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GREAT BRITAIN & IRELAND

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Editor's foreword

Welcome to the latest issue of the *Journal of Vascular Societies Great Britain and Ireland (JVSGBI)*. This issue opens with an editorial addressing the increasingly important topic of assessing and

managing frailty in vascular patients and, in particular, patients with peripheral arterial disease. The first original research paper outlines research priorities for carotid conditions. This is the final report from the pan specialty James Lind Alliance priority setting process. All nine Special Interest Groups (SIGs) have now published their individual subspecialty reports. This is a fantastic achievement and I would like to thank all SIG groups for their hard work and commitment.

Original research articles in this issue include two papers evaluating modifications in vascular service provision – the first for ruptured aneurysms in Merseyside and the second in CLTI in London.

Two further original articles assess interventions in patients with CLTI – the first assesses the outcomes of covered stents for severe aorto-iliac occlusive disease and the second evaluates popliteal sciatic nerve block to facilitate endovascular management.

Three further original articles report qualitative research evaluating quality of life implications of surgical wound healing by secondary intention, UK trends in lower limb DVT and associated interventions, and a network review of transfusion requirements following elective open AAA repair.

Finally, this issue concludes with a case report of a novel hybrid intervention for an infected carotid patch.

It is really pleasing to receive submissions from so many different vascular units, addressing a variety of topics using an array of research designs. Many of these studies appear to be important studies underpinning larger grant applications/research.

Please continue to submit your papers for publication – which will hopefully ensure the ongoing success of the *JVSGBI*.



lan Chetter Editor in Chief JVSGBI VSGBI Research Committee Chair EDITORIAL

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Frailty in peripheral arterial disease

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Introduction

It has been consistently demonstrated that frail vascular patients have poorer outcomes compared with their robust counterparts.¹ Consideration of frailty is particularly important, not only as our population continues to age but as advances in anaesthetic, surgical and endovascular techniques are enabling a broader range of interventional options for those people who may have traditionally been labelled as unsuitable for surgery.²

Frailty has implications for health and social care at the micro and macro level, and failure to consider the differing needs and natural histories of people living with frailty could result in avoidable harm and suboptimal resource allocation. National guidelines recognise the growing urgency in the need to recognise and manage frailty, yet standardised methods for this have not been identified and agreed upon.³ Despite undeniable prognostic value, the aetiology and pathophysiology of frailty in peripheral arterial disease (PAD) remains poorly understood, albeit new data are emerging. This has challenged a uniform approach to assessment and management.

This editorial considers the theories of frailty and applies these to the assessment and management of patients with peripheral arterial disease.

Frailty: definition and theories

Frailty may be defined as a syndrome of increased vulnerability to external stressors due to a failure in homeostatic reserves brought about by age-associated deficits accrued across multiple domains. Two main underpinning theories are accepted which are not mutually exclusive: the phenotypic and cumulative deficit models. The

Fried phenotype of frailty is characterised by progressive age-related deterioration in underlying physical substrate.⁴ It is defined by the presence of three or more energy-negative components existing in a self-perpetuating cycle: unintentional weight loss, weakness, exhaustion and reduced walking speed and activity levels. Rockwood's cumulative deficit theory describes a multifactorial and dynamic biological construct where frailty is graded by the progressive accrual of multi-domain deficits.⁵ Deficits can be quantified to create a Frailty Index (FI) through summation of the number of deficits from a predefined list.

Frailty is related to, but not synonymous with, concepts of comorbidity, disability and sarcopenia (Figure 1). Comorbidity describes the coexistence of two or more chronic conditions. Approximately 70% of frail patients are comorbid, yet only 20% of comorbid patients are frail.⁶ Disability refers to a limitation in physical or cognitive ability to perform activities of daily living independently,7 whereas frailty describes a vulnerable state at increased risk of developing disability.^{4,8} Lastly, sarcopenia is a biological syndrome characterised by generalised and progressive loss of skeletal muscle mass and quality.⁹ Comparing sarcopenia and frailty according to Fried's definition, low grip strength and slow gait speed are characteristic of both constructs, while low activity levels and weight loss are physical manifestations of frailty and aetiological risk factors for sarcopenia.10

Biology of frailty

Frailty can be considered an accelerated or unsuccessful ageing process which occurs either primarily due to intrinsic dysregulation of homeostatic pathways or secondary to physiological burden imposed by diseases and/or

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



their treatment. Several ageing hallmarks have been defined, including altered intercellular communication, mitochondrial dysfunction, genomic instability, telomere shortening and epigenetic changes.¹¹ Underpinning these age-related changes are chronic inflammation and oxidative stress (Figure 2).

Chronic inflammation

'Inflammaging' describes an age-related, chronic, sterile increase and dysregulation of inflammatory processes. Most studies demonstrate significant relationships between frailty and (pro-) inflammatory biomarkers of C-reactive protein and interleukin- $6.^{12}$ To a lesser extent, elevated levels of clotting pathways constituents (D-dimer, Factor 8 and fibrinogen), tumour necrosis factor- α and total white cells, or reduced levels of haemoglobin and haematocrit are also correlated with frailty, even after correcting for factors like age, sex, smoking status, comorbidities and medications.^{13,14}

Oxidative stress

Frailty has been associated with higher oxidative stress levels and possibly lower antioxidant levels.^{15,16} This theory describes a cumulative burden of reactive oxygen species causing gradual cell damage, loss of recovery/regeneration and apoptosis or cellular senescence resulting in tissue deterioration and organ dysfunction.^{17,18} Depending on the tissue/organ affected, different effects are felt (eg, CNS involvement could cause cognitive decline or disrupt neuroendocrine function¹⁹⁻²¹). A role for oxidative stress in age-related conditions of the kidney and cardiovascular disease has also been demonstrated.²² Once these effects reach a



threshold across multiple organ systems, the person becomes clinically frail.

Environmental exposure

Extrinsic exposures have been proposed as initiators/drivers of frailty. Among several factors correlated with frailty are environmental (lower income, social isolation), clinical (comorbidities, poor self-rated health) and 'lifestyle' factors (smoking, alcohol, diet).²³⁻²⁸

Epidemiology of frailty in PAD

Approximately 10% of the general population aged over 65 years are frail.²⁹ The estimated prevalence in patients with PAD is 20–60%.³⁰ The greater prevalence and implications in patients with PAD may be driven by shared aetiological risk factors and possibly synergistic biological mechanisms.^{31–33} Chronic inflammation, increased oxidative stress and shared risk factors (eg, smoking and obesity) are associated with both PAD and frailty.^{32,33} A bidirectional **Figure 3** Illustration comparing the effects of major limb amputation in robust and frail patients. Robust patients demonstrate greater rehabilitative potential with capacity to return to a level of functional independence. Frail patients demonstrate poorer rehabilitative potential and a greater likelihood of long-term functional dependence requiring greater levels of social support on discharge.



relationship is apparent as PAD is an independent risk factor for frailty and vice versa.²³ This high prevalence of frailty is seen in other vascular diseases such as stroke.³⁴ While heterogeneity in frailty assessment challenges accurate epidemiological reporting, it is clear that global population ageing will result in an increased prevalence of frailty in surgical populations.³⁵

Implications of frailty in PAD

Considered 'the most problematic expression of population ageing',¹⁷ frailty diminishes resilience to physiological insults, impairs recovery and complicates return to pre-morbid functional levels (Figure 3). In open surgery and endovascular techniques alike,³⁷ frailty significantly increases risk of morbidity, short- and long-term mortality, prolonged hospital admission, discharge with greater social care requirements and functional decline (Figure 4).^{1,30,36}

While there is a paucity of health economic data specific to

Figure 4 The implications of frailty in vascular surgery outcomes.^{1,31,39}



frailty and vascular surgery, undifferentiated economic data demonstrate that, after controlling for confounding factors, frailty significantly increases total healthcare costs by 54–290%.^{38,39} Frail patients are more likely to have greater social care requirements with estimations suggesting a 16-fold increase in care costs.²² In-hospital costs for frail elective surgical patients are also substantially higher than for their robust counterparts.⁴⁰

Given these pressures, maintaining the status quo is not an option. Many vascular services are looking at innovative clinical pathways facilitating frailty identification and management (Figure 5).

Assessment of frailty in PAD

The first step in managing frailty is its identification. A recent review confirming the prognostic value of frailty in vascular patients identified the use of 16 different frailty assessment tools.³⁷ Broadly, such tools have been categorised into phenotypic, cumulative deficit/FI and 'other' measurements.³⁷ Phenotypic measurements included grip strength, gait velocity, timed-up-and-go test and wearable sensor technology.^{41–46} Importantly, the majority of vascular-themed frailty research involves patients undergoing lower limb revascularisation.³⁷ Ischaemic rest pain will impair mobility, which may skew results if solely relying on phenotypic measurements. However, end stage arterial disease is systemic, with a propensity to produce critical comorbidities. It remains to be clarified if this 'skew' represents a bias in assessment or, in fact, a true estimation of frailty. The original FI incorporated 70 items, reflecting themes included in a comprehensive geriatric assessment (CGA).⁵ However, this is burdensome for practical clinical application, so more concise iterations have been produced. Expected standards of an FI are to include at least 30 multi-domain variables that have an association with health status and increase in prevalence with age without premature saturation.⁴⁷ Nine different FIs have been identified in vascular surgery research, and all demonstrate predictive validity despite none conforming with these expectations (all <30 variables).³⁷ Novel frailty markers include nursing home residency,⁴⁸ biomarkers,^{49–51} nutritional⁵² and isolated

Figure 5 Two different examples of established clinical service models that have been modified to successfully provide relevant medical and social care adapted to the requirements of frail vascular surgery patients

Service model 1

Team: Consultant geriatrician, Speciality doctor (acute care, anaesthetics and intensivist special interest), advanced nurse practitioners (geriatric and surgical interest), clinical fellow, occupational therapists and nurse discharge coordinator.

Funding: Initially by unscheduled care board as a test of change then continued by surgical directorate.

Roles: Daily screening of acute surgical admissions. Patients identified as frail are enrolled in a frailty pathway which encompasses a collaborative approach between frailty team and the parent surgical speciality. The frailty team complete comprehensive geriatric assessment for perioperative optimisation and follow patient journey to completion. The team also provide a daily ward presence and accept referrals daily alongside weekly collaborative surgical ward round to help with medical care and support patient flow

Ninewells Hospital - NHS Tayside

Service model 2

Team: Consultant Vascular Perioperative Physician/Geriatrician Funding: Vascular surgical directorate

Roles: a sentinel role in perioperative care of vascular patients, from the moment of contemplating surgery right the way to postop care and discharge. Outpatient care involves identification of frailty from the outset, medical optimisation through liaising with other medical specialities and anesthesia and prehabilitation of patients undergoing surgery. For patients deemed unsuitable for surgery due to severe frailty, shared decision-making clinics with a focus on advance care planning and symptom control are offered Inpatient care entails identification of frailty to aid preoptimisation of acute patients prior to surgery, post-operative medical care and discharge planning.

Hull Royal Infirmary - Hull and East Yorkshire Hospitals NHS Trust

functional assessments.^{53–55} The use of radiologically-detected sarcopenia as a frailty marker has also been investigated.⁵⁶ Standardisation in frailty assessment will benefit research and clinical practice by improving comparison of services, facilitating data pooling and enhancing translatability of results into clinical practice.

Frailty assessment may allow improvements in healthcare including improved prognostication and targeted optimisation of frailty-related domain deficits. First, the prognostic value of several frailty assessment tools has been demonstrated. Tools that are reproducible and quick without requiring additional training or equipment are likely to be more rapidly adopted. One example is the Clinical Frailty Scale (CFS), a 9-point person-assessed tool applicable in less than 1 minute.⁵ Incorporating frailty assessment into preoperative decision-making may guide patient-centred management. Electively, frailty assessment may be of particular use when considering the suitability of offering prophylactic surgical treatments (eg, carotid endarterectomy) while, in urgent settings, frailty scores may aid decision-making around a patients' suitability for invasive treatment compared with palliative measures (e.g. in patients with chronic limb-threatening ischaemia). To inform targeted frailty-related optimisation, more exhaustive methods should be considered such as those seen with CGA. The maximum benefit of this assessment is only achieved when applied by an experienced healthcare professional in the correct setting with access to the necessary means and time to implement relevant changes. Incorporating this into a vascular surgery practice mandates establishing service models with regular interdisciplinary contribution from geriatricians, pharmacists, physiotherapists and occupational therapists, complemented by communication with social support services and community follow-up links. To ensure such a resource-intensive service is directed appropriately, it may

prove valuable to operate a two-stage system with early frailty screening using a tool such as the CFS, to identify and select those most likely to benefit from CGA.

Frailty management in patients with PAD

Frailty exists along a spectrum of severity with potential for bidirectional transitions between ageing successfully and vulnerability. At a societal level, public health responses to ameliorate frailty effects through health promotion, education and improving access to healthy interventions will drive the biggest benefit to population health. However, even if successful preventative measures are implemented, societal demographic changes suggest frailty will still be prevalent in secondary care, and so it remains imperative that pathways are adjusted accordingly.

The British Geriatrics Society (BGS) has published the 'Silver Book', a best practice guidance on addressing the care requirements of older people living with frailty during the first 72 hours of unscheduled medical and surgical admissions.⁵⁷ Specific to surgery are the BGS and Centre for Perioperative Care guidelines on Perioperative Care for People Living with Frailty.58 Briefly, the guidelines recommend a multidisciplinary holistic approach across primary, secondary and social care. This incorporates preoperative risk assessment and optimisation, lifestyle modification, optimised intraoperative techniques, appropriate postoperative rehabilitation and proactive discharge planning that incorporates links to community and primary care follow-up. There will be inherent challenges in overcoming anticipated issues of funding, resource availability and coordinating the synchronisation of such a multidisciplinary approach across all components of health and social care.

In vascular surgery, the importance of frailty has also been recognised through national guidelines advocating patients have

KEY MESSAGES

- Frailty is increasingly common in vascular surgery populations.
- Frailty predicts poor outcomes and carries real economic and resource implications.
- Discrepancies in its assessment impairs the adaptability of clinical service models.
- New frailty-centric services are vital to safeguard equity in healthcare provision.

access to CGA.³ However, there remains a paucity of research to inform evidence-based guidelines. Preliminary studies confirm clinical and financial advantages to incorporating CGA in perioperative pathways for vascular surgery patients. For example, a randomised controlled trial (n=209) confirmed clinical and costeffectiveness of introducing preoperative CGA-based prehabilitation compared to standard care for patients undergoing elective arterial reconstruction.⁵⁹ This benefit was primarily through reductions in length of stay, but also due to reductions in intensive care use, postoperative clinical reviews, care packages and community rehabilitation referrals. Importantly, a challenge specific to vascular surgery is the time-sensitive nature of a significant proportion of presentations, which precludes meaningful prehabilitation. The use of frailty assessments to quide postoperative involvement of geriatric services for emergency vascular admissions has also demonstrated similar positive effects, with reductions in length of stay and improved short-term readmission rates.⁶⁰ Large multicentre and long-term follow-up studies are required to substantiate this evidence and support clinicians and policy makers in driving forward suggested augmentations to clinical service models.

Conclusion

While there is debate around the biology of frailty, there is no debate that frailty is common and associated with poor surgical outcomes. Multidisciplinary approaches to assessment and management in vascular surgery have been identified as a priority.⁵⁸ However, there is a lack of robust evidence to support frailty-centric adaptations to services. A collaborative approach between researchers, multidisciplinary clinicians and policy makers is needed to ensure high-quality, person-centred care for this growing surgical population.

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ORIGINAL RESEARCH

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Research Priorities for Carotid Conditions: results of the UK Vascular James Lind Alliance Priority Setting Process

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Plain English Summary

Why we undertook the work: More research is needed to help improve treatment and delivery of care for people with vascular conditions, but funding is limited. The Vascular Society of Great Britain and Ireland (VSGBI) undertook a Priority Setting Process (PSP) to find the most important research priorities. This will help researchers to better focus their work and funders to direct support to projects that aim to answer questions important to people with lived experience as well as vascular health professionals. This paper presents the results of this process on carotid condition-related research priorities.

What we did: Vascular patients and healthcare professionals participated in surveys and were asked to suggest priorities for vascular research. Responses were summarised and organised into nine overall vascular condition areas. Summary questions were then sent out in a second survey for scoring according to order of importance. The lists of patient and professional priorities were then combined into a shared list for discussion at a final workshop meeting where a mix of patients and healthcare professionals agreed the 'top 10' research priorities for carotid condition research in the UK.

What we found: A total of 481 healthcare professionals and 373 patients or carers submitted research priorities about vascular conditions, which were combined into a list of 14 priorities specifically about carotid conditions. At a final workshop involving patients, carers and clinicians, these priorities were put into a 'top 10' list ranked according to perceived importance. Research priorities relate to risk prediction and personalised treatment, prevention, screening and surveillance.

What this means: Carotid research priorities that are most important for people with lived experience and vascular health professionals have been identified. It is hoped that researchers and funders will focus on addressing these priorities and supporting studies in these areas.

Abstract

Introduction: Recent estimates of the prevalence of carotid plaque disease and carotid stenosis in people aged 39–79 years are 21.2% and 1.5% of the global population, respectively. Carotid artery disease and its management has one of the largest evidence-based areas of surgical practice, but several important questions remain unanswered. The Vascular Society of Great Britain and Ireland (VSGBI) in association with the James Lind Alliance (JLA) undertook a national Priority Setting Process (PSP) to identify carotid disease research priorities. This paper presents the results of this process.

Methods: A modified JLA Priority Setting Partnership was developed to gather clinician, patient and carer research priorities for vascular conditions. Consensus workshops were held to discuss clinician and patient priorities and agree a list of joint research priorities. Consensus was achieved using a nominal group technique and a ranked 'top 10' list of research priorities for carotid conditions was established.

Results: In the first phase (survey), 481 clinicians submitted 1,231 research priorities related to general vascular conditions. There were overlapping themes within the 1,231 priorities and, of these, 68 were carotid-specific research priorities which were reduced to six main priorities recirculated for interim scoring. In the second phase (patient and carer-led survey), 373 patients and carers submitted 582 vascular research priorities. Of these, 18 carotid priorities

were reduced to 10 and recirculated for interim scoring. In the third phase (consensus workshop), clinician and patient priorities were amalgamated into 14 priorities for discussion. Finally, a ranked final 'top 10' list of carotid research priorities was established addressing themes including risk predication, personalised treatment, prevention, screening and surveillance.

Conclusion: The 'top 10' carotid-related research priorities identify areas considered to be most important from the perspective of patients, carers and healthcare professionals. Researchers can now focus their efforts on addressing these important questions and funders should increase their investment to support new studies in these areas of greatest importance.

Key words: carotid stenosis, clinician, patient, research priorities, priority setting process

Background

Fifteen percent of ischaemic strokes are thought to be caused by thrombotic or embolic carotid artery disease, and these carotid-related strokes are commonly fatal or disabling.¹ Globally, carotid disease and specifically carotid stenosis affects an estimated 21.2% and 1.5%, respectively, of those aged 39–79 years.² In 2016, 9.6 million cases of ischaemic stroke led to 2.7 million deaths.³

Despite a wide range of treatment options for carotid artery disease and associated guidelines, the efficacy and cost effectiveness of these different interventions are still unclear. The recent ESVS 2023 Clinical Practice guidelines on the management of atherosclerotic carotid and vertebral artery disease has identified 24 unanswered questions, which remain important for the future management of carotid artery disease.⁴

To ensure optimal clinical carotid management more research is needed, but funding is limited and competitive. Funding bodies seek to ensure their limited investment is directed to areas with greatest potential for improving clinical services and health outcomes.⁵ Priority Setting Processes (PSPs) are an increasingly popular methodology to address this issue by systematically identifying and prioritising gaps in research, and they are seen as an effective way to highlight important topics for funding consideration.⁶

The Vascular Society of Great Britain and Ireland (VSGBI) in association with the James Lind Alliance (JLA) undertook a national PSP for vascular conditions.⁷ Prior to this, there were no specific patient-led research priorities in the vascular specialist community. The aim was to survey vascular health professionals, patients and carers, identifying and prioritising the most important research priorities. This paper presents an overview of the vascular condition PSP, focusing on the recommendations for carotid-related priorities and implications for future research in this area.

Methods

The VSGBI undertook a research priority setting process (PSP) in association with the James Lind Alliance (JLA) to identify research priorities for vascular conditions. The work was overseen by a steering committee involving representation from all the leading UK Vascular Societies and patients. Nine overarching vascular

Table 1 List of nine Special Interest Groups (SIGs), categorised by overarching vascular condition.

Vascular PSP Special Interest Groups (SIGs)

Access	Amputation	Aortic
Carotid	Diabetic foot	Peripheral arterial disease
Service organisation*	Venous	Wounds

*This category was established to support generic priorities that apply across all SIGs (e.g., questions about access, organisation and service delivery).

condition Special Interest Groups (SIGs) were established to help support the process and ensure that each area retained their important research priorities (Table 1). A detailed description of the process has been provided previously;⁸⁻¹⁴ however, the process is outlined again below and presented in Figure 1.

A clinician-led Delphi survey was conducted to produce a list of research priorities to reflect the opinions of vascular healthcare professionals. This was followed by a separate patient and carerfocused JLA survey to identify important research priorities from the perspective of vascular patients and carers. The two processes were then brought together at final workshops held separately for each SIG, where patients, carers and clinicians worked together to agree a shared list of 'top 10' research priorities.

Scope of the Carotid SIG

The remit of the Carotid SIG is to support research into the care of patients living with or affected by carotid conditions and the services that surround their treatment and management. The Carotid SIG aims to develop the list of top 10 priorities into funded carotid research studies that addresses these important areas.

Clinician-led research Priority Setting Process

Healthcare professionals were surveyed using a modified Delphi approach that consisted of:

Survey Round One: In the first round, an open-ended survey invited participants to submit their priorities for vascular research.



An electronic link to the survey was emailed via the following membership bodies: The Vascular Society of Great Britain, The Society of Vascular Nurses, and The Society of Vascular Technicians of Great Britain and Ireland and the Rouleaux Club. Letters including the survey link were sent to each vascular unit registered on the National Vascular Registry (NVR) and the survey was also promoted via Twitter. Responses were collated and categorised into pathological topics and research themes by a core subgroup of the steering committee. Similar responses were amalgamated and summarised into an overarching priority. Responses considered out of scope (eg, too broad or logically unclear) were removed and remaining priorities checked for current evidence.

Survey Round Two: The refined list of priorities was redistributed in a second survey for scoring. Participants were asked to rate the importance of the summary priorities on scale of 1–10 (1 being the least important, 10 being the most important). This process was completed in 2018,10 and the results of clinicians' carotid-related priorities are summarised in Table 2.

Patient/carer-led Research Priority Setting Process

Vascular patients and carers were surveyed using a modified JLA approach, with guidance from a JLA advisor, and used similar methodology as the clinician-led PSP.

Survey Round One: In the first round, patients and carers were invited to take part in an openended survey that asked them to submit their own research priorities. The survey was provided in paper and electronic format and advertised to UK-based societies involved with care of vascular patients. Participant packs were sent out to vascular units and included paper surveys with freepost return address and promotional materials such as posters and postcards that could be left in waiting areas. The survey was also advertised via social media (Twitter), websites and newsletters. Responses were categorised and delegated to each SIG for further review. Similar responses were amalgamated and summarised into an overarching priority. Responses considered out of scope (eg, too broad or logically unclear) were removed and remaining responses checked for current evidence.

Survey Round Two: The refined list of priorities was redistributed in a second survey for scoring. Participants were invited to rate the importance of research priority using a Likert scale (scores

ranged from "not at all important" to "extremely important"). This process was completed in 2020 and the results of patient and carer carotid condition priorities are summarised in Table 3.

Special Interest Group Prioritisation Workshops

For each SIG, the results of the clinician and patient/carer-led

 Table 2 Carotid research priorities from the clinician survey and prioritisation process, with the mean ranking score.

Research priority	Mean Score
Can we characterise carotid plaque to identify patients at high risk of events and target interventions?	7.99
What is the optimal management of patients with carotid disease using individualised risk benefit ratios?	7.68
What is the optimal antiplatelet regime following carotid endarterectomy	? 7.08
Is there an association between carotid disease and cognitive decline?	6.93
Is enhanced recovery beneficial following carotid endarterectomy?	5.89
What is the role of transcranial doppler in carotid surgery?	5.80

Table 3 Carotid research priorities from the patient/carer survey	
and prioritisation process, with the mean ranking score.	

Research priority	Mean Score
Can doctors predict which people with carotid artery disease are most at risk of a stroke accurately?	4.38
Can the appearance of carotid narrowings (also called plaques) help predict an individual patient's stroke risk?	4.31
What is the best treatment (eg, medicines, lifestyle changes, intervention for carotid artery disease?) 4.29
How can we better explain the problems carotid artery disease can cause (eg, warning signs and stroke risk) to patients and members of the publi	e c? 4.23
Is screening for carotid artery disease worthwhile, and if so, what is the best screening test?	4.21
Does carotid artery disease cause dementia?	4.08
How do we prevent re-narrowing and recurrent symptoms following carotid surgery?	4.08
Is surveillance of patients with known carotid artery disease worthwh	ile? 3.93
Following carotid surgery, is surveillance (ie, scanning to detect re-narrowing) of the treated artery necessary?	3.77
Are chronic kidney disease and carotid artery disease connected?	3.38

interim prioritisation processes were combined. Similar or duplicated priorities were amalgamated and any technically worded language from the clinician priorities was revised with patient input. Care was taken to ensure that the original substance of the priority remained. This process generated a refined list of joint priorities for discussion at individual SIG workshops.

The final prioritisation workshop for carotid conditions was conducted virtually on 21 September 2021 using the Zoom platform to accommodate COVID-19 restrictions. All attendees (including healthcare professionals, patients and carers) were recruited via direct contact or were approached if they expressed an interest during the initial prioritisation process. Participants were sent details of the workshop, an agenda and a list of the research priorities to be discussed in advance. Prior to the workshop, participants were asked to consider the combined list of clinician and patient research priorities shown in Table 4 and to rank them in order of importance from 1 (most important) to 14 (least important).

The workshop was led by two experienced JLA advisers, a JLA coordinator and a technical lead who were skilled in the JLA PSP process and leading such workshops. Members of the Carotid SIG attended as observers and to provide emotional support to attendees if required (they would join a separate breakout room). SIG members were not directly involved in the priority setting and had no influence over the final agreed list of priorities. Following welcome and introductions, participants were split into two breakout rooms which consisted of a mix of patients and healthcare professionals. Small group discussions were facilitated by an advisor and followed a nominal group technique to reach a consensus for an ordered list of 'top 10' priorities.

Table 4 Collated research priorities that were circulated to all attendees prior to the final workshop. The priorities were listed randomly and assigned a letter rather than a number.

А	Are chronic kidney disease and carotid artery disease connected?
В	What is the role of monitoring brain perfusion during surgery (eg, transcranial doppler)?
С	What can be done to prevent re-narrowing and recurrent symptoms following carotid surgery?
D	Is there an association between carotid disease and cognitive decline?
E	Following carotid surgery, is surveillance (ie, scanning to detect re-narrowing) of the treated artery necessary?
F	What is the best treatment for carotid artery disease (eg, medicines, lifestyle changes, intervention)?
G	How can the problems carotid artery disease can cause be better explained to patients and members of the public (eg, warning signs and stroke risk)?
Н	Can doctors accurately predict which people with carotid artery disease are most at risk of a stroke?
I	What is the optimal management of patients with carotid disease using individualised risk benefit ratios?
J	Is screening for carotid artery disease worthwhile, and if so, what is the best screening test?
K	What is the optimal antiplatelet regime following carotid endarterectomy?
L	Can the appearance of carotid narrowings (also called plaques) help predict an individual patient's stroke risk?
М	Is enhanced recovery beneficial following carotid endarterectomy?
N	Is surveillance of patients with known carotid artery disease worthwhile?

First round of discussion: Participants shared their top three and lowest three priorities with a brief explanation for why. This was followed by an open discussion about similarities and differences and any priorities that were not initially mentioned.

Second round of discussion: The JLA facilitator presented onscreen a potential order of priorities based on initial feedback and discussion. Participants had an opportunity to reconsider their initial placement of priorities whilst the facilitator moved priorities on screen to reflect an agreed order of priorities 1–14.

Third round of discussion: The ranked priorities of the two separate groups were combined by the lead facilitator using a geometric mean of the respective ranked positions. All participants came together as one group and the lead facilitator presented the combined results of the group rankings. Participants were then split into new groups and, again, participants had an opportunity to reconsider the order of priorities before reaching a final ranked 'top 10' list of carotid research priorities. As before, the ranked priorities of the separate groups were combined to form a final shared ranking.

Results

Clinician research priority identification and prioritisation

A total of 481 clinicians submitted 1,231 research priorities relating to vascular surgery in general. Of these, 68 carotid conditionrelated research priorities were submitted, 10 of which were excluded outright as they were too specific to single patient experience or there was no apparent question (eg, nonsensical or broad statement). The remaining 58 priorities were combined and summarised into six clinician priorities for scoring, the results of which are shown in Table 2.

Patient/carer research priority identification and prioritisation

A total of 373 patients/carers suggested 582 research priorities related to vascular surgery in general, of which 18 responses were specific to carotid conditions. After data cleaning (eg, removing nonsensical suggestions, separating out submissions with multiple suggestions and combining overlapping priorities), 10 research priorities were redistributed for scoring and the results are shown in Table 3. Prior to the workshop, the SIG team pooled clinician and patient/carer research priorities, resulting in a list of 14 for discussion (Table 4). In order to reduce the risk of bias, these priorities were randomly ordered and each assigned a letter (rather than a number).

Final prioritisation workshop

The final prioritisation process was conducted via a virtual online meeting on 21 September 2021. It was attended by eight patients

 Table 5 Final ranked 'top 10' list of carotid condition research priorities.

Ranking	Question
1	Can doctors accurately predict which people with carotid artery disease are most at risk of a stroke?
2	Is there an association between carotid disease and cognitive decline?
3	What is the optimal management of patients with carotid disease using individualised risk benefit ratios?
4	Can the appearance of carotid narrowings (also called plaques) help predict an individual patient's stroke risk?
5	What is the best treatment for carotid artery disease (eg, medicines, lifestyle changes, intervention)?
6	What can be done to prevent re-narrowing and recurrent symptoms following carotid surgery?
7	Is screening for carotid artery disease worthwhile, and if so, what is the best screening test?
8	Following carotid surgery, is surveillance (ie, scanning to detect re-narrowing) of the treated artery necessary?
9	Is surveillance of patients with known carotid artery disease worthwhile?
10	What is the optimal antiplatelet regime following carotid endarterectomy?

and 11 healthcare professionals (stroke nurses, consultant neurologists, vascular surgeons, senior stroke fellow and a senior trainee) with five observers. The final prioritisation resulted in a final 'top 10' research priority list (Table 5). The priorities are ordered according to importance as determined at the workshop. There was general consensus that the list correctly represented the discussions and viewpoints which occurred in the breakout groups. Results from the participant feedback indicated that 100% agreed or strongly agreed that the process for determining the top 10 priorities was robust and fair.

Discussion

The 'top 10' research priorities for UK carotid conditions research have now been established. Using a modified JLA methodology, vascular healthcare professionals and patients with lived experience of carotid conditions have jointly agreed the most important priorities for future research in this area. It should be noted that there was some divergence between patient priorities which were more patient-centred, and clinician priorities which were more technical and procedural. This emphasises the importance of meaningful patient involvement and engagement in the priority setting process.

The four priorities that did not make the ranked 'top 10' list are still considered important. Overarching themes within the final 'top 10' list relate to: risk prediction and personalised treatment, prevention, screening and surveillance.

Strengths and limitations

The Vascular PSP used well established methodologies throughout, with oversight from a multidisciplinary steering committee. The Delphi method, often used in PSPs, is regarded as a flexible research technique but one that tends to focus on the identification of expert opinion.¹⁵ To mitigate this, the Vascular PSP sought the input of the JLA who provide a transparent and structured framework that emphasises patient participation in PSPs, with patients having an equal voice to clinicians and researchers in influencing the research agenda.^{16,17} It is possible that the modified approach of having two separate processes before bringing the clinician and patient views together may have resulted in a different 'top 10'. However, during the amalgamation process there was already plenty of overlap with similar priorities and the format of the final workshops did establish shared priorities.

Due to the nature of survey data collection there is potential for responder bias,¹⁸ and consideration was given to whether responses would be adequately reflective of the opinions of people with lived experience of carotid conditions and those treating them. Under-representation is recognised as a limitation of many PSPs,^{19,20} and therefore there may have been potentially relevant priorities not submitted and consequently not considered within the analysis. However, the value of PSPs is not in their universal coverage but in eliciting some new insight and perspectives, especially from people with lived experience.

KEY MESSAGES

- A total of 14 research priorities relating to carotid conditions were considered by a group of patients, carers and healthcare professionals.
- Working with the James Lind Alliance, a final list of the 'top 10' most important carotid research priorities have been established.
- Carotid priorities broadly encompass research aimed at risk prediction, treatment and prevention strategies, screening and surveillance and associations with cognitive decline.

The Vascular PSP sought to minimise this risk in a number of ways. The survey was made available in electronic and hardcopy format (with freepost address) and it was promoted via a number of platforms with the help of affiliated charity groups and organisations who regularly work with the population targeted for input. Furthermore, the introduction of SIGs meant that each vascular condition area had a dedicated review of responses by a group of interested professionals and patients who could highlight if there were any expected topic areas missing.

Most workshop participants found the use of a virtual platform acceptable, although it is recognised that potentially lack of access to IT may have limited participation and altered representation. On the other hand, the virtual platform meant patients did not have to travel, and this may have made the workshop more accessible for some patients. Positive comments collected from the feedback survey following the final workshop demonstrated that clinicians and patients found the process of discussing priorities in mixed groups a positive and worthwhile experience. It gave participants an opportunity to hear about the experiences of others and to reassess their initial judgments.²¹ Although the mixed discussion groups were not strictly balanced in terms of patient attendance, this was carefully moderated through the skilled JLA facilitators who ensured that patient participants were regularly included and asked for their views. Some participants expressed a preference for a different ranking order of the priorities, but this is not uncommon for PSPs and is a known factor of a consensus approach.

Implications for future research

The carotid conditions priorities now provide researchers with essential guidance on where best to focus their efforts in the immediate and long term. Studies and projects should now be developed to address these important priorities and we call on funders to recognise and support the delivery of this work.

Conclusion

The Vascular PSP has established a 'top 10' list of priorities for UK carotid conditions research from the shared perspective of vascular patients, carers and health professionals. Researchers and funders can confidently invest resources into these areas of carotid

Conflict of Interest: TG was the lead JLA advisor for the Vascular PSP and was paid to Chair the Steering Committee for the project. The other authors declare no conflicts of interest.

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ORIGINAL RESEARCH

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Outcome of covered stents for severe aorto-iliac occlusive disease (AIOD) in patients with chronic limb-threatening ischaemia

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Plain English Summary

Why we undertook the work: In peripheral arterial disease (PAD), the arteries fur up with thick fatty deposits resulting in less blood flowing down to the leg muscles. The disease and risk factors are like those of heart attacks and stroke. One in 50 patients with PAD develops an extreme form with severe pain at rest and gangrene; this is called critical limb-threatening ischaemia and is associated with a high risk of limb loss and death. This usually requires urgent restoration of blood flow. When the disease affects the main arteries supplying the legs (aorta and iliac arteries), restoration of blood flow requires major surgery: aorto-femoral bypass (open surgery) or aorto-iliac stent grafting (endovascular procedure). Endovascular surgery is a keyhole technique to restore blood flow through blocked arteries. It is minimally invasive and can be applied to many different parts of the body. It is a safe alternative technique to open surgery and is generally tolerated better by patients but thought to be less durable. This study looked at using this technique to insert covered stents into severely diseased aorta and iliac arteries (aorto-iliac occlusive disease; AIOD) to improve the blood supply in patients presenting with severe pain in the legs at rest and/or gangrene.

What we did: We reviewed clinical records and x-rays of patients undergoing stenting for AIOD in Birmingham Vascular Centre between 2006 and 2017. We followed up the patients looking at whether they survived, underwent an amputation, or had further surgery for the same problem.

What we found: Eighty-eight patients with severe AIOD were treated. Fifty-four had rest pain and 34 had tissue loss. The surgery had a high rate of procedural success (99.8%). Four patients died within 30 days of the procedure. Postoperative complications occurred in one in three patients. Two out of three patients were alive and eight out of 10 did not require any further intervention at three years after surgery. In seven out of 10 patients, the stents were still carrying blood at three years after the procedure. Patients with gangrene had much worse outcomes than patients with rest pain. Seven patients underwent major limb amputation during the follow-up. We found that the late amputation was not associated with patency of the stent graft or additional procedures to maintain the patency.

What this means: The technique using the simple configuration of covered stents may be a very good option for patients presenting with severe AIOD as it is less invasive than open surgery. This group of patients has a high mortality rate, particularly if presenting with tissue loss, and therefore increased durability may not be of benefit to them. Our results compared favourably with other published results including studies using more elaborate techniques to improve blood supply in AIOD.

Abstract

Objective: To determine early and medium-term outcomes in patients with chronic limbthreatening ischaemia (CLTI) due to Transatlantic Inter-Society Consensus (TASC) C/D aorto-iliac occlusive disease (AIOD) treated with covered stents (CS).

Design: A retrospective single-centre case series.

Methods: Analysis of consecutive patients treated with CS for TASC C/D AIOD and CLTI between 2006 and 2017. The primary outcome was amputation-free survival (AFS). Secondary outcomes were survival, major limb amputation (MLA), patency, complications and freedom from re-intervention.

Results: Eighty-eight patients (61 men; 7 TASC C; 81 TASC D) were treated for CLTI (54 rest pain; 34 tissue loss). One hundred and twenty limbs were revascularised with 99.8% technical success. The 30-day mortality was 4.5%. Postoperative complications occurred in 30 (34%) patients. Seven (8%) patients underwent MLA. AFS was 76.0% (95% CI 65.6 to 83.6) and 66.6% (95% CI 55.2 to 75.7), primary patency 83.9% (95% CI 71.0 to 91.4) and 70.5% (95%

CI 52.8 to 82.6), and freedom from re-intervention 92.4% (95% CI 83.8 to 96.5) and 83.2% (95% CI 71.2 to 90.5) at 1 and 3 years, respectively. MLA was not associated with target lesion revascularisation (OR 4.35, 95% CI 0.89 to 21.18, p=0.073) or CS patency (OR 0.33, 95% CI 0.03 to 3.43, p=0.360). Age (HR 1.10, 95% CI 1.05 to 1.14, p<0.001), creatinine (HR 1.01, 95% CI 1.00 to 1.02, p<0.001), urgency (emergency: HR 3.10, 95% CI 0.97 to 9.98, p=0.057; urgent: HR 3.71, 95% CI 1.25 to 10.97, p=0.018), tissue loss (HR 5.34, 95% CI 2.36 to 12.07, p<0.001), postoperative respiratory complications (HR 5.37, 95% CI 1.44 to 20.01, p=0.012), congestive cardiac failure (HR 0.23, 95% CI 0.05 to 0.99, p=0.049) and implantation of bilateral CS (HR 0.38, 95% CI 0.15 to 0.94, p=0.036) were independently associated with AFS.

Conclusions: Covered stents in patients with TASC C/D AIOD presenting with CLTI are associated with acceptable early and medium-term outcomes in these multi-morbid patients with reduced life expectancy. CS patency was not associated with MLA or AFS and may therefore represent a poor surrogate endpoint for assessing the efficacy of endovascular intervention for AIOD.

Key words: aorto-iliac occlusive disease, aorto-iliac/iliac artery stenting, angioplasty, chronic limb-threatening ischaemia, amputation

Introduction

The most recent iteration of the Inter-Society Consensus Document for the Management of Peripheral Arterial Disease from 2015 (Trans-Atlantic Inter-Society Consensus; TASC II) has suggested that all types of aorto-iliac occlusive disease (AIOD) may be treated using either an endovascular or open approach, provided the clinical team has sufficient expertise in the given modality, and after considering the patient's functional status, co-morbidities, prognosis and life expectancy.¹ This recommendation is supported by a recent systematic review and meta-analysis of 11 observational studies which demonstrated equivalence of open surgical and endovascular revascularisation with respect to limb salvage and patency rates, with open surgery associated with a small survival advantage (HR 0.75).²

While percutaneous transluminal angioplasty is considered appropriate for short stenotic lesions, stenting is advocated for more extensive disease. Covered stents (CS) have been shown to be associated with better freedom from re-stenosis than bare metal stents in one randomised controlled trial.³ However, a recent metaanalysis of 18 observational and one randomised study failed to demonstrate a significant difference in primary patency.⁴ However, an inability to accurately assess and compare the extent of the lesions between studies and the heterogeneous nature of the disease severity and clinical presentations makes it challenging to interpret such analyses.

The present study aimed to report the early and medium-term outcomes of a homogenous group of patients presenting with CLTI due to TASC-C and TASC-D AIOD who were treated with CS in a single UK vascular centre.

Methods

This case series has been reported in line with the PROCESS guidelines.⁵ Data were collated and the results are presented in accordance with the reporting standards of the Society for Vascular

Surgery for endovascular treatment of chronic lower extremity peripheral arterial disease.⁶ This was a retrospective single-centre case series using anonymised, routinely collected data within a clinical audit framework; no intervention was performed, and patients were not contacted outside their routine clinical care. Therefore, specific ethical approval was not required and patients' consent was not sought.

Patient selection

We interrogated an electronic database of consecutive patients who underwent treatment with primary CS for CLTI secondary to TASC C and D AIOD in a single UK centre between June 2006 and March 2020. Patients presenting with acute limb ischaemia and those with a history of prior endovascular or open intervention on the aorto-iliac segment were excluded. Patients were routinely assessed within a multidisciplinary team framework involving vascular surgeons, vascular interventional radiologists and vascular anaesthetists. All patients were considered to be high-risk or unfit for open anatomical bypass and a considerable majority were unsuitable for a standard radiological approach due to the need for a concomitant outflow procedure. An endovascular procedure was considered the first-line treatment in patients who were also suitable for an extra-anatomical bypass.

Endovascular procedures and follow-up

All procedures were performed by endovascular surgeons, initially in a standard operating theatre using a mobile image intensifier (OEC9900, GE Healthcare, Chalfont St Giles, UK) and, from October 2015 onwards, in a dedicated hybrid operating suite (Discovery, GE Healthcare, Chalfont St Giles, UK). Cases were planned on TeraRecon Workstation (Aquarius Intuition, TeraRecon GmbH, Germany) using vessel analysis module.

Access included open surgical femoral artery exposure or ultrasound-guided percutaneous common femoral artery puncture. If required, proximal access was achieved using right infraclavicular axillary artery exposure. Following access, patients were administered 5000 IU of intravenous unfractionated heparin. If required, common femoral endarterectomy (CFEA) and profundaplasty with an autologous or prosthetic patch was performed first and extended into the distal external iliac artery creating a landing zone above the inquinal ligament for the CS. Lesions were crossed intraluminally and/or subintimally using a combination of retrograde and antegrade approaches. The CS reconstruction was performed from distal to proximal usually using a combination of distal self-expanding GORE® VIABAHN® (W. L. Gore & Associates Inc; minimum diameter 7 mm) and proximal balloon-expandable Atrium® V12® (Maguet- Getinge AB) or GORE® VIABAHN® VBX® (W. L. Gore & Associates Inc) to ensure accurate proximal deployment. Reconstruction of the aortic bifurcation involved simultaneous balloon-expandable CS deployment at the same level in the infrarenal aorta and simultaneous post-dilatation. Since there is no high-level evidence favouring any type of stents, covered rather than bare metal stents were used in our unit based on surgeons' preference. Although chosen due to a hypothetical risk of rupture of a stented vessel, we recognise that it was supported only by anecdotal evidence.

Patients were not enrolled into a specific CS surveillance programme but were reviewed based on presenting symptoms, the clinical picture at the time of discharge and the risk of limb loss.

Data collection and definitions

The following data were collected: demographic details, comorbidity, American Society of Anesthesiologists Physical Status Classification System (ASA), essential medications, smoking status, anatomical and clinical grading of the disease, procedural details, perioperative complications, total hospital and critical care length of stay, patient survival, amputation and re-intervention during follow-up.

Anatomical grading of lesions was based on TASC II guidelines.⁷ Analysis of CT angiograms was performed by four assessors (MTJ, HN, AE and MC). Equivocal cases were resolved by consensus.8 Clinical severity was recorded using Rutherford staging criteria.

The severity of infra-inguinal disease was assessed and defined, irrespective of the level, as none (absence of stenotic or occlusive disease), moderate (presence of stenotic disease) and severe (presence of occlusive disease).

Technical success was defined as immediate angiographic patency demonstrated by post-procedural intraoperative imaging without evidence of failure (clinical or radiological) within the first 24 hours. Patency was defined as either palpable groin pulse or absence of radiologically significant (>70%) re-stenosis or occlusion in the target artery on follow-up duplex imaging. Target lesion revascularisation was defined as any procedure performed to restore luminal patency after luminal loss or to prevent luminal loss in previously treated AIOD.

The time (days) from index procedure to discharge to the

patient's usual place of residence or another healthcare provider was defined as length of hospital stay (LOS). Unplanned admission to the hospital for any reason within 30 days of discharge was considered readmission.

Outcomes

The primary outcome was the amputation-free survival (AFS). Secondary outcomes were major limb amputation (MLA), reintervention and patency rates, incidence rate of complications, LOS during the index admission and overall survival. Survival status was verified by cross-referencing electronic patient records with the NHS-wide mortality database (Spine, NHS Digital) derived from death records from the Office for National Statistics. The amputations were verified using hospital and primary care records.

Statistical analysis

Results were analysed in pseudonymous format using R statistical environment (R version 4.0.4, R Foundation for Statistical Computing, Vienna, Austria; https://www.R-project.org/).

Continuous variables were presented as median (interguartile range; IQR) unless indicated otherwise (irrespective of outcome of normality assessment). Categorical data were presented as frequencies (proportions; %). The Student's t-test and Wilcoxon rank-sum test were used to compare continuous data and the Pearson's x² test and Fisher's exact test were used to analyse categorical data. The Haldane-Anscombe correction was used when appropriate. Median follow-up was reported as the observed follow-up in all subjects (irrespective of outcome). The follow-up data were locked on 1 July 2020.

Overall survival, AFS and freedom from re-intervention were assessed by calculating the Kaplan–Meier product limit estimator with right-censoring of survival data. The overall patency was determined by calculating the Kaplan-Meier product limit estimator



iliac and infra-inquinal segments.

Figure 1 Diagram demonstrating disease distribution in aorto-

CIA, common iliac artery; IIA, internal iliac artery; EIA, external iliac artery; II, infra-inguinal.

Total (n=88)

69.6 (63.4-75.3)

P value

0.662

Tissue loss (n=34)

70 (65.7–74.2)

with left-censoring of patency data. The results were presented as estimates with 95% confidence intervals (95% CI) unless stated otherwise.

Variable

Age, mean (range)

The effects of covariates (clinical, anatomical and procedural factors) were estimated using univariable (χ^2 , log-rank test) and multivariable (logistic regression and Cox proportional hazards model) analysis. Effect size was presented as hazard ratio (HR) or odds ratio (OR) with 95% CI. Purposeful selection of covariates for multivariable models was based on univariate p<0.1, data quality and clinical judgement. Missingness was treated by pairwise deletion. A p value of <0.05 was considered significant; a p value correction for multiple testing was not performed to avoid type 2 error.

Results

Between September 2008 and March 2020 a total of 120 limbs in 88 consecutive patients of mean age 69.6 years (range 46.8-95.4) were treated. Patient demographics and clinical characteristics are shown in Table 1 and disease distribution is shown in Figure 1.

Clinical presentation

Seventy-eight patients (89%) presented with unilateral symptoms and 10 (11%) with bilateral symptoms. Fifty-four patients (61%) had ischaemic rest pain (Rutherford stage 4) and 34 (39%) had tissue

44 (81.5) 69 (78.4) 0.537 25 (73.5) 2 (3.7) 2 (5.9) 4 (4.5) 1.000 3 (5.6) 2 (5.9) 5 (5.7) 1.000 ACEi, n (%) 20 (37.0) 10 (29.4) 30 (34.1) 0.614

7 (20.6)

ACEi, angiotensin converting enzyme inhibitor; AF, atrial fibrillation; APA, antiplatelet agent; ASA, American Society of Anesthesiologists Physical Status Classification System; BB, beta-receptor blocker; CCF, congestive cardiac failure; CFEA, common femoral endarterectomy; CKD, chronic kidney disease (CKD >2); CLD, chronic lung disease; CVA, cerebrovascular event; DM, diabetes mellitus; DOAC, direct oral anticoagulant; eGFR, estimated glomerular filtration rate; HTN, hypertension; IC, intermittent claudication; IHD, ischaemic heart disease; IQR, interquartile range; LoS, length of hospital stay; TASC, Trans-Atlantic Inter-Society Consensus.

14 (25.9)

loss (Rutherford stage 5 and 6). Seven patients had TASC C lesions (8%) and 81 (92%) had TASC D lesions (Table 1).

BB, n (%)

Procedural details

Twenty-four patients (27%) underwent elective intervention, 37 (42%) were treated urgently and 27 (31%) required emergency surgery.

Femoral access was gained with open exposure of 111 groins and percutaneous in nine.

Fifty-seven patients (65%) underwent unilateral CS implantation: two of these had bilateral symptoms but only the most symptomatic limb was treated, and one patient had a femoro-

Female 22 (40.7) 5 (14.7) 27 (30.7) Sex, n (%) 0.019 Male 32 (59.3) 29 (85.3) 61 (69.3) 11 (20.4) 1 (2.9) ASA, n (%) Ш 12 (13.6) 62 (70.5) 111 35 (64.8) 27 (79.4) 0.068 IV 8 (14.8) 6 (17.6) 14 (15.9) С 1 (2.9) 7 (8.0) TASC II category, n (%) 6 (11.1) < 0.001 81 (92.0) D 48 (88.9) 33 (97.1) Symptom laterality Unilateral 46 (85.2) 32 (94.1) 78 (88.6) 0.347 Bilateral 8 (14.8) 2 (5.9) 10 (11.4) eGFR, median (IQR) 77.6 (63.7-86.4) 85.7 (69-90) 78.8 (64.8-90.0) 0.091 CKD, n (%) 13 (24.1) 6 (17.6) 19 (21.6) 0.476 CVA, n (%) 4 (7.4) 3 (8.8) 7 (8.0) 1.000 CLD, n (%) 16 (29.6) 11 (32.4) 27 (30.7) 0.974 IHD, n (%) 16 (29.6) 10 (29.4) 26 (29.5) 1.000 AF, n (%) 7 (13.0) 3 (8.8) 10 (11.4) 0.802 CCF, n (%) 3 (5.6) 5 (14.7) 8 (9.1) 0.283 0.849 HTN, n (%) 31 (57.4) 18 (52.9) 49 (55.7) DM, n (%) 13 (24.1) 13 (38.2) 26 (29.5) 0.239 Smoking, n (%) Active 18 (33.3) 12 (35.3) 30 (34.1) 0.401 Ex-smoker 30 (55.6) 15 (44.1) 45 (51.1) Non-smoker 6 (11.1) 7 (20.6) 13 (14.8) APA, n (%) 38 (70.4) 25 (73.5) 63 (71.6) 0.938 Statin, n (%) DOAC, n (%) Warfarin, n (%)

femoral crossover bypass to permit bilateral revascularisation. Thirty-one patients (35%) had bilateral CS implantation; 24 of these presented with unilateral symptoms. The aorto-iliac revascularisation procedure was technically successful in 87

21 (23.9)

0.753

patients (99%). An outflow procedure was performed in 108 limbs (69 patients, 78%). CFEA alone in 82 limbs (45 patients, 51%) and an outflow procedure other than CFEA was performed in 26 limbs (24 patients, 27%). These data are listed in Table 2.

Complications and length of stay

The 30-day mortality was 4.5% (4/88). Peri-procedural

Table 1 Cohort characteristics stratified by presence of chronic limb-threatening ischaemia (CLTI).

Rest pain (n=54)

69.1 (61.4-75.8)

Variable	Rest pain (n=54)	Tissue loss (n=34)	Total (n=88)	P value
Traatmant laterality n (%)				
Unilateral	38 (70.4)	19 (55.9)	57 (64.8)	0.240
Bilateral	16 (29.6)	15 (44.1)	31 (35.2)	0.240
CFEA alone, n (%)	29 (53.7)	16 (47.1)	45 (51.1)	0.540
Femoro-femoral crossover, n (%)	8 (14.8)	3 (8.8)	11 (12.5)	0.519
Bypass, n (%)	2 (3.7)	7 (20.6)	9 (10.2)	0.025
Angioplasty, n (%)	2 (3.7)	4 (11.8)	6 (6.8)	0.200
Hybrid procedure, n (%)	11 (20.4)	13 (38.2)	24 (27.3)	0.113
Technical success, n (%)	53 (98.1)	34 (100.0)	87 (98.9)	1.000
Total LoS, median (IQR)	6 (2.0–9.8)	11 (6.2–24.2)	7 (2.8–14.0)	0.002
Amputation, n (%)	2 (3.7)	5 (14.7)	7 (8.0)	0.103
Overall mortality, n (%)	18 (33.3)	21 (61.8)	39 (44.3)	0.015
Complications				
Bleeding/haematoma	15 (27.8)	15 (44.1)	30 (34.1)	0.179
SSI	1 (1.9)	0 (0.0)	1 (1.1)	1.000
Cardiac	8 (14.8)	3 (8.8)	11 (12.5)	0.620
Respiratory	5 (9.3)	2 (5.9)	7 (8.0)	0.869
Gastrointestinal	0 (0.0)	0 (0.0)	0 (0.0)	1.000
Urological	4 (7.4)	2 (5.9)	6 (6.8)	1.000
Immediate re-intervention	5 (9.3)	12 (35.3)	17 (19.3)	0.006
Target lesion revascularisation	8 (14.8)	4 (11.8)	12 (13.6)	0.931

able 2 Procedural details and outcomes.

days in the Intensive Care Unit (ICU; level 3 care). Twelve patients (12; 14%) required unplanned readmission within 30 days of discharge.

Mortality and amputation-free survival

The median observed follow-up was 39.3 months (IQR 18–71.6). Forty-six patients died during the follow-up period (36.8%). The estimated overall survival was 85.6% (IQR 78.1–90.7%) at 1 year and 73.8% (IQR 64.7–80.8%) at 3 years (Figure 2A).

The median (observed) follow-up for AFS was 29.9 months (IQR 12.1– 59.5). The estimated AFS was 76.0% (IQR 65.6–83.6%) at 1 year and 66.6% (IQR 55.2–75.7%) at 3 years (Figure 2A). Tissue loss was associated with inferior AFS at 3 years (51.1% (IQR 32.8–66.7%) versus no tissue loss 76.1% (IQR 61.5–85.8%); HR 2.90 (IQR 1.55– 5.46), p<0.001; Figure 2B), while bilateral treatment was associated with better AFS at 3 years (77.4%

CFEA, common femoral endarterectomy; IQR, interquartile range; LoS, length of hospital stay; SSI, surgical site infection.

complications occurred in 30 patients (34%; Table 2). There were 17 (19%) surgical complications which required unplanned reintervention. The median LOS was 7.0 days (IQR 2.8–14.0). Seventeen patients spent a total of 35 days in the High Dependency Unit (HDU; level 2 care) and five patients spent 21 (IQR 58.4–88.5%) versus unilateral 60.9% (IQR 46.3–72.6%); HR 0.46 (IQR 0.22–0.96), p=0.039).

Stent graft patency and the fate of the treated limb

Twelve patients (14.0%) required target lesion revascularisation



Figure 2 Kaplan–Meier curves representing (A) overall survival, amputation-free survival and primary stent graft patency, and (B) amputation-free survival stratified by severity of disease (tissue loss vs no tissue loss). Overall effect calculated using log-rank test.

(TLR). Five patients (6%) experienced permanent CS occlusion. The overall estimated CS patency was 96.3% (IQR 84.7–99.1%) at 1 year and 90.1% (IQR 74.7–96.4%) at 3 years, with median observed follow-up of 9.9 months (IQR 2.2–25.3).

The estimated primary patency was 83.9% (71.0–91.4%) at 1 year and 70.5% (52.8–82.6%) at 3 years (median observed followup 7.9 months (IQR 2–22.1); Figure 2A) and was not different for patients with or without tissue loss (HR 0.76 (95% CI 0.24 to 2.43), p=0.642). The secondary patency rates were 96.3% (84.7-99.1) and 90.1% (74.7–96.4) at 1 and 3 years.

Thirteen of 14 CS occlusions (primary patency) did not result in MLA. Seven patients (8%) underwent MLA and CS occlusion was present in only one of these patients. All MLA occurred in patients with moderate and severe concomitant infra-inguinal disease, and the majority (5/7) had TASC D AIOD.

Figure 3 Forest plot representing results of Cox proportional hazard model investigating associations of demographic and clinical factors associated with amputation-free survival following lower limb revascularisation with aorto-iliac stent grafts. Effect size represented as hazard ratio (HR) with 95% confidence intervals (CI); x-axis representing level of hazard ratio (log). Overall effect calculated using log-rank test.

			Haza	rd ratio					
Age	(N=86)	1.09 (1.046-1.14)							<0.001***
Crea	(N=86)	1.01 (1.005-1.02)				•			<0.001***
T 1	No (N=54)	reference							
IL	Yes (N=32)	5.34 (2.360-12.07							<0.001***
Cordioo	0 (N=76)	reference				-			
Garuiac	1 (N=10)	2.47 (0.804-7.61)					-		0.114
	Elective (N=24)	reference				-			
Emergency	Emergency (N=26)	3.10 (0.966-9.98)							0.057
	Scheduled (N=36)	3.71 (1.255-10.97)				-			0.018*
CCF	0 (N=79)	reference				•			
001	1 (N=7)	0.23 (0.054-=0.99)		_		-			0.049*
Treated	1 (N=56)	reference				•			
limb count	2 (N=30)	0.38 (0.154-0.94)		-	-	-			0.036*
Symptomatic	1 (N=76)	reference				•			
limb count	2 (N=10)	0.23 (0.037-1.37)		_		-			0.106
	0 (N=79)	reference				-			
Respiratory	1 (N=7)	5.37 (1.441-20.01)				-	-	-	- 0.012*
			0.05 0.	1 0.2	0.5	1	2 5	10 2	20

Events: 40 Global p-value (Log-Rank): 0.000000002 AIC: 259.26; Concordance Index: 0.83

CCF, congestive cardiac failure; Crea, creatinine; TL, tissue loss; CARDIAC, cardiac complications (myocardial infarction, heart failure, cardiac arrest); RESPIRATORY, respiratory complications (respiratory failure, pneumonia, pulmonary embolism).

Multivariable analysis

Major limb amputation (MLA) rate

The MLA rate was associated with diabetes (OR 9.5 (95% Cl 2.3 to 38.5), p=0.002), tissue loss (OR 5.6 (95% 1.5 to 20.7), p=0.08) and re-interventions (OR 4.4 (95% Cl 0.9 to 21.2), p=0.069). Multivariable analysis showed diabetes to be independently associated with limb loss (OR 6.0 (95% Cl 1.1 to 46.6), p=0.048).

Amputation-free survival (AFS)

Factors associated with AFS on univariable analysis are shown in Table 3. Multivariable analysis showed that age (HR_(per unit increase) 1.10 (95% CI 1.05 to 1.14), p<0.001), presence of tissue loss (HR 5.34 (95% CI 2.36 to 12.07), p<0.001), preoperative creatinine (HR_(Cr per unit change) 1.01 (95% CI 1.00 to 1.02), p<0.001), non-elective status (emergency: HR 3.10 (95% CI 0.97 to 9.98), p=0.057; urgent: HR 3.71 (95% CI 1.25 to 10.97), p=0.018), congestive cardiac failure (HR 0.23 (95% CI 0.05 to 0.99), p=0.049), bilateral CS treatment (irrespective of laterality of symptoms; HR 0.38 (95% CI 0.15 to 0.94), p=0.036) and postoperative respiratory complications (HR 5.37 (95% CI 1.44 to 20.01), p=0.012) were independently associated with AFS (Figure 3, Table 3).

Discussion

The present study describes a large single-centre series of consecutive patients with CLTI and severe AIOD managed endovascularly with CS combined with an outflow procedure in the

Table 3 Uni	variable	and mul	tivariable	analysis	of factors
associated	with amp	outation-	free surv	ival.	

	Univariable	Multivariable	
Factor	P value	Effect size HR (95% CI)	P value
Age	<0.001	1.09 (1.05 to 1.14)	< 0.001
Emergency status			
Elective		Ref	
Emergency	0.02	3.10 (0.97 to 9.98)	0.057
Urgent	< 0.001	3.71 (1.25 to 10.97)	0.018
Creatinine	<0.000	1.01 (1.00 to 1.02)	< 0.001
CCF	0.10	0.23 (0.05 to 0.99)	0.049
Tissue loss	< 0.001	5.34 (2.36 to 12.07)	< 0.001
Treatment laterality			
Unilateral	Ref	Ref	
Bilateral	0.04	0.38 (0.15 to 0.94)	0.036
Symptom laterality			
Unilateral	Ref		
Bilateral	0.09	0.23 (0.04 to 1.37)	0.106
Complications			
Cardiac	< 0.001	2.47 (0.80 to 7.61)	0.114
Respiratory	0.20	5.37 (1.44 to 20.01)	0.012

CCF, congestive cardiac failure; HR, hazard ratio.

majority. The immediate technical success was high (>99%), 30day mortality was low (4.5%) and overall AFS at 3 years was acceptable (tissue loss 51% vs rest pain 76%). CS occlusion was independent of anatomical and clinical factors (including TASC category and Rutherford staging criteria) and there was no association between MLA and TLR or CS patency. Advanced age, emergency intervention, tissue loss and postoperative pulmonary complications were independently associated with reduced medium-term survival.

While guidelines and systematic evidence reviews may, to some extent, support an endovascular-first approach for AIOD, controversy remains regarding the optimal intervention for TASC C and D lesions.^{1,2,9} The present study demonstrates that, at the very least, an endovascular-first approach can be justified in the majority of patients who present with tissue loss secondary to TASC C and D AIOD as the burden of co-morbidity is high, medium-term life expectancy is low (54% 3-year survival), and consequently many are unlikely to benefit from the greater durability of open surgery. Open surgery may have a continued role in patients with rest pain who have a better medium-term survival.

CS patency is an attractive hard endpoint for a research study and may provide useful information on technical aspects of the procedure as well as being a marker of a functional graft surveillance programme. In the present study, CS occlusion was clinically inconsequential in most patients and neither patency nor TLR were associated with limb preservation. Most of the literature on CS in patients with severe AIOD uses patency as the primary or surrogate outcome without examining its relationship with limb salvage, which is the main therapeutic objective and the most important clinical outcome in patients with CLTI.^{2,10} The lack of association between MLA rate and patency undermines the validity of CS patency as the primary or surrogate outcome in patients with CLTI. CS patency may, however, be an appropriate outcome measure in patients with intermittent claudication.

AIOD extending to involve the infrarenal aorta has traditionally been managed by aorto-bifemoral bypass grafting. Endovascular revascularisation can be performed with CS in a double-barrelled or kissing configuration (DBCS) or by using a single large aortic CS and bilateral iliac CS extensions (Covered Endovascular Reconstruction of Aortic Bifurcation, CERAB).¹⁰ Taeymans et al described 130 patients treated with CERAB over a 7-year period, the majority of whom had TASC D lesions (89%), but only one-third had CLTI, 19% required common femoral artery endarterectomy and none required an outflow procedure.¹¹ Saratzis et al described CERAB in 116 patients treated over 8 years in six UK centres with less than half treated for CLTI.¹² It is difficult to compare the outcomes of the present study with the publications on CERAB when the major indication for treatment was intermittent claudication. In patients with CLTI, the most clinically relevant and directly comparable outcome is the MLA rate, and this was not significantly different between the study by Taeymans et al and the present study: four of 42 (10%) patients at median 24 months

KEY MESSAGES

- Covered stent-grafting may represent a good alternative for extra-anatomical and anatomical bypass in multi-morbid patients with limited life expectancy.
- Stent-graft patency is not associated with meaningful clinical outcomes.
- We postulate that stent-graft patency may not represent a good surrogate endpoint for clinical studies assessing efficacy of surgical management of AIOD with CLTI.

follow-up after CERAB compared with four of 31 (12.5%) who had DBCS in the present series at median 37 months follow-up (OR 0.71 (95% CI 0.12 to 4.19), p=0.72). Based on presented results, the simpler DBCS configuration appears to be as effective as CERAB for limb salvage in CLTI. However, CERAB has been shown to have a different flow pattern to other CS configurations. If this were to have a positive effect on CS patency, this may confer clinical advantage to patients treated for intermittent claudication where greater durability is key to improving quality of life.¹³

The present study cohort was relatively homogeneous in terms of TASC category and clinical presentation, and this makes it difficult to interpret the findings compared with previous studies which describe small numbers of patients who are invariably heterogeneous in terms of clinical presentation (with the majority having intermittent claudication), disease severity and the requirement for outflow reconstruction.^{14–16}

The limitations of the present study include its retrospective nature and the relatively small numbers of patients treated over a long period where practice inevitably changes. Another potential weakness of the study was a lack of standardised imaging-based follow-up. This may make the analysis of TLR difficult. However, standardised imaging in follow-up does not seem to be supported by any evidence and, as such, is not required. We also argue that TLR may not be associated with the main composite outcome, and hence would defy the purpose of standardised/protocolised surveillance.

In conclusion, the present study demonstrates acceptable limb salvage when CS are used to treat advanced AIOD causing CLTI. The fate of the limb was not determined by the CS patency, and this does not appear to be a useful outcome measure in patients with CLTI.

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ORIGINAL RESEARCH

Restructuring of the UK Vascular Services: does the hub versus spoke model affect patient mortality in ruptured abdominal aortic aneurysms?

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Plain English Summary

Why we undertook the work: Ruptured abdominal aortic aneurysms are a serious, often fatal, condition. They require immediate specialist intervention. The Get It Right First Time programme recommended restructuring of UK vascular services. This led to a central hub site which would act as the referral centre for surrounding spoke sites for vascular pathology.

What we did: A retrospective review of data from 110 patients presenting to hub and spoke sites with ruptured abdominal aortic aneurysms from 2017 to 2020 was undertaken. We then investigated the possibility of a link between mortality and the presenting site.

What we found: Forty-one patients presented to the hub site and 69 patients presented to a spoke site. The overall mortality rate was 53%. There was no link between presenting site and patient death.

What this means: Our study is aligned with other published data which favour the centralisation of vascular services and therefore the transfer of patients to a specialist hub site.

Abstract

Background: Ruptured abdominal aortic aneurysms (AAA) are a frequently fatal vascular condition. The centralisation of vascular services in the UK was driven by the positive volume–outcome relationship witnessed within vascular surgery and other major surgical specialities. In 2018, The Get It Right First Time (GIRFT) programme officially recommended the restructuring of vascular services in England to a hub and spoke model where AAA repairs should be performed in higher volume centres, the hub sites. This study aims to assess the mortality rates in patients presenting at hub versus spoke sites in the Merseyside region.

Methods: We conducted a retrospective review from 1 January 2017 to 31 December 2020, identifying 110 patients with a ruptured AAA presenting to hub and spoke sites. We determined if there was any association between mortality and the presenting site.

Results: Forty-one patients presented to the hub site (Royal Liverpool University Hospital) and 69 patients to the spoke sites. 81% underwent operative intervention and 19% died in Accident and Emergency or were palliated. 57% of those who underwent an intervention survived. The overall mortality rate in hospital was 53% (58 patients). There was no association between mortality and transfer from a spoke site (p=0.585).

Conclusion: This study is concordant with further published data supporting the centralisation of services for ruptured AAA.

Key words: vascular surgery, AAA, hub, spoke

Introduction

Ruptured abdominal aortic aneurysms (AAA) are a frequently fatal vascular condition with a mortality rate of up to 80%.¹ The Office for National Statistics (ONS) identified over 4,000 deaths from aortic aneurysm and dissection in England and Wales in 2019, with the highest prevalence in men over 65 years old.² Current management involves either open surgical repair or endovascular aneurysm repair (EVAR).

The drive for centralisation of vascular services and the move towards hub sites was

supported by the positive volume-outcome relationship noted within peripheral vascular surgery.³ A study looking at AAA repairs from 2006 to 2018 in England highlighted that volume had a profound impact on outcomes - more specifically, open repairs compared with EVAR.⁴ The current literature suggests that patient, hospital and surgeon factors all significantly influence outcomes such as mortality in patients presenting with a ruptured AAA.⁵ In 2018, the Get It Right First Time (GIRFT) programme recommended the restructuring of vascular services throughout the NHS in England.⁶ The implementation of a network consisting of a 'hub and spoke site' would primarily aim to reduce mortality for those patients with potentially fatal conditions such as ruptured AAA. This centralisation of vascular procedures would provide 24/7 care for elective and, more importantly, emergency procedures.^{6,7} A systematic literature review confirmed the notion that AAA repairs (elective and ruptured) should be performed at higher volume centres due to reduced mortality rates.8 Therefore, the reconfiguration of vascular services should positively influence the quality of patient care and outcomes.9 The Society for Vascular Surgery recommends target times of less than 90 min from presentation to treatment: 30 min diagnosis, 30 min transfer and 30 min door to intervention time.¹⁰

Current literature debates the effect of patient transfer from community to tertiary centres on mortality rate with a ruptured AAA. Some evidence suggests that, when patient-specific factors are taken into account, patient survival is lower in those being transferred.¹¹ Other studies show that that there is no effect on mortality based on operative site, but patients transferred have a higher risk of complications.¹² Morbidity rather than mortality is influenced in those studies.

The purpose of this study was therefore to investigate if there was a correlation between mortality and presentation site in patients with a ruptured AAA.

Methods

We conducted a retrospective review of patients presenting with a ruptured AAA to hub and spoke sites in the Merseyside Region from 1 January 2017 to 31 December 2020.

The theatre database was used to search for patients who had been coded as having 'aaa, rupture, EVAR, aneurysm, repair, stent'. Admission data were used to search for patients by looking at those diagnosed with 'I713 – Abdominal aortic aneurysm, ruptured'. Our initial search generated 116 emergency coded AAA repairs and 120 diagnosed on admission with ruptured AAA. We crossreferenced for any duplicates and excluded elective AAA repair, ward ruptures and those who had been incorrectly coded. This resulted in 110 relevant patients who had presented to the emergency department (ED) with a ruptured AAA over the 4-year period (Figure 1).

At initial assessment, demographics (age, gender) were recorded and the location of the presenting site. We also recorded whether a patient had a known AAA in their past medical history or



if this was a new presentation. Intervention was separated into those who underwent an operation and those who were deemed inoperable, therefore palliated as a result. Method of repair, open or EVAR, for those who had an intervention was noted.

For all patients from spoke and hub sites, arrival to ED time, diagnosis to ruptured AAA time and arrival to theatre time was identified. The time for a spoke site patient to be transferred to the hub was also recorded. Diagnosis time was defined as the time of computed tomography (CT) scan.

Our primary outcome was to investigate if there was any significant difference in mortality in patients with a ruptured AAA presenting to a hub site over a spoke site. The secondary outcome was whether the overall length of pathway time from presentation to ED to intervention affected mortality. We also looked specifically at whether spoke sites target of <90 min from door to intervention influenced mortality.¹⁰

Data were collected, anonymised and entered into a standardised spreadsheet (MS Excel, Microsoft, USA). The association between presentation site and mortality was analysed with χ^2 testing using SPSS statistics package (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 21.0. Armonk, New York, USA). A significant difference was defined by p<0.05.

Spoke site mortality rates were analysed using a χ^2 test.¹⁰ The correlation between length of time from presentation to intervention on mortality was calculated using χ^2 testing. Significance was defined as p<0.05.

Results

A total of 110 patients were identified. The mean age was 76 years (range 60–92) and 78% were male. Forty-one patients presented to a hub site (Royal Liverpool University Hospital) and 69 patients were transferred from the surrounding spoke sites (A, B, C). These sources of referrals from spoke sites included A:18, B:24 and C:18 and seven out of region.

Thirty-two patients had a previous AAA diagnosis and 56 patients were new presentations. Eighty-nine patients (81%) underwent operative intervention (76 patients open repair and 13 EVAR). Twenty-one patients (19%) died in ED or were palliated at admission.

Mortality

The overall mortality rate in hospital was 53% (58 patients). 47% (52 patients) survived after admission and were subsequently discharged from hospital. 57% of the 89 patients who underwent an intervention (open repair/EVAR) survived and 43% of patients died. The remaining 21 patients who did not undergo any intervention had a mortality rate of 95%. One patient survived to discharge.

There was a 55% mortality rate for those presenting to spoke sites compared with 66% mortality at the hub site. There was no association between the mortality rate and presenting sites (p=0.585).

Timings (Figure 2)

ED diagnosis time was recorded with a target time of 30 min; 83 patients were available for analysis. The median time for the hub site was 90 min (Figure 3). The median diagnosis time for the spoke sites also exceeded the target 30 min with three referring sites having times of A: 126 min, B: 204 min, C: 160 min (Figure 4).

Transfer from spoke sites had an average time of 112 min, exceeding the target time of 30 min (Figure 5).

Arrival at hub A&E to theatre time was measured for both the hub site and spoke sites. Hub sites had a median time of 146 min, which exceeded the target of 60 min (30 min diagnosis time and 30 min arrival in theatre time). When measuring spoke sites, we









looked at arrival at hub A&E after initial spoke site ED arrival, diagnosis and transfer time. Therefore, arrival at hub A&E to theatre time had a target time of 30 min. This time was exceeded with a median of 40 min (Figure 6).





Overall diagnosis to theatre time had a median time for patients presenting to the hub of 70 min (30 min target) and for those presenting to the spoke sites of 136 min (60 min target) (Figure 7).

A comparison of overall targets from A&E arrival to intervention time for hub (60 min) and spoke sites (90 min) showed no significant association with mortality (p=0.585).

Discussion

Our study supports recently published UK data looking at outcomes in ruptured AAA following the centralisation of vascular services. Leighton *et al* reported no difference in 30-day mortality following ruptured AAA in South-West England post centralisation.¹³ Proctor et al found no difference in AAA mortality post centralisation but did find complications to have increased; however, they recommended prudent interpretation of their data given the small sample size.¹⁴

International studies appear to reinforce the UK data. Tripodi *et al* analysed the impact of centralisation in high volume centres in Catalonia for AAA repair.¹⁵ Their study supported this restructuring

as it highlighted reduced mortality and length of stay.

An International Registry looked at the variation of vascular networks across 11 countries and the subsequent patient outcomes following repair of ruptured AAA. They concluded that perioperative mortality was lower in high-volume centres and suggested restructuring could improve this.¹⁶

The volume and outcome relationship in abdominal and vascular surgery was a significant driving factor in formulating specialist hub sites.⁸ It is well established, particularly in the USA, that hospital mortality is influenced by surgeon and hospital volumes.^{17,18} Increased volume centres result in reduced mortality rates. The mortality rates in an open AAA repair is significantly lower at specialist hub sites when both volumes of surgeons and hospitals are higher.¹² Our study supports this narrative.

When managing a ruptured AAA, the Society for Vascular Surgery sets a target time of less than 90 min: 30 min diagnosis, 30 min transfer and 30 min door to intervention time.¹⁰ These targets were used as the framework for the secondary outcome in our study. Our secondary outcome showed no significant association of door to intervention time with mortality rate between spoke and hub sites.

Strengths and limitations

A strength of our study is the initial dataset and subsequent analysis of patients presenting with ruptured AAA from all sites across the Merseyside region. We were able to look at patient demographics, timings, previously diagnosed AAAs and type of intervention. This enabled us to establish the significant outcomes within our study whilst providing a foundation for future discussions.

This study has limitations. First, our small sample size limits definitive conclusions. However, our findings add weight and support to the currently available UK and international data focusing on pre- and post-centralisation outcomes. As this is a retrospective study with data collected from theatre and HES coding, it is possible that patients may have been missed or coded incorrectly.

A limitation of our study is that we have no data on patients §with ruptured AAA at spokes who were not transferred. Patient transfer and intervention is primarily based on clinical judgement and/or professional opinions and there is ongoing debate regarding criteria for transfer of patients with ruptured AAA.¹⁹ The impact of transfer delays on mortality in patients with ruptured AAA is controversial.^{11,19-21}

We also appreciate that our data highlight a bias towards open repair over EVAR, despite current data recommending EVAR for ruptured AAA.^{22,23} This is a reflection of the availability of hybrid theatre for emergency EVAR, particularly out of hours.

Lastly, some studies also focus on the concept of permissive hypotension during management of a ruptured AAA.^{24–26} This is recommended by NICE during regional transfer of a patient with a ruptured AAA.²⁵ Fluid resuscitation is key preoperatively; however, if done aggressively before intervention, it has been shown to increase a patient's risk of death.²⁴ Our study obtained systolic BP

KEY MESSAGES

- Our study supports the centralisation of vascular services.
- The transfer of patients with ruptured AAA to a highvolume hub site has no apparent negative effect on mortality/outcomes.
- Various factors influence arrival to intervention time.
- Patient transfer and intervention is primarily based on clinical judgement and/or professional opinions which could account for varying outcomes.

on arrival, but the study design resulted in difficulty establishing volume of fluid administered to patients and subsequent preoperative blood pressures and therefore was not presented.

Conclusion

Our study supports the published data detailing that centralisation of vascular services has no detriment on mortality in patients with ruptured AAA. These findings support the transfer of patients to centralised high-volume sites whilst acknowledging various factors that influence arrival to intervention time. Further research and development to optimise this hub and spoke model throughout the UK may be beneficial.

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ORIGINAL RESEARCH

Patient-reported quality of life factors in vascular surgical wounds healing by secondary intention (SWHSI): a qualitative patient and public involvement (PPI) exploration

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Plain English Summary

Why we undertook the work: There are times when surgical wounds cannot be closed with staples or stitches after an operation because of infection or other concerns about the wound (called 'open surgical wounds' or 'surgical wounds healing by secondary intention' (SWHSI)). In these situations, these wounds are often allowed to heal naturally and monitored by the healthcare team in the community. To understand how living with open surgical wounds affects the patient's day-to-day life, we brought together a group of patients and carers with experience of this.

What we did: We identified 12 patients with experience of living with a SWHSI, along with those caring for a person with a SWHSI. Two small informal focus group sessions were conducted over a 1-month period, guided by the research team. These sessions were recorded, transcribed and were analysed for common themes amongst the group discussions.

What we found: After analysing the group discussions, we found that the impact of SWHSIs on quality of life in these patients could be divided into four main categories: mental health, physical symptoms, lifestyle symptoms and service-based impacts. We also found that people experienced these symptoms differently and to varying extents.

What this means: This exploration helps us to better understand the experience of living with a SWHSI and will help us target future research into tackling the areas that impact patients the most. This may include targeting new treatments or services to improve areas that cause the biggest negative impacts on quality of life.

Abstract

Background: Surgical wounds healing by secondary intention (SWHSI) represent a significant burden to patients and services. An understanding of quality of life factors affecting this population is essential to recognise the impact of this wound entity on patients. Understanding of the patient experience is necessary to building effective services and designing high-quality research studies to improve care in this population.

Methods: Twelve individuals with lived experience of living with a SWHSI or caring for a person with a SWHSI were recruited to one of two focus groups. Participants were identified from those who had previously been recruited into the NIHR-funded SWHSI-2 trial (NIHR17/42/94; a study assessing healing of surgical wound healing by secondary intention). All participants in this cohort had lower limb SWHSIs and a history of peripheral vascular disease. Sessions followed a general topic guide and were guided by the research team. Sessions were audio-recorded, transcribed and analysed using thematic analysis methods.

Results: Four main areas of impact on quality of life were identified: mental health, physical symptoms, lifestyle symptoms and service-based impacts. There was a clear heterogeneity of experience seen within the group, with some reporting a more significant impact than others. This was ascribed to the loss of social and professional functioning, and the subsequent impact on mental health. There was a differential impact of this on younger participants (who tended to be employed and hold caring roles for children or family members) compared to older participants who did not have these social roles to fulfil, and were less affected in these areas.

The need for improved preoperative counselling was highlighted, as many participants reported feeling unprepared for the postoperative course.

Conclusions: This study considered the experiences of patients with a SWHSI and identified the main areas of impact on quality of life. This work will help to underpin future research into treatments and services for the SWHSI population. It may also form the basis for identifying an appropriate patient-reported outcome measure (PROM) related to quality of life in SWHSI for use in the research setting. Limitations of the study included the number and diversity of participants, and the impact of the SARS-CoV-2 (COVID-19) pandemic on the experiences of participants. Further exploration of the area through formal qualitative study is warranted to understand the breadth, generalisability and possible future applications of the work.

Key words: SWHSI, open surgical wounds, quality of life

Introduction

Over 10 million surgical interventions are performed in the National Health Service (NHS) every year.¹ Most surgical wounds are closed by primary intention and the edges of the wound are held together with sutures, staples or glue. In cases of wound infection, contamination, dehiscence or where wound edges cannot be approximated, surgical wounds may be managed by secondary intention, allowing healing to occur from the wound bed up.^{2,3}

Treating surgical wounds in this way can have significant effects on patients' quality of life. A qualitative study specifically designed to explore patients' perspectives of living with an open wound found a range of wound-related factors had a detrimental effect on daily life, physical and psychosocial functioning, and wellbeing.⁴ Participants reported heavy amounts of exudate, malodour and difficulties with personal hygiene due to the wound, which resulted in withdrawal from normal daily activities and socialising. The extended time to healing was difficult for many and all participants interviewed expressed a longing for complete wound healing. Participants reported feeling disconnected from their normal lives and many participants experienced worsening mental health.

This qualitative exploration aims to build on previous work to further analyse and categorise the lived experiences of patients and carers and their ideas, concerns and expectations relating to surgical wounds healing by secondary intention (SWHSI) in the vascular surgery population. In this paper, the phrases 'SWHSI' and 'open surgical wounds' will be used interchangeably.

Background

Large and robust epidemiological datasets of SWHSI are generally lacking. In recent years, several projects have been conducted to quantify and characterise the population living with open surgical wounds in England.⁵⁻⁸ Hall *et al*⁸ surveyed over 1000 people in Leeds, UK and found a prevalence of 0.07 dehisced surgical wounds per 1000 population. Chetter *et al*⁵ surveyed 187 patients in Hull and East Riding of Yorkshire and calculated a prevalence of 0.41 SWHSI per 1000 population. For a UK population of 67.3 million people, this amounts to an annual prevalence of approximately 27,500 people living with a SWHSI.

Chetter et al9 conducted a prospective cohort study looking at

clinical characteristics, outcomes and quality of life in patients with SWHSI. They found that participants fell broadly into three groups: individuals with abdominal wounds after colorectal surgery, leg/foot wounds following vascular surgery, and a third mixed group. The most prevalent locations for wounds were the abdomen, foot and perianal area.

Physiologically, wound healing occurs in four phases: haemostasis, inflammation, proliferation, and remodelling. There is overlap between these phases and time for each phase will vary based on numerous factors. In the proliferation phase, granulation tissue is formed and fills the wound, edges are pulled together (contraction) and epithelialisation can occur.² In healing by secondary intention, these four phases still occur but granulation tissue must fill the wound from the bottom up and the wound must contract significantly prior to epithelialisation.³

Management of SWHSIs creates a large burden of care on community and primary healthcare services with a requirement for frequent dressing changes, advanced topical therapies including negative pressure wound therapy (NPWT) and specialised nursing care.¹⁰ Occasionally, hospital review or admission may be required for treatment of infection or wound debridement to promote healing.^{10,11}

Evidence for effectiveness of different types of treatment is limited. Vermeulen *et al*¹² summarised the evidence for effectiveness of different dressings and topical agents for SWHSIs. The 13 trials included used a variety of different interventions, control groups and endpoints. Most studies were underpowered. There was insufficient evidence to support any significant difference between types of dressings and topical agents. A Cochrane systematic review summarising evidence on NPWT for SWHSI included only two studies with a total of 69 patients.¹⁰ The studies were underpowered, data limited, and risk of biases were unclear.

This lack of effective and accessible treatments to facilitate wound healing in this population means that many patients will live with these wounds and their potential impacts for extended periods of time, with the median time to healing for a SWHSI being 86 days.¹³ A patient-centred understanding of this experience is essential to allow any future research in this population to be valid, valuable and impactful.

Methods

Patients enrolled within the NIHR-funded SWHSI-2 trial (NIHR17/42/94; a study assessing healing of surgical wound healing by secondary intention) recruited from vascular wards and outpatient clinics, as well as carers and family members, were invited to participate in a patient and public involvement (PPI) focus group exercise exploring their experiences of living with a SWHSI. Patients were approached via telephone call and invitation letter, which included an information sheet regarding the purpose of the recruitment into the focus group. Written informed consent forms were signed on the days of the meetings.

Participants were interviewed in two small focus group sessions of six participants (while maintaining social distancing) over a 1-month period. Funding was provided by the Yorkshire and Humber Research Design Service Patient and Public Involvement grant, and funding constrictions limited the size of the sample we were able to recruit. Participant costs were reimbursed, in addition to a stipend provided according to the NIHR public contributor payment policy for their time.¹⁴ The meetings were conducted in an informal manner and consisted of open-ended questions followed by discussion amongst the members. Each session was aimed to last approximately 90–120 minutes. At the beginning of the second session, feedback and ideas from the previous meeting were presented to explore them in detail with the new panel members and gain valuable and meaningful insights. All sessions were recorded with written consent from panel members.

The groups were facilitated by a research doctor and chaired by a senior member of the vascular academic unit. A pre-prepared topic guide was used to guide the conversation (Figure 1).

Following the sessions, the interview transcripts were reviewed by a research doctor and primary coding of key themes for thematic analysis was undertaken. Thematic analysis is a commonly accepted tool for analysis of qualitative data, initially utilised in the field of psychology but now frequently employed in qualitative studies in the health sciences.¹⁵ It is distinct amongst qualitative analysis methods as it offers a flexible and pragmatic method of analysis that is not bound to the strict principles of methodology required in other approaches.¹⁶ Thematic analysis took a theoretical approach and was based around a research question of "How does having a SWHSI affect quality of life?" This process is presented in Figure 2.

This involved identifying recurring and emphasised ideas, points that elicited a great deal of agreement from the group and ideas that generated significant discord or disagreement. The data were further recoded, with redundant codes eliminated and overly broad codes expanded through multiple cycles until a final list of codes was obtained. This list was felt to encompass the breadth of experience shared in the focus group meetings and reflected the most pertinent data points. These codes were assigned to overarching sematic themes.

As these sessions were undertaken as a PP) exercise to inform the foundations of future research, no ethical approval was required **Figure 1** Diagrammatic representation of topic guide used to facilitate focus group discussions. The topic guide was intentionally broad to allow space for contributors to bring their own experiences and ideas to the discussion.







in accordance with guidance from the Health Research Authority (HRA).

Results

Twelve individuals (nine men and three women) participated in the meetings (Table 1). Two of these members were carers of a patient. The participants of the focus groups were given opportunities to speak to their personal experiences of living with a wound if they so wished; all participants verbally consented to share their stories during the session. Diversity of age, employment status, health status, education and circumstance between the participants allowed for a range of experiences to be heard. A lack of diversity in

Characteristics		N=12
Sex	Male Female	9 (75%) 3 (25%)
Role	Patient Carer	10 (83%) 2 (17%)
Age	Lower limit of range Upper limit of range Mean	31 years 77 years 63 years
Ethnicity	White British	12 (100%)
Employment status	Employed Unemployed Retired	3 (25%) 2 (17%) 5 (50%)

For age and employment status, only the participants in the patient category have been included (n=10). For gender and ethnicity characteristics, the two carer participants were included as these characteristics may impact their lived experience as a carer.

ethnicity was reflective of the population local to and served by the research centre, and posed a significant limitation to the generalisability of the results beyond a white English population. This is further explored in the Discussion section.

Thematic analysis of the transcripts identified four main domains of impact on quality of health, with 23 sub-themes distilled from 81 primary individual finalised codes (Figure 3).

Mental health

A prominent and recurring theme for participants was the effect on mental health; most patients reported that their mental health was affected to some extent by the experience of having an open wound, with severity of impact varying greatly between patients. This was also reflected in the experiences of carers and family members. Participants almost universally reported some level of depressive symptoms, and often these contributed to wider issues with isolation, loss of social functioning and emotional deterioration.

Many patients reported a visceral reaction to the loss of bodily integrity, with feelings of 'disgust' reported by multiple participants. This experience was commonly compared to a form of grieving for the previous healthy state and a deep sense of loss. The impact of this was reported to be less keenly felt in those participants who regained the functional capacity of the injured body part (ie, those who were able to return to walking or their normal activities) and retained a mostly cosmetic impairment following healing, while those whose injury was associated with a loss of functioning reported a much greater sense of loss.

Physical

Most patients reported a mixture of physical symptoms, the most common being pain and altered sensation of various kinds. This included perceptions of burning, tingling, itching and a feeling of wetness. Experiences of pain tended to be more common in the



acute phases of injury and improved with time and healing, although some patients did report longstanding 'phantom' pains and altered sensation.

Participants also described swelling of the affected area and foul-smelling discharge. Often these symptoms were related to wound deterioration or attributed to delays in dressing changes and routine care. Participants strongly linked physical symptomatology to service-related issues and these areas were often spoken about together. Overall, though physical symptoms were common, most participants felt they were more manageable than the psychological impacts of the wound on mental health.

Lifestyle

Lifestyle or general living symptoms encompassed a wide range of impacts reported on the participant's ability to live, work, socialise and generally function in their daily life as they would have prior to the development of the wound. Patients reported extensive impairments including loss of mobility, difficulty sleeping, loss of independence, financial loss and inability to work.

The severity of impact varied hugely between participants depending on the individual circumstances, family and social support and wider governmental support available to them. The impacts were also not contained to the participant's singular experience and had a 'ripple' effect extending to partners, dependents and employees. Loss of social roles such as that of 'provider' or 'breadwinner' reduced the ability to participate actively in parenting, and loss of positions of responsibility at work or in wider life were also noted to have significant impacts on this patient group. These impacts were also closely interrelated with issues with mental health and deterioration of general physical health.

Service-related

All participants reported a significant impact on quality of life related to the extensive burden of care involved with an open wound. This included routine interactions with planned care primarily facilitated by community and district nurses, primary care practices and wound care clinics. It also encompassed a level of interaction with unscheduled care including emergency departments, urgent care centres and inpatient services in cases of wound deterioration, or occasionally experiences of wound care in these settings when admitted for management of another condition.

The participants shared a varied range of experiences, some excellent and some poor. Many key themes emerged including unfamiliarity of healthcare staff with managing and dressing wounds. Participants reported often feeling unsupported in their wound management, while also often having to take on an 'expert' role when interacting with services that seemed to the participant to be unfamiliar with the requirements of wound care.

Participants also reported the difficulty in scheduling visits, irregular timing of attendances and unreliability of wound care services, resulting in a further deterioration of the participant's ability to engage in general life. Additionally, the high number of interactions with healthcare staff resulted in a further burden of care.

Participants reported a variety of attitudes towards the level of care they received, with some reporting a feeling of over-interaction with services and others who reported a preference for more frequent reviews.

Discussion

This qualitative exploration of the patient experience of living with SWHSIs identified major recurring themes that would need to be addressed by future wounds research. Participants reported many quality of life aspects that were impacted in living with a SWHSI. Through the process of thematic analysis, these have been summarised into the categories of mental health, physical symptoms, lifestyle symptoms and service-related issues.

Experiences varied depending on the type and location of wounds. All participants interviewed in this exercise had experienced wounds that resulted from a primary diagnosis of peripheral vascular disease and all wounds were located on the lower limb, but even within this subgroup there existed a degree of heterogeneity of experience. This was mostly reflected in how participants interacted with their changed circumstances - some were able to maintain higher levels of mobility, general functioning and participation in their usual daily lives and roles, while others reported experiencing a much greater breakdown in their ability to sustain usual activities and routines. Impairment of individual mobility, restrictions on driving and reduced ability to perform in their usual social roles were highlighted by some participants and identified as a significant psychological burden. Others, whose social roles did not require them to fulfil these specific functions, did not report this particular impact and burden on their lives.

Participants also reported a lack of understanding or forewarning about the probable postoperative course. Given that most of these operations were emergency procedures with a significant risk to life or limb without urgent surgical management, the participants felt satisfied in their understanding that an operation was necessary but discussion amongst the participants revealed that most of them did not fully appreciate what living with a SWHSI might mean for them. Previous studies have shown that almost half of all SWHSIs are planned. However, from our exploration it is clear that there remains a gap in patient education that requires addressing in this population.¹⁷

While there is reason to hypothesise that the experiences of other groups commonly experiencing SWHSI may be similar, it must be stated as a clear limitation of this study that participants with other common SWHSIs (eg, from abdominal surgery or perianal wounds) were not represented in the sample. However, studies which have explored the psychological effects of surgical wound complications such as dehiscence, which is often managed by secondary intention following initial wound breakdown, found similar effects in these patient groups as were noted in this exercise.^{18–20}

Impacts on working life were noted to be significant, ranging from the need for extended absence from the workplace through to inability to maintain business functioning and loss of entire businesses. These impacts were more heavily reported in younger participants who often maintained active working lives, while older participants tended to be retired from formal employment. This finding further reinforced the need for appropriate preoperative patient education and counselling, as the wider impacts of the
KEY MESSAGES

- Living with a SWHSI has a substantial impact on quality of life across multiple domains. Reported experiences were very diverse. This heterogeneity of experience likely stems from the variable impact of loss of function and how this interacts with the wider circumstances of the individual patient.
- A significant insufficiency in preoperative patient counselling was noted; most patients did not adequately understand the challenges they might face in the postoperative period.
- Further work is required to identify optimal methods of measuring wound-specific quality of life to account for the impact of living with a SWHSI.

postoperative course on employment and financial considerations were often underestimated.

It was outside the scope of this exercise to attempt to quantify the independent and relative impacts of each of these symptom areas on overall quality of life. However, some aspects – such as poor mental health resulting in feelings of anxiety, stress and severe depression – were emphatically reported and were almost ubiquitous within the interviews.

The focus group exercises were undertaken in October 2021, just as policies from the government and health service regarding the SARS-CoV-2 (COVID-19) pandemic were moving towards reducing precautionary restrictions in healthcare settings, as well as in wider life. However, the experiences recalled during the focus group sessions had occurred while public health measures were in force throughout the UK. The impact of the SARS-CoV-2 pandemic and related measures on the reported experiences of the group cannot be isolated from the overall wound-related experience of the participants, and presents a significant confounding factor in the findings.

Additionally, this exercise was undertaken in East Riding of Yorkshire where 94.6% of the local population identify as white British, English, Welsh, Scottish or Northern Irish²¹ All participants in the study were of white British ethnicity, which limits the validity of the findings among the general UK population. It is therefore advised that further qualitative and explorative work is undertaken with a broader sample of the UK population to ensure future research is valid, appropriate and acceptable to the experiences of this population at large.

Conflict of Interest: IC holds the position of Editor-in-chief of JVSGBI.

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ORIGINAL RESEARCH

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Trends in lower limb deep vein thrombosis and associated deep venous procedures across the United Kingdom from 1998 to 2022

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Plain English Summary

Why we undertook the work: In the UK there are ongoing efforts to reduce the number of blood clots (deep vein thrombosis, DVT). Despite these initiatives, around 35,000 people in the UK suffer from DVT each year. In the short term, DVT can go on to cause blood clots in the lungs, known as a pulmonary embolism; this can impair the body's ability to pass oxygen to the blood stream. In the longer term, DVT can cause post-thrombotic syndrome (PTS), which is a term used for the collection of symptoms such as swelling, pain and other long-term issues that occur in up to 50% of those affected by DVT. A potential way of shortening the recovery time and reducing the chance of developing PTS is to have the blood clot removed through a procedure known as early thrombus removal. This can be achieved by open surgery or minimally invasive keyhole procedures such as clot-busting medicines (thrombolysis), catheter-based suction/aspiration techniques, or catheter-based mechanical removal techniques. For established PTS, the scarred and narrowed veins can be treated with stretching of the vein (balloon venoplasty) and placement of a stent. These are referred to as interventions for chronic disease. Since the introduction of these techniques there has been conflicting evidence from clinical studies and a lack of certainty in the scientific community. For the UK, there are no up-to-date reports on the number of people suffering from DVT or PTS, or the number of procedures performed to treat these conditions. These findings are important as they will provide us with a barometer of current practice across the UK and may provide a strong rationale for further clinical studies.

What we did: To identify how many cases of DVT and PTS were diagnosed and how many procedures were performed, we searched the national database published by NHS England. From this, we extracted information for the period from 1998 to 2022. We undertook statistical tests to assess if the trends in the data were significant. From this, we gain an appreciation for the clinical care being provided and the potential impact of this on the healthcare service.

What we found: The rate of hospital admission for DVT has decreased since 1998. This may be because hospitals are now increasingly likely to see patients in same-day assessment units, such as 'ambulatory care', rather than admitting them to hospital. There was a single year in which the cases of DVT were much higher, coinciding with the COVID-19 pandemic. The rate of procedures undertaken for early thrombus removal after DVT is increasing year on year. The rate of procedures for chronic venous disease had been increasing up until the year 2014, after which they have levelled off.

What this means: The increase in procedures for early thrombus removal and for established chronic venous disease may indicate that specialist venous services are likely to be required to deliver this care consistently. This cannot be explained by a rise in cases of DVT or PTS alone. However, the recent plateau in the rates of interventions for established chronic venous disease suggests that this practice is still in its early phases of adoption and its widespread use may be limited by the lack of clear evidence in this field.

Abstract

Introduction: Following acute iliofemoral deep vein thrombosis (DVT), early thrombus removal may reduce the risk of subsequent post-thrombotic syndrome (PTS). For those with established chronic venous disease (CVD) secondary to obstructing iliac vein lesions, venoplasty and venous stenting can be used to restore patency. Currently, these interventions are associated with significant costs with a lack of clear evidence to support their use, hence an understanding on the trends of intervening is required. This study assesses overall trends in diagnoses of DVT and PTS resulting in hospital admission, alongside the number of deep venous procedures performed across the UK from 1998 to 2022.

Methods: National database analysis was undertaken using Hospital Episode Statistics (HES) data from NHS England from 1998 to 2022. The number of primary diagnoses for DVT and PTS episodes resulting in hospital admission, in addition to primary procedure codes for open and percutaneous deep venous procedures, were extracted for analysis. Rates of DVT and PTS episodes were analysed to contextualise the rates of deep venous procedures undertaken. The Mann–Kendall test was undertaken to assess for trends within the data.

Results: There has been an overall significant (p<0.05) downwards trend in admissions for DVT between 1998 (33,205) and 2022 (29,831). There was an isolated peak in cases coinciding with the coronavirus pandemic, at which time numbers increased 2.4-fold. Diagnoses of PTS as the primary diagnosis for admission have significantly risen (p<0.05) but overall reported numbers were low across all time points (range 19–446). Regarding acute deep venous interventions, the number of percutaneous venous thrombus removal procedures demonstrated a significant upward trend (p<0.05), with peak cases in 2019 of 451. Percutaneous transluminal venous thrombolysis was the most common procedure performed across all time points. Percutaneous mechanical or aspiration venous thrombectomy procedures also significantly increased (range 7–113, p<0.05), and demonstrated the most persistent upward trend for a given technology. Regarding interventions for chronic disease, percutaneous venous stenting and venoplasty procedures have shown a significant upward trend since 1998 (range 0–1,469, p<0.05). Numbers increased to a peak of 1,469 in 2009, after which the gradient has levelled and potentially plateaued.

Lessons learnt: Considering these increasing practices, contemporary randomised controlled trials are required to provide certainty of effectiveness.

Conclusion: The number of early thrombus removal procedures, mainly catheter-directed thrombolysis, continues to increase despite the backdrop of conflicting evidence supporting its use. This does not coincide with an increase in hospital admissions for DVT. Interventions for iliac-obstructing CVD, including venoplasty and stenting, dramatically increased but have since plateaued.

Key words: deep vein thrombosis, early thrombus removal, catheter-directed thrombolysis, post thrombotic syndrome, hospital episode statistics

Introduction

Deep vein thrombosis (DVT) affects as many as 35,000 people per annum in the UK.¹ DVT causes substantial morbidity, with as many as 50% of those affected developing post-thrombotic syndrome (PTS), characterised by lifelong leg pain, oedema, skin changes and ultimately venous ulceration.^{2,3} PTS results in reduced quality of life (QoL) and an overall disability burden comparable to chronic obstructive pulmonary disease or heart failure.⁴

PTS is thought to develop due to venous obstruction and/or valvular reflux following the pathophysiological process of DVT resolution, with conversion of fibrin to collagen (ie, scarring),⁵ subsequently leading to venous hypertension.⁶ Those with iliofemoral DVT are more likely to develop PTS than those with distal DVT, hence they represent a key cohort of patients when considering treatments in the prevention and subsequent treatment of PTS.⁷

Deep venous practice has changed dramatically over the past three decades with the introduction of catheter-directed thrombolysis (CDT) for early thrombus removal and the use of venous stenting for restoring patency in chronic iliac disease (circa 1994).^{8,9} Percutaneous catheter-delivered pharmacomechanical thrombectomy and non-lytic mechanical thrombectomy are now clinical realities^{10–12} alongside the widespread availability of dedicated venous stents.^{13–15} These interventions are offered within the National Health Service (NHS) in Trusts offering complex venous services with designated acute and chronic clinical pathways.¹⁶

Despite this, there is still a lack of clarity regarding the evidence to support early thrombus removal in acute iliofemoral DVT alongside a complete lack of comparative randomised evidence to support venous stenting for chronic venous outflow obstruction.^{17,18}

Illustrating this lack of clarity with respect to acute thrombus removal is the National Institute for Health and Care Excellence (NICE) guidelines stating that CDT for symptomatic iliofemoral DVT can be 'considered'.¹⁹ The European Society for Vascular Surgery 2022 Clinical Practice Guidelines reiterate this lack of clarity, suggesting 'consideration' for selected patients with a class 2a recommendation.²⁰ The result of this uncertainty is that deep venous practice is in a state of flux.

Lim *et al* previously reported an increasing trend in percutaneous deep venous procedures between 2005 and 2015, with open deep venous procedures declining and remaining persistently low.²¹ Contemporarily, the PTS after Catheter-directed thrombolysis for deep Vein Thrombosis (CaVenT) study, published in 2012, had reported very promising results supporting the use of early thrombus removal in preventing PTS.²² However, seven years, two further pivotal randomised controlled trials (RCTs)^{23,24} and the global COVID-19 pandemic have since passed. The Acute venous Thrombosis: Thrombus Removal with Adjunctive Catheter-directed Thrombolysis (ATTRACT) trial, published in 2017, cast doubt on the benefits of early thrombus removal in the prevention of PTS.²⁴ Additionally, the ultrasound-accelerated CAtheter-directed thrombolysis Versus Anticoagulation for the prevention of post-thrombotic syndrome (CAVA) trial, published in 2020, failed to demonstrate any benefit in reduction of PTS or quality of life.²³

Furthermore, although commercially sponsored registries report promising results, there is still yet to be any comparative evidence on the use of venous stenting in chronic occlusive ilio-caval venous disease.^{13,14}

The nuanced and complex interpretation of RCTs investigating early thrombus removal in acute DVT, alongside the sparsity of evidence for chronic deep venous interventions, means that there has been a lack of clarity over the last decade.

Aims and hypothesis

Using the Hospital Episode Statistics (HES) from 1998 onwards reported by NHS England, we aimed to provide a contemporary report on the trends in the number of primary open and percutaneous procedures for deep venous pathology and the rates of hospital admissions for DVT and PTS (which are the main clinical indications for these procedures) in England from 1998 to 2022. We hypothesised that the rates of deep venous procedures across the UK are decreasing. This is a critical period spanning publication of pertinent RCTs and key registries investigating the use of deep venous procedures in the prevention and treatment of PTS.

Methods

The HES database, containing information relating to all inpatient hospital admissions, outpatient appointments and emergency department attendances within the NHS, was searched for hospital admissions with primary diagnoses of DVT and PTS as well as for primary deep venous procedures on 29 September 2022. Records were searched from 1998 up until 2022, spanning a 24-year period.²¹

The data processing pathway has previously been described and is available through NHS Digital.^{21,25} The HES database is published per financial year, generated from regular data submissions by healthcare providers to NHS commissioners for financial reimbursement. NHS Digital processes the data to allow for secondary analysis for national monitoring and research purposes.

Each hospital episode, defined as a finished admission under the care of a named consultant within an NHS Trust, is represented once within the database, with the primary diagnosis requiring admission and the most resource-intensive procedure being selected. Ad hoc data quality checks are performed, and investigations based on information supplied by providers or from feedback from HES data users.²⁵ Diagnoses and procedures are recorded according to the International Classification of Disease 10th Edition (ICD-10) and Office of Population Censuses and Surveys Classification of Interventions and Procedures version 4 (OPCS-4) codes, respectively. No unique diagnostic code for non-thrombotic iliac vein lesions (NIVLs) exists. Regarding nomenclature, when referring to interventions for iliac-obstructing CVD, this includes chronic PTS and NIVLs.

Data handling and analysis

Appendix 1, supplementary Table 1 (online at www.jvsgbi.com) shows the ICD-10 codes used for the extraction of data relating to hospital admissions with a primary diagnosis of DVT. In addition, the data pertaining to admissions with a primary diagnosis of PTS (ICD 187.0) were also extracted. Appendix 1, supplementary Table 2 (online at www.jvsgbi.com) shows the OCPS-4 codes used to identify hospital admissions with relevant primary deep venous procedures, as well as the groupings of similar primary procedures for analysis.

Analysis included simple descriptive statistics in addition to Mann–Kendall trend testing. The Mann–Kendall test was undertaken in R using the Kendall library. A p value of <0.05 was set as the level of significance, with additional Holm–Bonferroni correction (Holm's sequential Bonferroni procedure with ranking of p values) for multiple testing. Parametric assumptions could not be fulfilled, hence the Mann–Kendall test was deployed in place of linear regression. Locally Weighted Scatterplot Smoothing (LOWESS) was also undertaken.

Results

Rates of hospital episodes with primary diagnosis of DVT Figure 1 illustrates the number of hospital admissions within the NHS with a primary diagnosis of DVT between 1998 and 2022.



Figure 1 Number of hospital episodes with primary diagnosis of DVT between 1998 and 2022.



There was an overall reduction in total admissions for DVT between 1998 (33,205) and 2022 (29,831), with a significant downwards trend (tau=–0.39, p<0.05); LOWESS illustrates this (Appendix 2, supplementary Figure 1 - online at www.jvsgbi.com).

Across the year 2020–2021 there was a sharp increase in episodes of DVT (n=73,413), 2.4-fold greater than the baseline rate from 1998–2020 (range 24,411–37,926).

Embolism and thrombosis of the vena cava as an indication for admission has varied substantially but overall remained static since 1998 (range 64–4,299, p=0.50). There was an abrupt decline in the rate of inferior vena cava (IVC) thrombosis from the year 2004–2005, since when there has been a steady increase from 2005 onwards up to 2020. Similar to DVT of the lower extremity veins, thrombosis of the IVC increased dramatically in the year 2020–2021, 5.8-fold greater than the baseline rate from 1998–2020 (range 164–1,511) (Appendix 2, supplementary Figure 2 - online at www.jvsgbi.com).

Rates of hospital episodes with primary diagnosis of postthrombotic syndrome (PTS)

Figure 2 shows that admissions for PTS have significantly risen from 1998, particularly after 2012 (tau=0.84, p<0.05). The overall reported numbers of hospital admissions for PTS were low across all time points (range 19–446).

Rates of hospital episodes with primary procedure of early thrombus removal procedures

Numbers of percutaneous venous thrombus removal procedures demonstrate a significant upward trend from 1998–2022 (tau=0.85, p<0.05; Figure 3). There were no cases of percutaneous early thrombus removal until 2006. Since 2019, total numbers of percutaneous early thrombus procedures have levelled off and slightly reduced (not significant), from a peak of 451 across the year 2019–2020 to 323 episodes per year contemporarily.

Percutaneous transluminal venous CDT was the most common procedure performed across all time points for early thrombus



Figure 3 Number of hospital episodes with percutaneous or

removal, the trend of which mirrored the overall increasing trend for percutaneous early thrombus removal (range 0–349, tau=0.68, p<0.05). Percutaneous mechanical or aspiration venous thrombectomy procedures have also significantly increased (range 7–113, tau=0.80, p<0.05), and demonstrate the most persistent upward trend for a given device technology, although it does remain less frequent than CDT interventions.

Open venous thrombectomy numbers continue to remain low and static (range 14–44, p>0.05). Percutaneous thrombolysis with reconstruction (ie, early thrombus removal with adjunctive stenting) demonstrated a significant upward trend (0–99, tau=0.67, p<0.05), mirroring that of early thrombus removal.

Rates of hospital episodes with primary procedure of percutaneous deep venous interventions without mention of thrombectomy/thrombolysis

Figure 4 demonstrates the number of hospital episodes with

Figure 4 Number of hospital episodes with percutaneous venoplasty/venous stenting listed as the primary procedure between 2005 and 2022.



primary procedures pertaining to percutaneous endovenous reconstruction with venoplasty and venous stenting (interventions used for chronic disease).

Total percutaneous venoplasty and venous stenting procedures (without mention of thrombus removal or thrombolysis) demonstrated a significant upward trend since 1998 (range 0–1,469, tau=0.38, p<0.05). There were no cases of percutaneous endovenous reconstruction prior to 2006. Numbers increased up to a peak of 1,469 in 2009, after which the gradient has levelled and potentially plateaued. Percutaneous venoplasty (without mention of stenting) peaked at 972 cases in 2009 and, since 2014, numbers have remained relatively static (range 0–972). Since 2005 the trend has not significantly changed.

Stenting procedures without mention of thrombolysis (ie, for chronic disease) demonstrated a significant increasing trend from 2005 (range 0-776, tau=0.63, p<0.05).

Discussion

We present the most comprehensive report on the current status of deep venous interventions in the UK using data from a national registry over a 24-year period.

We have demonstrated a significant downward trend for the rate of hospital admissions for DVT since 1998. This is unsurprising given the change in patient pathways for the investigation and management of DVT, with hospitals offering ambulatory pathways avoiding the need for admission. The rate of DVT dramatically increased across the year 2020–2021, which corresponded to the peak incidence of infections during the COVID-19 pandemic in the UK.²⁶ The incidence of DVT in those testing positive for COVID-19 has been demonstrated to be as high as 16%, coinciding with the 2.4-fold increase reported in our analysis.²⁷ Reassuringly, the rate of DVT returned to within the baseline range the following year.

Rates of IVC thrombosis remained unchanged within the study period. However, there was a step-like reduction in 2005, from which there has been a slow increase each year (non-significant). We explored the impact of the number of admissions for IVC filter placement over this time period; however, the decline appears unrelated as the number of IVC filter placements had not significantly increased between the years 2004 and 2006. It is currently unclear as to what caused this change in coded IVC thrombosis episodes; this cannot be explained by changes in coding descriptors (ie, ICD-9 to ICD-10).

The rate of admission for PTS reported in this study is incredibly low, likely reflecting the underutilisation of diagnostic coding for this condition, with use of chronic venous insufficiency or venous ulceration instead. Epidemiological data on PTS are generally poor given the difficulties in reaching a standardised diagnostic criterion. The increase reported in this study is likely to reflect increased utilisation of the PTS code rather than a true increase in incidence, but we lack evidence to support this.

This study demonstrated a significant increasing trend of early thrombus removal procedures performed in the NHS which cannot

be explained by an increase in hospital admissions for DVT. The bulk of evidence for early thrombus removal consists of three large RCTs investigating whether early thrombus removal in acute proximal DVT using CDT reduces risk of subsequent PTS.^{22–24,28,29} The CaVenT study, published in 2012, was the only study of the three key RCTs to report a significant difference in favour of CDT for PTS prevention.²² This significant finding corresponds with an increasing rate of percutaneous venous thrombus removal procedures within the NHS from 2011 to 2017.

Subsequent publication of the ATTRACT trial in 2017²⁴ and the CAVA trial in 202023 then cast doubt on its efficacy. Both of the trials produced a negative result. The gradient of the increase for percutaneous venous thrombus removal procedures levelled off from 2017 onwards, corresponding to this conflicting evidence. Regression analysis of the results up to the COVID-19 pandemic demonstrated a similar finding, suggesting that the stimulus for the plateau occurred prior to the pandemic.

However, subgroup analysis of those participants in the CAVA trial who achieved successful recanalisation showed a significant reduction in the severity of PTS, suggesting appropriate patient selection and improved endovascular protocols may show a potential benefit of CDT.²⁸ The above trials have suffered heavy criticisms for methodological weaknesses, detailed elsewhere in the literature.^{30,31} Despite an upward trend, the lack of clear evidence to support its use is likely stemming the floodgates from widespread adoption of early thrombus removal within the NHS.

An interesting observation is that open surgical thrombectomy is rarely performed, but its trend has not significantly altered. Open surgical thrombectomy tends to be performed as an emergency for phlegmasia cerulea dolens rather than for the risk reduction of subsequent PTS. Previously, percutaneous procedures would often not be able to restore patency immediately, explaining why percutaneous measures have not completely replaced open thrombectomy but supplemented it for a different clinical indication. However, the effect of contemporary thrombectomy devices such as Aspirex[™] (BD, New York) and ClotTriever[™] (Inari, Caifornia) catheters have yet to be seen.

The rate of interventions for iliac-obstructing CVD seems to have plateaued. A potential explanation could have been the COVID-19 pandemic; however, regression analysis at earlier time points demonstrated similar results. This practice is still within a phase of early adoption, hence the overall number remains low. There remains a lack of high quality RCT data relating to the use of percutaneous deep venous stenting or venoplasty for established CVD, reflected in the lack of recommendations by current NICE guidelines. A previous systematic review reported non-randomised evidence which supported the use of venous stenting;¹⁸ however, the authors noted the quality of the literature to be poor, limiting its findings.

A single RCT exists in the literature, containing as few as 58 participants. The trial randomised patients to either iliac vein stenting or best non-stenting (medical) therapy.³² A significant

improvement in severity of disease, as assessed by the Venous Clinical Severity Score, was reported. The trial had several limitations including being a single-centre trial with small numbers, of which only 16 of the 51 participants had PTS. Publication of a large externally valid RCT will likely impact the rates of percutaneous deep venous stenting in the future. The C-TRACT (USA) and BEST (UK and Europe) trials are currently underway, which should provide grade A evidence to guide this practice in the future.³³

Limitations

There are several limitations in the interpretation of this analysis. HES data are collated from service providers as part of the Commissioning Data Set and are used for monitoring and reimbursement. These data are not collected primarily for research purposes and their accuracy cannot be assured.

Data included in this study relate only to admitted patient care. Because of this, we are unable to comment on overall trends of DVT and PTS episodes which would include those treated via ambulatory or outpatient pathways. Hence, all conclusions drawn are in relation to admitted patient care.

Furthermore, combined procedures are often performed within one hospital episode, but only one – that which is most resource intensive – is represented as a single primary procedure code. For example, a procedure following acute DVT may include thrombolysis, venoplasty and deep venous stenting; however, it is likely to be coded with thrombolysis as the primary procedural code, meaning that the whole picture is not represented. Therefore, using primary procedures within HES data is likely to under-report the number of procedures undertaken. Similarly, the number of admissions with a diagnosis is also likely to be under-represented in a similar manner, but also due to the HES database not capturing episodes of DVT and PTS managed without hospital admission.

Although a primary procedure performed is often associated with a specific presentation, it is not possible to ascertain this as the indication for a procedure is not recorded within the HES data.

Lessons learnt

The rate of patients admitted for DVT has been slowly downtrending since 1998. This is likely due to change in patient pathways and a move to ambulatory management of DVT.

Despite a decline in admissions for DVT, there has been an increase in early thrombus removal procedures. Considering the increasing acute and chronic interventional practices across the UK, additional dedicated complex venous services might be required in the future to deliver this care consistently. Achievable and affordable complex venous services with defined acute DVT and CVD clinical pathways have been demonstrated in the NHS.¹⁶ The lack of certainty in the evidence, alongside lack of clinical expertise, is likely preventing national widespread adoption of this model.

KEY MESSAGES

- Across the UK, the rate of hospital admissions for deep vein thrombosis (DVT) has shown a significant downwards trend from 1998 to 2022
- COVID-19 led to a significant increase in DVT and inferior vena cava thrombosis: 2.4-fold and 5.8-fold increases, respectively
- Rates of percutaneous interventions for acute DVT have significantly increased, with catheter-directed thrombolysis being the most performed intervention
- Rates of percutaneous intervention for iliac-obstructing chronic venous disease have significantly increased, but have potentially plateaued in recent years
- Given these increasing practices, complex venous services using dedicated venous pathways might be required in the future

Conclusion

Although rates remain high, hospital admissions for DVT have been significantly declining since 1998. The number of early thrombus removal procedures, mainly CDT, continue to increase despite the backdrop of conflicting evidence supporting its use. Interventions for iliac-obstructing CVD, including venoplasty and stenting, dramatically increased but have since plateaued, suggesting that this practice is still in the early phases of adoption and its widespread use may be limited by a current lack of comparative evidence.

Conflict of Interest: The lead authors are chief investigators and co-chief investigators of the British Heart Foundation (BHF) funding for the BEST Trial (Best Endovenous treatment, including STenting, versus non-endovenous treatment in chronic proximal deep venous disease). We have mentioned the BHF-funded BEST trial in this manuscript.

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ORIGINAL RESEARCH

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Ambulatory vascular clinics provide a safe and effective pathway for management of chronic limb threatening ischaemia

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Plain English Summary

Why we undertook the work: The management of patients with diseased blood vessels in the lower limbs severely reducing blood supply resulting in pain at rest and ulcers is challenging.

What we did: We looked back at the outcomes of patients who attended the Guy's and St Thomas' (GSTT) Emergency Vascular Clinic (EVC). We used electronic hospital records to gather information about each patient who attended the EVC from 31 July 2017 to 19 April 2021 and documented their outcome after treatment.

What we found: We found that the GSTT's EVC service provides a safe and effective model of care for the management of this frequently complex and frail group of patients.

What this means: Further national research is needed to see whether this ambulatory EVC model can be used in other vascular units across the country.

Abstract

Introduction: The management of chronic limb threatening ischaemia (CLTI) has changed rapidly over recent years. The outcomes of lower limb revascularisation, despite improvements since centralisation, remain poor. Ambulatory emergency care has emerged in several surgical subspecialties as the optimal pathway to ensure timely access to specialist services whilst avoiding unnecessary urgent hospital admission and lengthy inpatient stays. This study aims to describe the outcomes of such a service for those with CLTI.

Methods: This study includes all patients with suspected CLTI presenting to the Guy's and St Thomas' (GSTT) Emergency Vascular Clinic (EVC) between 31 July 2017 and 19 April 2021. Demographic, clinical and admission data were gathered from a prospectively maintained database. Operative details, in hospital and mid-term outcomes were gathered retrospectively from electronic hospital records. Frailty data were calculated using the Edmonton Frailty Scoring (EFS) System.

Results: There were 799 encounters at the EVC for suspected CLTI. 375 (46.9%) of these encounters resulted in a confirmed diagnosis of CLTI and admission, either the same day as an emergency (187 (23.4%)) or as a planned urgent admission (188 (23.5%)). Time from referral to EVC review was a median of 1 day (interquartile range (IQR) 1–3 days) and median time from EVC review to revascularisation or amputation (in cases where this was the primary treatment strategy) was 8 days (IQR 4–16 days). Median time to admission was 1 day (IQR 0–13 days and length of stay was a median of 7 days (IQR 2–15 days). Amputation-free survival (AFS) from the first patient encounter (with presentations for each leg taken separately) was 95% at one month and 78% at one year. Overall survival was 98% at one month and 84% at one year. Frailty was significantly associated with mortality (p=0.03), but not AFS (p=0.085).

Conclusion: These data suggest that an EVC pathway provides a safe method of treating CLTI with minimal delays to urgent planned admission, revascularisation and AFS, in keeping with nationally reported data.

Key words: peripheral arterial disease (PAD), chronic limb threatening ischaemia (CLTI), Emergency Vascular Clinic (EVC), frailty

Introduction

The management of chronic limb threatening ischaemia (CLTI) has changed rapidly over recent years, both due to the newer technologies in the realm of endovascular surgery¹ and the current model of centralising vascular services.² The outcomes of lower limb revascularisation, however, remain fairly poor, with a recent randomised controlled trial showing a 33–37% mortality in those CLTI patients undergoing surgery.³ The Global Vascular Guidelines⁴ recommend specialist vascular limb salvage services in order to reduce adverse outcomes in this group.⁵

The Peripheral Arterial Disease Quality Improvement Framework by the Vascular Society of Great Britain and Ireland (VSGBI) supports this approach, recommending timely access to intervention for CLTI (5 days for inpatients and 14 days for outpatients).⁶ However, only a minority of vascular centres currently provide outpatient facilities within 7 days of referral and less than a third of vascular surgeons think that a 14-day referral to treatment pathway is feasible for patients who are not admitted to hospital.⁷

Ambulatory emergency care has emerged in several surgical subspecialties over recent years as the optimal pathway to ensure timely access to specialist services whilst avoiding unnecessary urgent hospital admission and lengthy inpatient stays. Evidence from general surgery demonstrates that ambulatory emergency care is associated with decreased length of inpatient stay, expedited clinical decision making and improved financial efficiency when managing emergency surgical patients.⁸ Urgent one stop outpatient clinics for emergencies have also been demonstrated to reduce acute admission.^{9,10} However, adverse outcomes have been reported with ambulatory general surgery associated with frail patients, with frailty rather than age being associated with an increased risk of complications after surgery.¹¹

Vascular surgery has always presented a unique challenge, with a multi-morbid and frail patient group.¹² Ambulatory emergency 'hot clinics' are now established in several UK arterial hub centres and reported benefits for vascular patients include decreased length of stay with no difference in time to procedure, return to theatre or 30-day readmission.¹³ Similarly to general surgery services, financial efficiencies related to decreased hospital stay have also been reported. It is well recognised that elderly frail patients become deconditioned rapidly during in-hospital stays, and there is some evidence that an ambulatory patient pathway may benefit outcomes, both in terms of reduction in frailty¹⁴ and also in reduced rate of major limb amputation.¹⁵

The Guy's and St Thomas' (GSTT) NHS Trust Emergency Vascular Clinic (EVC) was established in 2018 after a pilot project in 2017 proved to be a safe and effective service. This study describes the outcomes of this clinic service for those with CLTI.

Methods

This observational cohort study includes all patients with suspected CLTI (defined as ischaemic rest pain or tissue loss persisting for more than 2 weeks)⁴ presenting to the GSTT EVC between 31 July

2017 and 19 April 2021. All patients were referred urgently via the on-call vascular registrar or a consultant vascular surgeon and deemed appropriate for an EVC pathway after further triage by the EVC team. Referrals were accepted from networked hospitals, podiatrists and clinical nurse specialists.

The EVC is a daily clinic, active from Monday to Friday. All patients were assessed by a clinical nurse specialist with additional gualifications in patient assessment and prescribing. Following history and examination, laboratory tests, ankle brachial pressure index and imaging (duplex ultrasound scans and/or CT angiography) were arranged and reviewed the same day. Photographs were taken and uploaded onto the electronic patient record if appropriate. Patients were then reviewed along with their investigations by a consultant vascular surgeon and a management plan made. In some cases, a referral for Comprehensive Geriatric Assessment (CGA) by the Perioperative medicine for Older People Undergoing Surgery (POPS) team was arranged prior to hospital admission, and where possible on the same day as the EVC appointment. This service is thus far limited to those undergoing major revascularisation procedures or with significant multimorbidity/functional limitations.

Demographic, clinical and admission data were gathered from a prospectively maintained database. This database covers the time until definitive treatment or decision for conservative management, therefore operative details, in-hospital and mid-term outcomes (including complications) were gathered retrospectively from electronic hospital records. Frailty data were calculated using the Edmonton Frailty Scoring (EFS) System, with a score of \leq 3, 4–5, 6–7, 8–9 and \geq 10 indicating no frailty, vulnerable, mild, moderate, or severe frailty, respectively.¹⁶ This was documented as part of the CGA.

Data were stored in a password-protected anonymised database. The study was registered as an audit within the Trust and all data were pseudo-anonymised under institutional governance obviating the need for ethical approval.

Statistical analysis was performed using R v4.2.2 (R Foundation for Statistical Computing, Vienna, Austria). The first part of the analysis was performed on all encounters leading to an emergency or planned admission. The second part of the analysis, pertaining to frailty, survival, and amputation-free survival (AFS), was performed from the first encounter for each patient, per leg (thereby removing patients who represented unless they did so for the opposite leg).

Descriptive analysis was done using the mean for parametric data and the median for non-parametric data, reporting interquartile ranges (IQR) where appropriate. Testing for normality was undertaken using the Shapiro–Wilk test. Proportional testing for complication rates based on primary management was undertaken using the χ^2 test. Kaplan–Meier curves were generated to demonstrate overall survival and AFS and, where this was done to compare by frailty severity, Cox regression was performed with the log-rank test reported. We used a two-sided α level of 0.05.

Results

There were 799 consecutive encounters at the EVC for suspected CLTI between 31 July 2017 and 19 April 2021. Figure 1 summarises the inclusion flowchart for the subsequent data analyses.

Results by encounters

During this time frame, 375 (46.9%) of these encounters resulted in a confirmed diagnosis of CLTI and admission, either the same day as an emergency (187 (23.4%)) or as a planned urgent admission (188 (23.5%)). Other outcomes after EVC included conservative management and discharge (127 (15.9%)), planned clinical review in routine OPD (274 (34.3%)), or an alternative diagnosis to CLTI (23 (2.9%)).

With respect to the 375 encounters that resulted in admission, 130 were for ischaemic rest pain (Rutherford 4 (34.7%)), 203 for ischaemic ulceration (Rutherford 5 (54.1%)) and 42 for tissue necrosis (Rutherford 6 (11.2%)).

Median time from referral to EVC review was 1 day (IQR 1–3 days) and median time from EVC review to revascularisation or amputation (in cases where this was the primary treatment strategy) was 8 days (IQR 4–16 days). Median time to admission was 1 day (IQR 0–13 days, and length of stay was a median of 7 days (IQR 2–15 days). Median follow-up was up to 9.9 months (IQR 3.4–18.8). When taking only those who were admitted the same day, median time from EVC review to intervention was 5 days (IQR 2–8 days).

Of the 375 encounters resulting in an admission, 63 (16.8%) underwent conservative management, 180 (48.0%) undrwent endovascular revascularisation as the primary procedure, 48 (12.8%) underwent hybrid revascularisation, 54 (14.4%) underwent open surgery, 9 (2.4%) underwent primary major lower limb amputation (MLLA) and 20 (5.3%) underwent minor procedures. The 30-day readmission rate was 69 (18.6%) and 90-day readmission rate was 85 (22.9%).

Complications were experienced in 68 admissions (18.1%), including 15 (4.0%) respiratory complications, 17 (4.5%) wound complications, 8 (2.1%) cardiac complications (including acute coronary syndromes and tachyarrhythmias) and five (1.3%) patients with acute kidney injury. When comparing the complication rate of different primary treatment modalities, there were no significant differences in cardiac (p=0.50), respiratory (p=0.64), renal (p=0.51) or wound complications (p=0.97).

Results by unique patients/legs

This group included 331 unique patient legs (mean (SD) age 70.8 (11.9) years), 217 (65.6%) male, 114 (34.4%) female). AFS was 95% at one month and 78% at one year (Figure 2A) and survival was 98% at one month and 84% at one year (Figure 2B) per unique patient leg.

Frailty data for those who were admitted following EVC review were available for 183 patients; 148 patients had missing data



CLTI, chronic limb threatening ischaemia; EVC, Emergency Vascular Clinic.

points. Frailty scoring suggested that 42 patients (23.0%) were not frail, 37 (20.2%) were vulnerable, 45 (24.6%) were mildly frail, 39 (21.3%) were moderately frail and 20 (10.9%) were severely frail. We found no statistically significant relationship in this cohort between frailty and AFS (log-rank p=0.085; Figure 3A). However, an overall trend is apparent upon inspection of the forest plot and some individual hazard ratios reached significance (Figure 3B). Frailty was shown to be associated with survival (p=0.03, Figure 4A), with hazard ratios all reaching significance (Figure 4B).

Discussion

This study adds to the existing evidence^{13,15} examining ambulatory care pathways for CLTI in demonstrating safety and efficiency for a group noted to be living with frailty.

The National Vascular Registry reported that, in 2020, the median (IQR) length of stay for non-elective endovascular, open and hybrid procedures was 11 (6–22), 13 (8–22) and 12 (7–22) days in the UK. Our results using the EVC model show a reduced length of stay compared with this, even in the context of the COVID-19 pandemic which was known to cause delays due to



Figure 2 (A) Kaplan–Meier curve for amputation-free survival (AFS). (B) Kaplan–Meier curve for survival.

staffing levels and issues with theatre and intensive care capacity.¹⁷ This is most likely a result of the EVC pathway avoiding a lengthy preoperative hospital admission (resulting from delays to preoperative imaging and urgent unplanned theatre slots) when limited theatre slots were unavailable and there was no immediate urgency for admission due to sepsis or other emergent factors.

Our data show that there is a significant burden of frailty in the population with peripheral vascular disease, even in those deemed suitable for ambulatory treatment. It is known that frailty and its related syndrome of sarcopenia results in poorer outcomes after treatment for CLTI, and this has been shown in multiple populations globally.¹⁸⁻²² Our data support this finding.

Perioperative CGA and optimisation in older frail surgical patients has demonstrated clinical and cost effectiveness.²³ The POPS service has spearheaded the implementation of CGA in our unit for multiple specialities including vascular surgery and has shown improvement in postoperative complications, delirium and a reduced length of hospital stay.^{24,25} The implementation of this

service alongside the EVC has facilitated safe ambulatory treatment for this high-risk multi-morbid and frail population group.

An advantage of the ambulatory care model is that it avoids unnecessary out-ofhours inter-hospital transfer, thereby saving costs on patient transport and also relieving pressure on off-peak healthcare staff, both in specialist vascular centres and in emergency departments. Cognisant of the data showing increased mortality and need for ICU following night-time transfer,26 an EVC service provides an alternative pathway for timely senior vascular surgeon review that can remove pressure on out-of-hours resources with improved safety, without introducing delays to decision making. In addition, it can be argued that a more streamlined patient journey will result in an improved patient experience by reducing time waiting in emergency departments for a bed to become available and reduced time kept inappropriately nil-by-mouth. It is important to carefully triage those who still require emergency admission and distinguish those who can wait until the next day for a specialist review.

It is worth noting that, while we did treat a frail cohort via EVC, many patients who were at the worse end of the frailty spectrum (particularly if non-ambulatory) were not deemed appropriate for this pathway. For these patients we offer an outreach service that provides inpatient consultant reviews or

virtual support to community teams with video/telephone consultations if appropriate. In addition, the times to admission and intervention were occasionally lengthy; this can be explained by theatre capacity still being a limiting factor and complicated revascularisations still requiring careful planning and CGA by the POPS service.

Our study is in agreement with previously published data on similar services in the UK, including the Leicester Vascular Limb Salvage (VaLS) clinic which showed reduced rates of MLLA in those managed via an ambulatory pathway after adjustment for multiple variables including disease severity.¹⁵ Our EVC shows similar rates of AFS at one year to the Leicester VaLS service (75% vs 72.8%). This has similarly been trialled in Manchester, where appropriately timely revascularisation time frames using a hot clinic model were demonstrated with comparable short- and long-term outcomes to emergency admission (81% AFS, albeit with a shorter follow-up time compared with our study).¹³

An advantage of our service is that we have managed to



Figure 3 (A) Kaplan–Meier curve for amputation-free survival (AFS) by frailty (log-rank, p=0.085). (B) Forest plot for AFS by frailty.

capture the whole cohort of CLTI patients who underwent intervention via the EVC pathway due to the prospective nature of the database used to monitor each encounter. We also have high quality follow-up data in this study due to the electronic nature of our hospital records which are linked to the centralised NHS Spine database, allowing us to reliably access data on re-intervention rates, follow-up encounters and death. We also include data prior to and during the COVID-19 pandemic, which allows us to demonstrate efficacy of this ambulatory model in both contexts.

A major limitation of this study is the retrospective nature of most of the clinical data collected. In particular, it would have been useful to gain information on rates of wound healing in those who presented with tissue loss; however, this was not possible from the electronic record notation system. We also have a lack of comparative data in this study, meaning we can draw conclusions about safety and efficacy but not superiority or non-inferiority. In addition, our service covers a large network with local follow-up protocols in place with incomplete data held at the hub site. Quantitative frailty information was also difficult to extract; while it was occasionally encoded as part of the CGA, it was not possible to retrospectively calculate this from the notes.

In addition, our single-centre experience may not apply to units across the country due to variation in geography, catchment area and patient demographics and co-morbidities. Despite these limitations, the study supports ambulatory emergency care for patients with CLTI and demonstrates the safety and efficiency of this approach.

Conclusion

This study shows that the GSTT NHS Trust's EVC service provides a safe and effective model of care for the complexity and frailty of the CLTI patient cohort. Prospective multicentre research is needed to assess whether an ambulatory care pathway can be used as a model for vascular units and, in addition, further health economic analysis may help guide services in funding and staff allocation.



KEY MESSAGES

- Our single-centre data suggest that an ambulatory care pathway provides a safe and effective model of care for the frequently complex and frail CLTI patient cohort.
- Further research is needed to assess whether the ambulatory care pathway for CLTI patients can be used as a model for vascular units throughout the country.

Conflict of Interest: None.

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ORIGINAL RESEARCH

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Popliteal sciatic nerve block in the endovascular management of critical limb ischaemia: a UK single-centre experience

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Plain English Summary

Why we undertook the work: Patients with poor blood supply to the leg may find it difficult to tolerate procedures to open up the vessels (angioplasty) due to severe pain such that the procedure may need to be abandoned or performed under sedation or general anaesthetic. Another option is to inject local anaesthetic around the main nerve supplying the lower leg as it passes behind the knee joint in order to "block" this nerve and relieve the pain. This study assesses how effective this is compared with similar patients who didn't have a nerve block.

What we did: Nerve blocks were carried out in 63 patients with severe leg pain undergoing angioplasty. Pain severity was measured before and after the nerve block using a score from 0 (no pain) to 10 (worst pain). We recorded whether any sedation was given and whether any procedures were abandoned. These results were compared with 62 similar patients who underwent the same type of procedure before the nerve block procedure was introduced.

What we found: Patients receiving the nerve block had significantly less pain during the procedure, and no procedures were abandoned, unlike in the group with no nerve block where three procedures were abandoned due to pain. With the nerve block, fewer patients needed sedation and, when it was required, the dose was smaller.

What this means: Patients with severe leg pain due to poor blood supply appear to benefit from a nerve block behind the knee to reduce their pain severity, reduce the need for sedation and reduce abandoned procedures due to pain.

Abstract

Objective: This study aims to assess the safety and efficacy of the use of popliteal nerve block (PNB) in the endovascular management of patients with critical limb threatening ischaemia.

Design: Single-centre retrospective observational study.

Methods: All patients with rest pain who received PNB from March 2018 to August 2021 were included. Pain scores were recorded before and after block using a visual analogue scale (VAS). Requirements for analgesia or sedation, complications related to nerve block, and level of intervention were recorded. Results were compared with a historical cohort of patients prior to implementation of nerve blocks.

Results: 68 nerve blocks were performed in 63 patients (M:F 46:17) of mean age 71.7 years (range 43–91). All patients were Fontaine classification III–IV. Sonographically, all nerve blocks were technically successful. The mean VAS pain score was 8.2 pre-block, reducing to 0.3 (p<0.0001) post-block. There were no complications related to the block. Four patients required supplementary analgesia for breakthrough ischaemic pain. Compared with the historical comparison group of patients (n=62), there was a statistically significant reduction in the requirement for conscious sedation (p=0.004) and no procedures were abandoned due to pain compared with three in the historical comparison group (p=0.034).

Conclusion: Popliteal sciatic nerve block is safe and effective in patients with critical limb threatening ischaemia undergoing lower limb endovascular intervention, significantly reducing the need for conscious sedation and risk of procedural abandonment.

Key words: peripheral vascular disease, critical limb ischaemia, rest pain, regional nerve block, angioplasty

Introduction

When performing endovascular treatments in patients with critical limb threatening ischaemia (CLTI), providing safe and effective pain management can be challenging, particularly with the increasing length and complexity of such procedures. The patient often needs to lie flat for a prolonged period and needs to be still through critical parts of the procedure. In addition, the patient will often require bed rest following the procedure to reduce access site complications. Patients with CLTI may hang their leg in a dependent position in order to bring their pain to a more tolerable level. This is not possible during the procedure and pain is often exacerbated.

Conscious sedation (CS) using a combination of opioid and benzodiazapine has been used, but can be ineffective within safe dose limits and the patient may become agitated or confused such that the procedure has to be abandoned.¹ Airway, respiratory and cognitive risks associated with CS require additional staff to safely administer and monitor the effects of these medications.² More invasive alternatives to control CLTI-associated pain include spinal, epidural and general anaesthesia, but there is variability in anaesthetic availability within interventional radiology (IR) units across the UK, and patients often have multiple co-morbidities increasing the risk of anaesthetic.³ This is of particular importance with current targets for treatment of CLTI.⁴

Regional nerve block techniques have been performed by anaesthetists for many years. This is an attractive option for treating patients with CLTI-associated pain, and several studies have reported the use of nerve blocks to facilitate endovascular intervention in such circumstances.⁵⁻⁸ This study describes the development of a popliteal nerve block (PNB) service within IR with support from anaesthetic colleagues, and aims to assess the safety and efficacy of PNB in endovascular treatment for CLTI in comparison with a historical cohort of patients treated before the introduction of the service.

Methods

Study design and data collection

This is a single-centre retrospective observational study of patients with CLTI undergoing PNB to facilitate endovascular intervention in a tertiary referral regional vascular unit from March 2018 to August 2021. No formal ethics board approval was required because this is a well-established anaesthetic technique routinely carried out in other clinical settings and was instituted as a quality improvement practice. Inclusion criteria were patients with CLTI-associated pain undergoing lower limb revascularisation. The only strict contraindication was any documented reaction to local anaesthetic agents, of which none were recorded. Given the nature of the work and logistics within the department and gradual implementation of PNB, not all patients with CLTI over the study period were captured.

Technical success was defined as sonographic visualisation of adequate tumescence around the nerves in the popliteal fossa. Clinical success was determined by a reduction in objective pain score taken pre and post PNB using a visual analogue scale (VAS) on a scale from 0 (no pain) to 10 (worst pain). VAS was chosen because it is a standard valid and reliable method commonly used to evaluate pain. Clinical failure was defined as a requirement for supplementary CS. A two-tailed t-test was used to compare pre and post block. Data including the use of any supplementary analgesia and sedation, complications and success of the intervention were recorded.

A historical comparison group of 62 patients was created using a key word search of the radiology information system (CRIS) for consecutive patients undergoing lower limb angioplasty for rest pain from 2017 to 2018. Given that this was a retrospective study, there was no formal randomisation process. Data collection in both groups was performed by the study authors, who also followed up patients to the point of discharge for any complications that may have arisen as a result of block. Day case patients were discharged when they had fully recovered sensation and mobilised successfully. Inpatients were discharged when assessed to be ready by the vascular surgeons. Data were collected and analysed on Microsoft Excel (Microsoft Corporation, 2010). Means and standard deviations were calculated and, where appropriate, numerical data were compared with a two-tailed t-test. A χ^2 test and Z test was used where suitable for categorical data.

Implementation of the nerve block service

Following approval within the radiology department, proctoring was provided to a single radiologist (CD) by an anaesthetist (MG) for the first 10 cases of PNB. Once all involved were confident that the procedure could be done safely, it was performed by the same consultant radiologist who then taught the technique to eight other IR consultants and IR trainees within the department. This continued in the form of mentoring until all involved were comfortable performing the procedure. The consultants continue to support each other when necessary. No formal competence assessment was undertaken for consultants, but IR trainees are assessed using the Royal College of Radiologists (RCR) Radiology Direct Observation of Procedural Skills (Rad-DOPS) framework. PNB is now used regularly by all nine IR consultants and a standard operating procedure (SOP) has been written. This includes the consent process, complications, a recommended standard report and guidelines for the management of local anaesthetic toxicity.

Performing the block

Following informed consent, the PNB is performed within the IR suite with the patient on their bed in the lateral decubitus position with the index limb uppermost. The area is prepared and draped using sterile precautions and ultrasound used to identify the sciatic bundle within the popliteal fossa and its division into tibial and common peroneal nerves. Initially, a Siemens Helx Evolution ultrasound machine (Siemens Healthcare GmbH) was used, using a high frequency probe (9–4 MHz) on 'nerve-tint' setting, to allow optimal visualisation of the nerve. Specific 'nerve' settings were subsequently installed on other ultrasound machines within the department.

Figure 1 (A) Nerve demonstrated as a rounded echogenic structure (*) anterior to the vein (V). (B) Hypoechoic 'lake' of tumescent local anaesthesia within the paraneural sheath (†) with needle tip visualised (arrow). (C) Completion image demonstrating circumferential tumescence around the nerve and relationship to vein (V) and artery (A) posteriorly.



The sciatic bundle presents itself in the transverse view as a round echogenic structure lying superficial to the popliteal vein and artery (Figure 1A). Imaging should identify the bifurcation of this bundle into the tibial and common peroneal nerves with the block performed just proximal to it. This is important to identify because it may be at or above the popliteal skin crease rather than the usual place below it. A 22G Stimuplex Ultra 360 needle (B Braun Medical Ltd, UK) is inserted under ultrasound guidance, using a lateral approach, to the edge of the nerve. This can be performed with the needle either in-plane or out-of-plane to the ultrasound probe. The in-plane technique is preferred to allow constant needle visualisation with the nerve visualised transversely (Figure 1B). Once the needle is in place, local anaesthetic is injected by a second operator to allow better control and accuracy of needle placement. The local anaesthetic used was 1% prilocaine (Citanest, AstraZeneca, 10 mg/mL), aiming for a volume of 20 mL which is below the maximum safe dose of 6 mg/kg. The aim is to achieve tumescence within the paraneural sheath surrounding the nerve (Figure 1C). Following this, the needle is removed and the patient transferred to the fluoroscopy table. The PNB results in anaesthesia of the entire lower two-thirds of the leg, with the exception of the medial aspect of the leg which receives sensory supply from the saphenous nerve. The PNB is performed in patients with CLTI pain mostly affecting the foot and is therefore usually adequate.

Discharge

Day case patients on the Radiology Day Case Unit (RDCU) are normally discharged within 6 hours of the procedure. This is nurse-led following a written protocol. In addition to the standard discharge protocol, patients undergoing PNB will only be discharged once sensation has returned and the patient has mobilised safely. The discharge protocol includes provision for admitting patients for an overnight stay should they not be fit for discharge by the time the RDCU closes for the day. All patients have access to the surgical assessment unit should any problems occur following discharge.

Results

Sixty-eight PNBs were performed in 63 patients (M:F 46:17) with an average age of 71.7 years (range 43–91) from March 2018 to January 2022. Patients between PNB and comparison groups were well matched for age and sex (Table 1). Fifty-two procedures (76%) were performed on inpatients, with the other 16 (24%) performed as day case procedures. All day case patients had fully recovered sensation and movement before discharge with no delayed discharge or overnight admission. Inpatient stay following PNB ranged from 1 to 90 days with a median stay of 8 days following the procedure. All patients met criteria for a Fontaine classification of III–IV.⁹ All patients had CLTI-associated pain despite receiving regular analgesia including a combination of paracetamol, ibuprofen, codeine, tramadol and opiates, together with gabapentin

 Table 1 Characteristics of popliteal nerve block (PNB) and comparative groups.

	Comparison group	PNB group	P value
n (cases)	62	67	-
Age	72.8±9.9	71.7±12.6	0.59
Sex (M:F)	43:18	46:17	0.76
Fontaine score (III:IV)	33:29	20:47	0.007
Conscious sedation for ischaemic symptoms	15 (24.1%)	4 (5.9%)	0.004
Average midazolam dose (mg)	2.2±0.87	1.5±0.5	0.061
Average fentanyl dose (µg)	68.2±30.3	50±15.1	0.053
Procedures abandoned	3	0	-



or pregabalin if there was thought to be a neuropathic element to the pain. Forty-seven patients had additional necrosis/gangrene or ulceration. The level of intervention is shown in Figure 2.

Four patients had angiography only without intervention. The block was performed on the left in 38 cases and on the right in 28. One case had bilateral PNB during the same procedure. All cases were performed prior to intervention. PNB can be performed with the patient supine and therefore could be potentially used as rescue analgesia, but this is not our standard practice. In general a 20 mL standardised dose of 1% prilocaine was given, although this ranged from 13 mL to 40 mL with an average dose of 19.98 mL. Sonographically, all blocks appeared technically successful. Four (5.9%) cases required supplementary midazolam or fentanyl (or a combination) for CLTI-associated pain (Table 2). Further cases required analgesia (Table 2) due to slow onset of block (n=1), musculoskeletal pain (n=3), as an anxiolytic to manage hypertension prior to puncture (n=3), and for CLTI-associated pain in the contralateral foot (n=1). Levels of intervention between the historical comparison and PNB groups showed a similar distribution of intervention, but with a higher proportion of multilevel disease treated in the PNB group (Figure 2). No data on length of procedure or lesion specifics were collected. When given, an average of 1.5 mg midazolam was used (range 1–2 mg), and an average of 50 µg of fentanyl (range 25–75 µg) in the PNB group.

Before PNB the mean VAS pain score was 8.2, significantly reducing to 0.3 after PNB (p<0.0001). Time of onset varied from 5 to 40 minutes and, although no strict objective measurements were taken to assess the progression of the block, the vast majority experienced effective relief within 10 minutes. The recording of the post-block VAS was not strictly timed, but was performed as near as possible to the start of the procedure. When compared with the historical group, there was a significant reduction of sedation required (p=0.004) and no procedures were abandoned (Table 1). When analgesia was required there was a trend to a decreased dose of midazolam and fentanyl, but this did not reach statistical significance. All patients were Fontaine score III or IV but, of note,

lovel of intervention	Midazalam	Fontonul	Doocon for	
Level of intervention	(mg)	(µg)	Reason for supplementary analgesia	
Infra-popliteal	1	50	Anxiolytic	
Infra-inguinal	-	50	Musculoskeletal knee pain	
Infra-inguinal	2	50	Anxiolytic	
Infra-inguinal and infra-popliteal	_	50	Musculoskeletal hip pair	
lliac	2	75	Breakthrough pain	
Bypass graft	-	50	Breakthrough pain	
lliac	-	25	Breakthrough pain	
Infra-inguinal	_	50	Slow onset block	
lliac and infra-inguinal	_	50	Breakthrough pain	
Infra-inguinal	1	25	Anxiolytic	
lliac	_	75	Musculoskeletal back pair	
lliac and infra-inguinal	-	50	Pain in contralateral foot (non-block side)	

Table 2 Use of supplementary midazolam and fentanyl during

there was a significantly higher proportion of patients with tissue loss in the PNB group (Table 1).

Discussion

The results of this study demonstrate a significant reduction in CS (p=0.004) and the number of procedural abandonments (p=0.034) following the implementation of PNB. PNB is a well-established technique in other settings such as foot and ankle surgery,¹⁰ although there is limited evidence of its use in the endovascular treatment of CLI. Marcus et al first described a combination of femoral nerve block and PNB in 11 patients undergoing lower limb angioplasty.⁵ In this study, more proximal sciatic block with or without femoral nerve blocks were used. Average VAS pain scores reduced from 10 to 3.7 and the procedure was deemed to be as safe and effective when compared with a control group of epidural anaesthesia patients. Unlike the current study, use of supplementary CS was not documented. Subsequent work by Tureli et al⁶ and Getikoglu and Eker⁷ in 30 and 10 patients, respectively, demonstrated similar safety and efficacy. In the former study, only two patients (6.6%) required midazolam as an anxiolytic. Two patients reported suboptimal pain reduction and an extra 20 mL of 1% prilocaine prior to the procedure such that no supplementary analgesia was required. In the latter paper, further nerve blocks were performed after the procedure in three patients for breakthrough pain due to distal emboli. Our results compare favourably, with four patients (5.9%) experiencing breakthrough pain treated with CS rather than further PNB.

The most recent work on nerve block in critical limb ischaemia by Danisan and Taydas randomised 60 patients to receive ultrasound-guided subgluteal sciatic nerve block or fentanyl sedation.⁸ Strengths of this study include formal randomisation and two measures of pain including a VAS score and FLACC (Face, Legs, Activity, Cry, Consolability). The latter score is particularly useful when patients are unable to express pain (for example, with dementia). A few patients still reported pain in the medial lower leg due to saphenous nerve supply.

Subgluteal sciatic nerve block was chosen for the randomised study⁸ based on data suggesting a lower volume of anaesthetic is required compared with peripheral nerve block,¹¹ although this case series only had five patients. Despite this, the volume of local anaesthetic was 25-30 mL of 1% lidocaine/0.25% ropivacaine/epinephrine 1:400.000, which is greater than the average volume used in this study (19.98 mL). Higher volumes¹² and mixing both short- and long-acting local anaesthetics¹³ will extend the duration of the nerve block. This may increase time to sensation and motor function recovery which is of importance for the patients admitted through the RDCU with the potential to delay discharge. Total time to recovery and mobilisation following PNB was not formally assessed in the current study, but there were no delayed discharges or unexpected admissions from the RDCU following PNB. In addition, all PNB patients were discharged before closure of the RDCU (20:00 hours), demonstrating its safe use in this setting.

In contrast to previous work, the current study includes multiple operators (both IR consultants and trainees). Only four patients (5.9%) required supplementary analgesia for ischaemic breakthrough pain, suggesting that the technique has been effectively adopted although formal assessment of the learning curve was not undertaken. Only one case had slow onset PNB most likely due to inadequately positioned tumescence, but the block was ultimately effective.

A significantly higher number of patients with a Fontaine score of IV were present in the PNB group (p=0.007). It is difficult to ascertain whether this has a bearing on the overall results, although it is encouraging to see a reduction in analgesia in a patient group with greater disease severity. Given the retrospective collection of data in the comparison group with variable documentation of CS administered, the overall benefit incurred using PNB may be higher than reported, particularly given the more complex disease in this group. The majority of PNB patients received CS for symptoms unrelated to rest pain, but it was not possible to determine if this was the case for most of the historical patients. It is reasonable to assume that, in the absence of other means of analgesia, the majority would have received sedation primarily for rest pain.

Given the benefits of PNB, it is likely that it will have a cost benefit. Patients with rest pain will be more likely to have a successful procedure first time, reducing the impact on IR service capacity given that it is less likely the patient will need a second procedure. Anaesthetic support is costly to the Trust and may

KEY MESSAGES

- Popliteal nerve block significantly reduces rest pain in patients with critical limb ischaemia
- Popliteal nerve block significantly reduces the need for conscious sedation during angioplasty for critical limb ischaemia with rest pain
- Patients with popliteal nerve block are more likely to have their procedure completed

impact other services, preventing them being deployed elsewhere. With PNB it is likely that more patients with CLI and rest pain can be treated as day cases without needing an overnight stay. Formal evaluation of cost effectiveness will be useful in future studies.

Despite the additional benefits PNB can bring, some potential pitfalls should be highlighted. Absence of sensation could increase the risk of adverse procedural events going unnoticed, but this is considered to be low because completion angiography will identify any potential vessel injury or embolic disease and reperfusion injury or compartment syndrome is uncommon following revascularisation for chronic limb ischaemia. An antisympathetic effect is possible with PNB that could obscure angiographic findings. This was not assessed as part of this study but, given the nature of atherosclerotic disease, this would seem unlikely.

There are several limitations to this study. The lack of formal randomisation and use of a historical control group is a limiting factor when compared with the most recent work by Danisan *et al.*⁸ Some aspects of data collection were not rigorous due to the nature of the study, such as time to onset of effective PNB and length of procedure and exact time to return of normal sensation and mobility. Historical comparison group data relies on the detail of information recorded at the time of their procedure. Recording data from multiple operators including during their learning curve may produce more varied results than if a single operator was evaluated, particularly with the relatively small number of patients. In addition, with more operators there is likely to be potential for variation in practice – for example, the small variation in the volume of local anaesthetic used in this study.

Conclusion

This study demonstrates that PNB provides effective and safe anaesthesia for CLTI patients undergoing lower limb endovascular intervention with a significant reduction in the requirement for CS and procedural abandonments. It can be performed by IRs, reducing the need for anaesthetic support. The results of this study are similar to the limited amount of previous work in this area providing additional evidence to support its introduction in other IR departments.

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Transfusion requirements in elective open abdominal aortic aneurysm repair: a network review of practice

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Plain English Summary

Why we undertook this work: When there is a shortage of blood for transfusion the NHS recommends that surgery likely to require blood transfusion should be postponed. Open surgery for a dilated artery (aortic aneurysm) in the abdomen is traditionally considered likely to require blood transfusion and thus affected by these recommendations.

What we did: We reviewed 3 years of data from patients undergoing open surgery to repair aortic aneurysms in order to assess how many required blood transfusion.

What we found: Only seven of 90 patients (7.8%) undergoing open aortic aneurysm surgery needed a transfusion.

What this means: The transfusion rate following open aortic aneurysm surgery is much lower than the 15% risk limit suggested for postponing surgery in the current NHS guidelines when blood stocks are low. Therefore, in such circumstances, open aortic aneurysm surgery should continue.

Key words: transfusion, abdominal aortic aneurysm, elective open surgery

Abstract

Introduction: Patients undergoing elective open abdominal aortic aneurysm (AAA) repair are considered a high-risk group for transfusion, with transfusion rates quoted around 15%. In the context of an NHS blood transfusion (NHSBT) Amber Alert, it is suggested that surgeries with a high risk of transfusion (>15%) are postponed unless otherwise clinically indicated. This review of network elective open AAA activity aimed to improve our understanding of transfusion requirements and risk profile.

Methods: National Vascular Registry data for patients undergoing elective open AAA repair in the Dorset and Wiltshire Vascular Network (DWVN) between January 2019 and February 2022 inclusive were retrospectively reviewed and cross-referenced with electronic patient records, pathology results, transfusion database and theatre records.

Results: Ninety patients (seven women and 83 men) undergoing elective open AAA repair were identified. Seven (7.8%) patients required a postoperative transfusion.

Conclusion: This contemporary review suggests elective open AAA repair should continue during

an NHSBT amber alert as the risk of transfusion is lower than previously reported.

Background

During a recent NHS blood transfusion (NHSBT) Amber Alert¹ for a shortage of Group O red cells available for transfusion, a recommendation to review higher risk surgeries which may require transfusion was implemented. Vascular surgery, and particularly open abdominal aortic aneurysm (AAA) repair, is often cited as being a particularly high-risk group (>15% transfusion requirement); however, specific data on transfusion requirements are largely lacking in contemporaneous UK practice. Previous studies have suggested a packed red blood cell (PRBC) transfusion requirement in 46-48.9% of patients undergoing open AAA repair.^{2,3} We undertook a retrospective review of our elective open AAA cases, with an aim to better understand transfusion requirements and risk profile.

Method

All elective open AAA repair cases from Dorset and Wiltshire Vascular Network (DWVN) between January 2019 and February 2022 inclusive

Table 1 Patient characteristics for those requiring PRBC transfusion.									
Patient no	Age (years)	Type of repair	Preoperative Hb (g/L)	PRBC requirement	Transfusion timing (POD)	Complication	Mortality		
1	69.3	Tube graft	103	1	3	-	-		
2	72.0	Aorto-bi-iliac	138	3	2	POD 2 Limb bleed = EVAR	-		
3	70.8	Aorto-bi-iliac	118	3	4, 7, 9	POD 2 Left colon ischaemia = Hartmanns POD 8 HIT	POD 9		
4	84.7	Tube graft	127	1	3	-	-		
5	75.1	Tube graft	130	1	3	-	-		
6	59.5	Tube graft	143	3	2, 2, 3	POD 3 Dehiscence	-		
7	75.6	Aorto-bi-femoral	115	2	5	-	-		

Hb, haemoglobin; PRBC, packed red blood cells; POD, postoperative day; EVAR, endovascular aneurysm repair; HIT, heparin-induced thrombocytopenia.

submitted to the National Vascular Registry were retrospectively reviewed. Data were cross-referenced with electronic patient records, pathology results, transfusion database and theatre records.

Results

Ninety cases were identified, all with complete data sets available. All cases were performed as per the DWVN protocol within a designated vascular operating theatre with intraoperative cell salvage autologous transfusion in use for all cases. All cases were performed or supervised scrubbed by a Consultant Vascular Surgeon.

Seven female and 83 male patients were analysed with median (IQR) ages of 70.6 (65–74) years and 72.0 (68–76) years, respectively. The median AAA size was 59 and 56 mm for female and male patients respectively. The average length of stay following elective open repair during this period was 9 days (range 6–10) with a risk adjusted 30-day elective AAA repair survival of 99.4%.⁴

In total, seven patients received a PRBC transfusion (7.8%), all of which occurred in the postoperative phase of care. Table 1 outlines their characteristics.

A total of 14 PRBC units were transfused after appropriately triggering the local transfusion protocol of haemoglobin <80 g/L (mean 0.16 units/case). Three of these PRBC transfusions were single unit, one was two units and three were three units. Notably, all three patients receiving three units of transfusion required a return to theatre in the postoperative period for a complication. The median preoperative haemoglobin was 128.5 g/L (range 103–143 g/L) in this group (vs 130.1 g/L, NSD).

During the study period, the availability and use of intravenous iron in the postoperative care of vascular patients became more common with agreed standard operating procedures in place. This is considered likely to have positively impacted the transfusion requirements in this patient cohort and should also be considered alongside these data.

KEY MESSAGES

- PRBC transfusion was required in only 7.8% of open AAA repairs.
- Overall PRBC transfusion requirements were 0.16 units per case.
- In the context of an NHSBT Amber Alert, elective open AAA repairs should be permitted to be performed alongside contemporary practice: preoperative optimisation of haemoglobin, use of intraoperative cell salvage autologous transfusion and postoperative availability of intravenous iron.

Conclusion

The requirement for PRBC transfusion following elective open infrarenal AAA in our network was 7.8%. This is well below the perceived and historic transfusion requirements in this group of patients. In the context of contemporary practice, our data would support such cases continue to be delivered during times of blood shortages.

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CASE REPORT

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Carotid EndoVAC: a novel hybrid technique for carotid Dacron patch infection

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Received: 8th February 2023 Accepted: 17th February 2023 Online: 9th May 2023 **Key words:** EndoVAC, graft infection, carotid, Dacron

Abstract

This paper reports the use of the EndoVAC technique in a case of left carotid artery Dacron patch infection. The EndoVAC technique involves a sequence of endovascular relining with a stent graft, surgical debridement with explantation of infected graft material and secondary intention wound healing with a vacuum-assisted closure (VAC) device and long-term antibiotic treatment. Our patient was considered a high-risk surgical candidate due to previous cranial nerve injury, high carotid stent graft positioned in zone 3 of the neck, and high stroke risk due to aberrant cerebrovascular anatomy. The carotid EndoVAC technique was performed without complication and a successful outcome was observed at 1-year follow-up. Although currently not recommended as first-line management in treating vascular graft and endograft infections of the carotid vessels, the EndoVAC approach should be considered in a select cohort of patients when neither traditional radical surgery nor conservative simple VAC therapy are considered feasible or safe.

Introduction

Vascular graft and endograft infections (VGIs) are one of the more challenging postoperative complications in vascular surgery. Traditional recommendations for treating VGIs include two extremes of either radical debridement with in situ or extra-anatomical revascularisation, or conservative management with life-long antibiotics and endovascular stent grafts (SG).¹ The EndoVAC technique is a hybrid approach to the management of VGI first described in 2011 by Kragsterman *et al.*² This paper discusses the use of the EndoVAC technique in treating a challenging carotid Dacron patch infection.

Case report

In 2017, a 75-year-old woman was referred for a left carotid endarterectomy (CEA) for a symptomatic left internal carotid artery (ICA) stenosis. Other medical history included hypertension, polymyalgia rheumatica, Barrett's oesophagus, hiatus hernia, hyperlipidaemia and osteopenia. A left CEA with Dacron patch was performed under local anaesthesia with conversion to general anaesthetic. Postoperatively, a left recurrent laryngeal nerve palsy was diagnosed, which fully resolved. Three years later she presented with left-sided neck swelling and pain. A carotid duplex showed a linear and hypoechoic area anterior to the left ICA patch which was corrugated, suggesting patch infection (Figure 1).

Computed tomography angiography (CTA) suggested an infected collection or thrombosed pseudoaneurysm at the caudal end of the patch. A 2-deoxy-2-[fluorine-18]fluoro-D-glucose integrated with computed tomography (¹⁸F-FDG PET CT) and ultrasound-guided fine needle aspiration was arranged on an urgent outpatient basis. The following week the patient presented with bleeding from the left neck lump. CTA confirmed anastomotic dehiscence and partially thrombosed pseudoaneurysm.

Emergency endovascular relining of the left ICA was performed with two (6 mm x 25 mm and 5 mm x 40 mm) Viabahn Endoprosthesis SG (W L Gore & Associates Inc, Flagstaff, Arizona, USA). A 7 mm Amplatzer plug (Abbott Medical, Plymouth, Minnesota, USA) was placed into the external carotid artery (ECA) to prevent retrograde flow (Figure 2). She remained on dual **Figure 1** Carotid duplex of the left internal carotid artery (ICA) with a linear hypoechoic area anterior to the left ICA patch (yellow arrow) and the Dacron patch showing corrugated appearance (green arrow).



antiplatelet therapy to reduce the risk of SG thromboembolism. The patient initially declined surgical explantation and reconstruction. She trialled conservative management with antibiotics, but this failed as she reported new night sweats and recrudescence of the left neck lump.

She was considered a high-risk surgical candidate due to a previous history of cranial nerve injury, high carotid SG encroaching on zone III of the neck, incomplete circle of Willis, and a left ICA supplying both the anterior and posterior circulations of the left cerebral hemisphere. Full explantation and autologous vein repair would likely require dislocation of the mandible with no bail-out option to ligate the left carotid system due to an unacceptably high stroke risk.

The EndoVac procedure was considered as per the European Society of Vascular Surgery Guidelines on Vascular Graft and Endograft Infection.³ Endovascular re-lining was performed into the previous SG. New 6 mm x 100 mm and 8 mm x 100 mm Viabahn SG were deployed from the skull base to the left common carotid artery origin. The infected Dacron patch was explanted with minimal debridement (Figure 3). The carotid vessels were not controlled and the underlying carotid SG was left undisturbed. The ECA continued to backbleed, so the Amplatzer plug was removed and the ECA was formally ligated. The exposed vessels and Viabahn SG were partially covered by the overlying sternocleidomastoid muscle. A white (denser) polyurethane foam sponge was placed over the wound, and the VAC was applied and set at a continuous pressure of 125 mmHg. There were no immediate postoperative complications. Dual antiplatelet therapy was continued postoperatively with a plan to consider switching to the COMPASS regime after a few weeks.

Three days postoperatively, the prosthesis was completely covered with sternocleidomastoid and granulation tissue. Nineteen

Figure 2 Angiography showing emergency endovascular lining of the left internal carotid artery (ICA) performed for bleeding cutaneous fistula. The external carotid artery was embolised with an Amplatzer plug (green arrow). Two Viabahn Endoprosthesis stent grafts were deployed from the ICA above the patch to the common carotid artery below (yellow arrow). The most proximal end of the stent graft was located at the level of the angle of the mandible.



days postoperatively, the VAC dressing was switched to regular dressings. She was discharged the following day. Five weeks postoperatively the wound was fully healed. She continued on lifelong oral doxycycline (as a suppressive measure). A ¹⁸F-FDG PET CT performed 13 weeks post-EndoVAC showed significant improvement in appearances compared with prior studies. One year post-EndoVAC, the patient has clinically improved and her neck wound remains healed.

Discussion

VGIs are recognised as rare but serious life and limb threatening complications of vascular surgery.⁴ Synthetic patches are advantageous during CEA due to their wide availability, low graft rupture rate and preservation of the saphenous vein. Disadvantages of synthetic patches include suture hole bleeding, pseudoaneurysm and a higher rate of infections. Although synthetic CEA patch infections are rare with a reported incidence of 0.25–0.5%, they remain a recognised complication of CEA with a high morbidity of 29%, ischaemic stroke rate of 5.8% and infection-related mortality rate of 2.3%.^{1,5} Only 131 cases of carotid patch infection have been reported in the literature.⁶ Risk factors include poor oral hygiene, long-term steroid usage, immunosuppressants, smoking and diabetes.³

The majority of post-CEA patch infections present with neck swelling, chronic sinus and/or pseudoaneurysm formation, usually **Figure 3** (A) Left common endarterectomy scar with two cutaneous sinuses prior to EndoVAC procedure. (B) Surgical exposure of infected left carotid artery Dacron patch. (C) Removal of Dacron patch resulting in an exposed carotid artery Viabahn stent graft. (D) Amplatzer plug removed from left external carotid artery. (E) Exposed left carotid artery covered with a white (denser) polyurethane foam sponge. (F) First vacuum-assisted closure dressing change performed 3 days postoperatively with black polyurethane foam sponge.



>6 months from original surgery.⁶ In our case, a diagnosis of Dacron patch infection was made on carotid duplex findings of hypoechoic collection and corrugated patch appearance.³ CTA is considered the gold standard investigation modality for VGI. Signs of VGI on CTA include gas, fluid, soft tissue enhancement, pseudoaneurysm and discontinuation of the aneurysmal wall. Although CTA can confirm a diagnosis of VGI, it is often insufficient in isolation and a second imaging modality is recommended with ¹⁸F-FDG PET CT or white blood cell scintigraphy (WBCS) combined with single photon emission CT. WBCS identifies areas of increased radiolabelled white blood cells over time, thus showing potential sites of infection.³

The gold standard for treatment of CEA patch infections is radical debridement involving removal of the prosthetic graft and infected tissue with autologous vein revascularisation.⁴ This approach is associated with stroke and mortality rates of up to 9–12%.⁷ Revision carotid artery surgery is associated with a high incidence of blood loss, cranial nerve injury (8%), perioperative stroke (6%), recurrent infection (8%) and death (5%).^{5.8} No agreed consensus regarding the optimal approach to arterial reconstruction exists, although the use of autologous vein patch seems sensible given high re-reinfection rates (50%) with synthetic material.^{5.7} Ligation of the carotid artery is controversial due to high

stroke rates (50%) and mortality, although this may be useful in patients with ICA occlusion.⁷ Factors against radical debridement with reconstruction include significant comorbidities, unfavourable anatomy and, of course, patient choice. For this cohort of patients, other options include long-term antibiotics, endovascular SG, negative pressure dressings and superficial debridement with or without muscle flap coverage.⁹ Endovascular SG is an attractive option for those at immediate risk of haemorrhage, although this is balanced with the risk of embolisation, thrombosis and recurrent infection. In isolation, SG is often viewed as a temporising 'damage control' measure or a pseudo-palliative approach if no further vascular surgery is planned.

In patients where radical debridement or conservative VAC therapy are not considered options, the EndoVAC technique may be considered in selected patients, albeit supported by low levels of evidence.³ The EndoVAC technique offers a relatively safe method of removing the infected synthetic material with minimal dissection and without arterial clamping. The EndoVAC technique involves three steps: (1) endovascular relining with SG; (2) minimal surgical debridement with explantation of infected graft material, without arterial clamping; and (3) secondary intention wound healing with a VAC device and long-term antibiotic treatment.^{2,4}

Kragsterman et al recommend using continuous negative

KEY MESSAGES

- We report our experience with the EndoVAC technique to successfully treat a carotid Dacron patch infection in a very challenging case.
- The EndoVAC therapy is a viable management option in a selected cohort of patients.
- More evidence regarding the indications and long-term outcomes of the EndoVAC technique is required before it can be widely recommended to treat vascular graft infections.

pressure of 125 mmHg for the first 24 hours followed by intermittent negative pressure.² The VAC dressing should be changed every 2–4 days. Once the carotid vessels/stent are fully covered by granulation tissue, the white polyurethane foam sponge can be switched to a black polyurethane foam sponge.

Although EndoVAC outcomes have been promising so far, this procedure can of course be criticised for the controversial placement of a synthetic SG within an already infected field. This argument can be rebutted by the accepted use of vascular reconstructions with graft preservation methods with negative pressure dressings and/or muscle flap coverage.⁹ Similar steps are taken during the accepted management of mycotic aneurysms. The largest European single-centre study reported positive outcomes in using endovascular SG for the management of mycotic aortic aneurysms.¹⁰ There are no reports of recurrent infection with the EndoVAC technique, although limited cases have been performed.

Conclusion

This paper highlights the challenges of managing VGIs and reports our experience with the EndoVAC technique to successfully treat a carotid Dacron patch infection in a very challenging case. Although not officially recommended as first-line or gold standard management in treating carotid VGIs, the EndoVAC approach is a viable management option in a highly selected and specific patient cohort. We encourage readers to publish their similar experiences to clarify the indications and long-term outcomes of the EndoVAC technique. **Conflict of Interest:** None. MAB is personally supported by the British Heart Foundation.

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NEWS

Updates from the Vascular Societies

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

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

www.bacpar.org @BACPAR_official



The British Association of Chartered Physiotherapists in limb Absence Rehabilitation (BACPAR) is currently celebrating its 30th year.

Dr Miranda Asher continues to represent BACPAR on the Editorial Board of the Journal of the Vascular Societies of Great Britain and Ireland as part of her role as one of BACPAR's research officers.

As of 24th April, the BACPAR Spring Journal is being printed before dissemination to the membership and stakeholders. There will be a mix of case studies and sharing of good practice from the Annual Scientific Meeting as well as regional updates from BACPAR's regional representatives.

BACPAR has representation at the upcoming National Conference of the Advanced Practice Physiotherapy Network (APPN). The APPN supports advanced practice roles across all sectors and specialities of physiotherapy practice and was keen to have BACPAR there to understand examples of advanced roles in areas outside of Trauma and Orthopaedics.

The Executive Committee met in March 2023 and has subsequently produced and disseminated the objectives for the current membership year, which of course includes the planning of an increasingly multidisciplinary BACPAR programme for the Dublin Vascular Society Annual Scientific Meeting. There are ongoing guideline update review projects for which we have sought the support, as Stakeholders, from the Vascular Society and the Society of Vascular Nurses and we look forward to progressing these as a result.

> Louise Tisdale BACPAR Chair, April 2023

The British Society of Endovascular Therapy (BSET) www.bset.co.uk @BSETnews



The BSET Annual Meeting will be held on Thursday 29th and Friday 30th June. The meeting is the only dedicated UK meeting for the presentation of endovascular research and is an excellent opportunity for vascular and interventional radiology trainees to present their research.

The meeting will be held at Tortworth Court Hotel, Wotton under Edge, South Gloucestershire. The hotel is easily accessible from the M5 motorway. Bristol Parkway railway station is 30 minutes from the venue and Bristol Airport 40 minutes.

We are delighted to welcome the following guest speakers to this year's meeting:

Tim Resch, *Professor of Vascular Surgery, Copenhagen, Denmark*

Santi Trimarchi, Professor of Vascular Surgery, Milan, Italy

Michael Lichtenberg, *Chief Medical Officer* of the Angiology Department at Vascular Centre Clinic, Arnsberg, Germany

Barend Mees, Vascular and Endovascular Surgeon, Maastricht, Netherlands

The meeting will include talks on:

- Aortic endovascular repair
- Innovations in lower limb treatmentVenous treatments, outcomes and
- training
- Treatment of type B dissection
- BEST-CLI study
- BASIL-2
- Al and Technology
- Update on major upcoming endovascular trials in the UK
- Case discussions
- Joint Rouleaux Club and BSIRT Symposium including talks on the
 - Impact of dual consultant operating on vascular training
 - Radiation protection among vascular trainees
 - Update on IR training challenges and opportunities
 - Vascular Society update
- BSET Fellowship update
- Aortic and Peripheral abstracts

A National Vascular Training Day will be held on Wednesday 28th June for trainees, providing an opportunity for interactive workstation experience.

British Society of Interventional Radiology (BSIR)

www.bsir.org @BSIR_News



The BSIR continues to be led by Dr Phil Haslam, Newcastle upon Tyne Hospitals NHS Foundation Trust, as President. Phil will hand over to his successor, Professor Rob Morgan, St George's University Hospitals NHS Foundation Trust in November this year. Our new chief executive officer, Ms Nike Alesbury, is now in post. Nike began working with BSIR at the beginning of March with great enthusiasm. She has an excellent background in fundraising and charity leadership within medical education and research. Her previous roles include Director of External Relations, Communications and Marketing at St George's, University of London, and Head

George's, University of London, and Head of Research Information and Engagement at Cancer Research UK (CRUK).

The BSIR 2023 annual scientific meeting will take place on 8–10 November 2023 in Newport, Wales. Newport will provide a marvellous backdrop for BSIR 2023 with the conference centre overlooking stunning views of the Welsh countryside. The International Conference Centre promises to be a venue like no other, with world class facilities suited for an event of this size.

BSIR is working with the CIRSE Congress Innovation Research GmbH as the official professional congress organiser (PCO) to deliver this year's BSIR Annual Scientific Meeting. This partnership will enable us to simplify the workload for our Scientific Programme Committee and bring added benefits, including an onsite app and access to all content online for 12 weeks after the conference has taken place. Registration for BSIR 2023 will be available summer 2023 (www.bsirmeeting.org).

The Programme Committee chair is Dr Salil Karkhanis, Queen Elizabeth Hospital, Birmingham. As always the programme has great breadth and from a vascular perspective:

In Arterial Interventions, we will be looking at the latest advances in the management of chronic limb ischaemia and discuss controversial topics in below-the-knee arterial disease. Visceral arterial interventions allow us to understand the management of these pathologies better in the D2D session.

Similarly, in another D2D session, we look to explore current topics in aortic disease and understand their diagnosis and management. In the panel discussion, we look to our experts to help unpick the controversies in aortic dissections.

Our Venous Disease D2D session explores

various topics in venous thrombotic disease in the limbs, ileocaecal system and mesenteric venous system. The Vascular Access Society of Great Britain and Ireland (VASBI) meets BSIR in our venous access session with a stellar speaker line-up. We also take a deep dive into pulmonary thromboembolism as well as talk to the experts on controversies in the management of portal hypertension.

Other BSIR meetings are IOUK in Southampton on 23–24 May, the advanced practice course in Manchester on 1–2 June and the paediatric IR meeting in Manchester on 22 May.

We continue to seek funding to employ an IR fellow based within the NVR, alongside the existing vascular surgery fellow. Partial funding has been committed by both Circulation Foundation and BSIR. We are applying for funding from the RCR via the Kodak fellowship programme. We should know the outcome in Autumn 2023.

Rouleaux Club www.Rouleauxclub.com @RouleauxClub



It has been another busy year for the Rouleaux Club. We are pleased to see that there is progress from the Rouleaux Bullying, Undermining and Harassment Trainee Survey with the Vascular Society developing a training course in conjunction with the Royal College of Surgeons of Edinburgh (RCSEd), involving trainees in the pilot course. There is still a long way to go to improve this issue, but it is reassuring that Executive Committees of the majority of surgical specialities are taking it seriously.

The Rouleaux focus on student and trainee development continues with five courses run through the year: Introduction to Vascular Surgery at the Vascular Society's Annual Scientific Meeting (VSASM), CX International Symposium and the Association of Surgeons in Training (ASiT), as well as two stand-alone "So you want to be a Vascular Surgeon?" courses in conjunction with RCSEd. These are well received by medical students and foundation and core trainees and show promise in recruitment to vascular surgery. The monthly online ASPIRE Junior series continues and has been attracting an international audience, which aligns with our latest collaboration with the World Federation of Vascular Societies to initiate a Global Training Collaborative.

Trainee involvement has increased, with this academic year seeing the launch of two trainee competitions. The first is the VSASM Trainee MDT competition, where trainees were encouraged to submit an interesting case for the meeting's MDT with the top three submissions being invited to present their case and a trainee-focused discussion facilitated by the panel. The second competition is the Hurting Leg Competition, run in conjunction with the CX International Symposium and BIBA Medical, where trainees were invited to submit an Infographic or two-minute Infomercial to raise awareness and educate members of the public in chronic limb-threatening ischaemia. These are in addition to the yearly Medical Student and Foundation Trainee Essay Competition and ASiT Rouleaux Vascular Poster Prize.

Rouleaux has also launched a Medical Student Surgical Society Affiliation Section to the website to improve links between Rouleaux and Medical Student Surgical Societies to improve access to vascular surgery at an early stage.

In the meantime, there has been ongoing work with the SAC and the Joint Committee on Surgical Training to create guidance regarding dual consultant operating. We have also forged stronger links with the SAS representatives, promoting diversity and inclusion within vascular surgery and trying to improve accessibility for non-NTN trainees.

Over the upcoming years, Rouleaux aims to continue working with medical students and junior trainees to improve awareness and understanding of vascular surgery whilst aiding recruitment and giving teaching, training and leadership opportunities to more senior trainees. We also continue to represent all trainees, not just NTNs, within the Vascular Society and wider vascular community to increase trainee involvement and to create and maintain a supportive and inclusive training environment.

Society of Vascular Nurses (SVN)

www.svn.org.uk @vascularnurses



Within our nursing profession, we started this year with national nursing strikes that have then led to conversations and an offer of a pay rise, which has gone on to create further controversy with the acceptance by Unison members but declined by the RCN membership. We are now awaiting the outcome of a court ruling regarding further strike action by members of the RCN as to whether the planned strike action over the Bank Holidav period is lawful. We are thankful to all our healthcare colleagues for their support shown during the nursing strike action and we continue to support the junior doctors. We currently do not know how long the pay disputes will last, but I am confident that all staff in the NHS will continue to provide the appropriate high quality care and professionalism to every individual we encounter.

On 19 April the Society of Vascular Nurses (SVN) supported the launch and publication of the document 'A guide for establishing a nurse-delivered venous intervention service'. This was facilitated by Medtronic with a panel of experts and other contributors. The aim of the document is to guide and support nurses who are looking to undertake nurse-delivered venous intervention to address identified service need. We are aware that this has not come without controversy; however, we believe the document is an important step to help ensure services are developed safely and effectively.

At our first meeting in January we welcomed four of our five new seconded committee members. In our favour, Paula O'Malley is from Dublin and applied with the offer to help us with organising this year's conference that is to be held in her home city. We also gained Charlotte Hooper who is now based in the community as a vascular nurse after having worked in a vascular arterial centre. We are always keen to ensure we improve and keep these links as we acknowledge there is still a huge gap in the work we do in the community setting. We also welcomed Melissa Hughes and Jayne Snellgrove who both bring years of experience as vascular nurses. We welcome each of these and look forward to the year ahead, hoping it brings value to them and us as a committee. Secondment positions remain an integral part of the committee to ensure we remain in touch with what our membership want, and helps us to deliver this.

We are looking forward to a joint session again this year with the Venous Forum in London on 9 June. However, the programme starts on 8 June with workshops to suit both doctors and nurses, and again this year they are offering free registration to 10 nurses. More information regarding this is available in our 2nd quarter edition of Vascular Matters.

Lastly, at this time of year we like to remind our SVN membership about the opportunity to start thinking about sharing their work and achievements by entering our James Purdie Prize Presentation session. There are also opportunities for our SVN members to apply for a bursary to either help attend Conference or help towards the cost of improving patient care. An 'Emma's Gift' bursary is available to band 5 nurses starting out in their career within the vascular speciality who would like to attend Conference; please see our website for more details.

> Gail Curran SVN President

Vascular Anaesthesia Society of Great Britain & Ireland (VASGBI) www.vasgbi.com @vasgbi



The Vascular Anaesthesia Society of Great Britain & Ireland (VASGBI) promotes best practice in the perioperative care and anaesthetic management of vascular surgical patients, from preoperative assessment clinics, through surgery, to postoperative care. Our activities focus on developing the knowledge and skills of our members in order to support continual improvement in the care provided to patients referred for vascular surgery.

Providing the best care for our patients is a central aim of VASGBI. This year the patient information leaflet "Your Anaesthetic for Vascular Surgery", which VASGBI coauthored in conjunction with the Royal College of Anaesthetists, is being revised. Any comments or suggestions are welcome.

(https://www.rcoa.ac.uk/sites/default/files/d ocuments/2020-08/14-VascularSurgery2020web.pdf)

We are in the final editing stages of a new vascular anaesthesia e-learning package developed in conjunction with colleagues in the east of England. This resource will soon be available on the Royal College of Anaesthetists website and will also be able to be accessed via a link from the VASGBI website.

The report of the seventh national anaesthetic audit project (NAP7) examining perioperative cardiac arrest has been completed. A whole chapter of this report will be dedicated to perioperative cardiac arrest in vascular surgery, based on realworld data collected over 1 year. It will include key findings and recommendations that will be of interest to vascular anaesthetists and surgeons. The full report of NAP7 results will be published in November 2023. Key lessons for vascular surgery and vascular anaesthetists will be presented at our ASM in September.

The research and audit sub-committee will be involved with further revision of anaesthesia-related fields of the National Vascular Registry (NVR) in the coming year and will be publishing the VASGBI summary of the NVR report which will be available via a link on our website in the next few weeks: Home - VASGBI.

Three applications were received for the VASGBI/ACTACC research grant which has been awarded to a team in Bristol for a project investigating perioperative smoking advice and cessation (£68,426). The most recent trainee grant (£5000 to a team in Lothian) was awarded to a project looking at machine learning to examine which cpex data most accurately predict complication rates after open TIV thoracoabdominal aortic aneurysm repair. The next round of

applications will close on 22 September 2023.

VASGBI supports the conduct of important surveys up to a limit of two per year. If you wish to explore the possibility of running a survey through VASGBI, please take a look at the survey guidelines published on our website: VASGBI SURVEY GUIDELINES -VASGBI.

Registration is now open for the VASGBI ASM 2023 which will take place at the Hilton Metropole in Brighton. We are looking forward to hearing from our surgical colleagues across the country as well as from North America. The programme can be accessed via this link: Website Programme v2 VF.pdf - Google Drive. We are proud of the cross-specialty collaboration that is reflected in the conference programme and look forward to seeing some of you there.

The Vascular and Endovascular Research Network (VERN) www.vascular-research.net

@VascResearchNet



The Vascular and Endovascular Research Network continues to deliver national and international trainee-led research and audit projects to improve the care of those with vascular diseases. Since our last update in February 2023, I am pleased to announce the CAASP, VISTA and DEFINITE projects have now finished data collection and data validation. We would like to thank all collaborating centres for their efforts in collecting data for these important studies. The executive committee is now undertaking the data analysis. We look forward to sharing the manuscript with our collaborators shortly.

I would like to encourage anyone who has not yet completed the MAID Survey to take part. The MAID Survey is looking to gather information on current practice in the management of deep venous disease (link: https://imperial.eu.qualtrics.com/jfe/form/SV

_6XWuOAPcpk1QuPQ). Any healthcare professional is welcome to take part, even if

they do not have a regular deep venous practice. Collaborative authorship will be granted to those who provide their details.

Want to be involved in VERN? Our new study is planned to launch in the summer and we are looking to expand our executive committee – stay in the know via our twitter, newsletter and website.

The Vascular Society for Great Britain and Ireland

www.vascularsociety.org.uk @VSGBI



Industrial action

An NHS workforce crisis feels real when there are unfilled posts and a shortage of staff to fill them. In a recent survey of Society members, half of consultants who responded stated that they plan to retire during the next few years. Whilst some healthcare unions have reached agreement with the Government, widespread NHS industrial action continues over rates of pay and conditions. If the Government does not meet the BMA's demands for reforming the NHS pay review body and pay restoration, the BMA will soon ballot NHS Consultants in England for strike action. Industrial action is putting pressure on some vascular units, but many were under pressure before, with longer than recommended waiting times for elective aortic aneurysm repair. Resolution of the disputes with the Government and a workforce plan for the NHS are needed urgently to address the recruitment and retention of UK healthcare staff.

Committees

The Audit and Quality Improvement Committee is managing the transition of medical device data to the new National Medical Device Outcome Registry. The reporting of cases up to 31 December 2022 has closed and work has started on producing the 2023 National Vascular Registry (NVR) annual report. In addition, a recent special NVR report will be published on COVID-19 vaccination and vascular surgery outcomes. The Education and Training Committee has plans to deliver ASPIRE courses to all levels of UK Speciality Trainees. Plans are in place to expand ASPIRE to early years Consultants and Vascular Surgery CESR applicants. The development of an open aortic model for simulation training is progressing well. The Research Committee reports that significant NIHR platform trial funding has been allocated to vascular research, something for which both the Society and the SIGs should take great credit. A vascular clinical trials day is being run in Leicester on 20 June

(https://www.eventbrite.co.uk/e/vascularclinical-trials-2023-tickets-609193914397? aff=ebdssbdestsearch). The Workforce Committee has held a well-received trial of their professional behaviours course developed jointly with the Royal College of Surgeons of Edinburgh (RCSEd) (with special thanks to Alice Hartley, Olivia McBride and Alex Phillips). This is proving to be a productive collaboration between the Vascular Society and RCSEd. The goal is to run this course in every UK surgical department.

The Circulation Foundation is looking to formalise Memorandums of Understanding with the affiliated vascular societies to put the charity on a solid long-term footing. It is also celebrating its 30th year this year, with fundraising events planned for September and at the ASM.

Annual Society Meeting

We have a draft programme for the Society's 2023 ASM, 22–24 November, at the Conference Centre in Dublin. The theme of the meeting, chosen by Rachel Bell as President, is clinical leadership. There are excellent programmes for the President's (clinical leadership) and Vice-President's (net-zero vascular surgery) sessions.

More details will follow soon, with registrations opening in July.

Venous interventions

The publication by the Society of Vascular Nurses (SVN) of 'A guide for establishing a nurse-delivered venous intervention service' https://assets.radcliffecardiology.com/s3fspublic/webinar/2023-04/SVN%20Guide%2 0WEB%20Singles.pdf has thrown a spotlight on venous disease management and prompted social media debate. This debate was discussed at Open Council with input from the Venous Forum and SVN. We recognised that there has been a wider NHS 'deprioritisation' of venous services, but that this should not lead to less robust clinical care. Training is key and there is a need to address this, both for nursing and medical staff (including trainees). Examples of best practice in training were shared. Overall, the SVN document was welcomed for providing a clear pathway and governance frameworks for advanced nurse practitioner (or surgical care practitioner)-led superficial venous services.

Other news

The Society has appointed LightMedia to develop new websites for the Vascular Society and Circulation Foundation. Miss Meryl Davis retired from NHS vascular surgery practice in April and has asked to step down from VS Council. Mr Marco Baroni, Consultant Vascular Surgeon in York, has been appointed to serve for the vacant term on Elected Council. We are grateful for Meryl's work at vice-chair of the CF and look forward to welcoming Marco to his new role. Mr Arun Pherwani, Chair of the Audit and Quality Improvement Committee, has been recognised by BSIR for his work with Interventional Radiology and the National Vascular Registry (NVR) by the award of an Honorary BSIR Fellowship. Professor Matt Bown, Chair of the Research Committee, has been awarded a British Heart Foundation (BHF) Professorship in Vascular Surgery.

> Marcus Brooks Honorary Secretary

VASCULAR **RESEARCH UK**

A platform for Communication, Collaboration and Dissemination of high-guality research into vascular conditions

WWW.VASCULAR-RESEARCH.CO.UK WERSITE

VASCULARRESEARCHUK VOUTURE CHANNEL





CONNECTING THE VASCULAR RESEARCH COMMUNITY

Who we are

NH₂

Vascular Research UK was founded in November 2022 by the UK Vascular Surgical Specialty Research Leads.

It was established as a platform to support Communication, Collaboration and Dissemination, providing healthcare professionals, researchers and patients with the latest information and evidence for high-quality research into vascular conditions.

Aims

Vascular Research UK is dedicated to improving the quality and accessibility of research. Our aim is to be a leading resource, helping to ensure that the latest evidence is used to inform clinical practice and the development of services.

Whether you're a healthcare professional, a researcher, or a patient, we want to ensure that everyone has access to the latest evidence in an accessible format and to promote awareness of vascular conditions to the wider public and policy makers.

How can I support VRUK?

With the VRUK platform we want to facilitate and promote greater understanding and collaboration among researchers, healthcare providers, patients and policy makers, to drive progress in high quality evidence and to disseminate research which is relevant worldwide.

Please subscribe to the YouTube channel and click to receive notifications. If you like content then please promote and share it. This will help us to build the channel and ensure that the content we produce reaches as many people as possible.





Vascular Access



Venous Disease



Service

Organisation



How do we do this?

VRUK provides information completely free of easy access to a variety of content through a website and Youtube channel which will include; information and presentations about new and ongoing trials, expert insights on vascular conditions, and interviews with leading vascular

You can also get involved with the special interest groups (SIGS) supporting research development, funding and delivery in the nine subspecialist areas of vascular practice.

VASCULAR

SOCIETY

Royal College of Surgeons of England







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

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

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

Research

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

Getting involved

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

Become a Foundation Ambassador



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

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

To visit the

Circulation

Foundation

Website



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

Join us to reach the 60,000 miles and raise funds for Circulation Foundation. Sign up at the stand at the Vascular Soceities' Annual Scientific Meeting!

To donate to the Circulation



Foundation

🗍 SCAN ME

To discuss getting involved in the Circulation Foundation by fundraising, legacy donations, becoming an ambassasdor or corporate support, please call 020 7205 7151 or email info@circulationfoundation.org.uk. Text **CIRCULATION** to **70560** to donate £10. Texts will cost the donation amount plus one standard network rate message. www.circulationfoundation.org.uk

Annual Specialist Registrar Educational Programme (ASPIRE Digital)



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

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

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

- Management of the Diabetic Foot Attack
- Surgical management of CLTI
- Battle for claudication exercise vs angioplasty
- Current Management of Acute Aortic Syndrome
- Principles of major lower limb amputation
- How to write a paper
- Strategies for Vascular Trauma
- EVAR planning
- Concept of angiosomes
- Tips and tricks for safe open AAA repair
- Renal Access
- Mesenteric ischaemia
- Carotid Disease Management Symptomatic and Asymptomatic
- Upper limb ischaemia
- Management of the infected groin
- Managing the rupture AAA building a team approach
- TOCS
- Why should I consider a career in academic vascular surgery?
- Management of acute / chronic deep venous disease
- Open management of complex AAA
- Options for treating superficial venous reflux

- Endovascular management of complex aortic disease v2
- Iliac intervention How I do it
- NOTS in vascular surgery
- Radiation Safety in the Hybrid Suite
- New assessments for a new curriculum: The multi-consultant report
- A renal access MDT
- Optimisation of older vascular surgery patients
- Key aspects from the new European Venous
 Guidelines
- Paediatric Vascular Surgery
- Aortic MDT
- Through knee amputation
- Thoracic Aortic Disease
- Everything you need to know about to manage AAA except how to fix them
- ASPIRE Digital Fellowships How to get one, what to get out of it
- Management of the left subclavian artery in complex aortic interventions
- The foot in diabetic foot disease biomechanics and operative approaches to manage clinical problems
- New Developments in Vascular Access
- Thoracic Aortic Disease
- Through Knee Amputation

ALL YOU NEED TO KNOW

To access the above resources, visit the Education section on the Vascular Society members' website www.vascularsociety.org.uk





The Vascular Societies' Annual Scientific Meeting 2023

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

