prove beneficial to all and that we will have more shared conferences in future years.

This year VASGBI committee members have been involved in the NCEPOD ALI study and have worked with the Royal College of anaesthetists to develop quality improvement and audit tools for vascular anaesthetists. We continue to work with the NIAA to support research in the field of

vascular surgery and anaesthesia. We are looking forward to working with colleagues to develop the NAAASP exit strategy and supporting primary care with non-referral of patients unlikely to benefit from surgical intervention.

We regularly undertake surveys on behalf of our members; our current survey is investigating current practice with regard to analgesia for open aortic surgery. You can take part via a link on our homepage Open Aortic Surgery Analgesia Survey -VASGBI.

Registration has just gone live for the biennial virtual VASGBI CPD meeting which will take place on Friday 13th March 2026 and will be hosted by Dr Carolynn Wai and team from Preston. The programme will include an overview of the NCEPOD ALI study results and recommendations, assessment and management of right heart dysfunction, anaesthesia for complex aortic surgery and much more. For details of the full programme visit the VASGBI.com website (vasgbi-cpd-meeting-programme-2026.pdf).

Vanessa Fludder Committee Chair

### The Vascular Society for Great Britain and Ireland

www.vascularsociety.org.uk @VSGBI



#### **Annual Scientific Meeting 2025**

Autumn is a busy for the Vascular Society Council and Committee members as we prepare for the Annual Scientific Meeting. The meeting this year is being held from the 26th to 28th November in Hull. The theme for this ASM is "Evidence based, patient centred, service provision". We can look forward to an interesting and varied programme of talks. Following a morning of parallel abstract sessions the meeting opens with the joint vascular societies' symposium on Claudication – the Multiprofessional team. This is followed by

Professor Chetter's presidential symposium on leadership. Keith Jone's Vice-President's session the following day is wide ranging from education; to the specialist doctor role; to delivering change through outcome data.

There are several clinical trial sessions across the meeting, including presentations from the PCAAS, MIDFUT, DOMINO-DFU, REVIVAL, RAF, RAVE, KID, EARNEST, ESTABLISH, MOSAIC2, Stepforward, ROSSINI, DRESSINg and HAMLET trials. Simon McPherson will present the results and recommendations of the NCEPOD Acute Limb Ischaemia study. The Circulation Foundation session will be another highlight, with talks from Marc Bailey on better medical treatment and Henry Davies on End-of-Life care. VERN will again host the Dragons, Prof Rob Hinchliffe and Rachael Forsythe, with four projects competing this year for funding.

Five courses are being run on the Tuesday prior to the ASM: ASPIRE Venous, ASPIRE

Trauma, ASPIRE Leadership, Conflict Resolution and the new VS Mentorship programme.

A change for this year is the SAS and LED doctors' session moving to Thursday afternoon, and in another break from tradition, Ms Hannah Travers an early years Consultant will give the Kinmonth Lecture. Ms Ellie Atkins will give her Huntarian lecture on the Friday.

The other invited lectures are the BJS lecture – Jon Boyle – and Edinburgh College Lecture – Prof David Clutterbuck.

We look forward to seeing many members at the ASM this year alongside their professional colleagues attending the SVN, CSVS and BACPAR programmes.

#### NHS 10-year plan

The other recent focus for the Council has been lobbying NHS England and the Department of Health for the inclusion of peripheral arterial disease (PAD) in the cardio-vascular modern service framework (CVD-MSF) of the new NHS 10-year plan. This internal NHS England plan will set the agenda for healthcare in England. To date, 'cardio-vascular' disease has focused on cardiac disease, and to some extent renal disease, with little or no input from vascular surgeons.

We feel it's important this changes due to the impact of vascular disease, specifically PAD, on quality of life, major lower limb amputations, and life years is lost. There are striking inequalities between the north and south of England in PAD outcomes.

The inclusion of PAD in the CVD-MSF aligns with the NHS plans aims to transition from hospital care to community care, from analogue ways of working to digital, and from treatment to prevention. It also has a focus on addressing inequality.

We would first like a public awareness campaign backed by evidence based and joined up care pathways for people with Intermittent Claudication across primary and secondary care.

### **Endovenous intervention by Non-Medical Professionals**

The Vascular Society has published its statement on a treatment of varicose veins by non-medical professionals We felt it important that the society has a clear position statement on this area of practice given how emotive it has been. We recognise that a people with superficial venus disease often wait too long for their surgery and welcome improvements in service provision. This cannot, however, be at the cost of the standard as a care, patient safety, or the training of our future

vascular specialists. There must audit of outcomes of procedures and multiprofessional team working.

The document has been written with input from our Allied vascular societies, including the Society of Vascular Nurses (SVN), the College and Society of Vascular Scientists (CSVS) and the Rouleaux Club. Huge credit is due to Patrick Coughlin for leading this work.

#### Mentorship programme

The Vascular Society has launched a mentorship programme for early years consultants (1 to 5 year of practice) with the first mentors receiving training next week. This initiative to support members is accompanied by the "The Rising Tide Project", a well-being programme, supported by Lizzie Paish a professional transformational coach, which all members can access via the Society's website members area.

#### **New appointments**

The ASM also marks the time when we announce the election results for the President (2027-8), Vascular Society RCS Eng. Council representative, and two new council members.

This year has an additional significance as Keith Jones will be the first Vascular Society President elected by full member. This feels important milestone for the Society and is very much in keeping with the current focus on listening to members and greater trasparency.

Professor Ian Chetter will continue as Editor-in-Chief for the *JVSGBI*. I am confident we will see the Journal continue to grow in impact and reach.

Other appointments which come into effect are Marco Baroni as Honorary Secretary, James McCaslin as Honorary Treasurer, Rao Vallabhaneni as Research Committee Chair and Kaji Sritharan as Education and Training Committee Chair.

#### Webinar programme

The Society has successfully launched a series of webinars though which members can connect and contribute to the Society. Each month a member of the Executive or a Committee Chair will host, and members are invited to ask questions.



#### Recognition

The Research Committee and PAD SIG have received the Global PAD Research Team of the Year Award, recognising the international impact of UK-led vascular research.

Professor Athanasios Saratzis, University of Leicester, has been awarded a NIHR Research Professorship with provides funding up to £2 million. His work will focus on improving healthcare for people with PAD to improvement treatment, prevent amputations and save lives.

Marcus Brooks

Honorary Secretary, Vascular Society secretary@vascularsociety.org.uk

