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The Vascular Society for Great Britain and Ireland

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

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

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Editor's foreword

Welcome to the latest issue of the *Journal of Vascular Societies Great Britain and Ireland (JVSGBI)*.

This issue contains 2 editorials. The first written by myself in collaboration with Barbara Wren, a Consultant Psychologist is a reflection on an emotive session entitled "The patient I cannot forget" at the recent Vascular Society of Great Britain and Ireland Annual Scientific Meeting. The second editorial consolidates current evidence and management guidelines of iatrogenic acute limb ischaemia in the paediatric intensive care unit population.

Four original research papers include: a report of a single UK centre's experience of using the Gore Excluder Conformable EVAR device in a cohort of octogenarians with highly angulated aneurysm necks; a survey of core trainees feedback on a vascular anastomosis course; a survey investigating opinion regarding surgical site infection prevention in vascular surgery; and a report of a single UK centre's long term outcomes in a cohort of patients undergoing minor and major lower limb amputations.

Two protocols linked to the vascular and endovascular research network are also included in this issue. The first outlines the plans for a multicentre prospective observational study to investigate the prevalence and short-term impact of frailty, multi-morbidity and sarcopenia in patients with chronic limb threatening ischaemia (the FraiLTI study). The second outlines plans for a multicentre international audit of surgical site infection in patients undergoing major lower limb amputation (the SIMBA study).

Finally this issue closes with 3 short reports which describe cases with important learning outcomes

It is particularly pleasing to receive research submissions led by trainees addressing a variety of topics. I also once again would like to thank the hard work of the reviewers and editorial team without which production of the *JVSGBI* would simply not be possible. I would ask authors to continue to submit your papers for publication – which will hopefully ensure the ongoing success of the *JVSGBI*.

Finally having submitted an application for Medline recognition in 2023, and having recently responding to application queries, we hope to receive notification of outcome in the very near future

Ian Chetter
Editor in Chief JVSGBI
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EDITORIAL

An extraordinary conference session

Chetter I,[1] Wren B[2]

1. Chair of Surgery, Hull York Medical School, UK
2. Consultant Psychologist, Barbara Wren Psychology Ltd, UK

Corresponding author:
Barbara Wren
Barbara Wren Psychology Ltd
16 Wyneham Road, London
SE24 9NT. UK
Email: info@barbarawrenpsychology.com

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I have attended innumerable sessions at countless conferences over my career but a late afternoon session on Wednesday 22 November 2023 at the Annual Scientific Meeting of the Vascular Society of Great Britain and Ireland at the Convention Centre in Dublin will live long in the memory. It ran from 17:00–18:30 hours in a packed Liffey Hall 2 and was entitled *"The patient I cannot forget"*. Four vascular surgeons described their experience of a patient who had left them with feelings of which they had not been able to fully let go. The four surgeons were Rachel Bell, Ian Loftus, Becky Sandford and Ross Davenport. Rachel and Ian are vascular surgeons of international renown, both past presidents of the Vascular Society, whilst Becky and Ross are younger consultants in the earlier part of their career but both with extensive training and experience. Telling the story of the four cases was clearly traumatic and there were tears, tissues and soul searching. Two cases involved paediatric trauma, one iatrogenic in an unfamiliar environment. Two cases involved prolonged attempts at limb revascularisation where nothing seemed to go to plan, and the final case outlined the stresses and anxieties of being involved in a coroner's case. I have never experienced open, honest, transparent reporting of raw, emotional cases in this way.

The session was facilitated by a psychologist (Barbara Wren) who has developed her work bringing psychology to the UK implementation of Schwartz rounds,[1,2] to go on to create psychological interventions like this one for doctors in general and surgeons in particular. The aim of the session was to create a safe space where the emotional and psychological impact of being a vascular surgeon could be named and explored using their story as a way to contain distress, risk and anxiety. In-depth preparation was undertaken with each surgeon beforehand to understand their experience, agree a central focus for their story which reflected the true source of their distress (eg, helplessness, guilt) and then develop their stories into a shape that they were comfortable to share. This work informed the session design, which was structured to create the safe environment needed to manage the risk inherent in sharing and exposing emotional experiences in public.
A scene-setting introduction facilitated consideration of the 'rules' of medical culture and how they orientate us to those medical experiences that can be shared and those that must be filed away in order to succeed, demonstrate robustness, compete and survive. These rules create the courage necessary to be a doctor, but at what cost? Where do unwanted medical experiences of fear, vulnerability, loss and regret go? What toll do they take? A Brian Friel[3] quote was shared to orientate attenders to the questions posed by the session: What if the rules of medical culture thwart some of the emotional needs of doctors? How can we authentically and safely find ways to manage the emotional complexity that being a surgeon truly involves especially over the course of a successful career?

"It can happen that a culture can be imprisoned in a linguistic contour that no longer matches the language of experience".

With this quote the stage was set to release some painful consequences of being a surgeon from imprisonment. Each surgeon then beautifully articulated the emotions associated with these

Key words: surgeon distress, medical culture, trauma at work

Ken Schwartz and his family. Ken Schwartz founded The Schwartz Center in 1955. He wanted to create an organization that would ensure that patients receive compassionate and humane care by improving the relationship between clinicians and their patients.

cases, which included helplessness, guilt, inadequacy and a sense of failure and weakness. The impact of these experiences was clearly intense, causing these highly skilled and respected surgeons to question their own competence, doubt their career choices, reconsider how to manage their work/life balance and even whether the cost of the work was worth it. Support from colleagues, friends and family and in one case formal therapy had helped them to bear the pain of these hugely stressful situations, of which they were still impossible to fully let go.

Facilitated audience feedback was profound, validating, genuine and heartfelt. There was a sense of gratitude to these four surgeons that, in taking the risk to talk of their pain, they had given permission for the cost of the work to be acknowledged, for self-doubt and self-recrimination to be released and for 'messy' feelings to be normalised. The session overran despite being extended to an hour and a half, and still there was not enough time to hear from everyone who wanted to speak. Some surgeons in the audience acknowledged we all have these 'nightmare' cases which could be considered 'normal' and how we deal with this 'cemetery at the back of our mind' ultimately defines our relationship to work and to ourselves. Experienced surgeons in the audience expressed opinions on how to prepare for, manage and deal with the aftermath of these situations in order to limit their negative impact. Non-judgemental review by colleagues and embracing a no-blame culture can be useful. Perhaps the most important aspect to limiting the impact of such cases is to realise it is happening and to seek support. Finally, trainee educational events should include the topic of identifying, managing and processing these difficult and traumatic cases.

In summary, in order to continue to provide holistic care for our patients and protect ourselves from the physical, psychological, emotional and social consequences of difficult cases and adverse events, which are unavoidable throughout the course of a long career, it is essential to feel that we have permission to release complex emotions and attend to our own vulnerability and sense of helplessness when things don't go as we hoped and planned. Being a surgeon requires one to walk a fine line between potency and vulnerability (which is usually denied) while conveying total confidence to patients and their families who are sometimes desperate for unachievable certainty. Designing our work so there is space to process this complexity, and create a sense of compassion for ourselves and our colleagues, would go some way towards mitigating the unavoidable costs of the work which can pose tremendous risks to our health and happiness if they are denied.

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EDITORIAL

Management of iatrogenic acute limb ischaemia in the paediatric intensive care unit population

Kwan JY,[1] Stocco F,[1] Ali RK,[1] Bourke G,[2] Natalwala I,[2] Richards M,[3] Puppala S,[4] Finn D,[5] Scott J,[1] Stansfield T,[1] Forsyth J[1]

1. Leeds Vascular Institute, Leeds General Infirmary, UK
2. Department of Plastic Surgery, Leeds General Infirmary, UK
3. Department of Paediatric Haematology, Leeds General Infirmary, UK
4. Department of Interventional Radiology, Leeds General Infirmary, UK
5. Department of Paediatric Intensive Care Unit, Leeds General Infirmary, UK

Corresponding author:
Jing Yi Kwan
Leeds Vascular Institute,
Leeds Teaching Hospitals
NHS Trust, Great George Street,
Leeds LS1 3EX, UK
Email: jingyi.kwan@nhs.net

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In the Paediatric Intensive Care Unit (PICU) an arterial line is often inserted in critically unwell children to allow for reliable blood pressure monitoring and access to arterial blood for point-of-care blood gas analysis and laboratory testing. However, arterial catheterisation is a procedure that carries the risk of serious complications including impaired tissue perfusion, thrombotic events and limb ischaemia.[1] The typical clinical features of iatrogenic acute limb ischaemia (ALI) in PICU patients include: (1) pallor (pale discolouration, mottling, cyanosis), (2) perishingly cold (cold to touch, use of temperature probe), (3) pulseless (absent distal pulses in affected limb), and (4) 3As (increasing analgesia requirements, anxiety and agitation). Importantly, other classical features of ALI such as pain, paralysis and paraesthesia are less useful in a PICU setting where patients are often sedated and ventilated.

Most cases of iatrogenic ALI in PICU patients are successfully managed with non-operative management alone, with a low risk of limb loss. King *et al*[2] quoted a limb loss risk of 0.6% in 10,394 patients >1 month of age with femoral artery catheterisation, whilst Totapally *et al*[3] quoted a limb loss risk of 3.1% in 961 children with extremity arterial thrombosis.

Most commonly, patients are anticoagulated with an intravenous heparin infusion and, if the limb remains viable, this is generally converted to therapeutic low molecular weight heparin for a further 5–7 days.[4–6] The evidence base for anti-coagulation duration is limited, and it may be effectively extended for up to 3 months if needed, guided by arterial duplex and clinical assessment.[7] It is important to be aware that the evidence for heparin in children and neonates is minimal, but it is generally considered a UK medicolegal standard. If a negative outcome such as amputation arose in a paediatric ALI patient not receiving appropriate anticoagulation (except in neonates deemed to be at high haemorrhagic risk), it would likely be deemed to have fallen below the expected standard of care. Other conservative measures include the use of glyceryl trinitrate patches, milrinone and peripheral nerve blockade.[8–11]

Rarely, in cases of severe ischaemia when conservative medical management fails, surgical or endovascular intervention may be considered when expertise in microsurgery, micro-sheaths, wires and catheters may be required, especially in neonates.[12] However, such interventions, despite being with the best of intentions, can still cause further severe iatrogenic injury. A multidisciplinary approach is generally required with the involvement of vascular, paediatric and plastic surgery; vascular interventional radiology; and paediatric haematology if thrombolysis is being considered. Both systemic and catheter-directed (CD) thrombolysis may be considered. However, systemic thrombolysis is associated with a significant bleeding risk. Woods *et al*[13] highlighted that although almost 80% of paediatric patients receiving systemic thrombolysis achieve complete or partial thromboembolism resolution, up to 15% have major bleeding complications. Whilst there are no randomised controlled trials comparing systemic and CD thrombolysis in children, low-level evidence suggests that CD thrombolysis is safer and more efficacious. Rizzi and Albisetti[14] describe a thrombus resolution rate of 70% with systemic thrombolysis versus 85% for CD thrombolysis, and a major bleeding rate of 9–40% for systemic thrombolysis versus 7% for CD thrombolysis.

Key words: paediatric, acute limb ischemia, arterial line, iatrogenic, thrombolysis

Open surgical intervention in very small children should be avoided if possible. Lin *et al*[15] found that adverse events and postoperative mortality all occurred in those aged <2 years ($p<0.05$), whilst those aged >2 years all regained palpable pedal pulses in the follow-up period. This suggests a need for increased caution regarding surgical intervention in children aged <2 years. This is reflected in the European Society of Vascular Surgery (ESVS) 2020 Management Guideline for ALI, which recommends initial conservative management with heparin for infants and children younger than 2 years of age.[12]

In the surgical repair of iatrogenic common femoral artery injuries in children (average age 5.8 years), Aspalter *et al*[16] recommended primary vein patch angioplasty using heparin, topical papaverine, a microsurgical technique with optical magnification and a longitudinal arteriotomy to facilitate access to profunda femoris and superficial femoral arteries. Lin *et al*[15] reported outcomes of femoral artery catheter-related ALI in 14 paediatric patients (average age 4 years) managed using size #2 or #3 Fogarty embolectomy catheters in all patients and saphenous vein patch angioplasty in the majority. Fogarty embolectomy catheters may cause vasospasm and intimal injury, therefore the smallest sized catheter possible should be used with caution.

Iatrogenic aortic injury and/or thrombosis is a recognised complication of umbilical artery catheterisation (UAC), which is considered the standard of care for arterial access in neonates.[17] Aortic thrombosis secondary to UAC classically presents with a triad of congestive cardiac failure, severe hypertension and bilateral ALI.[18] In infants with mild and transient ischaemia that resolves with catheter removal, conservative management may be all that is required and includes heparinisation, protective wrapping of the limb/s, reflex warming and careful observation.[19]

For patients with bilateral severe ALI secondary to aortic thrombosis from UAC, open surgical management (eg, transabdominal aortotomy with thrombectomy) has been advocated.[18,20,21] However, open surgical intervention for aortic thrombosis/iatrogenic injury within the context of UAC and bilateral ALI should be tempered with rationalisation and discretion. Aggressive conservative management is appropriate in the majority of cases of ALI secondary to UAC, and thrombolysis may also be considered within the appropriate clinical context. Current evidence does not mandate open surgical intervention, but as a consideration.

It is crucial to consider what constitutes a 'realistic' outcome following iatrogenic ALI in the PICU population. Chaikof *et al*[22] described their experience of operating on seven infants under the age of 6 months on PICU with iatrogenic ALI. Although there were no instances of limb loss, palpable pulses were restored in only 56% of limbs. Additionally, long-term outcome is often poorly recorded, highlighting the need for appropriate follow-up. The authors concluded that "… although thrombectomy is a safe and simple procedure in even the very youngest of patients with arterial insufficiency, surgical optimism should be tempered by frequent inability to achieve full and durable success …". It is important for clinicians to remember that these patients are likely to be frail and sick neonates, and despite the notion that surgical intervention may well be possible, it needs to be categorised and considered within the overall holistic context.

KEY MESSAGES

- First-line management of iatrogenic line-associated ALI in PICU patients should be conservative (catheter removal and IV heparin) in the majority of cases, especially for children <2 years of age.
- In patients failing to respond to conservative management, catheter-directed thrombolysis should be considered.
- In patients failing to respond to conservative management, unsuitable for thrombolysis, multidisciplinary surgical intervention should be considered.

Finally, in the devastating situation of a PICU patient with non-salvageable ALI, amputation should be delayed for as long as possible as the eventual line of demarcation may be some way distal to the original line of ischaemia.[23] Amputation should be undertaken with full consideration of future prosthetic limb application and joint contracture prevention. Amputation should be performed by a multidisciplinary team of surgeons experienced in paediatric major amputation, paediatricians, occupational therapists, physiotherapists and prosthetists to ensure the best outcome for the child.

Conclusion

Iatrogenic ALI in the PICU population is a rare but potentially catastrophic event associated with the possibility of limb loss, long-term disability and mortality. Conservative management with anticoagulation and ongoing specialist input from a multidisciplinary team should be considered the standard of care. The multidisciplinary team should include clinicians from PICU, vascular surgery, vascular interventional radiology, plastic surgery, paediatric surgery and paediatric haematology. This multidisciplinary team approach is likely to yield the best long-term result in most of these patients.

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ORIGINAL RESEARCH

Endovascular aneurysm repair using the Gore Excluder Conformable Abdominal Aortic Aneurysm Endoprosthesis with active control system in octogenarians with highly angulated aneurysm neck: a UK single-centre experience

Elsharkawy A, Mahmood A, Sirinivasamurthy D, Sayed S, Matharu N

Department of Vascular Surgery, University Hospitals of Coventry and Warwickshire, Coventry, UK

Corresponding author:
Ashraf Elsharkawy
Consultant Vascular Surgeon, Department of Vascular Surgery, University Hospitals of Coventry & Warwickshire, Clifford Bridge Road, Coventry CV2 2DX, UK
Email: ashraf.elsharkawy@uhcw.nhs.uk

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Plain English Summary

Why we undertook the work: Endovascular aneurysm repair (EVAR) is a minimally invasive procedure to prevent an aortic aneurysm from bursting. It involves inserting a graft within the aneurysm through small groin incisions using X-rays to guide the graft into place.

It is particularly useful in patients of advanced age with multiple medical problems who would be unsuitable for major open surgery. However, it requires certain anatomical features of aneurysm shape. Those with highly angulated aneurysm necks (the part of the aorta between the level of the kidney arteries and the sac) may represent a challenge for EVAR with most commercially available grafts. A new device manufactured by Gore medical company has been designed to accommodate this angulation and achieve a robust seal in this unfavourable anatomy. We think the use of this device in patients of advanced age with an unsuitable aneurysm shape is feasible with satisfactory early results.

What we did: We looked retrospectively at the hospital records of all patients aged ≥80 years who have been treated with this graft at our unit between January 2020 and July 2023. We assessed the outcomes, technical success, early complications and the rate of secondary intervention during the first 30 days after the procedure.

What we found: The initial technical success of this device is 95%, which means successful insertion of the device within the aneurysm in the absence of surgical conversion or death, graft blockage or significant leak of blood between the graft and aneurysm sac. None of the 20 patients included in the study who had this device implanted required secondary intervention during the first 30 days. No device-related deaths were reported in the same period.

What this means: This device enabled patients of advanced age with frailty and those with unfavourable aneurysm shape to be treated with EVAR according to the Instructions for Use designed by the manufacturer of the device. Although the initial results are encouraging, long-term outcomes need to be investigated further.

Abstract

Objective: Abdominal aortic aneurysm (AAA) with highly angulated neck (>60°) in octogenarians represents a challenge to treatment with endovascular aneurysm repair (EVAR). In such cases, EVAR may be used outside the manufacturer's Instructions for Use and attendant higher risk of failure. The new device Gore Excluder Conformable AAA Endoprosthesis with active control (CEXC) system has been designed to achieve optimal aortic wall apposition and seal in these more challenging geometries. This study reports the initial results and technical success of this device in octogenarians with highly angulated aneurysm necks (≥60°).

Methods: All patients aged ≥80 years who had AAAs treated with the CEXC device at a single UK centre between January 2020 and July 2023 were analysed. The primary endpoint was technical success, which was defined as successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III endoleaks or graft limb obstruction. The secondary outcomes included 30-day morbidity, mortality, endoleak and re-intervention rates.

Results: Twenty patients were included (17 (75%) males) of median age 81 (range 80–84) years. The median AAA diameter was 60 (57–63) mm and the median infrarenal neck angulation was 80 (70–89)°. The active control system was used in six cases. The median procedural time was 277 (254–316) minutes. The immediate technical success rate was 95%, with one type Ia endoleak (5%). In the 30-day postoperative period, four complications were reported. On the 30-day follow-up CT scan, five type II endoleaks were observed and one initial type Ia endoleak had persisted at 30 days. No re-intervention was required during the first 30-day postoperative period. One hospital death occurred during the coronavirus disease 2019 pandemic; however, the death was unrelated to the surgery.

Conclusions: EVAR with the CEXC device in octogenarians with hostile aortic neck anatomy is feasible inside the Instructions for Use, and shows satisfactory initial results.

Key words: abdominal aortic aneurysm, severe infrarenal neck angulation, endograft, octogenarians, frailty

Introduction

In March 2020 the National Institute for Health and Care Excellence (NICE) guidelines recommended open repair as the primary treatment option for unruptured abdominal aortic aneurysms (AAAs), while suggesting endovascular aneurysm repair (EVAR) as a viable alternative for individuals with a high anaesthetic risk. Octogenarians constitute a subset of the high-risk population. They exhibit increased frailty and operative mortality rates of 5–10% in open repair procedures.[1,2] Consequently, open repair is usually unsuitable for these patients, either due to the presence of multiple comorbidities or solely because of their advanced age. EVAR presents a less invasive alternative with reduced morbidity and mortality.[3] This approach offers certain advantages, particularly in preventing decompensation in patients characterised by increased frailty but an otherwise favourable life expectancy. However, hostile neck anatomy continues to pose a challenge for EVAR. EVAR in severe neck angulation (≥60°) has been associated with significantly higher rates of type Ia endoleak (EL), neck-related secondary intervention and device migration compared with those with non-severe neck angulation.[4] The use of EVAR devices outside the manufacturer's Instructions for Use (IFU) has been associated with reduced technical success rates and the increased use of adjunctive procedures.[5,6] This is especially pertinent in the case of octogenarian patients with increased frailty, who would be expected to decompensate with multiple interventions. The newly introduced device, Gore Excluder Conformable AAA Endoprosthesis with active control (CEXC) system (W. L. Gore & Associates, Flagstaff, Arizona, USA) has been designed to address these issues.[7] The active control system enables repositioning and adaptability of the device to the native aortic wall, thereby facilitating optimal wall apposition and aggressive infrarenal positioning. This, in turn, maximises the likelihood of achieving seal in complex aortic geometries and avoids early and late type 1aEL. Consequently, eligibility for EVAR within the IFU of this novel device has significantly expanded to include patients in their 80s with severely angulated aortic necks.

To date, only a few studies have explored EVAR with the CEXC device. Moreover, no reports exist on its use in octogenarian patients with increased frailty. This study aimed to present the first report of the immediate technical success and early outcomes associated with the use of the CEXC device in the treatment of highly angulated AAAs in octogenarian patients.

Methods

This study retrospectively reviewed data from 108 patients who underwent EVAR for AAAs at the University Hospitals of Coventry and Warwickshire (UHCW) between January 2020 and July 2023. The data for this analysis were obtained from the Department of Clinical Coding. Of the 108 patients, 20 individuals aged ≥80 years with severe neck angulation of AAAs (>60°) who were treated with the new bifurcated Gore Excluder CEXC system are included in this report. Patients who had EVARs with other devices were excluded from this study, as well as those with favourable anatomy, but the CEXC device used was based on the choice of the operating surgeon. A local study ethical approval has been obtained for this retrospective review.

Patient demographics, preoperative anatomical characteristics, procedural details, postoperative complications and follow-up details were reported. Baseline data, including age, sex, presence of hypertension, diabetes mellitus, ischaemic heart disease and chronic obstructive pulmonary disease, were collected from hospital records.

Anatomical characteristics of the aneurysms, along with all measurements, were recorded by a single observer from preoperative CT aortograms. The slice thickness of these CT scans was 0.625 mm. These measurements included the maximum AAA diameter, neck diameter, neck length and common iliac artery (CIA) diameters, all measured as the outer-to-outer wall diameter.

Operative details included technical success, utilisation of the active control system, the presence of ELs on completion angiography and the procedure time. Technical success was defined according to the Society of Vascular Surgery reporting standards as the successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III

ELs, or graft limb obstruction.[8] As per our unit policy, all patients and their preoperative CT scans were discussed in multidisciplinary team (MDT) meetings involving multiple vascular consultants, intervention radiologists and vascular anaesthetists. After the deliberations, the patients were deemed unfit for open surgery. All procedures were performed by two consultant vascular surgeons, at least one with EVAR experience.

The 30-day postoperative complications, mortality, CT scan findings and re-interventions were recorded.

Statistical analysis

All data were analysed using IBM SPSS Statistics, version 29 (IBM Corp, Armonk, New York, USA). Histograms were inspected visually to assess normality. Non-normally distributed variables are presented as medians with interquartile ranges (quartiles 1–3) for continuous data and as numbers and percentages for categorical data.

Results

Demographic characteristics

Of the 20 octogenarians treated with the CEXC device and included in this study, 17 (75%) were males and three (25%) were females. Sixteen (80%) patients were on antihypertensive medications while five (25%) were diabetic. Nine (45%) patients had ischaemic heart disease and eight (40%) had chronic obstructive pulmonary disease. All patients were receiving at least one form of antiplatelet therapy and/or anticoagulation, in addition to statins. Table 1 shows the demographic characteristics of the patients.

Anatomical characteristics

Table 1 summarises the preoperative anatomical features of the AAAs. The median AAA diameter was 60 (57–63) mm, neck length 23 (18–28) mm, neck diameter 24 (20–27) mm and infrarenal beta angulation 80 (70–89)°. The median right and left CIA diameters were 16 (13–25) mm and 14 (13–17) mm, respectively. CT imaging of severely angulated aortic neck and tortious iliac arteries is demonstrated in Figure 1.

Procedural characteristics

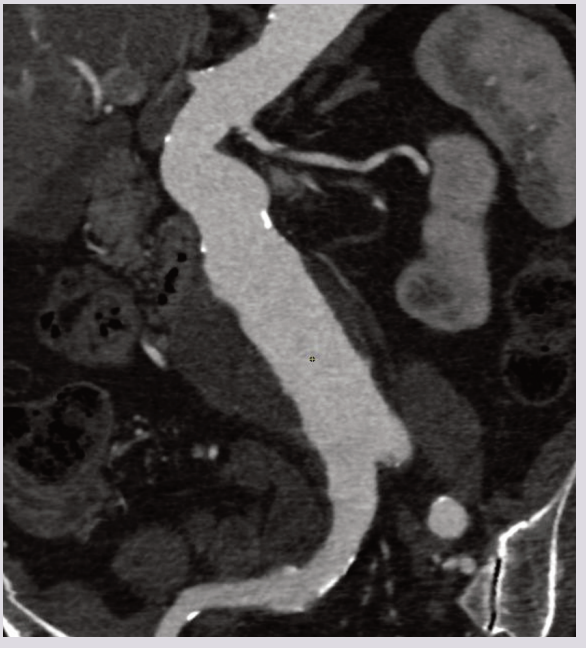
Table 2 shows the procedural characteristics. All patients (100%) were treated within the IFU of the device (neck length ≥15 mm and beta angulation >60°). The active control system was used in six (30%) patients to attain a proximal seal. In three (15%) patients, embolization of one internal iliac artery was required to enable limb extension to the external iliac artery for the treatment of a concomitant CIA aneurysm. The median procedural time was 277 (207–360) min. Technical success was achieved in 19 (95%) procedures, with one type Ia EL (5%). Additionally, two (10%) type II ELs were noted on intraoperative completion angiograms. However, these type II ELs were resolved on the 30-day CT scan.

Table 1 Demographic and anatomical features of study patients (n=20).

Demographic characteristics	
Mean age	81 (80–84) years
Males:females	17:3
Hypertension	16 (80%)
Diabetes mellitus	5 (25%)
Ischaemic heart disease	9 (45%)
Chronic lung disease	8 (40%)
Antiplatelet and/or anticoagulation	20 (100%)
Anatomical characteristics	**Median (IQR)**
AAA diameter	60 (57–63) mm
Neck length	23 (18–28) mm
Neck diameter	24 (20–27) mm
Beta angulation	80 (70–89)°
Right CIA diameter	16 (13–25) mm
Left CIA diameter	14 (13–17) mm
Concomitant CIA aneurysm	3 (15%)

AAA, abdominal aortic aneurysm; CIA, common iliac artery.

Figure 1 Preoperative sagittal CT aortogram depicting a highly angulated aortic neck.



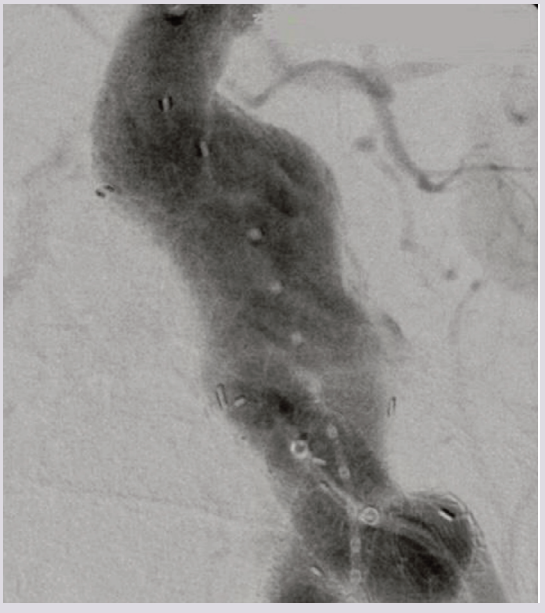
An intraoperative angiogram demonstrating the successful exclusion of the aneurysm with the endograft in situ is shown in Figure 2.

Table 2 Procedural characteristics (n=20)

Variable	
Treated inside the IFU	20 (100%)
Access method (open: percutaneous)	19:1
Planned infrarenal deployment	20 (100%)
Use of active control system	6 (30%)
Limb extension to EIA	3 (15%)
Median total procedure time	277 min
Endoleak on completion angiogram	
Type Ia	1(5%)
Type Ib	0 (0%)
Type II	2 (10%)
Type III	0 (0%)
Immediate technical success	19 (95%)

EIA, external iliac artery; IFU, Instructions for Use.

Figure 2 Intraoperative completion angiogram showing the endograft in situ.



30-day morbidity and mortality

We observed four (20%) surgical complications: ischaemic colitis in one patient, right buttock claudication in one patient, common femoral artery occlusion in one patient and groin surgical site infection in one patient. All patients were managed conservatively and did not require any intervention.

On the 30-day postoperative CT scan six (30%) type II ELs were observed; however, none of them required intervention. The initially observed type Ia EL on the completion angiogram has persisted on the 30-day CT scan. However, this has been successfully treated with balloon moulding of the top end of the graft, done under local anaesthetic on postoperative day 103 (Figure 3A–C). Figure 4 shows a 30-day postoperative CT scan demonstrating the Gore device conforming to the angulated aortic neck and tortuous iliac arteries. No re-intervention was required during the first 30-day postoperative period. One hospital death occurred, which was unrelated to the surgery. The death occurred during the coronavirus disease 2019 (COVID-19) pandemic and the patient died from COVID-19 pneumonitis. Table 3 summarises the postoperative morbidity and mortality.

Discussion

Octogenarians in this study were associated with advanced aneurysm morphology and hostile neck anatomy. The CEXC device was used effectively to achieve a good seal in such hostile anatomy with satisfactory initial results.

In this study the advanced age of the patients (≥80 years) was associated with an advanced disease process. The median AAA diameter was 60 mm and the infrarenal beta angulation was 80°. This hostile aneurysm anatomy in the advanced age group represents a challenge for treatment. Similarly, Lange *et al* [9] on behalf of the EUROSTAR collaborators found that octogenarians tend to have more advanced disease than younger patients, especially a larger diameter of the aneurysm neck and a higher incidence of angulation of the neck or iliac arteries. However, the use of the CEXC device in these patients overcomes these problems and has demonstrated a high technical success rate. In this single-centre study of octogenarians treated with this novel device, the initial technical success rate was 95%, with one type Ia EL noted on the completion angiogram which persisted on the 30-day postoperative CT scan. However, this has been successfully treated with prolonged balloon moulding of the proximal end of the graft, done as a separate procedure under local anaesthetic 103 days after the EVAR (Figure 3A–C).

High technical success rates in patients with hostile anatomy managed with the conformable Gore device were also reported by Bonvini *et al*,[10] Lee *et al*[11] and Mascoli *et al*.[12] However, these reports included a small number of patients (5, 24 and 25, respectively). A study by Zuidema *et al*[13] which included 64 patients also showed a 100% technical success rate using the CEXC device. In these four studies, no type Ia EL, type III EL or migration was seen. However, Lee *et al*[11] reported one type Ib EL at 3 months. These results are comparable to those of the current study.

In the current study, the incidence of type II ELs on the 30-day postoperative CTA was 30%, which is similar to that observed by Lee *et al* (29%).[11] This rate is also comparable to the incidence of type II ELs (39%) reported in a large systematic review that explored the use of different types of endoprostheses.[14]

We reported four postoperative complications: ischaemic colitis,

Figure 3 A) Thirty-day postoperative sagittal CT aortogram showing type Ia endoleak (red arrow). (B) Intraoperative image of balloon moulding of the top end of the stent graft to treat the type Ia endoleak. (C) Completion angiogram showing disappearance of type Ia endoleak.

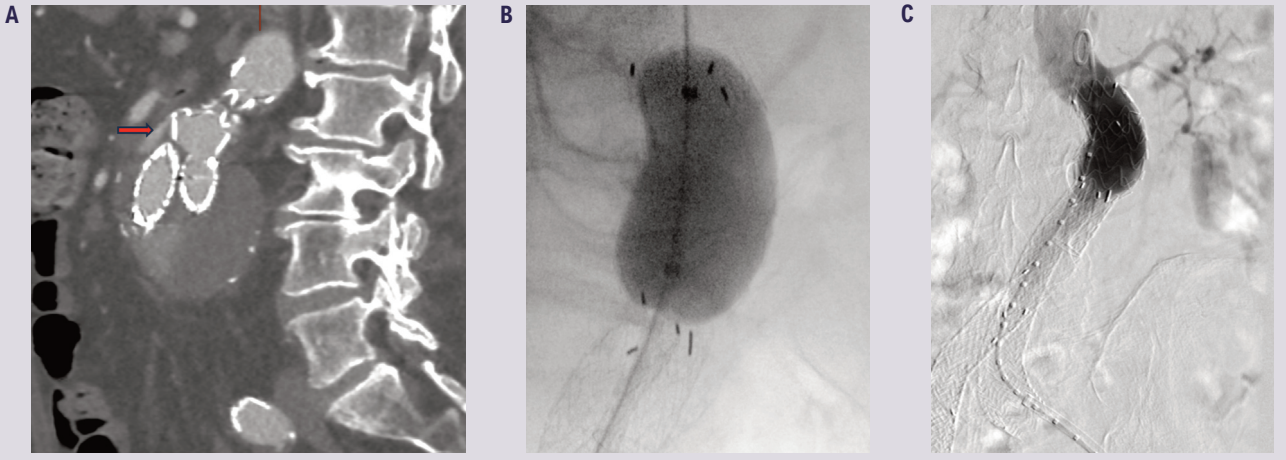
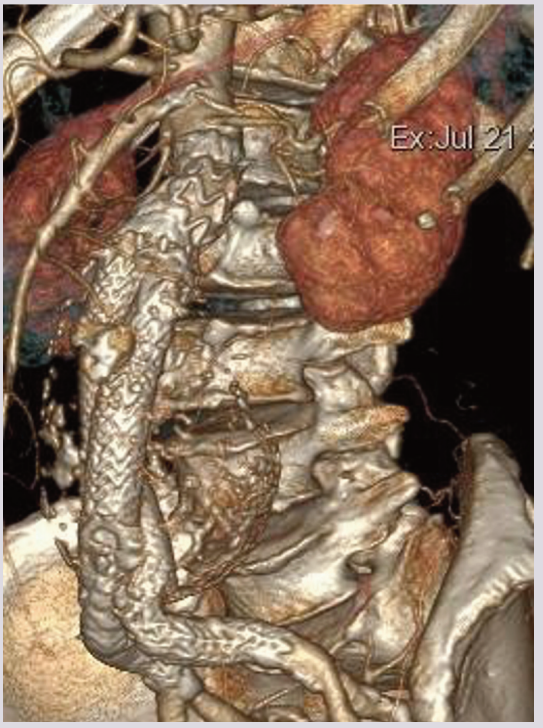


Table 3 30-day morbidity and mortality (n=20)

Variable	
30-day morbidity	4 (20%)
Ischaemic colitis	1 (5%)
Buttock claudication	1 (5%)
Leg claudication	1 (5%)
Groin SSI	1 (5%)
30-day CTA (performed)	20 (100%)
Type Ia	1 (5%)
Type Ib	0 (0%)
Type II	6 (30%)
Type III	0 (0%)
Migration of device	0 (0%)
30-day mortality	1 (5%)

CTA, computed tomography angiography; SSI, surgical site infection.

Figure 4 Volume-rendering image of a postoperative CT scan depicting the stent graft conforming to the angulated infrarenal aortic neck and tortuous iliac arteries.



unilateral buttock claudication secondary to internal iliac artery embolisation to treat a concomitant CIA aneurysm, intermittent claudication secondary to femoral artery dissection and superficial groin surgical site infection. All of these complications were managed conservatively. This 20% risk of 30-day morbidity is slightly higher than that reported in a meta-analysis by Antoniou *et al*[15] who reported a 15% rate of 30-day morbidity in patients with hostile anatomy using different types of endografts.

The slightly higher rate of complications in our series was expected as we included patients with advanced age and multiple comorbidities. However, our results were similar to those from the EUROSTAR data, which showed that the complication rate was somewhat higher among octogenarians compared with that among younger patients.[9] A similar pattern was also reported by Alberga *et al*[16] who observed a statistically significant higher rate of major complications after EVAR in octogenarians compared with non-octogenarians.

KEY MESSAGES

- The Gore Excluder Endograft with active control system could achieve a seal in highly angulated aneurysms.
- This device increased the eligibility of octogenarians with hostile aneurysm anatomy to be treated with EVAR inside the IFU.
- Despite encouraging initial results, longer term data are required.

Similar to the findings of Bonvini *et al*,[10] no aneurysm-related secondary interventions were required in the 30-day postoperative period, which indicates that this graft may be able to achieve seal of the whole landing zone. Subsequently, it may avoid early re-interventions. However, longer term follow-up is required to determine the rate of secondary intervention in the long term. In this study one patient required re-intervention for a type Ia EL on postoperative day 103. Long-term follow-up for this graft is very scarce in the literature; one-year results for the CEXC device have been reported by Rhee *et al*[17] who observed a 2.5% rate of re-intervention within the 1-year follow-up.

We reported one mortality, which occurred on day 28 postoperatively, and it was not aneurysm-related. This occurred during the COVID-19 pandemic, and the patient died from COVID-19 pneumonitis. Our findings suggest that the use of the CEXC device in octogenarians with severe aortic neck angulation is safe and effective within the IFU of the device.

The limitations of this study include selection bias, as patients were recruited by the consultant vascular surgeon who assessed the suitability of the device. However, all patients were discussed at MDT meetings involving multiple consultant vascular surgeons, intervention radiologists and anaesthetists. Furthermore, we did not compare the outcomes of the CEXC device with other devices or its use in a younger age group. Other limitations include the short follow-ups and the small sample size of the study, which may affect its validity. Further studies involving larger sample sizes and longer follow-ups to investigate long-term durability are warranted.

Conclusion

EVAR using the Gore Excluder CEXC system in octogenarians, particularly those with highly angulated aortic neck anatomy, is feasible within the IFU and has satisfactory initial results. However, despite these encouraging initial technical results, longer term durability needs to be investigated.

Conflict of Interest: The authors declare that there is no conflict of interest.

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ORIGINAL RESEARCH

Vascular Anastomosis Course for Core Surgical Trainees (VACT)

Condie N,[1,2] Al-Saadi N,[1,2] Matthews R,[1,2] Summerour V,[1,2] Wall M[1,2]

1. Department of Vascular Surgery, Black Country Vascular Network, Dudley, UK
2. Vascular Research Innovation Consortium (VaRICS)

Corresponding author:
Natalie Condie
Department of Vascular Surgery, Black Country Vascular Network, Russells Hall Hospital, Pensnett Road, Dudley DY1 2HQ, UK
Email: nataliecondie@doctors.org.uk

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Plain English Summary

Why we undertook the work: Prior to applying for a surgical specialty, surgical trainees complete a two-year programme called core surgical training. Over these two years the trainees are expected to gain understanding of the management of common vascular conditions and have practical experience of vascular surgery. The Vascular Anastomosis Course for Core Surgical Trainees (VACT) aims to provide Core Surgical Trainees (CSTs) with exposure to vascular surgery and the opportunities to develop these skills.

What we did: VACT is a one-day course for CSTs that involves four practical sessions and two lectures. The group size ranges from 10 to 12 for each session. The lectures aim to improve knowledge around common vascular conditions and vascular trauma. This course was held on three separate occasions. An anonymous online survey was distributed before and after the programme. The survey asked trainees about their experience of vascular surgery and to self-assess their confidence levels for each of the different areas.

What we found: Despite undergoing placements on vascular surgery, many trainees do not manage to meet their curriculum objectives. The feedback demonstrated that attending VACT improves knowledge and confidence in practical skills and therefore is beneficial to the trainees and the centres in which they work. Open text feedback was extremely positive, and CSTs reported that they had little exposure to these skills previously and would recommend this course to their colleagues.

What this means: VACT could be replicated in different centres nationally. This would provide CSTs with a better understanding of vascular surgery and encourage them to pursue the specialty as a career..

Abstract

Introduction: On completion of Core Surgical Training, Core Surgical Trainees (CSTs) are expected to have an understanding of emergency and elective vascular conditions as well as practical experience of vascular suturing. A proportion of CSTs will have a vascular rotation and may have been unable to acquire these skills during their placement. We used the postgraduate virtual learning environment (PGVLE) developed by Health Education England West Midlands (HEEWM) in combination with practical sessions to provide a Vascular Anastomosis Course for CSTs (VACT). There are few courses aimed at teaching CSTs the practical skills needed to become a vascular surgeon. VACT aims to improve tissue handling and teach anastomotic technique to CSTs whilst exposing them to the vascular specialty and increasing their knowledge of vascular disease and its management.

Methods: VACT is a one-day course consisting of one hour of online material and a one day in-person session. The online content was distributed via the PGVLE platform and included pre-course video tutorials, information and a survey. The in-person portion of the day included two lectures on vascular surgery and trauma and four practical stations covering embolectomy, inlay grafting, end-to-side anastomosis and patch repair. Course feedback was collected anonymously on PGVLE with automated certificate distribution after completion. The results were analysed qualitatively.

Results: Thirty East and West Midlands trainees attended the course, of whom 25 (83%) completed the post-course feedback. Three had been on a previous vascular course and 15 would consider applying for higher level vascular training. Eight trainees (32%) self-scored their knowledge of common vascular conditions as good/excellent before the course; this increased to 20 (74%) post-course. The number of trainees self-scoring themselves as

confident/very confident with vascular emergencies increased from 0 (0%) pre-course to 15 (56%) post-course. The delivery, content and equipment for the practical stations was rated as excellent/good by all participants in the embolectomy station and by 96% of participants in all other stations. Prior to the course one person (4%) rated their practical skills in vascular surgery as good/excellent. After the course this increased to 14 (56%). In all four practical stations, self-rated confidence levels increased after completing the course.100% of attendees would recommend this course to their colleagues.

Conclusion: Feedback from VACT was extremely positive with comments requesting further similar courses. With an increasing need for vascular surgeons, it is essential we provide CSTs with the skills required to complete core surgical training and pursue a career in vascular surgery. VACT could be replicated and adapted to provide vascular training to CSTs across the country.

Key words: core surgical training, education, vascular anastomosis

Background

On completion of Core Surgical Training, Core Surgical Trainees (CSTs) are expected to have an understanding of emergency and elective vascular conditions – specifically acute limb ischaemia, embolic arterial disease and vascular injury.[1] These are CST curriculum index conditions that CSTs are required to know how to manage.[1] In addition to this, an understanding of vascular suturing and anastomotic technique is expected from the CST curriculum.[1] There are a limited number of vascular surgery courses aimed at CSTs in the UK and these can be expensive and have limited availability. Many trainees will not gain any vascular exposure throughout their training due to non-vascular placements. This leads many CSTs to feel that they have inadequate exposure to vascular surgery and therefore do not want to commit to the specialty.[2] A survey by Hardy *et al* has shown that trainees with no previous placements in vascular surgery would not consider applying for the specialty.[2] Increasing access to vascular surgery and vascular surgery courses is likely to increase subsequent applications, as has been demonstrated in other specialties.[3–6]

Since COVID-19, hybrid courses containing online and in-person material have become increasingly popular. The postgraduate virtual learning environment (PGVLE) software developed by Health Education England West Midlands (HEEWM) has been used nationally as a platform for online learning. We aimed to use this in combination with practical sessions to provide a Vascular Anastomosis Course for Core Trainees (VACT). We aim to use case-based discussions and learning from lectures on vascular surgery principles to boost trainees' knowledge of vascular surgery and its operative techniques. The VACT course aimed to improve tissue handling and teach the anastomotic technique to CSTs whilst exposing them to the vascular specialty and increasing their knowledge of vascular disease and its management.

Methods

The VACT course was designed by West Midlands CST training programme director for training (a vascular surgeon) with experience in developing the vascular course as a course convenor for the Vascular Limb Salvage Academy. The course was designed based on the CST curriculum requirements for vascular surgery knowledge and basic surgical principles of vascular surgery and tissue handling. It involved one hour of online learning to be undertaken prior to the course (demonstration videos and lectures) and a one-day practical session with on the day lectures. We carried out three sessions using the same format over the course of one month. The course was advertised through the PGVLE CST training page and word of mouth.

PGVLE/online portion

Using the PGVLE platform, participants were provided access to pre-course video tutorials covering each of the practical stations, 'tips and tricks in vascular surgery' and the extended lecture material. They were asked to complete an anonymous pre-course survey self-assessing their knowledge and practical skills in vascular surgery using the 5-point Likert scale (1: very poor, 5: excellent). The survey also included questions regarding previous exposure to vascular skills courses and potential consideration of a career in vascular surgery. The survey finished with a free text question asking for any specific goals for the course, which was reviewed by faculty prior to the in-person session. Candidates were able to complete the survey at any point before the course date.

Practical session

The face-to-face practical portion of the course was held in a clinical skills laboratory in a vascular hub. Faculty included consultants, vascular surgery registrars and advanced nurse practitioners. Faculty ratio was a minimum of one faculty to two trainees. Each session was made up of 8–12 trainees and at least six members of faculty. The session lasted seven hours. Equipment for the sessions was sourced from clinical skills laboratories within the Black Country Vascular Network, sponsors (Ethicon and LeMaitre) and theatres. A list of all equipment used can be found in Appendix 1 (online at www.jvsgbi.com). The session consisted of two lectures and four practical skills sessions in the format shown in Table 1. Where necessary, one attendee initially started as the

Table 1 Vascular Anastomosis Course for Core Trainees (VACT) programme.

Time	Topic
08.30	Registration
08.45	Introduction and Lecture: Principles of Vascular Surgery
09.00	Practical: Embolectomy, Fasciotomy and Interrupted Closure
10.15	Coffee
10.30	Practical: Inlay Grafting
11.45	Lecture: Trauma and Bleeding
12.15	Lunch
13.15	Practical: Patch Closure
14.30	Coffee
14.45	Practical: End-to-Side Anastomosis
16.00	Finish and Feedback

assistant and the other as the lead surgeon before swapping over half-way. They were given the opportunity to ask questions throughout the session and carry out the procedure using vascular instruments and encouraged to try equipment (loupes, needle holders, ring tip forceps, etc) with which they often had little or no experience.

A post-course feedback questionnaire was collected anonymously on PGVLE with an automated certificate distributed after completion. We asked candidates to complete this immediately after the course. The survey was linked to the questions asked in the pre-course survey on knowledge and confidence in practical skills in vascular surgery for comparison.

Results

Thirty East and West Midlands trainees attended the course. Of these, 27 completed the pre-course feedback and 25 (83%) completed the post-course feedback.

Prior to the course, three trainees had been on a previous vascular course (12%) and 19 (76%) had undergone a rotation in vascular surgery. When asked in what specialty they would like to pursue a career, 16 said they would consider applying for vascular specialty training.

All candidates rated the delivery and content of the lecture 'Principles of Vascular Surgery' as excellent/good. Twenty-four (96%) thought the lecture on 'Bleeding and Trauma in Vascular Surgery' was excellent/good with one person rating it as average. The lecture content was used to break up the practical sessions and the combination of lectures and practical sessions received positive feedback from the trainees. The delivery, content and equipment for the practical stations was rated as excellent/good by all participants in the embolectomy station and by 96% of participants in all other stations. Figures 1 and 2

Figure 1 Pre- and post-course self-rated knowledge of common vascular conditions.

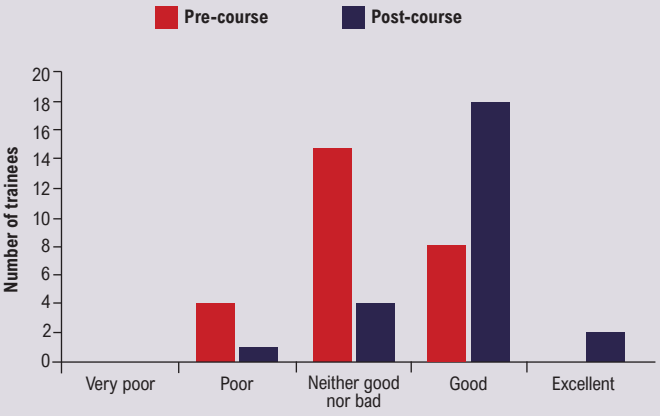


Figure 2 Pre- and post-course self-rated confidence of managing vascular trauma.

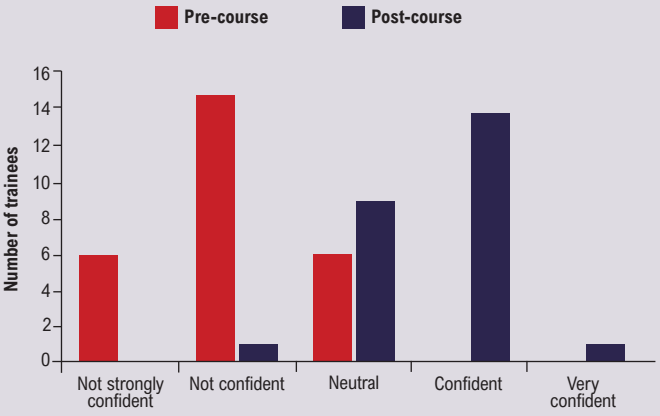


Figure 3 Pre- and post-course self-rated confidence at performing an embolectomy and repair of an artery.

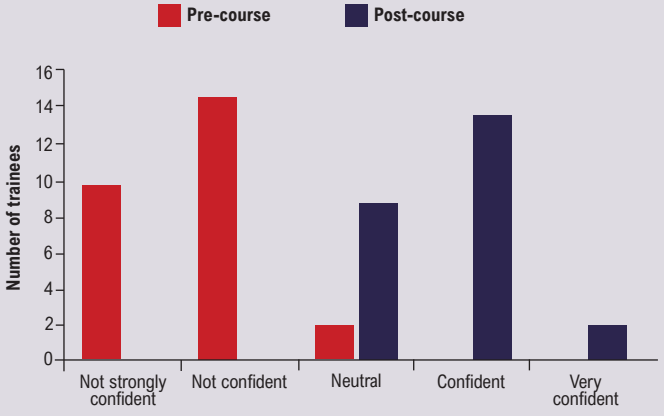


Figure 4 Pre- and post-course self-rated confidence at performing an anastomosis of an inlay graft in an aortic anastomosis.

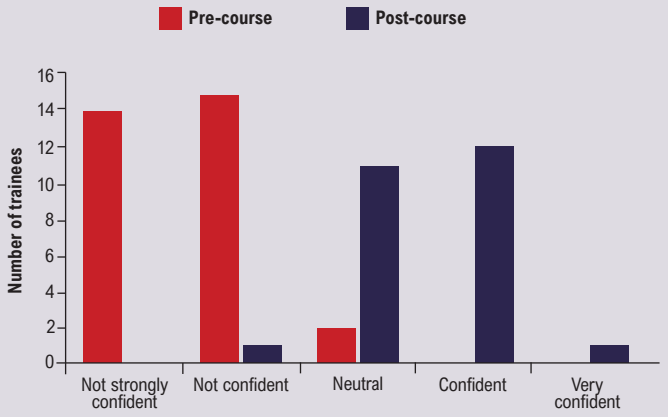


Figure 5 Pre- and post-course confidence at performing an end-to-side anastomosis of a vessel.

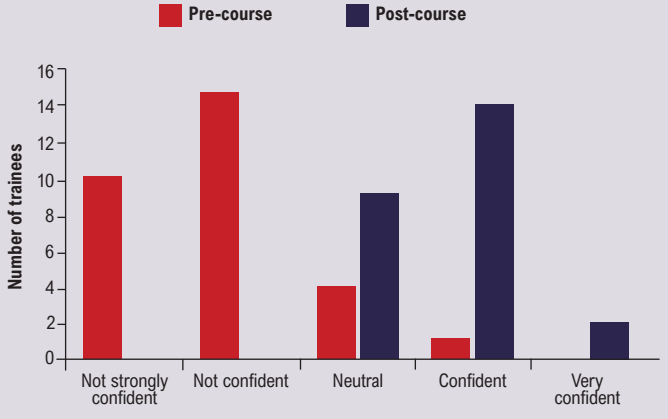
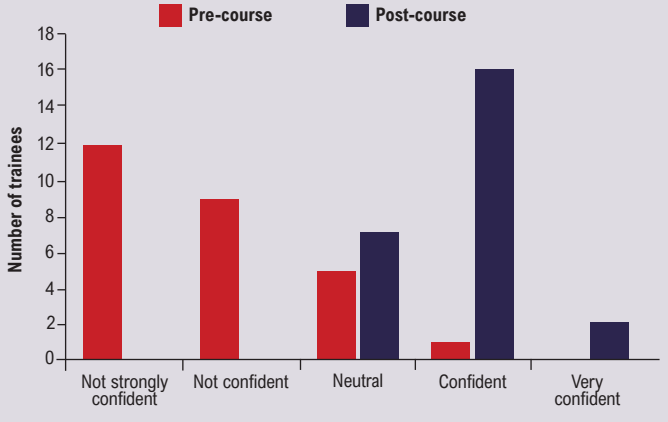


Figure 6 Pre- and post-course confidence at performing a patch repair of an artery.



show an improvement in confidence and knowledge of common vascular conditions and managing vascular trauma after the course. Eight trainees (32%) self-scored their knowledge of common vascular conditions as good/excellent before the course, which increased to 20 (74%) after the course. The number of trainees self-scoring themselves as confident/very confident with vascular emergencies increased from 0 (0%) before the course to 15 (56%) after the course.

Prior to the course one person (4%) rated their practical skills in vascular surgery as good/excellent, which increased to 14 (56%) after the course. Figures 3–6 show pre- and post-course confidence levels in each of the practical stations. The number of trainees rating their confidence as very confident/confident for each station increased from pre-course to post-course. For embolectomy this went from 0 to 14 (54%) and for aortic inlay graft it went from 0 to 52%. For patch repair of an artery one person (4%) ranked themselves as very confident/confident pre-course, which increased to 18 (72%) post-course. For end-to-side anastomosis, one trainee (4%) ranked themselves as very confident/confident before the course, which increased to 16 (64%) after the course.

Qualitative feedback from candidates

Pre-course material

'The pre-course videos were great to learn from. The lectures were short, clear and concise'.

'Theory knowledge online first meant greater focus on practical skills'.

Faculty to trainee ratio

'The faculty to student ratio was excellent. I was guided by a consultant or registrar for each skill, and I found this extremely useful to receive feedback throughout the course'.

'Great opportunity to practice and learn with close supervision. Ratio of faculty to student very good!'

The wish for more time

'Maybe even have it over 2 days and add more practical skills'.

'Maybe practicing each station twice?'

'Would have been good to have longer individual time of each specimen'.

Enjoyment of practising practical skills

'Lots of hands-on practical time which has increased my confidence'.

'Helped increase my confidence in performing surgical skills'.

'Run it more often, add more stations'.

'I feel much more confident in my own skills'.

Overall opinion

'Probably the best surgical course I have ever been on. I wished we had something like this at the start of CT1. Having considered, faculty feedback on our surgical skills was very valuable. Helped increase my confidence in performing surgical skills. Really enjoyed the lectures, practicals, and food'.

How to improve the course

- *'Maybe even practising each station twice'.*
- *'Run it more often'.*
- *'Have it over 2 days and add more practical skills'.*
- *'More courses like this'.*

When asked, 100% of attendees stated that they would recommend this course to their colleagues.

Discussion

It was felt within the West Midlands Core Surgical Training committee that the opportunities for trainees to access vascular surgery training were limited and that a course would be of benefit. The West Midlands region received its allocation of COVID recovery money and the course was funded through this programme. £6000 was allocated, which allowed for the purchase of equipment to teach, feed and water 30 candidates. Costs will be reduced going forward as jigs required are now purchased and inserts remain relatively cheap. The support from industry also blunted the cost with the use of out-of-date stock and free samples.

The course was over-subscribed, showing a strong desire for a vascular anastomotic and knowledge themed course amongst CSTs. Nineteen trainees who had previously undergone vascular rotations still felt the need to attend the course. This demonstrates that VACT is beneficial to all CSTs regardless of their placements. The course had some secondary aims as well which included giving CSTs the opportunity to talk to vascular surgeons and ask any questions about techniques and opportunities which they may not have had within their core surgical placements. The course therefore also doubled as advertising vascular as a specialty.

Vascular surgery to the non-indoctrinated remains a challenge. The teaching of the basics of vascular assessment can often struggle to get beyond the '6 p's'. The course pre- and post-questionnaires show that the use of multi-media teaching and practical sessions with good availability to knowledgeable faculty can bolster surgical confidence and technique to allow for fulfilment of the vascular part of the core surgical curriculum. 100% of trainees said they would recommend the course. This reflects the need to give trainees access to good training materials and opportunities. With the changes to rotas and ongoing challenges to training that the core group face, this structure of course offers multiple benefits. The course hones knowledge through directed single specialty materials and gives prolonged practical experience which the trainees clearly enjoy and from which they benefit.

VACT could be replicated and adapted to provide vascular training to CSTs across the country. The feedback has shown that it improves confidence in knowledge and practical skills and therefore is beneficial to the trainees and the centres in which they work. Future courses could collect feedback from faculty on the trainees and compare this with the self-assessment scores. They could also look at incorporating virtual reality simulation into the course; this would give trainees objective feedback on the tasks they're performing. However, setting this up would require initial funding for equipment and training for the faculty.

Courses on teaching basic surgical skills and trauma are already provided nationally and VACT could be rolled out in a similar way. The course administrators did notice the difficulty in getting faculty to volunteer their time for the course, which has been a challenge across the surgical Core Surgical Training since the pandemic and will likely continue to be so.

KEY MESSAGES

- A combination of virtual material via the postgraduate virtual learning environment (PGVLE), lectures and practical session results in a varied course with excellent feedback from Core Surgical Trainees.
- The feedback from the Vascular Anastomosis Course for Core Surgical Trainees (VACT) demonstrates the wish of Core Surgical Trainees to have more opportunities to practice vascular surgical skills and improve their confidence.
- There is a need for more courses providing this combination of knowledge and practical experience of vascular suturing. VACT could be replicated across the country to enable this.

Conflict of Interest: The authors declare that there is no conflict of interest.

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ORIGINAL RESEARCH

A feasibility survey to inform trial design investigating surgical site infection prevention in vascular surgery

Lathan R,[1] Hitchman L,[1]* Long J,[1] Gwilym B,[2] Wall M,[3] Juszczak M,[3] Smith G,[1] Popplewell M,[3] Bosanquet DC,[2] Hinchliffe R,[4] Pinkney T,[3] Chetter I[1]*

*Joint first authors

1. Centre for Clinical Sciences, Hull York Medical School, Hull, UK
2. South East Wales Vascular Network, Aneurin Bevan University Health Board, Royal Gwent Hospital, Newport, UK
3. Institute of Applied Health Research, University of Birmingham, Birmingham, UK
4. Department of Vascular Surgery, University of Bristol & North Bristol NHS Trust, Bristol, UK

Corresponding author:
Ross Lathan
Academic Vascular Surgical Unit, Hull Royal Infirmary, Hull, HU3 2JZ, UK
Email: ross.lathan2@nhs.net

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Plain English Summary

Why we undertook the work: Wound infections affect up to 4 in 10 people who undergo an operation involving a cut in the groin or a leg amputation. Wound infections are painful, debilitating and cause depression and anxiety. They also increase the risk of being admitted to hospital and having another operation. There is sparse good quality research on the best treatment to prevent wound infections after an operation, which are called surgical site infections (SSI). This means different surgeons do different things, which results in variation of care. We are designing a study to compare different treatments to prevent SSI. The first step was to find out which treatments surgeons currently use and whether they would be willing to use an alternative treatment. This will help us to decide which treatments to research in the study.

What we did: We created an online questionnaire asking vascular surgeons which treatments they currently use to prevent SSI when performing an amputation or operating on the groin. The questionnaire also asked whether they would be willing to use different treatments in a study setting. Before we sent out the questionnaire we tested whether it asked the right questions and collected appropriate answers. We tested the questionnaire by sending it to a group of vascular surgeons who suggested changes. We repeated this process until no further changes were needed. The questionnaire was sent out on 10 August 2023 and surgeons had until 30 September 2023 to complete the questionnaire. We sent the questionnaire out via a newsletter from the Vascular Society of Great Britain and Ireland and tweeted the survey on X (formally Twitter).

What we found: The questionnaire was completed by 58 vascular surgeons in the UK and Ireland. Before the operation surgeons often did not recommend a specific cleanser for bathing. Surgeons used a range of sterilising solutions to clean the skin before they made the first incision. Sometimes films are used to cover the skin, which can be plain or contain iodine. The questionnaire found no agreement between surgeons on the type of film used or using a film at all. Whether antibiotics were given and the course of antibiotics also varied. During the operation surgeons used different solutions to wash the wound or did not wash the wound. A drain was variably used. Most surgeons did not change their gloves or instruments before suturing the skin. The method and type of suture to close the wound also varied. There was no consensus on which type of dressing to use to cover the wound. Nearly 75% of surgeons who completed the questionnaire would be willing to use a different treatment to prevent SSI and would be agreeable to randomise (randomly allocate) to a different treatment in a study.

What this means: This questionnaire found that surgeons use many different treatments to prevent SSI in the UK. We found most surgeons would be willing to try out different treatments in a study. The results will be used to decide which treatments to test in a future study.

Abstract

Introduction: Current surgical site infection (SSI) prevention guidance indicates low-quality evidence supporting many of their recommendations. Subsequently, there is substantial variation in practice and often implementation of unsubstantiated interventions. There is therefore a need to rapidly evaluate best practices to prevent SSI. This survey aimed to evaluate current practice in the prevention of SSI and equipoise regarding potential interventions to reduce SSI rates in major lower limb amputation (MLLA) and groin incisions.

Methods: A cross-sectional national survey was developed from current international guidelines to prevent SSI, following CHERRIES and CROSS checklists. A study steering committee directed internal validation prior to dissemination via single stage sampling of the membership of the Vascular Society of Great Britain and Ireland.

Results: The survey received 58 responses from clinicians across 38 NHS trusts. Most respondents were consultant vascular surgeons (91%; 53/58). Preoperatively, there was variable practice in the use of preoperative bathing, surgical site preparation, antibiotic prophylaxis duration and the use of incise drapes for both MLLA and groin incisions. Intraoperatively there was little consensus for wound irrigation, drain insertion, changing gloves and instruments prior to skin closure, skin closure technique, and the use of dressings for both MLLA and groin incisions. The majority of respondents were willing to randomise patients to most interventions. Nearly three-quarters (72%; 42/58) of respondents agreed or strongly agreed that a combined outcome measure of SSI and wound dehiscence would be the ideal primary outcome in a trial investigating SSI prevention in MLLA.

Conclusions: Despite significant heterogeneity in practice to prevent SSI, the majority of surgeons surveyed showed they would be willing to randomise to interventions in a randomised controlled trial. This key finding is important in the design of future studies.

Key words: survey, surgical site infection, equipoise, randomized controlled trial

Introduction

Surgical site infection (SSI) is common following vascular surgery, complicating up to 40% of groin incisions and major lower limb amputations (MLLA).[1–3] SSI significantly impairs quality of life due to associated pain, reduced mobility, depression and anxiety.[4] SSI results in a fourfold increase in the risk of readmission and substantially increases healthcare costs, estimated at £6,103 per episode.[5,6]

The need for a high-quality, appropriately powered, multicentre, randomised controlled trial to inform SSI prevention practice is paramount. National and international SSI prevention guidelines highlight a clear lack of high-quality data for recommendations, resulting in substantial variation in practice and frequent implementation of unsubstantiated interventions further highlights the need for a randomised controlled trial.[7–10] The James Lind Alliance (JLA) Priority Setting Process in vascular wounds corroborated this by identifying SSI prevention as a top 10 research priority for both clinicians and patients.[11] Similarly, the lower limb amputation process identified improvement of stump healing as a top priority.[12]

This survey aims to assess current practice and equipoise of UK vascular surgeons with potential interventions to prevent SSI in groin wounds and MLLA.

Method

Objectives

- To identify the current practice in the use of potential interventions to reduce SSI
- To evaluate the equipoise regarding potential interventions to reduce SSI in a multi-arm multi-stage (MAMS) trial

Study design

This was a national cross-sectional survey of UK vascular surgeons which was open for responses between 10 August 2023 and 30 September 2023. A Study Steering Committee (SSC) of four consultant vascular surgeons, three professors of surgery and four vascular trainees provided oversight and a consensus-based approach to survey development, validation and distribution. The design, conduct and report of this study follow the checklist for reporting of survey studies (CROSS) and the checklist for reporting results of internet E-surveys (CHERRIES).[13,14]

Questionnaire development

Using SSI prevention guidelines and a prior survey conducted by this group, potential interventions for evaluation in a randomised controlled trial to reduce SSI in MLLA or vascular groin incisions were proposed to the SSC.[7–10] Initially two surveys were planned, one for MLLA and one for groin incisions. However, given the similarity in interventions and potential audience survey fatigue, the SSC advised that a combined survey addressing both patient groups would achieve optimal response rates. SSI prevention interventions were categorised as preoperative, perioperative and postoperative, dependent on the timing of administration in relation to the index procedure, and further classified according to their use for MLLA or groin incision. Questions were designed to follow Likert response options where possible with a combination of binary, multi-select and free-text options where required.

The SSC provided three rounds of internal validation following which, potential trial investigators provided final external validation. Questionnaire alterations were recorded as major (question added or removed) or minor (wording, syntax or response option modification). Twenty-nine SSI prevention interventions were initially proposed across both MLLA and groin pillars of the survey. The first internal validation round resulted in seven major (six questions removed, one added) and six minor alterations, the second internal validation round resulted in four major (zero questions removed, four added) and three minor alterations, whilst the final internal validation round yielded two major (zero questions removed, two added) and five minor alterations. No further alterations occurred following external validation.

The final survey included 54 questions; 26 related to

interventions (14 MLLA, 12 groin), 24 assessing equipoise regarding randomisation (13 MLLA, 11 groin), two demographic questions and two individual questions regarding MLLA outcomes and willingness to recruit to the proposed trial. The final version of the survey is provided in Appendix 1 (online at www.jvsgbi.com).

Survey administration

The survey was designed and published using the QualtricsXM PlatformTM, Washington, USA. The survey was open to vascular surgery consultants and trainees from the UK and Ireland. Participants' responses were invited through single-stage sampling of the members of the Vascular Society of Great Britain and Ireland (VSGBI), providing a representative model of the vascular surgical population. Survey distribution was primarily via email to the VSGBI membership with periodic reminders at two-week intervals, and pulsed dissemination from the @VascResearchUK twitter account. Further snowballing on social media was encouraged.

Participants completed the survey by following the anonymous study URL link or QR code. Multiple single participant responses were precluded using QualtricsXM options.

Statistical analysis

Responses were scrutinised by the SSC and non-response questionnaires removed. Partially completed questionnaires were included. Only responses submitted within the participation window were included in the analysis. Response data were exported to Microsoft Excel Version 16.79.1 for cleaning and analysis using IBM SPSS Statistics version 29.0.1.0 (IBM Corp, Armonk, New York, USA). Demographic and Likert responses were reported as percentages of responses. Responses with >60% concurrent responses were taken as good levels of agreement and >80% similarly were considered excellent levels of agreement.

Results

The survey received 58 responses from clinicians based in 38 NHS trusts/health boards in the UK and Ireland (Figure 1). Most of the respondents were consultant vascular surgeons (91%; 53/58). The other respondents were registrar level vascular trainees (7%; 5/58) and one physician associate.

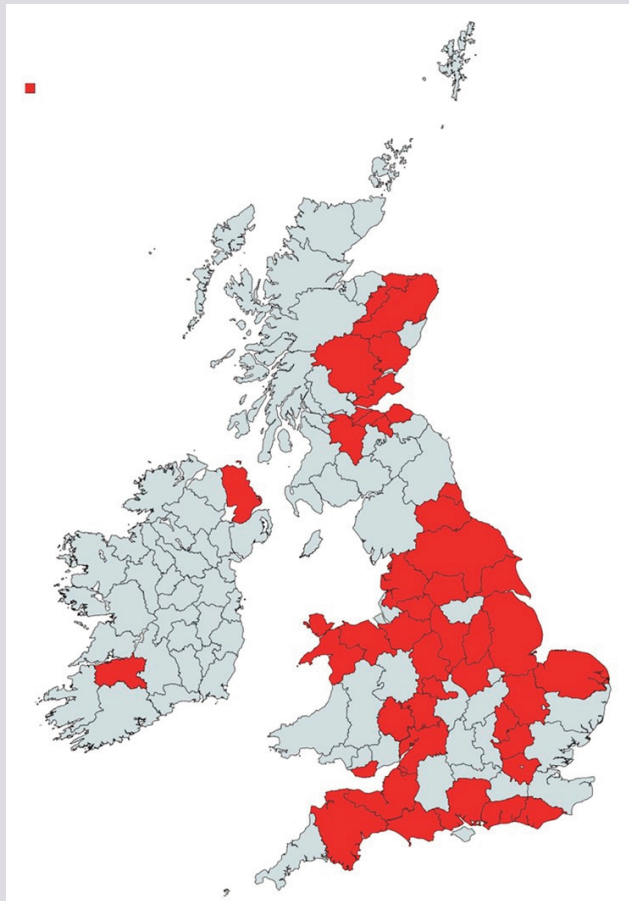
Major lower limb amputation

Preoperative SSI prevention practices in MLLA

Most respondents do not routinely recommend a specific solution for preoperative bathing. When preoperative bathing was recommended, soap was the preferred cleansing solution (22%; 11/51), followed by chlorhexidine (13%; 7/54) and chlorhexidine cloths (2%; 1/49). Other cleansing solutions recommended included Octenisan and Stellisept (13%; 3/24). The majority of respondents would be willing to randomise patients to different preoperative bathing solutions (Figure 2a).

Clipping was always or often used for preoperative hair removal by 58% (33/57) of respondents. One responder each always used epilation/waxing. The majority of respondents (61%; 34/56) would be willing to randomise patients to hair removal with a hair clipper (Figure 2b).

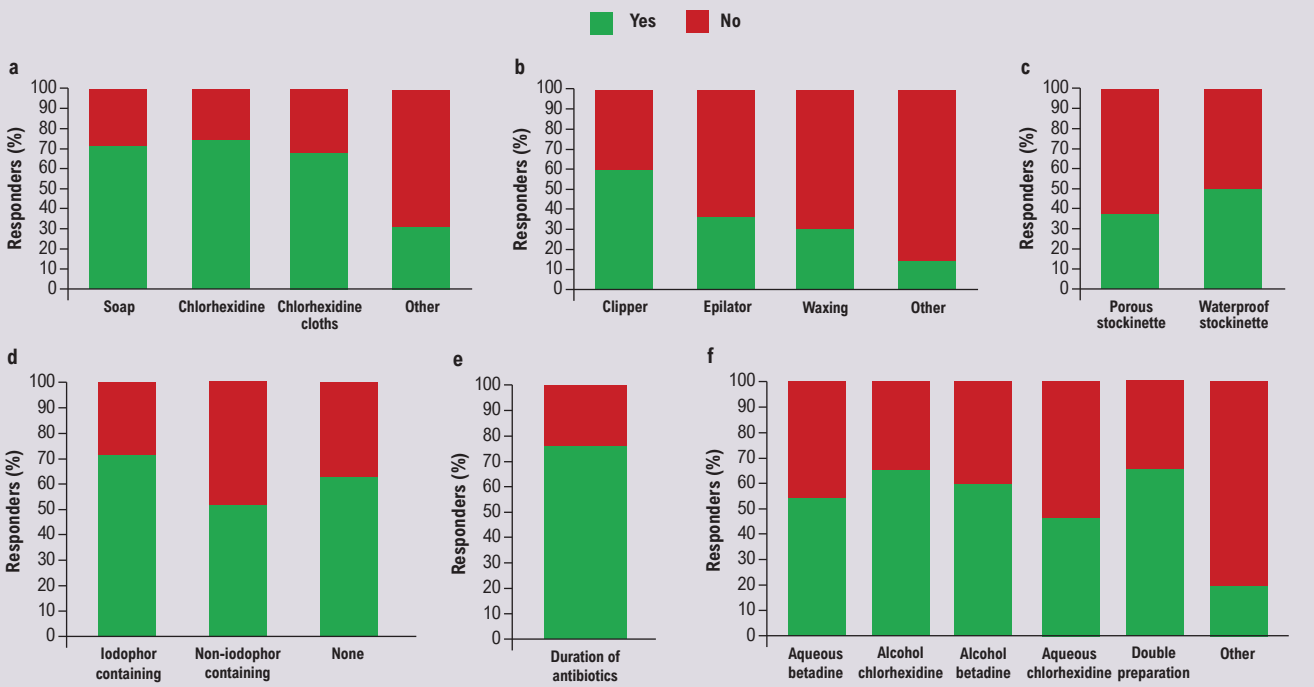
Figure 1 Location of survey respondents (Ref: mapchart.net).



Alcoholic chlorhexidine was always or often used for skin preparation by 68% (37/56) of respondents and alcoholic betadine was always or often used by 23% (11/48) of respondents. Aqueous betadine and aqueous chlorhexidine were infrequently used. In those who responded, a double preparation with any combination was always/often used by 41% (14/34) and sometimes used by 21% (7/34) of respondents. The most popular combination of double preparation was alcoholic chlorhexidine applied twice (33%; 3/9 respondents). The majority of respondents would be willing to recruit patients to a trial evaluating skin preparation with alcoholic chlorhexidine (67%; 37/55) and double skin preparation (67%; 37/55) (Figure 2f).

Preoperative prophylactic antibiotics were used by 76% (41/54) of respondents. The use and duration of postoperative prophylactic antibiotics was reported to be hugely variable. Over three-quarters of respondents (76%; 44/58) would be willing to recruit patients to a trial assessing the duration of postoperative prophylactic antibiotics (Figure 2e).

Figure 2 Respondents' willingness to randomise for different preoperative interventions to prevent surgical site infections in major lower limb amputations: (a) preoperative bathing; (b) hair removal method; (c) foot preparation; (d) incise drapes; (e) duration of antibiotics; (f) skin preparation solution.



Incise drapes were never/rarely used by 67% (37/55) of respondents. The majority of respondents would be willing to recruit patients to a trial assessing the use of incise drapes (Figure 2d).

A waterproof stockinette was always/often used to prepare the foot during MLLA by 77% (44/57) of respondents. Willingness to recruit patients to randomised trials based on method of foot preparation is shown in Figure 2c.

Intraoperative SSI prevention practices in MLLA

An antimicrobial substrate to prevent infection in the surgical field during the procedure was never/rarely used by 82% (47/57) of respondents. Nearly three-quarters (72%; 42/58) of respondents would be willing to recruit patients to a trial evaluating intraoperative antimicrobial substrates.

Saline wound irrigation prior to closure was always/often undertaken by 47% (27/58) of respondents. Betadine and other irrigation fluids were rarely used. Most respondents would be willing to recruit patients to a trial assessing wound irrigation using betadine (69%; 40/58) and saline (79%; 46/58).

A drain was always/often inserted during MLLA by 59% (33/56) of respondents. Over half of respondents would be willing to recruit patients to a trial assessing insertion of a drain (58%; 33/57).

Only 4% (2/58) of respondents reported that they always/often change the instruments and 5% (3/58) of respondents reported they always/often changed their gloves prior to wound closure. The majority of respondents would be willing to recruit patients to a trial evaluating change of instruments (71%; 41/58) and a change of gloves (77%; 44/57) prior to wound closure.

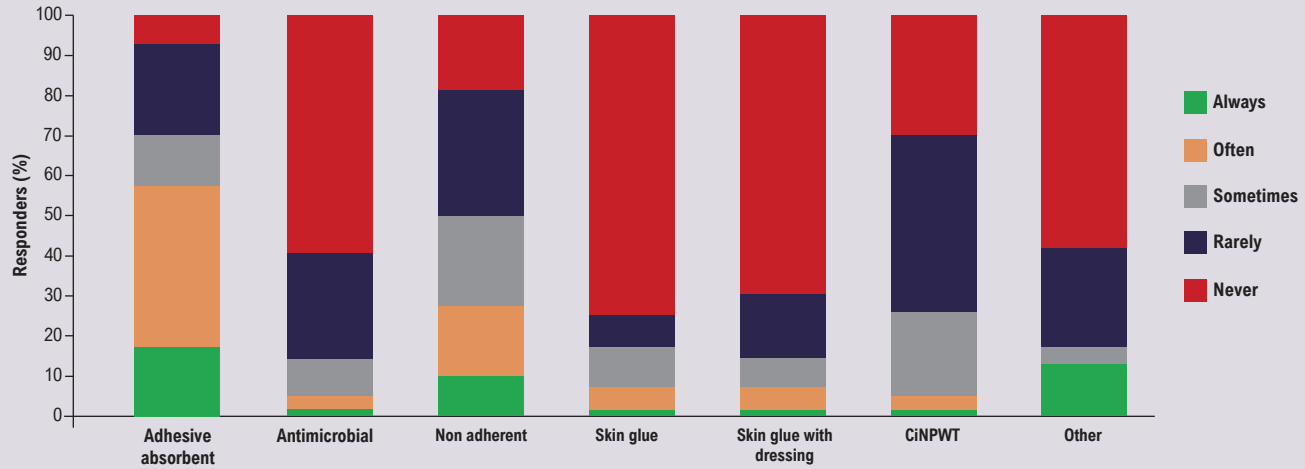
The method of skin closure was variable. Continuous subcuticular sutures were always/often used by 70% (40/57) of respondents and interrupted sutures were sometimes used by 38% (22/58) of respondents. Skin clips were rarely/never used by 73% (41/56) of respondents, the majority of whom would be willing to recruit patients to a trial assessing continuous subcuticular sutures (69%; 40/58) and interrupted sutures (67%; 39/58) but not skin clips (47%; 27/57).

Popular types of dressing used to cover the wound post MLLA included adhesive absorbent dressings and non-adherent dressings (Figure 3). Skin glue and closed incisional negative pressure wound therapy (CiNPWT) were rarely used. Most respondents would be willing to recruit patients to a trial evaluating an adhesive absorbent dressing (71%; 41/58), antimicrobial dressing (71%; 41/58), non-adhesive dressing (74%; 42/57) and CiNPWT (74%; 42/57). Fewer were willing to recruit to the use of skin glue with a dressing (61%; 35/57) and skin glue without a dressing (54%; 31/57).

The majority of the respondents always/often used gauze, wool and crepe (62%; 36/58) or no stump dressing (34%; 18/54). Rigid stump dressings are rarely used (86%; 48/56). The majority of respondents would be willing to recruit patients to a trial using gauze, wool and crepe stump dressing (71%; 40/56), a rigid stump dressing (63%; 36/57) or no stump dressing (60%; 32/53).

Respondents were asked if there were any other interventions

Figure 3 Frequency of dressings used by respondents following major lower limb amputation.



they felt should be considered. Responses included the use of absorbable sutures, blood glucose control, patient warming, preoperative optimisation, theatre environment (eg, laminar flow), nutritional assessment and optimisation, (non)-handling of skin edges and time the dressing is left undisturbed.

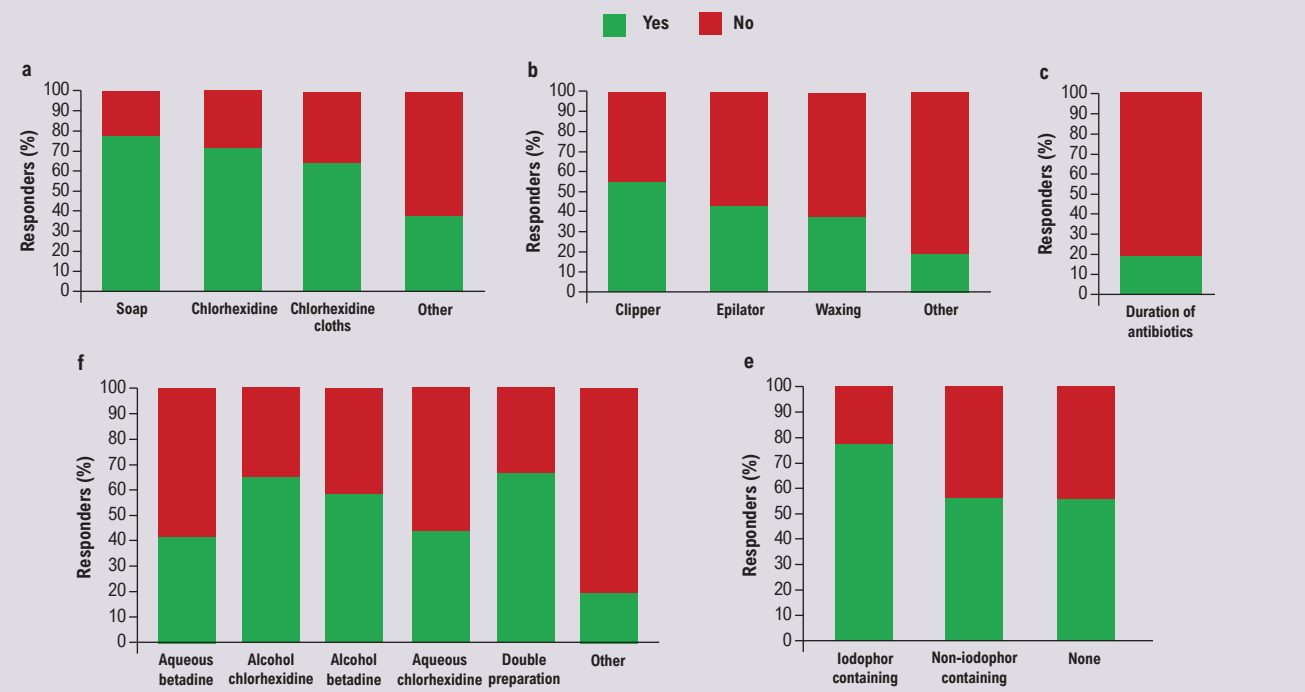
Vascular groin incisions

Preoperative SSI prevention practices

As with MLLA, respondents rarely recommended preoperative bathing prior to vascular surgery involving a groin incision. When preoperative bathing was recommended, soap was the most frequently recommended cleansing solution (25%; 11/44), followed by chlorhexidine (18%; 8/46). The majority of respondents would be willing to recruit patients to a trial investigating different preoperative bathing solutions (Figure 4).

Clippers were always/often used for hair removal prior to a vascular groin incision by 88% (40/45) of respondents. Epilation and waxing were never used by 98% of respondents (44/45).

Figure 4 Respondents' willingness to randomise for different preoperative interventions to prevent surgical site infections in groin incisions: (a) preoperative bathing; (b) hair removal method; (c) duration of antibiotics; (d) skin preparation solution; (e) incise drapes.



There was variability in the number of respondents willing to recruit patients to a trial assessing different methods of preoperative hair removal: clipping 57% (24/42), epilation (44%; 19/43) and waxing (40%; 17/43).

Alcoholic chlorhexidine was always/often used for skin preparation by 66% (29/44) of respondents. Alcoholic betadine (18%; 7/43), aqueous betadine (12%; 5/43) and aqueous chlorhexidine (9%; 4/42) were less frequently used. Double skin preparation was always/often performed by 26% (9/34) of respondents, and the combinations were variable. Respondents would be willing to recruit patients to a trial evaluating double preparation (67%; 29/43), alcoholic betadine (58%, 25/42) and alcoholic chlorhexidine (65%; 28/43) (Figure 4).

One preoperative dose of prophylactic antibiotic was always/often given by 93% (42/45) of respondents. Postoperative prophylactic antibiotics were given more variably. Postoperative prophylactic antibiotics were always/often given for 24 hours and for 48 hours by 38% (17/45) and 12% (6/48) of respondents, respectively. No respondents routinely gave prophylactic postoperative antibiotics for more than 48 hours. The majority of respondents (80%; 36/45) would not be willing to recruit patients to a trial of varying duration of prophylactic antibiotics.

Incise drapes were infrequently used by respondents. Non-iodophor drapes were always/often used by 9% (4/44) of respondents whilst iodophor-containing drapes were always/often used by 7% (3/44) of respondents. Respondents would be willing to recruit patients to a trial investigating iodophor-containing drapes (77%; 34/44), non-iodophor-containing drapes (58%; 25/43) or no incise drapes (58%; 23/40).

Intraoperative SSI prevention practices

Only 4% (2/44) of respondents always/often used an antimicrobial substrate in groin wounds. Respondents would be willing to recruit patients to a trial evaluating antimicrobial substrates (74%; 32/43).

Wound irrigation was always/often used by 16% (7/45) of respondents and saline was the most frequently used irrigation solution (11%; 5/45). The majority of respondents would be willing to recruit patients to a trial assessing wound irrigation with saline (74%; 31/44) or betadine (64%; 27/42).

A drain was always/often inserted by 36% (15/42) of respondents and rarely/never by 50% (21/42) respondents. Just over half of respondents would be willing to recruit patients to a trial investigating the impact of insertion of a drain (56%; 24/43).

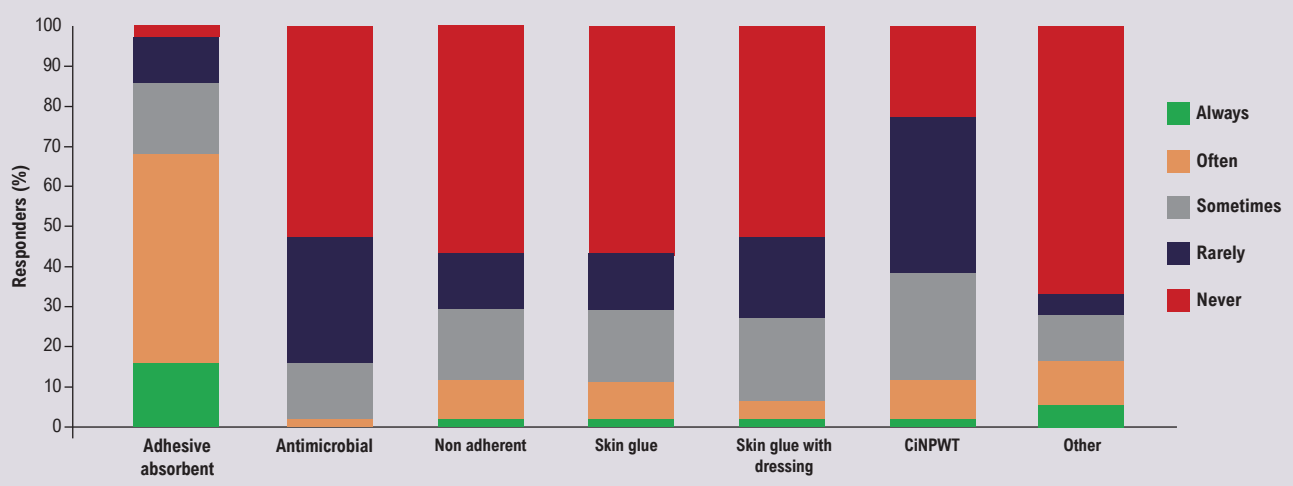
The majority of respondents never/rarely changed their instruments (95%; 42/44) or gloves (91%; 41/45) prior to vascular groin wound closure. The majority of respondents would be willing to recruit patients to a trial evaluating a change of instruments (66%; 29/44) and a change of gloves (77%; 33/43) prior to wound closure.

Continuous subcuticular sutures were always/often used for skin closure by 92% (42/46) of respondents. The majority of respondents would be willing to recruit patients to a trial assessing continuous subcuticular sutures (70%; 30/43) or interrupted sutures (65%; 28/43), but less than half of respondents would be willing to recruit patients to a trial investigating skin clips (48%; 20/42).

For dressings, most respondents used an adhesive adherent dressing to cover the wound, with antimicrobial, non-adherent, skin glue and CiNPWT being less frequently used (Figure 5). The majority of respondents would be willing to recruit patients to a trial evaluating CiNPWT (83%; 34/41), adhesive absorbent dressings (74%; 32/43), non-adherent dressings (68%; 30/44) and antimicrobial dressings (66%; 29/44). Regarding skin glue, 64% (28/44) of respondents would be willing to recruit patients to a trial assessing skin glue with a dressing and 55% (24/44) to a trial of skin glue without a dressing.

Other interventions proposed by respondents included number

Figure 5 Frequency of dressings used by respondents following a groin incision to access the femoral vessels.



of layers of closure, nutritional optimisation, type of diathermy and type of antibiotic used.

Future research

Nearly three quarters (72%; 42/58) of respondents strongly agreed/agreed that a combined outcome of SSI and wound dehiscence was an appropriate primary outcome measure in a trial investigating interventions to prevent SSI in MLLA and vascular groin incisions and were interested in recruiting participants to such a trial.

KEY MESSAGES

- Practice is varied in the use of interventions to prevent surgical site infection.
- Most surgeons would be willing to randomise patients in a study to evaluate these interventions.
- The design of future randomised controlled trials should consider these findings in decision of intervention arms.

Discussion

There appears to be a plethora of practices used to reduce the risk of SSI for patients undergoing MLLA and groin incisions in vascular surgery in the UK. Despite the heterogeneity in practice, the survey found the majority of surgeons have clinical equipoise on the many interventions to reduce SSI, demonstrated by a high willingness to randomise for most of the proposed interventions. This is important information for trialists designing studies in this field.

This study found a lower use of certain interventions thought to reduce SSI compared with previous studies. In a survey of UK vascular healthcare professionals at a national vascular meeting regarding their use of impregnated incise drapes, antimicrobial substrates and dialkylcarbamoyl chloride (DACC) dressings in groin wounds in vascular surgery,[15] over half of clinicians reported they used impregnated drapes (65%) and a third used antimicrobial substrates (32%). This is compared with only 13% and 4%, respectively, who always, often and sometimes use impregnated drapes and antimicrobial substrates in this study. The variation could be due to differences in survey structure. The current survey collected responses using a 5-point Likert scale whereas the previous survey used a dichotomous 'yes or no' response. Both surveys found similar results in terms of low DACC dressing use, a high level of equipoise/willingness to randomise to the proposed interventions and participate in randomised trials.

In a survey of SSI prevention practice in vascular surgery, which included 109 UK healthcare professionals, much higher numbers reported they did recommend practices such as preoperative bathing (67%), extended course of antibiotics beyond 48 hours (MLLA 74%, lower limb bypass 70%), antimicrobial substrates (72%) and CiNPWT (53%).[10] Differences could be due to differences in the survey structure, but this does not account for all the variation.

This survey highlighted that, although the reported use of SSI prevention measures such as impregnated drapes, antibiotic duration and antimicrobial substrates is high, it does not necessarily mean that clinicians use them on every case and individual practice varies between procedures. There also appears to be recognition among clinicians that many SSI prevention interventions lack a supportive high-quality evidence base behind their use, leading to a willingness to randomise. Additionally, there is variation across the evidence base of interventions. Within groin incisions, for instance, ciNPWT appears to reduce SSI (moderate level of evidence) whereas locally placed antibiotics do not (low level of evidence).[16] Some interventions exhibit a much greater cost profile than others, with varying degrees of efficacy. Stratification of patients using risk prediction models may yield greater results and personalised care.[1] This information is valuable when designing a trial by informing potential interventions to test and understanding the likelihood of whether clinicians will recruit to the trial. This will help ensure a future trial is deliverable and does not waste resources. A multi-arm multi-stage (MAMS) trial design enables simultaneous or sequential evaluation of multiple interventions using robust methodology at a fraction of the cost and time of individual independent trials.[17] Such a trial design would be well suited to the plethora of interventions and heterogeneity in evidence surveyed in this study.

The limitation of this survey is a low response rate. There are an estimated 376 vascular surgeons in the UK and Ireland, based on numbers registered with the VSGBI, giving the response rate of 15%. This could explain some of the variability in frequency of use of the interventions surveyed. An important consideration is that, within the months prior to dissemination of this survey, the VSGBI membership had received surveys on greener surgery and venous disease. The high volume of surveys in a short time frame may have contributed to 'survey fatigue' and the observed low response rate. Other reasons for a lower response rate include reach of the survey, whether only those who are actively engaged with the vascular community on X and the VSGBI email correspondence would have seen the survey, and the short data collection window. It is likely those who completed the survey are more interested in SSI prevention in vascular surgery. While this may not be representative of practice in the UK, it does provide an insight into potentially research active vascular centres to involve in a future randomized controlled trials.

Conclusion

This survey has highlighted, in those that responded, the frequency of use and willingness to randomise to various interventions to reduce SSI in patients undergoing MLLA and groin incisions in vascular surgery in the UK and Ireland. These results will inform the future trial design in this area to generate a high-quality evidence base for interventions to reduce the numbers of patients suffering an SSI after surgery.

Conflict of Interest: IC is Editor-in-Chief of *JVSGBI*. The other authors have no conflicts of interest to declare.

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ORIGINAL RESEARCH

Long-term outcomes of major and minor lower limb amputation: eight-year retrospective analysis from a single tertiary referral centre

Bergman H,[1] Clay B,[2] Lane T[3,4]

1. Clinical Research Fellow, Academic Section of Vascular Surgery, Department of Surgery and Cancer, Imperial College London, London, UK
2. Final Year Medical Student, School of Clinical Medicine, University of Cambridge, Cambridge, UK
3. Consultant Vascular Surgeon, Cambridge Vascular Unit, Addenbrooke's Hospital, Cambridge University Hospital NHS Foundation Trust, Cambridge, UK
4. Honorary Senior Clinical Lecturer, Section of Vascular Surgery, Department of Surgery and Cancer, Imperial College London, UK

Corresponding author:
Henry Bergman
Academic Section of Vascular Surgery, Department of Surgery and Cancer, Imperial College London, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF, UK
Email: henry.bergman@imperial.ac.uk

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Plain English Summary

Why we undertook the work: Amputations of the leg, feet and toes are being carried out more commonly as time goes on. Historically, patients undergoing amputation have poor outcomes after surgery. These patients often die within a year of the procedure, require multiple additional amputations and have a poor quality of life. We aimed to assess the outcomes of patients who underwent lower limb amputations in a large hospital performing many such procedures every year.

What we did: Using electronic patient records, we assessed the outcomes of patients who had undergone lower limb amputations in the 8 years prior to the study. We assessed their rates of death over time, particularly looking at how many patients had died at 30 days post-procedure and 1 year post-procedure. We also assessed the rates of patients requiring further amputations, their level of function with prosthetics 6 months after the procedure and how these measures changed over the 8-year period investigated.

What we found: For patients receiving major amputations of the leg (above-knee or below-knee amputations), 8% died by 30 days post-procedure and 24% died by 1 year post-procedure. This is a sign of how unwell patients having these amputations are, rather than that the operation itself causes death later. Patients receiving minor amputations (toes and middle of the foot) were more likely to undergo further amputation procedures. In patients who were fitted with prosthetic legs, all patients showed similar levels of function with their prosthetic limb regardless of what specific type of amputation they had.

What this means: Patients having any kind of amputation have significant risks of dying in the following year and needing further amputations. These risks should be thoroughly discussed with all patients who are being offered amputation so that they can make fully informed decisions.

Abstract

Objective: Lower limb amputation is increasingly common yet outcomes are historically poor, with high rates of short-term mortality, revisions and poor quality of life. This observational study evaluates outcomes from a high-volume tertiary vascular referral centre.

Methods: Retrospective electronic case note review was performed to elicit all major and minor amputations performed between 03/11/2014 and 31/05/2022 for peripheral arterial disease and diabetic foot sepsis. Cases of amputation for trauma or chronic pain were not included.

Results: A total of 1,566 amputations (865 major, 701 minor) were carried out in 1,237 patients during the study period. Mortality was significantly higher for patients undergoing major amputation compared with minor amputation at 30 days (7.9%, n=61/773 vs 1.0%, n=6/575; p<0.0001) and at 1 year post-procedure (23.7%, n=183/773 vs 13.6%, n=78/575, p<0.0001). Revision rates were significantly lower for major amputations than for minor amputations at 30 days (2.4%, n=19/799 vs 13.2%, n=91/691; p<0.0001) and at 1 year post-procedure (10.0%, n=68/677 vs 26.3%, n=163/619, p<0.0001). Of the patients with major amputation fitted with a prosthesis, there was no significant difference in the numbers of patients ambulating (p=0.19) or the mean ambulatory level (p=0.08) between above-knee and below-knee amputation at 6 months post-procedure.

Conclusions: Both major and minor lower limb amputations are associated with a high risk of revision and mortality within 1 year which should be discussed explicitly as part of the informed consent process.

Key words: vascular surgical procedures, amputation, peripheral arterial disease, lower extremity, rehabilitation

Introduction

Major amputation is a life-changing yet common endpoint in the management of diabetic foot disease (DFD) and chronic limb-threatening ischaemia (CLTI). Less commonly, amputation is performed for traumatic limb injury, deformity, chronic pain or loss of function.[1–4] Major amputation is estimated to affect 3–4% of all patients with peripheral arterial disease (PAD)[5] and 15–20% of those with CLTI.[6] When revascularisation fails, sepsis requires source control, pain is insurmountable or limb function is inadequate, major amputation is the terminal option to preserve life over limb.

Despite increasing numbers of major amputations being performed annually in the UK – more than 3000 major amputations were performed in 2021[7] – outcomes remain poor. This may be due to the generalised frailty and severely comorbid nature of this cohort.[8] There are well-documented high rates of revision to a higher level, major adverse cardiovascular and cerebrovascular events and short-term mortality in the literature, with below-knee amputations (BKA) and above-knee amputations (AKA) having 4.1% and 8.7% 30-day mortality, respectively, in the National Vascular Registry (NVR) 2022 report.[7]

Cambridge University Hospitals is a tertiary vascular referral centre receiving all referrals for lower limb ischaemia (acute, chronic, diabetic, traumatic) within the wider region in a hub and spoke model, serving a population of approximately 1.8 million. All major limb amputations are performed in the hub, with rehabilitation starting centrally before continuing in the spoke.

Here we assess 8 years of experience encompassing the years from 2014 to 2022 of major and minor amputation from a single high-volume tertiary referral centre to give an overview of the outcomes of contemporary practice and utilisation of the NVR.

Methods

Local approvals

Service evaluation approval was sought through the Cambridge University Hospitals NHS Foundation Trust Research and Development Department (registration number PRN10636).

Standardised practice

Major amputation was performed routinely as per an 'amputation pathway'. All amputations were performed under the supervision of a consultant vascular surgeon with a standardised approach in terms of planning, marking, limb division, haemostasis and flap reconstruction. All patients received a catheter inserted into the sciatic or tibial nerve with local anaesthetic infused for 5 days postoperatively, except in rare cases where a nerve was not identified. The authors acknowledge the ongoing trials surrounding the use of nerve catheters in amputation and the potential for practice changing in the future. All patients received a 5-day course of prophylactic antibiotics, DVT prophylaxis and their usual antiplatelet within 24 hours postoperatively. All major amputations received a wound drain which remained in situ for 48 hours or until output had ceased. All patients received a dressing comprising a non-adhesive layer directly contacting the wound, followed by gauze, wool and crepe bandage. All wounds were routinely inspected at 5 days postoperatively unless clinically indicated sooner (eg, bleeding or sepsis). Finally, all patients undergoing elective or semi-elective amputation were offered a preoperative consultation with the amputation physiotherapist (for emergency amputations, this was seldom possible) and postoperative intensive physiotherapy to fast-track rehabilitation and discharge planning. Revisions were primarily performed due to non-healing or progressive ischaemia of the stump.

Procedures were only performed out of hours if necessitated due to emergent sepsis or ischaemia that was acutely life-threatening. Any major amputation performed out of hours was performed with at least direct supervision in theatre by a consultant vascular surgeon. In the majority of cases this would mean the supervising consultant being scrubbed and performing or partially performing the procedure as per NVR guidance.

The unit acknowledges the Commissioning for Quality and Innovation framework for the expedited management of patients with CLTI and, where possible within the limitations of theatre, bed and staff availability, this standard was targeted.

Data collection

Retrospective case note review was performed via the EPIC Hyperspace patient management platform to elicit all patients undergoing major or minor lower limb amputation between 03/11/2014 and 31/05/22. Patients were only included if there was a hospital coding or inpatient episode where an amputation procedure was undertaken due to sequelae of PAD or DFD. Cases of amputation due to trauma or chronic pain without primary vascular compromise were not included. Through-knee amputations were not performed at this centre during the study period so were not captured.

Baseline patient demographics including postcode, date of birth, sex and age were recorded. Mortality status was interrogated for all patients to determine date of death, post-procedure days to death and the 30-day and 1-year mortality. Where mortality data were missing, the inter-hospital data spine, connected to all local hospitals and GP practices, was interrogated to complete the dataset.

Multiple instances of amputation in the same limb in the same patient recorded at separate time points were coded as revisions with interval to revision, level of revision and subsequent mortality status recorded for all instances.

Rehabilitation outcomes were extracted from prosthetic clinic notes. These visits were performed routinely at approximately 6 months following discharge. Rehabilitation outcomes were only available for local Cambridge patients (approximately half the cohort) due to the large geographical area over which prosthetic services are offered. All patients fitted with a prosthesis received a

prosthesis-related functional status 'K' score (0: no prosthesis, 1: cosmetic or transfer only, 2: ambulatory inside the home, 3: ambulatory outside the home, 4: high level of activity).

Case ascertainment was determined by cross-checking the EPIC Hyperspace and NVR reports for the study duration.

Statistical analysis

Statistical and graphical analyses were performed on Microsoft Excel v16 and IBM SPSS v29. Data were analysed with the patient as the unit of analysis. All tests of statistical significance were two-tailed. A p value of 0.05 was used as the threshold for statistical significance for all analyses.

Rates of mortality and revision were calculated at 30 days and 1 year post-procedure and presented as proportions. The mortality risk at 30 days and 1 year post-procedure was compared between amputation types with relative risk. Patients who died before 30 days or 1 year were removed from inclusion in calculations of the revision rate. Patients who underwent multiple revisions were included multiple times in calculations of revision.

Kaplan–Meier survival analysis was carried out for mortality after the index procedure. Patients were censored at their date of death or at the end of the outcome reporting period assessed. Statistical significance of Kaplan–Meier analysis was determined with the Mantel–Cox log rank measure with pooled and paired analyses performed.

Rehabilitation outcomes were presented as proportions of patients achieving a given K score at their 6-month outpatient rehabilitation visit. Patients were included twice in analyses if they were referred for prosthesis for separate AKA and BKA, even if in the same limb. Mean rehabilitation K scores were calculated for AKA and BKA cohorts and compared using an unpaired t-test.

Subgroup analyses of mortality, revision rate and rehabilitation outcomes were performed for each modality of amputation and the cohort of patients with revised amputations.

NVR utilisation was calculated using procedure rather than patient as the unit of analysis.

Caseload, 30-day and 1-year rates of mortality and revision and volume–outcome relationships were calculated for the years 2015–2021 and, where the data fit a linear trendline, the strength of correlation was tested using Pearson's R.

Results

Study cohort

A retrospective review of the electronic patient record returned a total of 1,566 amputations carried out in 1,237 patients for PAD or DFD over the period. The proportions of each amputation type, average age and gender ratio are shown in Table 1.

Mortality

Major amputation carried 30-day and 1-year mortality risks of 7.9% (n=61/773) and 23.7% (n=183/773), respectively, and minor amputation carried 30-day and 1-year mortality risks of 1.0% (n=6/575) and 13.6% (n=78/575), respectively. Thirty-day and 1-year mortality for each amputation type is shown in Table 2.

Major amputation was associated with a significantly higher risk of mortality than minor amputation at 30 days (RR=7.6 (95% CI 3.3 to 17.4), p<0.0001) and at 1 year (RR=1.7 (95% CI 1.4 to 2.2), p<0.0001). AKA was associated with a significantly higher risk of mortality than BKA at 30 days (RR=2.0 (95% CI 1.2 to 3.3), p=0.005) and at 1 year (RR=1.7 (95% CI 1.3 to 2.2), p<0.0001).

Kaplan–Meier survival curves were plotted for each amputation type (Figure 1). Amputation type was a statistically significant modulator of survival (p<0.001) when assessed by pooled analysis. Major amputation overall was found to result in significantly poorer survival than minor amputation over the study period (p=0.001), with survival poorer for the entire first 5 years post-procedure. AKA was found to have a significantly lower survival than all other amputation types: BKA (p<0.001), transmetatarsal (p=0.015), hallux (p=0.003) and toe (p<0.001). No other amputation was found to confer significant survival benefit relative to another, including within minor amputations (p=0.32).

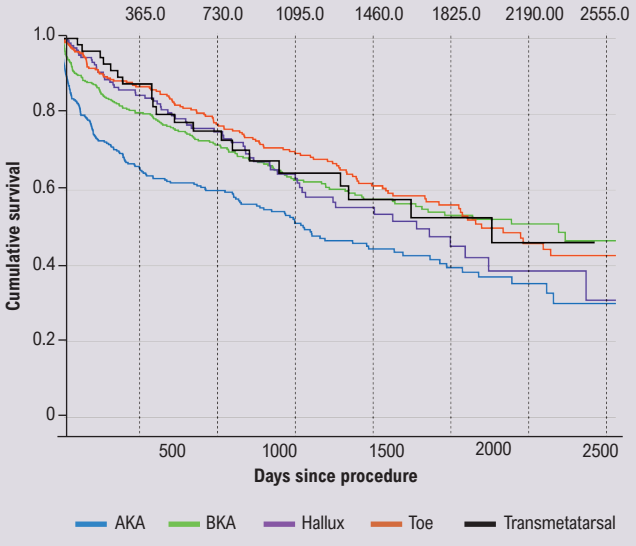
Table 1 Cohort demographics by amputation type

Amputation	Number of amputations		Number of patients		Mean age (years)	Male Sex	
	n	%	n	%		n	%
Major	865	55.2	773	62.5	66.3	534	69.1
Above knee	382	24.4	365	29.5	68.3	238	65.2
Below knee	483	30.8	456	36.9	64.6	323	70.8
Minor	701	44.8	575	46.5	67.8	434	75.5
Transmetatarsal	98	6.3	92	7.4	63.3	76	82.6
Hallux	226	14.4	205	16.6	68.1	154	75.1
Toe	377	24.1	344	27.8	68.5	262	76.2
Total	1,566	100	1,237	100	67	881	71.2

Table 2 30-day and one-year mortality and revision status by amputation type

Amputation	Mortality				Revision			
	30-day		One-year		30-day		One-year	
	n	%	n	%	n	%	n	%
Major	61/773	7.9	183/773	23.7	19/799	2.4	68/677	10.0
Above knee	39/365	10.7	110/365	30.1	5/343	1.5	19/272	7.0
Below knee	24/456	5.3	80/456	17.5	14/459	3.1	49/403	12.2
Minor	6/575	1.0	78/575	13.6	91/691	13.2	163/619	26.3
Transmetatarsal	1/92	1.1	11/92	12.0	15/97	15.5	30/87	34.5
Hallux	1/205	0.5	28/205	13.7	39/224	17.4	59/197	29.9
Toe	4/344	1.2	43/344	12.5	37/373	9.9	74/334	22.2

Figure 1 Kaplan-Meier survival curves by amputation type



Revision

Overall, 18.9% (n=234/1,237) of patients underwent a revision of amputation during the study period. Of the patients who were still alive following major amputation there was a 30-day revision rate of 2.4% (n=19/799) and a 1-year revision rate of 10.0% (n=68/677). The risk of revision for minor amputations was significantly higher than for major amputations at 30 days (13.2%, n=91/691, RR=5.5, p<0.0001) and at 1 year (26.3%, n=163/619, RR=2.6, p<0.0001). The 30-day and 1-year rates of revision for each amputation type are shown in Table 2.

For minor amputations, the rate of revision to major amputation at 30 days was 6.1% (n=42/691), with these revisions representing 46.2% of all revisions of minor amputations at 30 days. At 1 year the rate of revision to major amputation was 11.8% (n=73/619), with such revisions amounting to 44.8% of revisions of minor amputations at 1 year.

Rehabilitation

Of the 773 patients who underwent major amputation, 56.9% (n=440) were referred to prosthetic services in Cambridge and fitted with a prosthesis, with the remainder either referred to prosthetic centres outside the retrievable catchment area or not referred at all. Of the 440 patients referred within Cambridge, rehabilitation outcomes were reported for 97.5% (n=429/440) with 11 patients lost to follow-up.

Of the 429 patients with reported rehabilitation outcomes, 27.3% (n=117) had undergone AKA and 72.7% (n=312) had undergone BKA. At 6 months post-procedure there was no significant difference (RR=1.1, p=0.19) in the levels of patients who were ambulatory (K score >1) with their prosthesis between AKA (51.3%, n=60/117) and BKA (58.7%, n=183/312). The mean ambulatory level (K score) of patients fitted with a prosthesis was not significantly different (p=0.08) between AKA (mean=1.55, SD=0.79) and BKA (mean=1.71, SD=0.85).

NVR utilisation

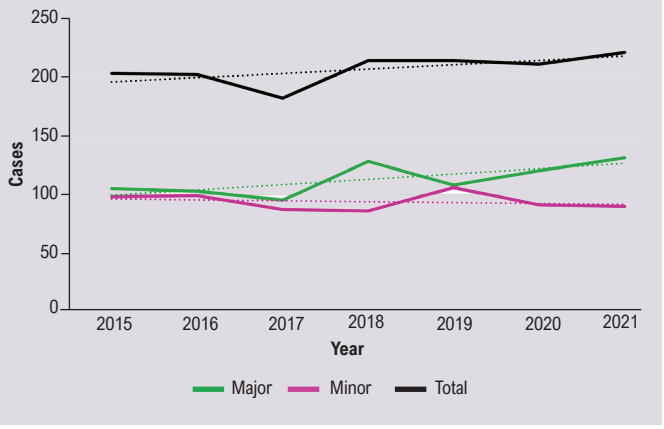
NVR case ascertainment for major amputations within the study period was 56.3% (n=487/865), comprising rates of 54.7% (n=209/382) for AKA and 57.6% (n=278/483) for BKA. For minor amputations, case ascertainment was lower: 3.6% overall (n=25/701), 7.1% (n=7/98) for transmetatarsal, 3.5% (n=8/226) for hallux and 2.7% (n=10/377) for toe amputations.

Temporal trends

In the seven years from 2015 to 2021 with complete capture of all amputations performed, linear trendlines showed that the overall caseload increased over time (Figure 2). The major amputation caseload increased over time with individual increases in both AKA and BKA. The minor amputation caseload decreased slightly over time, primarily due to a decrease in toe amputations, while transmetatarsal amputations increased slightly and hallux amputations remained stable over time.

On a per-patient basis, 30-day mortality did not change significantly between 2015 and 2021 for patients undergoing major (R=0.18, p=0.71) or minor (R=–0.16, p=0.73) amputation. One-

Figure 2 Temporal trends in caseload by overall amputation type



year mortality also did not change significantly for major (R=–0.61, p=0.15) or minor (R=0.34, p=0.46) amputation.

On a per-procedure basis, the 30-day revision rate did not change significantly between 2015 and 2021 for patients undergoing major (R=–0.26, p=0.57) or minor (R=0.71, p=0.08) amputation. The 1-year revision rate also did not change significantly for major (R=–0.40, p=0.38) or minor (R=0.35, p=0.44) amputation.

Considering volume–outcome relationships with respect to mortality, major amputation showed no significant correlation between caseload and 30-day mortality (R=0.35, p=0.44) or 1-year mortality (R=–0.14, p=0.77). Similarly, minor amputation showed no significant volume–outcome relationship for 30-day mortality (R=–0.40, p=0.38) or 1-year mortality (R=0.47, p=0.29). With respect to revision rates, major amputation again showed no significant correlation at 30 days (R=–0.25, p=0.59) or at 1 year post-procedure (R=–0.65, p=0.11). Minor amputation also showed no significant relationship for 30-day (R=0.35, p=0.44) or 1-year revision rates (R=–0.06, p=0.90).

Discussion

These data describe the outcomes of major and minor amputations performed between 2014 and 2022 in a tertiary vascular referral centre.

The observed rates of 30-day and 1-year mortality are comparable to the wider literature.[7,9–11] Survival analysis revealed significantly inferior survival for major compared with minor amputation, with survival lower over the first 5 years. This may reflect the physiological impact of a larger surgery and a greater volume of compromised tissue. Despite this, major and minor amputation survival curves begin to converge at 5 years, indicating the overall poor prognosis of any patient with CLTI and their significant frailty. Compared with other disease processes, even a minor amputation carries a comparable 1-year mortality risk to breast cancer[12] and a similar 5-year survival to lung cancer.[13]

The 1-year mortality rate was high, as expected, with this thought to reflect the systemic burden of atherosclerotic disease not just on the limbs but also on the coronary, renal and cerebral vasculatures.

Hallux and transmetatarsal amputations were found to have the highest rates of revision of any amputation type at 30 days and 1 year, respectively, in accordance with the wider literature.[14] When minor amputations were revised, approximately half of them were revised to a major amputation. Clinicians should be aware of the high rate of treatment failure with these strategies and the need for strict post-procedural wound care and cautious ambulation. Selection of a more definitive and durable intervention may be appropriate in some cases.

The inclusion of both major and minor amputations in this study, despite their different but overlapping aetiologies, was useful to allow identification of high-risk minor amputation types – hallux and transmetatarsal. Additionally, the results regarding need for revision, including revision to major amputation, highlight the likely insidious longitudinal progression of repeated minor amputations ultimately towards major amputation. In light of this, in some cases this journey may be beneficently shortened through more fastidious case selection for minor amputations and the selection of a single definitive major amputation rather than pursuing multiple minor amputations.

Positive volume–outcome relationships have previously been reported for carotid endarterectomy and open abdominal aortic aneurysm (AAA) repair[15,16] whereby the more procedures a unit completes, the better their outcomes. This 'learning curve' relationship has not been observed here – instead, no significant volume–outcome relationship was demonstrated for major or minor amputations with respect to mortality and revision at 30 days and 1 year post-procedure. This may reflect the lower degree of technical complexity of amputations compared with carotid endarterectomy and AAA repair.

The NVR estimates its own major amputation case ascertainment at 87% nationally,[7] aided by the automatic generation of an NVR entry for completion during admission for major amputation. Therefore, the observed rate of 56.3% at a tertiary referral centre is particularly notable. Factors which may contribute to this low rate include the performance of many amputations by more junior vascular trainees who may not be registered with or familiar with the NVR; a reduced focus on completion of NVR entries for amputations compared with the three key index vascular procedures (AAA repair, carotid endarterectomy and limb bypass); the frequent performance of amputation out of hours; and simply that there is limited time to complete paperwork during routine clinical practice. Methods to improve fulfilment of the clinician's responsibility to complete NVR entries could include annual reviews of personal case ascertainment rates during appraisals; teaching sessions to familiarise junior trainees about the importance of the NVR; assurance of access to the NVR by all surgical practitioners; and teaching regarding the practicalities of completing NVR entries for key vascular procedures.

The very low rate of ascertainment for minor amputations is less notable given the lack of automatic NVR entries for minor amputation and the context that minor amputations are often completed alongside a simultaneous revascularisation procedure and patients may undergo multiple interventions (including minor amputation) during a single admission, making them difficult to capture in terms of clinical coding. Given the frequency at which these procedures are performed and their high rate of revision to major amputations at later dates, judicious documentation of minor amputations should be a key development priority for the platform.

Linking of mandatory forms such as the NVR to electronic patient records and streamlining routine data collection are key challenges for the healthcare system to tackle to improve patient safety and the accuracy of reporting. Failure to document reduces our ability to track local, regional and national trends and hampers epidemiological research.

These results and conclusions are likely to be generalisable to other tertiary vascular centres in the UK due to the high caseload of the Cambridge Vascular Unit serving a catchment population over approximately 2 million spanning multiple counties, socioeconomic groups and the full scale of the deprivation index. Furthermore, the outcomes reported here are comparable to those of similarly sized centres in the NVR report.[7]

The contemporary outcomes data described could impact the informed consent process serving as a recent benchmark. In particular, patients undergoing a minor amputation should be made aware of the magnitude of risk to life, likely need for revision and the risk of revision to major amputation. These risks ought to be thought of less as theoretical risks (which patients are known to be poor at interpreting) and more realistically as the natural history of their underlying disease process.

Limitations of study

This study was retrospective in nature so no causative relationships between intervention and outcome can be asserted. Comorbidities including diabetes status, measures of PAD severity, smoking status and urgency of amputation were not captured during data collection, meaning that outcomes are not risk-adjusted, limiting the degree of translatability to other centres. Similarly, previous and contemporaneous limb salvage procedures such as angioplasty, stenting and bypass were not captured, which may confound the mortality and revision rates after amputation.

Through-knee amputations (TKA) were not performed at this centre during the study period but are increasingly performed at centres throughout the UK. As such, these outcomes may not be generalisable to patients undergoing TKA, with further work needed to compare outcomes, particularly rehabilitation outcomes between TKA, BKA and AKA.

The outcomes reported here are clinician defined, technical and are largely abstract from the patient's personal disease experience. Of note, the quality of life and communication outcomes specified in the core outcome set by Ambler *et al*[17] were not able to be thoroughly assessed in this study. Limited inferences regarding a quality of life benefit can be made from the reported rehabilitation outcomes. However, it is likely that exploration of the performance of activities of daily living, social reintegration, ongoing care requirements and longer-term ambulation would be valuable in evaluating and planning an amputation service.

KEY MESSAGES

- Short-term mortality and revision rates are high for both major and minor lower limb amputations even in a high-throughput tertiary centre.
- Registration of case data on the National Vascular Registry is poor for amputations, limiting the degree of national oversight of amputation outcomes.
- Pragmatic and evidence-based case selection has a significant role to play in reducing the rate of multiple amputations and the morbidity incurred in this journey.

Conclusions

Major amputation and, to a lesser extent, minor amputation are last resort procedures performed when a limb cannot be salvaged. As such, they are associated with a high short- and medium-term mortality and carry high revision rates. These contemporary statistics should form part of the informed consent discussion when performed in preference to a conservative or palliative management strategy. Further research into patient-reported outcomes and holistic rehabilitation outcomes will be necessary to provide personalised care, optimise patient pathways and facilitate a real-world patient quality of life benefit.

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ORCID iDs: Henry Bergman: https://orcid.org/0000-0002-8681-7075
Benjamin Clay: https://orcid.org/0009-0002-0511-8991
Tristan Lane: https://orcid.org/0000-0002-3493-5299

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PROTOCOL

The FraiLTI (Frailty in chronic Limb-Threatening Ischaemia) Protocol

Hickson B,[1] Sivaharan A,[2] El-Sayed T,[2] Baljer B,[2] Sillito S,[2] Shelmerdine L,[2] Nesbitt C,[2] James E,[3] O'Doherty AF,[3] Witham M,[4] Nandhra S[2]

1. The Medical School, Newcastle University, Newcastle upon Tyne, UK
2. Northern Vascular Centre, Freeman Hospital, High Heaton, Newcastle upon Tyne, UK
3. Department of Sport, Exercise and Rehabilitation, Northumbria University, Newcastle upon Tyne, UK
3. AGE Research Group, NIHR Newcastle Biomedical Research Centre, Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust, 3rd Floor Biomedical Research Building, Campus for Ageing and Vitality, Newcastle upon Tyne, UK

Corresponding author:
Sandip Nandhra
Northern Vascular Centre,
Freeman Hospital,
Freeman Road, High Heaton,
Newcastle upon Tyne,
NE7 7DN, UK
Email: Sandip.nandhra@nhs.net

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Plain English Summary

Why we are undertaking this work: Frailty is a medical term that describes physical weakness, vulnerability or fragility and is often associated with old age. We are undertaking this study to gain an understanding of the occurrence rates and effects of frailty, progressive loss of muscle mass and strength (sarcopenia) and having multiple health issues (multimorbidity) in patients suffering from a severe form of poor leg circulation called chronic limb-threatening ischaemia (CLTI). This is a serious condition affecting blood flow in the limbs and is usually associated with high rates of losing a limb or even death.

What we will do: In this study (FraiLTI), we recruit patients with CLTI who are undergoing an intervention to improve their poor leg circulation. We assess how common frailty, sarcopenia and multimorbidity are among CLTI patients and explore their influence on clinical outcomes. We are aiming to obtain a comprehensive understanding of the situation at a national scale by gathering data from hospitals throughout the UK.

What this means: The results from the FraiLTI study could provide crucial information on the prevalence of health issues such as frailty, muscle loss and weakness, and multiple health conditions among individuals in the UK with severe leg circulation problems, as well as their impact on overall health. This could enable healthcare professionals to identify high-risk patients who need extra care and attention to improve their outcomes. The study will also offer valuable insights for future research and contribute to the overall improvement of care and management for patients with CLTI.

Key words: chronic limb-threatening ischaemia (CLTI), frailty, sarcopenia, multimorbidity, quality of life.

Abstract

Background: Frailty, sarcopenia and multimorbidity are conditions commonly associated with the ageing process, and they are frequently observed in patients with chronic limb-threatening ischaemia (CLTI). Nevertheless, the extent to which these conditions are prevalent within the CLTI patient population has not been adequately examined in the UK. This proposed multicentre observational study aims to investigate the prevalence of these conditions in patients with CLTI and to assess their potential impact on important clinical outcomes including mortality, amputation and quality of life.

Methods: FraiLTI (Frailty in chronic Limb-Threatening Ischaemia) is a multicentre prospective observational study in the UK that that aims to investigate the prevalence of frailty, sarcopenia and multimorbidity associated with CLTI. The secondary objective is to investigate potential correlations between frailty, sarcopenia and multimorbidity, with clinical outcomes such as amputation, mortality, major adverse cardiovascular events and readmission rates within a 90-day period. FraiLTI is led by Newcastle University, supported by the Vascular and Endovascular Research Network (VERN) and funded by the National Institute for Health Research (NIHR) and the Newcastle Hospital Charities. REDCap will be used to collect anonymised patient data. All hospitals with a dedicated vascular centre are eligible to participate. Full ethical approval (21/PR/0750) was granted on 13 July 2021. The study is registered on the International Standard Randomised Controlled Trial Number (ISRCTN) registry.

Anticipated impact of the study: This study has the potential to address critical questions identified by the James–Lind Alliance (JLA) Priority Setting Partnership (PSP) in peripheral arterial disease. It is expected to make a substantial contribution to the creation of a prospective CLTI database, integrating essential data on frailty, sarcopenia and multimorbidity that are not currently captured by other registries, despite their profound impact on patient outcomes. This research could provide pivotal insights into the prevalence of frailty, sarcopenia and multimorbidity among the UK's CLTI population and their corresponding effects on clinical outcomes. Findings from the study will be shared at global scientific conferences and submitted to be published in peer-reviewed journals.

Introduction

Frailty, a concept gaining significant attention in recent years, is defined as a clinically recognisable state of increased vulnerability resulting from ageing-associated decline in reserve and function across multiple physiologic systems such that the ability to cope with everyday or acute stressors is compromised.[1] Frailty leaves patients vulnerable to stressors such as illness, trauma or surgery. The high prevalence of frailty, affecting 43.7% of adults aged 65 and older,[2] and its potential impact on health outcomes underscores the importance of this issue.[3]

The elderly population is particularly affected as they are more susceptible to both frailty[4] and cardiovascular pathologies.[5] Frailty has been linked as a predictor for inferior postoperative outcomes[6] as well as numerous adverse health outcomes including falls, disability, hospitalisation and mortality.[7,8] Additionally, frailty is associated with an increased risk of disability, which manifests as limitations in performing activities of daily living (ADL) and impacts a patient's quality of life (QoL).[9,10]

Sarcopenia, a key component of frailty, is characterised by skeletal muscle dysfunction that develops gradually and predominantly affects older patients,[11] leading to reduced strength and muscle mass.[12] Sarcopenia is an independent predictor of mortality following both open and endovascular procedures.[13,14]

Multimorbidity is another significant factor influencing outcomes in patients with chronic limb-threatening ischaemia (CLTI). Previous research in vascular surgery focused primarily on cardiometabolic comorbidities, highlighting the need to investigate the impact of other conditions beyond the central cardiovascular system. Our preliminary retrospective work has shown that sarcopenia[14] and anaemia[15] are negatively associated with survival and limb loss following revascularisation surgery for CLTI.

There are some retrospective data in the literature which suggest that frailty affects survival in those undergoing intervention for CLTI in Japan[16] and the UK.[17] A prospective cohort study from Canada found that frailty was associated with mortality and worsening disability post-intervention. There are also systematic reviews that suggest worse outcomes in a wide range of lower limb vascular operations.[18–20] However, thus far, data on this topic in the UK remain single-centre and retrospective.

FraiLTI (Frailty in chronic Limb-Threatening Ischaemia) is a multicentre prospective observational study in the UK which aims to investigate the prevalence of frailty, sarcopenia and multimorbidity and their effect on outcomes following a diagnosis of CLTI. This patient-led study addresses several questions raised by the James–Lind Alliance (JLA) Priority Setting Partnership (PSP) in Peripheral Arterial Disease (PAD), with a focus on exploring potential causes for poor outcomes.[21]

Methods

Study design

This is a multicentre prospective observational study conducted in UK Vascular Centres led by Newcastle University and supported by the Vascular and Endovascular Research Network (VERN). It is funded by the National Institute of Health Research (NIHR) and the Newcastle Hospitals Charity. Figure 1 is the flow diagram of the study protocol.

Study population

Inclusion

- All adults aged over 18, able to consent and participate with ongoing assessments.
- All patients with CLTI as per the consensus definition (the presence of PAD in combination with rest pain, gangrene or a lower limb ulceration >2 weeks duration),[22] irrespective of pathology, mode of presentation, plan to revascularise, or previous presentations with lower limb arterial disease.

Exclusion

- Admissions for non-CLTI.
- Unable to consent to assessments or participate in study assessments.
- Pregnant women.
- Age <18 years.

Study outcomes

Primary

Prevalence of the following conditions among CLTI patients:

1. Frailty
   - Fried's Frailty Phenotype (FP)
   - Rockwood's Clinical Frailty Scale (CFS)
2. Sarcopenia
   - Grip strength
   - Skeletal muscle area (SMA) at L3
   - Skeletal muscle index (SMI) at L3

   (Cut-offs highlighted below)
3. Multimorbidity (≥2 long-term health conditions)

Secondary

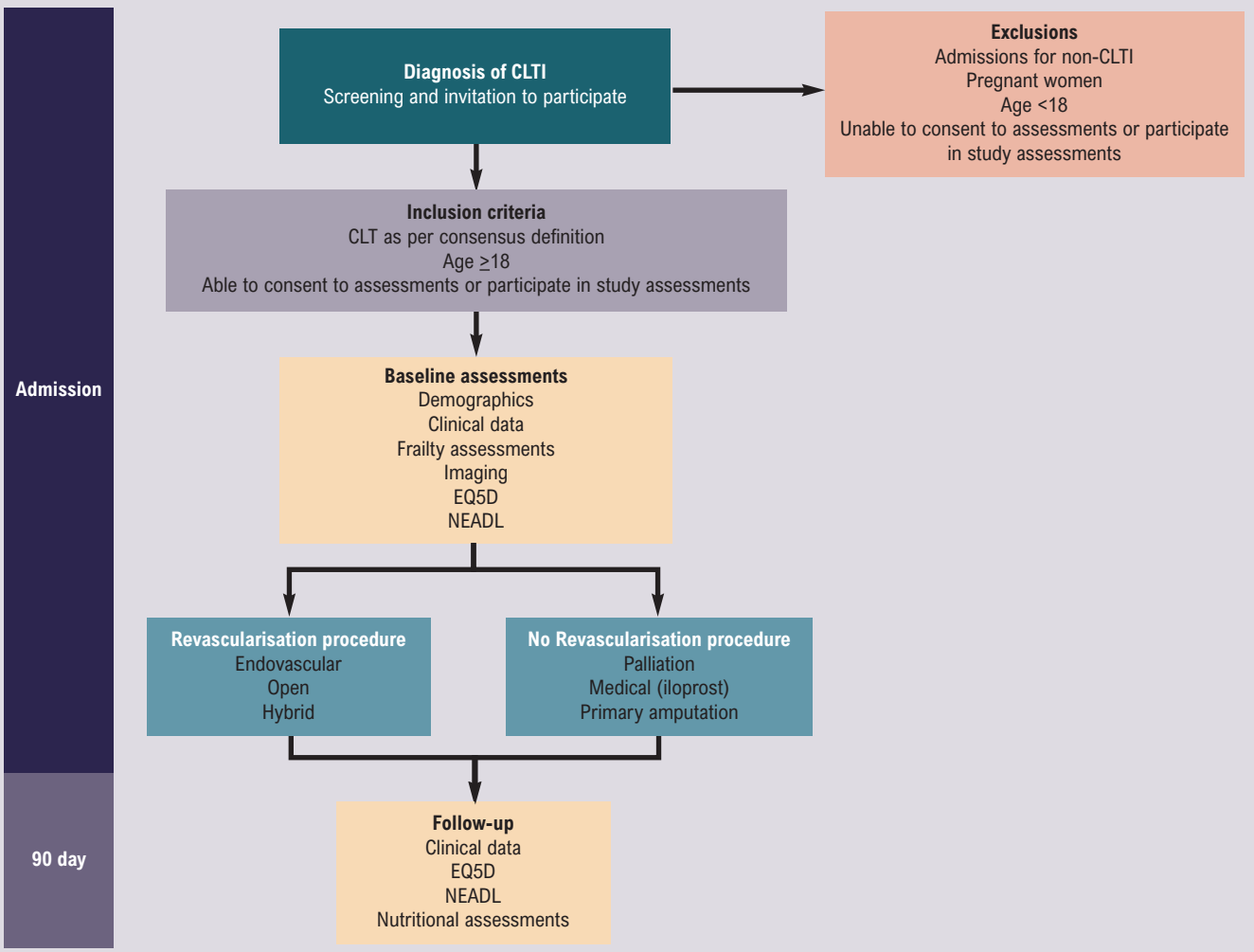
1. Associations between frailty, sarcopenia and multimorbidity with clinical outcomes, including:
   - Mortality
   - Major adverse limb events (MALE)
   - Major adverse cardiovascular events (MACE)
   - Readmission
   - Reinterventions
   - Discharge destination.
2. Impact of CLTI on patients' quality of life as measured by validated QoL assessment tools.

These outcomes will facilitate risk prediction, modelling and the identification of potential targets for intervention in future prospective research.

Recruitment

The FraiLTI study is open to all dedicated vascular centres with one team member acting as site lead clinician, who is the point of contact between the FraiLTI study team and the local team. The study is eligible for the NIHR Associate PI Scheme. All patients

Figure 1 Study flow diagram.



admitted with CLTI have a diagnosis confirmed by the admitting vascular surgeon. Potentially eligible participants are sign-posted to the relevant research team member only after the patient has suggested they would be agreeable for their details to be shared with a member of the research team on the delegation log at each site. Patients are formally screened according to the inclusion and exclusion criteria. All presentation modes are eligible including outpatient clinic, vascular "hot" clinic, and emergency departments.

The FraiLTI study team provides written and verbal versions of the participant information and informed consent. The local study lead is responsible for ensuring that this process is carried out in accordance with Good Clinical Practice (GCP).

Data collection

Anonymised data collected consists of patient demographics (including postcode for social-economic data), presenting symptoms, previous interventions, and admissions in the past six months.

The research team are collecting patient data in a prospective manner through hospital records, both electronic and paper-based. They then enter the collected data onto a custom-made electronic database hosted on the Newcastle Joint Research Office's Research Electronic Data Capture (REDCap) platform.

Definitions

Comorbidities are defined as per the American College of Cardiology guidelines[23] where possible. Diabetes is defined by documented medical history, and hypertension is defined by documented medical history and use of antihypertensive drugs for this purpose, or systolic blood pressure of at least 140 mmHg or diastolic blood pressure of at least 90 mmHg at admission determined by the average of the first two measurements. Other comorbidities recorded include ischaemic heart disease, stroke, chronic heart failure, atrial fibrillation, hypothyroidism, dementia, anxiety, depression, asthma, chronic obstructive pulmonary disease, osteoarthritis and inflammatory arthropathies.

The following diseases are recorded based on the patient's documented medical history: ischaemic heart disease or prior myocardial infarction, atrial fibrillation, hypertension, cerebrovascular disease (ischaemic stroke, haemorrhagic stroke or transient ischaemic attack), end-stage renal failure requiring dialysis and chronic obstructive pulmonary disease. Preoperative drugs are also recorded from the pre-assessment clinic documentation. Severity of presentation is measured using both the Rutherford classification and the WIfI score.

Laboratory results

Routine clinical care laboratory test results (including haemoglobin, white cell count, albumin, creatinine and estimated glomerular filtration rate, C-reactive protein and HbA_{1c}) are collected, as well as height and weight.

Sarcopenia assessments

CT angiogram

Axial imaging by means of a CT angiogram (where performed) will enable measurement of the skeletal muscle area (SMA) at the 3rd lumbar vertebra (L3) level (for comparison with previous studies), the mid-thigh and mid-calf levels (to enable detection of regional differences in muscle mass) (see Appendix 1 online at www.jvsgbi.com for details of measurement methodology).

We also calculate a value for the L3 skeletal muscle index (SMI) with the following formula:

$$\text{L3 SMI } (cm^2/m^2) = \frac{\text{L3 SMA } (cm^2)}{\text{height}^2\ (m^2)}$$

Cut-offs diagnostic of sarcopenia are 134.0 cm^2 for men and 89.2 cm^2 for women for L3 SMA and 41.6 cm^2/m^2 for men and 32.0 cm^2/m^2 for L3 SMI for women.[24]

Grip strength

Hand grip strength is measured using handgrip dynamometry (see Appendix 2 online at www.jvsgbi.com for detailed methodology).

Frailty assessments

Fried Frailty Index Phenotype

The Fried Frailty Score[1] is measured by combining five domains:

1. Weight loss (>4.5 kg in last year).
2. Low grip (<27 kg for men, <16 kg for women).
3. Low walk speed (we anticipate that most participants will have restricted mobility and so will score a point automatically; a cut-off of <0.8 m/s will be used for those who can undertake a 4 m walk test).
4. Exhaustion (measured using two questions from the Centre of Epidemiologic Studies Depression scale (CES-D scale)[25] used in the original Fried Score).
5. Low physical activity measured using four activity questions used in the English Longitudinal Study of Ageing.[26]

A score of ≥3 or more denotes frailty, 1 or 2 denotes pre-frailty, and zero denotes non-frail.

Rockwood frailty scoring

The Rockwood deficit accumulation model considers frailty as the accumulation of deficits in various domains of functioning including physical, cognitive and social domains.[27,28] This study uses the Clinical Frailty Scale, which categorises patients based on their function, morbidity and central nervous system impairment using a clinician's judgement.[28] Studies have verified that the Clinical Frailty Scale is a reliable predictor of negative outcomes.[29]

Nutrition assessment

We also collect information on activities of daily living, nutritional intake, place of living and mobility aids to provide a comparison for robustness in this disease group.

Quality of life assessment

Participants are invited to complete the Euro-QoL EQ-5D-5L health status assessment[30] and Nottingham Extended Activity of Daily Living scale (NEADL)[31] (see Appendix 3 (EQ-5D-5L) and Appendix 4 (NEADL) online at www.jvsgbi.com - for examples of the questionnaires).

Follow-up (90 days)

Following the baseline data capture, all patients are followed up irrespective of whether they undergo any revascularisation, and their 90-day outcome data are collected (including mortality, MALE, MACE, respiratory and wound-related complications, readmissions, reinterventions and discharge destination).

Participants are invited to receive a telephone call or postal EQ-5D-5L assessment as well as the NEADL. Food diaries are collected over 2 days (ideally one weekday and one weekend day) (see Appendix 5 online at www.jvsgbi.com).

Data management

Data are collected and uploaded onto a secure REDCAP database platform.

In line with General Data Protection Regulations,[32] no identifiable data are uploaded and each patient is assigned a specific audit identification number. The local hospital ID and corresponding audit ID is maintained by the lead clinician at each centre to ensure accurate follow-up data and is securely stored on an appropriate hospital computer.

Data will be kept for two years and then destroyed but will be available to others. A minimum dataset including fully anonymised patient data will be included in the FraiLTI results paper as a supporting information file.

Data analysis

Statistical analysis will be performed using R (R Foundation for Statistical Computing, Vienna, Austria). Normally distributed data will be presented as mean (SD) and hypothesis testing will be performed with unpaired t-tests/Mann–Whitney U tests as appropriate. Categorical data will be analysed by a χ^2 test.

A p value <0.05 will be considered statistically significant for single comparisons.

Kaplan–Meier survival curves will be used with a log-rank test to compare the overall mortality. Cox proportional hazards regression will be performed; hazards ratios (HR) with 95% confidence intervals (CIs) will be reported along with p values.

Binary logistic regression analysis will be used to identify associations with complications and multiple variates will be tested. The resultant significant variables will be presented as odds ratios (OR) with 95% CIs. An OR of >1 indicates an increased likelihood of the event occurring.

The NEADL scores will be analysed as continuous variables using the statistical tests outlined above. EQ-5D data will be analysed using the "eq5d" R package to provide both descriptive data and longitudinal data to assess how quality of life changes over the course of the study. Techniques to be used include the Paretian Classification of Health Change (PCHC)[33] and the Probability of Superiority.[34]

Nutritional data will be entered into Nutritics Professional Plus v5.81, 2022 software and analysed. The average for each participant will be grouped and then analysed. Total energy intake will be reported as kilocalories (kcal) per day and as a percentage of estimated resting energy expenditure using the Mifflin–St Jeor equation.[35] Average total daily intake of macronutrients and micronutrients will be reported. Macronutrients will also be reported relative to body mass. A threshold of 1.2 g/kg body mass/day will be used to identify people with low protein intake.

Regulatory approval and research governance

Full ethical approval (21/PR/0750) was granted on 13 July 2021 for this multicentre prospective observational study. The study is registered on the ISRCTN.

Authorship

This is a national trainee supported research collaborative. It is anticipated that VERN will support the FraiLTI project through one of the streams of collaboration once the regional study is underway. Contributions will be recognised in co-authorship of publications as part of a collaborative research authorship model. This will allow participating clinicians in training to meet the objectives of their training needs whilst providing vital research data, as well as recognising the research activity for the recruiting centre and lead.

Current status

The FraiLTI study recruitment of new centres was between September 2021 and September 2022. The expected date of the last patient to be included is July 2022 and data collection will end in September 2022. The results of this study are expected to be released in early 2024.

Discussion

An internationally agreed definition of frailty remains elusive due to its multifaceted aetiology[36,37] and the challenge of distinguishing it from other geriatric conditions.[38,39] While frailty is considered a geriatric condition and is closely related to ageing, disability and comorbidity, it is unmistakably different.[40,41] For example, despite its higher prevalence among older individuals, frailty cannot be solely attributed to chronological age.[36]

Research has revealed that frailty is not a static condition but rather a dynamic process that results from the compounded effects of multiple factors.[40,42,43] This improved understanding of frailty offers an opportunity to optimise management of underlying factors such as nutritional deficiencies, physical inactivity or chronic diseases, leading to better health outcomes and an improved quality of life.[27,42] Ultimately, this is achieved through correct identification and understanding of the scale of the problem through studies such as this one.[44]

The FraiLTI study represents a pivotal first step in establishing the current prevalence of frailty, sarcopenia and multimorbidity among patients with CLTI in the UK. This initial step is vital to evaluate the scale of the issue and any clinical consequences or associations related to CLTI on a national level. The findings of the study will ultimately inform the development of future intervention studies to improve health outcomes for patients with CLTI, thereby reducing the overall burden of these conditions on the healthcare system.

It is postulated that CLTI patients who also have frailty and/or multimorbidity could be associated with worse clinical outcomes, potentially independent of age. By identifying adverse health outcomes such as quality of life, activities of daily living and mortality, the study aims to enhance the detection of the most vulnerable individuals, thereby improving targeted treatment strategies.

The FraiLTI study is part of a national collaborative research effort led by VERN trainees. By leveraging this platform, the study employs a multicentre design that enables patient recruitment from various locations. This approach boosts the study's statistical power and increases the potential for a larger sample size. The utilisation of data from diverse sites improves the representation of the UK as a whole, which is crucial when analysing prevalence nationwide. These efforts contribute to more robust and impactful findings that advance the knowledge of CLTI and its correlation with frailty. VERN has a proven track record of producing multinational studies that have a large impact, increasing the credibility of this study.[45,46] One limitation of this study will be the inability to determine direct causality between practice and outcome; however, it benefits from being prospective, multicentre and unique in its use of the Fried Frailty phenotype model in this context. Outputs from the FraiLTI study will inform future quality improvement and research projects to improve the care of patients with CLTI.

Pathway to impact

This study is a collaborative effort between patients and clinicians and is supported by the Vascular Society Peripheral Arterial

KEY MESSAGES

- Patients with chronic limb-threatening ischaemia (CLTI) often have many concurrent medical conditions (multimorbidity) and suffer from frailty and sarcopenia.
- The aim of the FraiLTI study is to identify the prevalence of these conditions in those with CLTI.
- This protocol describes the methodology of the FraiLTI study.
- We hope that this study will contribute to the understanding of these conditions in this population and how it affects their outcomes.

Disease Special Interest Group (PAD SIG). The results will be presented to improve patient care at a national and international level. A writing team, including individuals involved in the design, implementation and dissemination of the FraiLTI study, will be responsible for submitting manuscript(s) for publication(s).

The study will prioritise patient and public involvement, working with the JLA PSP to produce a patient-facing lay summary of the results The JLA and Circulation Foundation will also be notified to promote the summary. Additionally, results of the FraiLTI study will be disseminated through VERN's social media accounts, newsletters and dedicated webinars.

Conclusion

The FraiLTI study will provide a comprehensive overview of the prevalence of frailty, multimorbidity and sarcopenia in CLTI patients. As a UK first multicentre prospective study, we set out to provide an understanding of the scale and clinical consequences of CLTI, leading on to the development of large-scale prospective research projects on developing more focused interventions for patients with frailty and sarcopenia with the aim of improving their clinical outcomes.

Conflict of Interest: The authors declare that there is no conflict of interest.

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PROTOCOL

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

*Fabre I on behalf of the SIMBA Study Group**

South East Wales Vascular Network, University Hospital Wales, Heath Park Campus, Cardiff CF14 4YS, UK

Corresponding author:
Ismay Fabre
South East Wales Vascular Network, University Hospital Wales, Heath Park Campus, Cardiff CF14 4YS, UK
Email: Ismay.Fabre3@wales.nhs.uk

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Plain English Summary

Why we are undertaking this work: In the UK in 2022 over 3,000 people needed an amputation of their leg. This meant they lost their leg above the ankle. This was mainly due to poorly controlled diabetes and blocked arteries that supply the foot and leg. Following amputation surgery, one of the risks is getting an infection of the wound. Wound infection can sometimes be minor, just needing antibiotic tablets to treat. Sometimes it can be serious, needing more surgery or even resulting in death. We do not know how many people get a wound infection after an amputation. We also do not know how infection affects patients, their loved ones or healthcare systems. Many things are used (eg, different dressings and stitches) to try to reduce the occurrence of wound infections, but we do not know if they are actually effective. Two large organisations in the UK have produced guidance designed to reduce infections and improve patient outcomes following amputation. It is also unknown if hospitals are using such guidance.

What we will do: To find out more about the rates of infection and how to reduce it we have designed a large multicentre audit across the whole of the UK and other countries. This will be known as the Surgical Site Infection in Major Lower Limb Amputation (or SIMBA) audit. We will record details of as many patients as possible undergoing amputation surgery. This will happen over 8 months from October 2023 to May 2024. Taking part in the SIMBA project will not affect the care of a patient. We are simply recording what happens to people during and after surgery.

What this means: We hope this will help us find out ways in which we can improve care for those undergoing amputation in the future. The results of the SIMBA audit will be reported to major organisations and charities involved in the care of patients who have amputations.

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

Abstract

Background: Over 3,000 major lower limb amputations (MLLA) occur in the UK per annum. A significant proportion of patients following MLLA will go on to develop a surgical site infection (SSI). SSIs can range from a simple superficial infection that is treated with oral antibiotic therapy to deeper infections which can lead to wound dehiscence and, ultimately, surgical revision. SSIs can have a significant impact on patient mobility, function, morbidity and mortality as well as wider effects on carers, community services and hospital systems. Despite these potential impacts there are limited data to determine the rate of SSI in patients undergoing MLLA, adjuncts that successfully prevent SSI, factors that predispose patients to SSI and compliance with national guidance set out by key stakeholders in vascular surgical care.

Methods: To address this gap in evidence we propose a large, international, prospective, collaborative audit that aims to compare current practice against recommendations set out by the National Institute of Health and Care Excellence and The Vascular Society of Great Britain and Ireland and to determine the frequency of significant outcomes related to SSI (as defined by the Centre for Disease Control) in consecutive patients undergoing MLLA over an 8-month period including the incidence of SSI, wound dehiscence and surgical revision at 30 days, frequency of use of adjuncts designed to reduce SSI and predictors of SSI. Outcomes will also be captured at 1 year post-MLLA if funding permits.

Discussion: This multicentre audit will allow us to describe the incidence and burden of SSI and wound dehiscence in patients undergoing MLLA. The strengths of this audit will lie in its use of contemporaneous data collection from numerous hospitals and the in-depth data collection focusing primarily on MLLA SSI. It is anticipated that the audit will provide impactful data for future comparisons with global practice and support the design of robust and meaningful studies.

Please see supplementary material (online at www.jvsgbi.com) for a visual abstract.

Introduction

Background and rationale

Surgical site infection (SSI) is a significant potential complication of any surgical procedure, acknowledged by the National Institute of Health and Care Excellence (NICE) as a leading cause of in-hospital morbidity and mortality.[1] In vascular surgery, patients undergoing major lower limb amputation (MLLA) may be at an increased risk of developing SSI due to underlying risk factors including ischaemia, pre-existing infection and diabetes.[2] The Vascular Society of Great Britain and Ireland (VSGBI) provides a best practice clinical care pathway designed to optimise quality of care to reduce the risk of complications.[3] NICE have also published guidance relating to the prevention and treatment of SSI.[4]

Evidence reporting the incidence of SSI in patients following MLLA due to vascular conditions is currently limited. Single-centre studies have previously reported an SSI rate of up to 27% in vascular patients.[5–8] Due to relatively high rates of SSI, many adjuncts have become available to surgeons such as antimicrobial dressings and negative pressure therapy. However, many of these have little evidence of clinical or cost-effectiveness for their use, particularly in MLLA wounds. Evidence for the use of any adjuncts to care other than a prolonged 5-day course of intravenous antibiotics following MLLA is sparse.[9,10] Furthermore, there is no consensus on the most effective operative practices – for example, wound closure technique or placement of drains to minimise the occurrence of SSI in MLLAs.

The importance of this issue has been recognised by both patients and multidisciplinary clinicians. The Priority Setting Partnership led by the Vascular Society of Great Britain and Ireland (VSGBI) in conjunction with the James Lind Alliance identified improving clinical outcomes for patients undergoing MLLA and improving wound healing as two of the top research priorities.[11]

In patients undergoing MLLA, the baseline SSI rate as well as compliance with national guidance is currently unknown. In 2022, VSGBI estimated that 3086 MLLAs were undertaken in UK vascular units. Given SSI rates were estimated at 40%,[12] this potentially represents a huge impact on patients, carers and hospital systems. To clarify the baseline SSI rate, adherence to national guidance and assess the adjuncts currently in use for SSI reduction, we have created the 'Surgical Site Infections in Major Lower Limb Amputation' (SIMBA) international multicentre audit.

Objectives

- To compare the performance of units with NICE guidance relating to SSI prevention specifically related to MLLA[4]
- To capture centre-specific data regarding pathways and policies surrounding MLLA and compare this with the VSGBI Best Practice Clinical care pathway for MLLA (for patents under the care of a vascular surgeon)
- To calculate a 30-day incidence of SSI post-MLLA
- To calculate a 30-day incidence of wound dehiscence post-MLLA
- To identify the cause of wound dehiscence post-MLLA (eg, ischaemia or haematoma)
- To calculate a 30-day incidence of revision surgery post-MLLA (to the same or higher level)
- To identify the patient and surgical risk factors associated with MLLA SSI
- To calculate the incidence of early complications related to SSI including sepsis, acute kidney injury, all-cause mortality, increased length of hospital stay or admission to critical care.
- To capture 1-year outcome data for these patients (mortality, amputation revision, ambulation status) and assess the impact of SSI on these outcomes.

Project design

- Multicentre international prospective audit of current practice.
- Non-interventional, only routinely collected data will be collected.

Methods

Participants, interventions and outcomes

Project setting

SIMBA will be disseminated via the Vascular and Endovascular Research Network (VERN). VERN is a trainee-led national research collaborative that is run by, and engages with, research-active vascular trainees and allied healthcare professionals, and has expertise in running national and international audits of practice.

Hospitals providing emergency and/or elective MLLA surgery in the UK and abroad will be recruited via VERN. MLLA surgery can be performed within a vascular surgery department, orthopaedic department or other appropriate department. Based on current interest, more than 30 units are expected to be enrolled, with an expected sample size of around 1000 records. Whilst the best practice policies are based on UK documents, SIMBA will also capture how non-UK centre practice aligns to these guidelines.

Eligibility criteria

SIMBA will capture data on consecutive patients undergoing MLLA. Any patient undergoing MLLA due to complications of peripheral arterial disease (PAD), diabetes mellitus, trauma, cancer and other

reasons are eligible for enrolment if they meet the specified inclusion criteria below. Eligible patients will be identified by screening data available to clinical teams; patients will not be approached/contacted and enrolment in SIMBA will not affect care decisions or choices. In patients undergoing MLLA of both limbs during the duration of SIMBA data capture, so long as the patient is eligible both sides will be included (as separate case records).

Inclusion criteria:

1. Patients aged 18 years and above.
2. Patients undergoing primary MLLA (including the following cases: elective/non-elective, hip disarticulation, above knee, through knee/Gritti-Stokes or below knee amputation)
3. Emergency or elective MLLA revision surgery (defined as any revision surgery which requires shortening of the bony length of the residual limb)

Exclusion criteria:

1. MLLA with complex reconstruction (eg, myocutaneous flap) to provide coverage of the amputation site (this does not encompass patients undergoing myodesis and/or myoplasty)
2. MLLA with a concomitant placement of an osseous integration
3. Staged amputation (defined as a MLLA performed in two or more separate planned visits to the operating theatre)

Outcomes

Data from consecutive patients undergoing MLLA meeting the inclusion criteria will be collected prospectively. Data will be captured for each participant until 30 days following surgery.

Outcomes are based on the short-term core outcome set for MLLA, including problems with amputation healing and infection, mortality, requirement for re-admission, re-operation or further specialist treatment for complications.[13] The 30-day postoperative morbidity grade will be recorded as per the Clavien–Dindo scale.[14] Outcomes will also include compliance with NICE guidelines on SSI prevention.[5]

The Centres for Disease Control and Prevention (CDC) define that, for MLLA, SSIs are wound associated infections presenting within 30 days of surgery.[15] SSIs will be limited to those apparent to the treating vascular clinicians within 30 days of surgery. It is recognised that this audit may not capture milder infections treated with oral antibiotics or simple topical therapies in the community; this will be accounted for and discussed in the analysis and dissemination of SIMBA.

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

Table 1 Key dates for the SIMBA audit.

SIMBA launch; new sites able to be enrolled	1 October 2023
Close of SIMBA to new site enrolment	1 January 2024
Return of outcome data for patients so far entered SIMBA	1 February 2024
End of new patient identification	1 April 2024
End of 30-day data capture	1 May 2024
End of 30-day data validation	1 June 2024
End of 1-year outcome data capture	1 May 2025
End of 1-year outcome data validation	1 May 2025

Participant timeline

Centre opening will be staggered, and centres will be permitted to start data collection once appropriate approvals are in place. Key dates are shown in Table 1.

Sample size

Sample size will be dependent upon enrolled unit activity and case volume.

Recruitment

SIMBA is required to be registered with each participating centre prospectively, prior to data collection. Within the UK, this is with the audit department. Participating centres outside the UK must comply with local regulations prior to commencement. SIMBA is open to all centres that undertake elective and/or emergency MLLA. In the case of UK vascular units, often they comprise a Hub and Spoke type model.

Each centre will require the support of a named supervising consultant/attending (or equivalent) who will act as guarantor of all activity undertaken at that centre, and a data collection team. The supporting consultant is expected to facilitate the data collection team to secure audit registration (or local research ethics committee/institutional review board approval if required for non-UK countries), provide unit support for engagement, act as guarantor for data capture, validation and upload, provide workplace-based assessment documentation for team members and facilitate local presentation of results.

The local audit team will be responsible for data collection and data validation. This team will comprise a maximum of a supervising consultant/attending and a further six individuals and can include medical trainees, medical students or allied healthcare professionals.

At enrolment each centre will be asked to complete a baseline unit survey. This will collect data on clinical care pathways and policies surrounding MLLA.

Local Information Technology (IT) systems, theatre lists and inpatient ward-based lists will be used to screen for eligible patients at each individual SIMBA centre once registered.

Data collection, management and analysis

Data collection methods

Key demographic data, baseline variables and intraoperative data should be collected as early as possible following MLLA surgery, ideally at the completion of the operation to reduce missing data points.

Postoperative sequelae data points will be collected up until 30 days following surgery. In the case of SSI development, further details will be required regarding extent of infection and subsequent patient outcomes. Such data can be obtained using a variety of routinely collected sources such as: patient hospital notes and electronic records; preoperative assessments, outpatient letters, theatre IT systems, discharge summaries, emergency department and primary care records (where available). Any patient enrolled in SIMBA will not receive additional unplanned follow-up other than what is considered as 'routine care' at each site.

Project organisation

The SIMBA Audit is partially funded by the ROSSINI platform as part of the accelerator award scheme (Award ID: NIHR156728).[16]

The study is coordinated by the Birmingham Centre for Observational and Prospective Studies (BiCOPS) at the University of Birmingham. BiCOPS was established in 2017 and provides methodological support and the infrastructure for the delivery of non-randomised prospective research. BiCOPS has established expertise in the design, coordination and analysis of large-scale national and international cohort studies across a range of clinical specialties. All BiCOPS projects are conducted in compliance with the UK Policy Framework for Health and Social Care Research, Data Protection Act 2018[17] and the Principles of Good Clinical Practice (GCP). BiCOPS enables the successful delivery of adopted projects through active interaction with national and international networks and collaborative groups.

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

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

Data management

Source data will be captured and uploaded electronically using an internationally recognised secure web application for building and managing online databases (Research Electronic Data Capture - REDCap).[18] It is encouraged that data will be uploaded directly to REDCap as close to the time of surgery as possible. Paper case report forms (CRFs) will be provided to centres to facilitate data capture when direct upload to REDCap is not possible at the time of surgery. No patient identifiable data will be transferred to REDCap. Each local centre will hold a secure database with a minimum of three patient identifiers and a three-digit pseudo-anonymised number used to link perioperative and postoperative data. A template document will be sent to centres on enrolment to be overseen by the local lead who will be responsible for ensuring this file is only stored on-site, is done so securely, and is disposed of appropriately following upload of all follow-up data to REDCap.

Data validation

Data completeness will be quantified following the initial data collection. Any datapoints left blank will be considered incomplete. Data points recorded as "unknown" will count as complete data. Cases with <95% data completeness will be returned to the local centre for completion. If this is not possible, these cases will be excluded from the analysis, as is standard within international collaborative audits.[19] Individual patient records with less than 95% completeness of mandatory datapoints will be returned for completion; if this is not possible the patient will be excluded from the analysis. All centres will be required to validate data accuracy in 20% of their uploaded cases (randomly selected); 25% of datapoints (randomly selected) per case will be validated, equating to 5% of total datapoints captured. Any centre reporting accuracy of less than 95% will be required to validate a further 20% of their cases and the lead team member will be asked to investigate and report back to the SIMBA Management Group. Data validation will be undertaken independently by a team member not involved in the initial data collection.

Statistical methods

Simple descriptive analyses will be used to describe variations in practice at registered SIMBA sites. Any continuous data will be tested for normality followed by parametric or non-parametric tests as appropriate. A χ^2 test will be used to analyse for differences for categorical variables. Missing data will be analysed to determine the pattern of missingness and, if appropriate, multiple imputation will be carried out using the Markov chain Monte Carlo method. Univariate and multivariate regression analyses will be used to identify independent predictors of 30-day SSI, 30-day wound dehiscence, 30-day stump revision, 30-day all-cause mortality, 1-year all-cause mortality, 1-year stump revision and 1-year ambulation status. Any variable reaching the threshold of $p<0.10$ on univariate analysis will be entered into a multivariable regression analysis. A p value <0.05 will be considered as statistically significant.

Monitoring

Data monitoring

Data validation comprises confirmation of case ascertainment and data accuracy. At the close of the data capture timeframe, centres will be asked to review theatre logs to ensure that all patients undergoing MLLA during the data collection timeframe were entered. Any patients not included can then be added retrospectively. It is appreciated that not all data may be available retrospectively, but the SIMBA team will account for this during analysis and dissemination.

As SIMBA is an international prospective audit, a data monitoring committee is not formally required.

Harms

As SIMBA is not an interventional study and is concerned only with events related to routine clinical practice, reporting of serious adverse events or similar is not required.

1-Year outcome data

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

Ethics and dissemination

Research ethics approval

The SIMBA methods do not meet the criteria of research as classified by the Health Research Authority decision tool[20] (see Appendix 2 (online at www.jvsgbi.com). Therefore, research ethics approval was not sought. Every participating centre will register the audit locally prior to data collection (audit and service provision registration at all NHS sites involved). Centres outside the UK should comply with local regulations.

Protocol amendments

Any amendments to the project or this protocol will be communicated immediately to each site directly. This version and any future versions of this protocol will be uploaded to the VERN website which is readily available to all sites.[21]

Consent or assent

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

Confidentiality

Only anonymised routinely collected data will be collected. All participant information, data and outcomes will be strictly confidential and only the central research team will have access to the complete dataset. All data will be handled in accordance with the principles of the Data Protection Act 2018 and GDPR.[17]

Declaration of interests

The SIMBA group have no conflicts of interest to declare.

Access to data

The final SIMBA dataset will be available to members of the core project management group listed in this protocol. Those outside of the study group may access the dataset on reasonable request. The data will be available following publication of the initial SIMBA findings. Data will be stored and accessed in accordance with the principles of GCP.

Dissemination policy

All publications and presentations relating to SIMBA will be authorised by the SMG. The results of SIMBA will be submitted for presentation at national and international meetings. Any manuscript(s) from the resultant data will be submitted for peer-reviewed publication. A writing team, including those involved with design, implementation and dissemination of the audit, and those contributing to data analysis will be responsible for both presentation(s) and publications(s). For both, a collaborative authorship model will be used, with a list of contributors clearly listed at the end of the manuscript. To qualify for citable collaborative co-authorship, individuals must have either:

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

OR

- Captured sufficient data to warrant authorship – this would be the equivalent of collecting baseline and follow-up data on approximately 10 patients, although it is appreciated individuals may participate in only baseline data collection or only follow-up data capture. Data collection is expected to be complete (>95% variables completed) and submitted in a timely manner

OR

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

OR

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

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

KEY MESSAGES

- SSI is a leading cause of in-hospital morbidity and mortality following MLLA.
- The prevention and management of SSI post-MLLA is heterogenous and compliance with the NICE guidelines is unknown.
- This audit will calculate the incidence of SSI post-MLLA and evaluate adherence to the NICE guidelines and to the Vascular Society's best practice pathway.

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

Discussion

This multicentre audit will allow us to reliably determine the incidence and burden of SSI and wound dehiscence in patients undergoing MLLA. The strengths of this audit will lie in its use of contemporaneous data collection from numerous hospitals, the in-depth data collection focusing primarily on MLLA SSI, and the capture of 1-year outcome data.

It is anticipated that the audit will provide impactful data for future comparisons with global practice and support the design of robust and meaningful studies.

Limitations of the audit will include its inability to define specific causative associations between factors and the incidence of SSI. Therefore, focus will be placed on factors either known to contribute to SSI or areas with limited evidence. Although the VERN Collaborative has experience of data collection from previous studies, it will be impossible to confirm reliable consecutive patient recruitment. Finally, the data will be limited to SSIs that are severe enough to prompt review or referral to secondary care, as per previous international SSI audits.[22]

***Management Committee and Protocol Writing Group (in alphabetical order):**

Miss Nina Al-Saadi, Vascular Trainee, Black Country Vascular Network; Email: nina.al-saadi@nhs.net; Mr David Bosanquet, Consultant Vascular Surgeon and Project Co-Lead, South East Wales Vascular Network, Email: David.bosanquet@wales.nhs.uk; Professor Ian Chetter, Professor of Vascular Surgery, Hull York Medical School, Email: ian.chetter@nhs.net; Miss Ismay Fabre, Core Surgical Trainee and Project Co-Lead, South East Wales Vascular Network, Email: ismay.fabre3@wales.nhs.uk; Mr Brenig Gwilym, Vascular Trainee, Aneurin Bevan Health Board, Email: blgwilym@gmail.com; Miss Louise Hitchman, NIHR Doctoral Research Fellow, Hull University Teaching Hospitals, Email: l.hitchman@nhs.net; Mr Terry Hughes, Research Administrator, Birmingham Centre for Observational and Prospective Studies, University of Birmingham, Email: t.hughes@bham.ac.uk; Mrs Judith Long, Vascular Research Manager, Hull University Teaching Hospitals, Email: judith.long3@nhs.net; Dr Laura Magill, Associate Professor of Clinical Trials, Birmingham Clinical Trials Unit, Email: e.l.magill@bham.ac.uk; Professor Thomas Pinkney, Professor of Surgical Trials, Institute of Applied Health Research, University of Birmingham, Email: Thomas.Pinkney@uhb.nhs.uk; Mr Matt Popplewell, Assistant Professor of Vascular Surgery, Institute of Applied Health Research, University of Birmingham, Email: m.a.popplewell@bham.ac.uk; Mr Michael Wall, Consultant Vascular Surgeon, Black Country Vascular Network, Email: michaelwall@nhs.net.

The SIMBA Study protocol was compiled using the Standard Protocol Items: Recommendations for Interventional Trials (2013) Checklist as a guide where relevant to the nature of the project. Available at: https://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/

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

Conflict of Interest: The authors declare that there is no conflict of interest.

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CASE REPORT

Traumatic thigh AV fistula leading to aneurysmal changes in aorta and iliac arteries

Zaki S,[1] Hilles A,[2] Chandrasekar R[3]

1. Senior Clinical Fellow in Vascular Surgery, Countess of Chester NHS Trust, Chester, UK
2. Consultant in Interventional Radiology, Countess of Chester NHS Trust, Chester, UK
3. Consultant in Vascular Surgery, Countess of Chester NHS Trust, Chester, UK

Corresponding author:
Shady Zaki
Flat 410C, Winchester Road, Southampton SO16 7DH, UK
Email: shady_mikhael@hotmail.com

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Key words: trauma, arteriovenous fistula, hybrid surgery, secondary aneurysmal dilatation, regression of aneurysm

Abstract

Penetrating traumatic arteriovenous fistulas (AVFs) have the tendency to be clinically silent for many years and could be misdiagnosed as deep venous thrombosis (DVT) on initial presentation. A 52-year-old male underwent a duplex scan to evaluate swelling of the limb, which detected an AVF in the thigh. He was stabbed in the lateral aspect of the thigh 16 years previously. His left leg was larger with a palpable thrill in the thigh. A CT angiogram confirmed the AVF and aneurysmal changes in the common iliac artery (29 mm) and infrarenal aorta (32 mm). A moulding balloon was placed across the AVF by an antegrade puncture of the common femoral artery to control the arterial inflow and outflow. Following disconnection of the AVF, the defect in the side wall of the femoral vein was primarily repaired with Prolene. The defect in the superficial femoral artery was repaired by transection, spatulation and end-to-end anastomosis of the arteries. A Duplex scan performed six months postoperatively showed that the aorta (29 mm) and the common iliac artery (27 mm) had regressed. The authors suggest that, when faced with an AVF with a huge calibre mismatch between the arterial segment proximal and distal to the fistulous tract in a young patient, a hybrid approach should be considered for control and surgical disconnection of the fistula.

Introduction

Traumatic penetrating arteriovenous fistulas (AVFs) are very rare, with only 291 cases accounted for in the literature.[1] The most common causes are stab wounds and gunshot wounds.[1,2] AVFs of the extremities tend to present with pain, swelling or limb size discrepancy.[3] If untreated, severe or chronic AVFs may lead to high output cardiac failure, functional impairment or steal, resulting in limb ischaemia and tissue loss.[3]

Case report

A 52-year-old male seen in the vascular clinic after an AVF was detected on a venous duplex scan. He complained of a swollen painful left leg for a number of years. After probing, he gave a history of a stab injury to the left thigh 16 years previously. On examination his left thigh was significantly larger than his right. He had a full complement of pulses, but a thrill could be felt on his inner thigh and a bruit could be heard.

A CT angiogram (Figure 1) showed dilatation of the common femoral artery (CFA) and the proximal two-thirds of the superficial femoral artery (SFA) and femoral vein (FV). Furthermore, due to the long-standing well developed AVF, the left common iliac artery (CIA) was tortuous and enlarged (29 mm), with mild aneurysmal dilatation (32 mm) of the infrarenal aorta.

Intraoperatively, an antegrade catheter angiogram was performed to locate the exact site of the AVF and a moulding balloon (Figure 2) was used to control the arterial inflow and outflow. This aided the dissection of the SFA and the adjacent FV, both proximally and distally. Following dissection and sloop control of the vessels, the SFA and FV were clamped and the AVF disconnected. The defect in the side wall of the FV was primarily repaired with a 6/0 Prolene suture. The defect in the SFA was treated by transection, spatulation and end-to-end anastomosis of the arteries. A completion on-table angiogram confirmed restoration of the blood flow and a three-vessel run-off to the foot.

An aortic arterial duplex scan performed six

Figure 1 Preoperative 3D CT angiogram

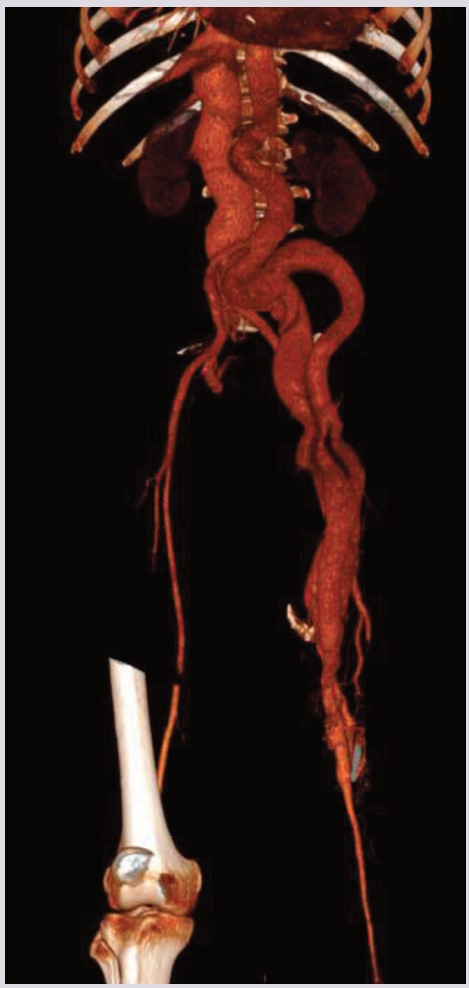
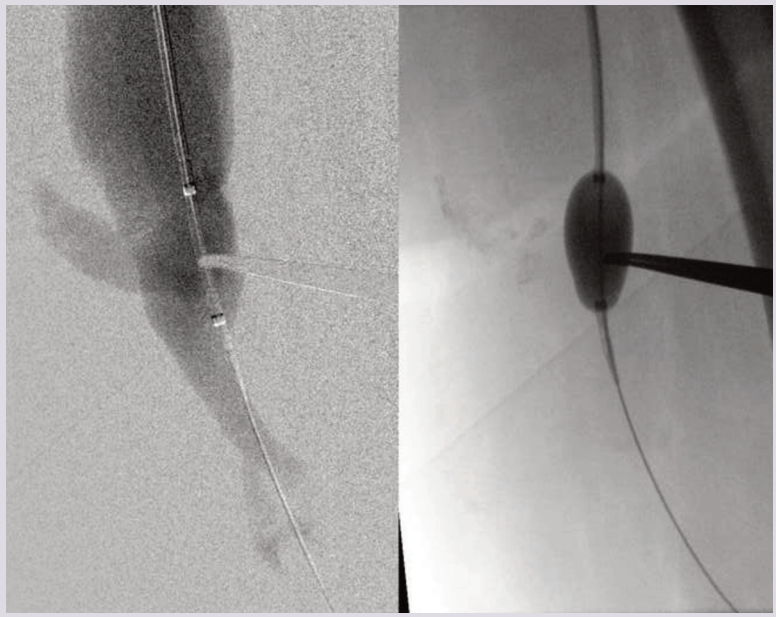


Figure 2 Intraoperative catheter angiogram localizing fistula site and placement of moulding balloon



KEY MESSAGES

- A hybrid approach should be considered when dealing with traumatic arteriovenous fistulas.
- Aorto-iliac aneurysmal dilatation secondary to arteriovenous fistulas tends to regress when the fistula is repaired.
- Gross mismatch in the size of the artery is best dealt with by transection, spatulation and end-to-end repair.

months post-operatively showed that the aorta had regressed in size to 29 mm and the left CIA to 27 mm.

Discussion

Penetrating traumatic AVFs may be clinically silent in the acute setting, demonstrating minimal to no symptoms initially. This leads to a missed diagnosis, especially if there was no neurovascular compromise on examination.[4,5] Even though some are self-limiting and would spontaneously heal,[6] most would develop a significant fistulous tract size which renders them problematic.[7,8]

The consensus from the literature is that traumatic AVFs should be managed surgically rather than conservatively,[9] and that an endovascular approach should be considered first as it is less invasive, more cost effective and has a lower rate of complications.[2] In our case, given the patient's young age and the calibre mismatch between the proximal and distal segments of the artery in relation to the fistulous tract, we opted for open surgery for a more durable outcome.

Conclusion

We suggest that, when faced with an AVF with a huge calibre mismatch between the arterial segment proximal and distal to the fistulous tract in a young patient, a hybrid approach should be considered for control and surgical disconnection of the fistula for a durable permanent solution.

Conflict of Interest: None.

Funding: There has been no financial support for this work that could have influenced its outcome.

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

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

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CASE REPORT

Pseudoaneurysm of the anterior tibial artery following arthrodesis on a background of ankle joint tuberculosis

Veeralakshmanan P,[1] Al-Saadi N,[1] Popplewell M,[1] Garnham A,[1] Shalan A,[1] Wall M[1]

1. Vascular Surgery Department, Russells Hall Hospital, Black Country Vascular Network, West Midlands, UK

Corresponding author:
Pushpa Veeralakshmanan
Vascular Surgery Department, Black Country Vascular Network, West Midlands DY1 2HQ, UK
Email: p.veeralakshmanan@nhs.net

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Key words: pseudoaneurysm, arthrodesis, endovascular stenting, anatomical variation

Abstract

A 65-year-old man presented with a 6-week history of worsening right anterior ankle swelling following an ankle arthrodesis. Examination revealed a warm pulsatile 8 cm swelling on the dorsum of the foot. Ultrasound doppler and computed tomography angiography revealed an 8 cm pseudoaneurysm arising from the anterior tibial artery. Fluoroscopic-guided embolisation successfully treated the pseudoaneurysm. Pseudoaneurysms following foot and ankle surgery are a rare but documented complication. Treatment options include conservative management, endovascular interventions or surgical correction. This case highlights that awareness of blood supply variations in the foot and ankle is essential.

Case presentation

A 65-year-old man presented to the emergency department with a 6-week history of increasing right ankle swelling following elective right ankle arthroscopy (via right ankle anteromedial and anterolateral ports) and arthrodesis on a background of successfully treated ankle joint tuberculosis. The joint was fused in the appropriate position using cannulated screws. At the end of the procedure, an inadvertent breach of the anterior tibial cortex was noted but no specific action was required at that point and a plaster cast was applied with the foot in the plantigrade position. Following removal of the cast at 6 weeks, the right ankle was tender and swollen and the patient was unable to weight bear. He was on a prophylactic dose of low molecular weight heparin following the operation.

On examination a warm, pulsatile 5×7cm swelling was noted on the dorsum of the foot (Figure 1). The dorsalis pedis pulse was not palpable, but biphasic doppler signals were present. The rest of the pulse complexes and the contralateral side were unremarkable. Following an initial duplex scan, a computed tomography angiogram (CTA) confirmed an 8 cm anterior tibial artery pseudoaneurysm anterior to the surgical fixation site (Figures 2 and 3), which was subsequently embolised using fibred coils of 5×70 mm and 33×70 mm (Figure 4). Post-embolisation ultrasound confirmed thrombosis of the pseudoaneurysm. In the presence of the

Figure 1 A 5x7 cm swelling of the dorsum of the right foot.

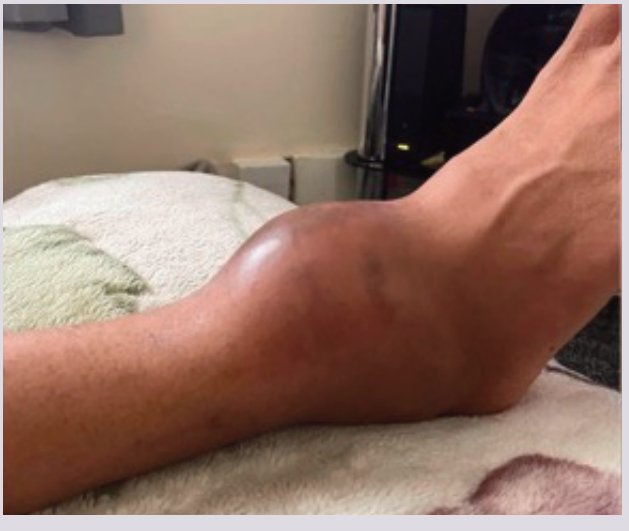


Figure 2 An 8 cm pseudoaneurysm arising from the anterior tibial artery, previous right ankle arthrodesis screws fixation.

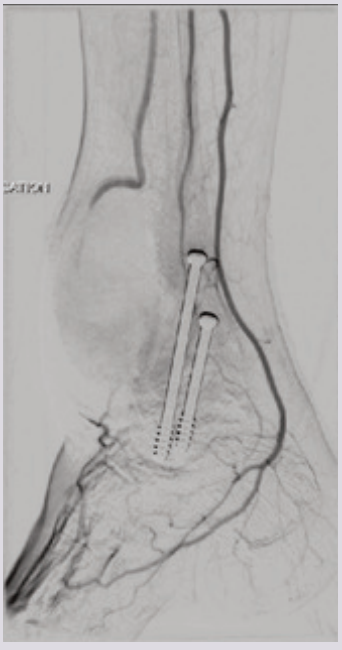


Figure 3 An 8 cm pseudoaneurysm arising from the anterior tibial artery.

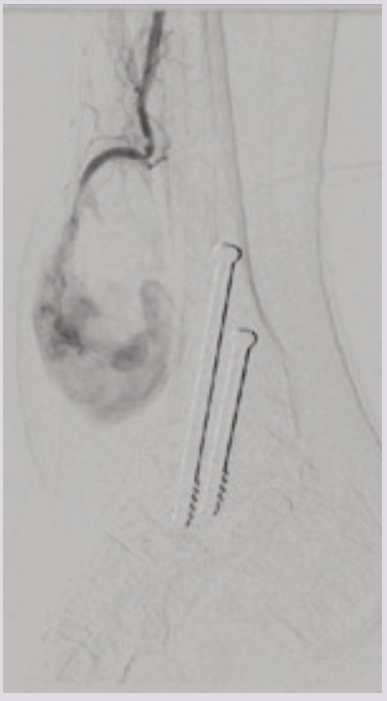
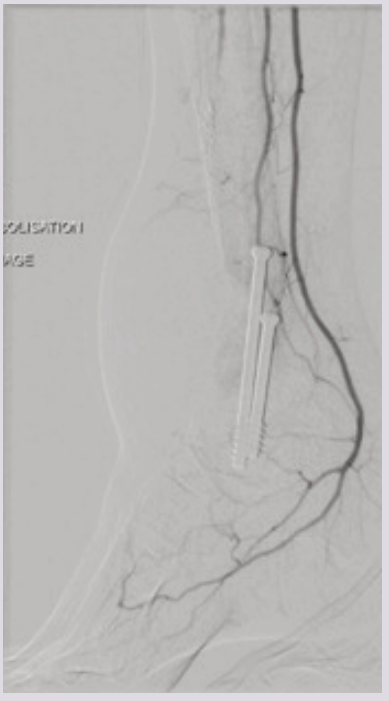


Figure 4 Post embolisation of the distal right anterior tibial artery.



metal implants from the arthrodesis and the treatment coils, with no local or systemic signs of infection, it was elected not to evacuate the haematoma. Two days post embolisation the patient was discharged with thromboembolism deterrent stockings. At the 6-week follow-up there was a substantial reduction in anterior ankle swelling and he was able to weight bear and mobilise.

Discussion

Pseudoaneurysms are a rare complication following foot or ankle surgery with only four previously reported cases, two following intramedullary nailing for tibial fractures[1,2] and two following ankle arthrodesis.[3,4] Variation in arterial anatomy around the ankle is not uncommon, with changes in the course of the anterior tibial and peroneal arteries reported in 5% of cadavers.[5] Appreciation of this anatomical variability is important when performing orthopaedic surgery and evaluating postoperative complications.

Pseudoaneurysm management varies with site and unit expertise. Options include conservative management, external ultrasound-guided compression,[6] endovascular or surgical correction. Endovascular treatment options include coil embolisation, ultrasound-guided thrombin injection or stent insertion.[7,8] Surgical management involves proximal and distal arterial control, haematoma evacuation (important if the pseudoaneurysm is associated with pressure effects) and arterial defect repair using direct closure, vein patching or interposition graft.

This case report of delayed pseudoaneurysm formation complicating orthopaedic ankle surgery highlights the importance of a heightened level of suspicion to prevent missed or delayed diagnoses. We encourage surgeons to remain vigilant for pseudoaneurysms when confronted with non-resolving haematomas including a low threshold for further investigations to prevent life-/limb-threatening complications.

KEY MESSAGES

- Pseudoaneurysms are a rare complication following foot or ankle surgery.
- Presentation varies ranging from asymptomatic to swelling, pain, pulsatile masses, potentially causing nerve compression or rupture.
- Management may be conservative, endovascular or surgical.

Conflict of Interest: None.

Funding: None.

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

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

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CASE REPORT

A deformed Lunderquist wire in a percutaneous endovascular aortic aneurysm repair procedure

Chan DML,[1] Gadhvi V,[1] Dindyal S[1]

1. Mid & South Essex NHS Foundation Trust, Basildon and Thurrock University Hospital, Nethermayne, Basildon, Essex, UK

Corresponding author:
Deona Mei Lam Chan
Mid & South Essex NHS Foundation Trust, Basildon and Thurrock University Hospital, Nethermayne, Basildon, Essex SS16 5NL, UK
Email: deonachan@gmail.com

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Key words: abdominal aortic aneurysm, endovascular aortic aneurysm repair, endovascular surgery, percutaneous endovascular aortic aneurysm repair, surgery

Abstract

Introduction: An endovascular aortic aneurysm repair (EVAR) is a minimally invasive procedure for repairing an abdominal aneurysm. The advantage of this procedure is that EVAR does not require a laparotomy, hence reducing the physical insult to the body with a quicker recovery time for the patient. Percutaneous EVAR (PEVAR) involves accessing the femoral arteries percutaneously using an access needle without the need of a groin dissection. In this case, a guidewire was damaged and an emergency 'cut down' was required to repair the femoral artery.

Case: An 85-year-old woman attended for an elective EVAR. The initial access was gained via percutaneous punctures to both her common femoral arteries under ultrasound guidance. On completion of the procedure the guidewire was removed with difficulty and an emergency right femoral dissection was performed and the common femoral artery was repaired. Postoperatively, the patient recovered well and was discharged the following day after observation.

Discussion: In PEVAR there is no need to make an incision to dissect down to the vessels. Although the vascular closure device comes with an access wire, a standard wire can be passed through; in this case, a stiff wire was used. After removal of the guidewire from the right groin it was found that the wire was severely deformed. It is thought that the wire was caught in the calcium within the vessel.

Conclusion: Although PEVAR is a common procedure, one must be mindful that many factors can affect the endovascular access and closure of the patient. The wire was damaged in this case, either in the femoral artery or in the closure device. It is paramount for vascular surgeons to anticipate that this could be a complication of PEVAR.

Introduction

Endovascular aortic aneurysm repair (EVAR) is a minimally invasive procedure for repairing an abdominal aneurysm. The advantage of this procedure compared with the open technique is that EVAR does not require a laparotomy,[1] hence reducing the physical insult to the body with a quicker recovery time for the patient. The conventional EVAR technique generally requires bilateral open femoral artery dissection ('cut down'). Percutaneous EVAR (PEVAR) is a more recent less invasive approach which involves accessing the femoral arteries percutaneously using an access needle. Like any endovascular procedures, a guidewire is required for the passing of endovascular sheaths and catheters and for the delivery of the stent. A femoral artery closure device is commonly deployed at the end of the procedure to achieve haemostasis, of which there is a wide range available. This report discusses a case in which a guidewire was damaged on removal and an emergency 'cut down' was required to repair the femoral artery.

Case report

An 85-year-old woman presented with a 74 mm abdominal aortic aneurysm which was deemed suitable for an EVAR. She had a background of chronic obstructive pulmonary disease with an admission to the critical care unit for non-invasive ventilation in the past. She underwent a preoperative assessment. General anaesthesia was deemed high risk and, following consultation

with the patient and her family, the procedure was planned to be undertaken under local anaesthesia and sedation.

Initial access into the abdominal aorta was gained via ultrasound-guided percutaneous punctures to both common femoral arteries. A soft wire was passed via an access needle and Prostar closure devices were passed into each common femoral artery via the guidewires. It was noted that access to the right common femoral artery was difficult at the time due to arterial calcification. Nevertheless, the Prostar closure device was able to pass followed by the sheath and the catheter via the use of guidewires. An aortogram was conducted and the renal arteries were delineated. It was identified that the right renal artery was the lowest. A GORE Excluder device was deployed into the abdominal aorta as the main body of the stent. An iliac contralateral limb was introduced from the left side, preserving iliac blood flow. The left limb was extended, however a completion angiogram showed a possible type 2 endoleak. The main body of the stent was ballooned.

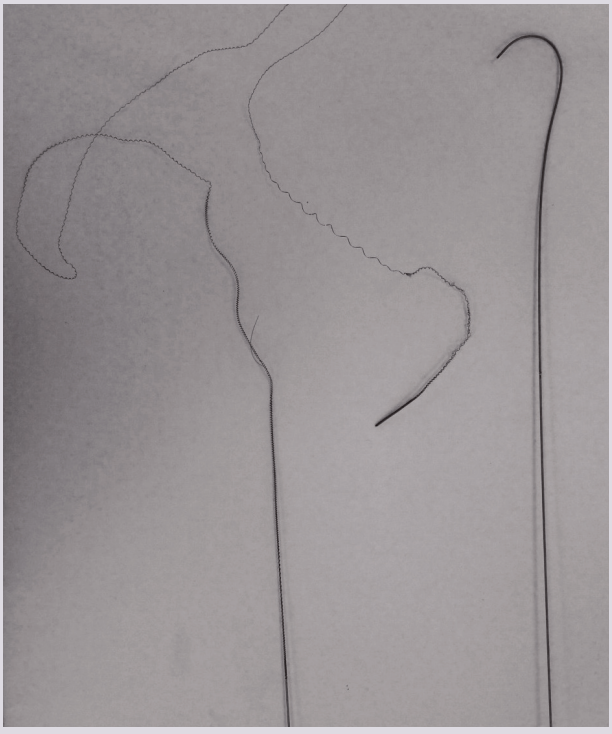
On completion of the procedure the left common femoral artery was closed with the Prostar closure device without problems. However, there were difficulties on removal of the Lunderquist guidewire inserted into the common femoral artery via the Prostar closure device. Once the wire was removed, the puncture site was bleeding. An emergency 'cut down' was performed, the common femoral artery was controlled proximally and distally, and the artery was repaired using 5/0 Prolene suture. The subcutaneous tissues and skin were closed with Vicryl and Monocryl sutures, respectively. Postoperatively, the patient was admitted for postoperative care in the critical care unit. She recovered well and was discharged the following day. A 6-week postoperative CT scan showed a decrease in the size of the aneurysm sac from 7.3 cm to 6.9 cm without endoleak and a good position of the stent graft. Her groin wounds healed completely.

Discussion

EVAR has the benefit over open repair in terms of shorter hospital stay, more rapid recovery and early survival.[2] As PEVAR does not involve a surgical femoral artery 'cut down' it is less traumatic than a standard EVAR. Several studies have shown fewer complications,[3] shorter operative time and shorter length of stay,[4,5] and these advantages translate into significant reductions in mean hospital costs.[6]

In order to perform a PEVAR, an access needle, guidewire and endovascular closure device are needed in addition to the equipment and devices for a standard EVAR. Although the Prostar device comes with an access wire, a standard wire can be passed through and can be used with the closure device for the procedure. In this particular case a Lunderquist wire was used, which is a stiff stainless steel wire.[7] The left femoral artery was closed using the Prostar device without problems. After insertion of a Prostar device into the right femoral artery, it was found that the Prostar device and the Lunderquist wire were caught in the artery. The Lunderquist wire was subsequently removed. On removal it was found that the wire was severely deformed (Figure 1). There was bleeding from the femoral artery and an emergency groin dissection was performed in order to gain haemostasis The wire had been caught in the calcium within the femoral artery.

Figure 1 Deformed Lunderquist wire after removal from the patient's right femoral artery (left) and a normal Lunderquist wire (right).



Conclusion

Although PEVARS are now standard procedures in most vascular units, one has to be mindful of the many factors that can affect endovascular access, closure and haemostasis. In the context of closure after a PEVAR, it is important to keep access to the femoral artery, either with a wire or the closure device, until haemostasis is achieved. Failing this, a surgical repair of the common femoral

KEY MESSAGES

- Be prepared to convert PEVAR to open procedure - have the equipment and theatre personnel to be prepared for it
- Understanding the relative contra-indications for femoral puncture access (eg high BMI, calcium in vessel, female patients who have smaller vessels)
- Understanding the composition of the equipment and the complications that they can present

artery may be required. The Lunderquist wire in this case was caught in either the femoral artery calcification or in the Prostar device. It is paramount for clinicians to recognise that closure devices have a failure rate of approximately 4%,[8] and plan for this potential complication of PEVARs, ensuring it is included in the consent process.

Conflict of Interest: The authors declare that there is no conflict of interest.

Funding: None.

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

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

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NEWS

Updates from the Vascular Societies

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

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

www.bacpar.org
@BACPAR_official

The British Association of Chartered Physiotherapists in limb Absence Rehabilitation celebrated its 30th year during 2023, culminating with presentations outlining its achievements and discussions re future priorities at the VS ASM in Dublin. BACPAR was pleased to see high delegate numbers from its membership.

As at previous meetings it was an excellent opportunity to network with fellow BACPAR members and others in the MDT. And we were pleased to note excellent representation of BACPAR members within regional Vascular Research networks' presentation.

Dr Miranda Asher will continue to represent BACPAR on the *Journal of the Vascular Societies Great Britain and Ireland* editorial board as part of her role as one of BACPAR's research officers.

The BACPAR 2024 Spring Journal is being prepared for publication further disseminating good practice from the 2023 Dublin programme.

There is continued progress in the update and development of practice guidance supporting the post operative and prosthetic assessment and rehabilitation of individuals with limb absence, funding for which is supported by the Chartered Society of Physiotherapy.

To be noted as well publication of the SPARG PPAM Aid guidance update in late 2023 – having been reviewed by BACPAR members as part of the process- the link to the infographic follows https://www.bacpar.org/data/Resource_Downloads/PPAMaidInfographic.pdf the use of this equipment is confirmed as fundamental to Physiotherapy practice in this speciality.

The publication of *All you need to know about Vascular Surgery* book has been widely disseminated and has been welcomed to support the education of BACPAR members and pre-registration students on placement in limb absence rehabilitation settings.

The Executive committee meets to plan its coming year business in early March 2024. The agenda will include discussion re 2024's collaboration with the Vascular societies; research, education, guidelines and the 2024 ASM programme. BACPAR is currently undertaking a survey of Physiotherapists involved in any part of limb absence rehabilitation to understand the status of the provision of Physiotherapy input, this will be shared at a NHSE Prosthetic centre managers' planning and engagement event in March.

British Society of Endovascular Therapy (BSET)

www.bset.co.uk
@BSETnews

The Annual Meeting will be held on Thursday 27th and Friday 28th June 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.

A National Vascular Training Day will be held on Wednesday 26th June for surgical and IR trainees, providing an opportunity for interactive workstation experience.

Registration for the meeting includes overnight accommodation at the hotel and dinner.

BSET promotes education and training in endovascular treatment and procedures. The Annual Meeting programme is designed to enhance professional development and promote good practice through information sharing and networking. The BSET meeting is the only dedicated UK meeting for the presentation of endovascular research and is an excellent opportunity for both surgical and IR trainees to present their work.

Confirmed speakers include:

Gustavo Oderich, *Professor of Surgery, Chief of Vascular and Endovascular Surgery and Director of the Aortic Center at the University of Texas Health Science Center, Houston, USA*

Caitlin Hicks, *Associate Professor of Surgery at The Johns Hopkins University School of Medicine, Baltimore, USA*

Barend Mees, *Associate Professor of Surgery at Maastricht University Medical Centre, Netherlands*

Rob Morgan, *Professor of Interventional Radiology at St George's Hospital, London, and President BSIR for 2023-24*

Steve Black, *Professor of Venous Surgery at King's College London*

New award for 2024
The BSET pump priming award is to support a research project within the field of endovascular therapy. The award can be used for a stand-alone project, or to compliment an existing body of research

which is either planned, or already underway. The award will be for up to £5,000.

The grant funding be used to purchase/fund equipment, device(s), consumables, database design and hosting (e.g. REDCap), technical assistance, supporting patient and public involvement (PPI) work/input, or other similar items.

Applicants can be any healthcare professional (doctors, nurses, allied healthcare professionals) within the UK working in the NHS, or UK students undertaking healthcare professional degrees.
Visit www.bset.co.uk/research to apply.
The deadline for applications is Monday 19th February. Interviews will be held on-line on Thursday 7th March (from 5pm).

Rouleaux Club

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ROULEAUX CLUB
UK Vascular Trainees' Association

The new year brings some new changes for the Rouleaux Club. Under the direction of past President, Leanne Erete, the association saw the election of the inaugural 'Specialty and Associate Specialist (SAS)/Locally Employed Doctor (LED)' representative, to help promote engagement and representation from SAS/LED colleagues. The association is also excited to see the creation of a representative role for Irish trainees, with the aim of building links between trainees of the two nations.

The Vascular Society's (VS) recent Annual Scientific Meeting (ASM) in Dublin was a busy period for the association, with the running of the 'Introduction to Vascular Surgery' course for medical students and junior doctors, and the second iteration of the MDT session. The conference also provided the opportunity to announce the winners of association's annual Essay Prize, which this year saw over 70 excellent submissions. New for this year, the two winning essays will now be published in the *JVSGBI*.

In the run up to the ASM, the vascular community were saddened to hear of the death of fellow trainee, Simon Lau, who died in 2023. The association are grateful to the VS who provided time at the ASM for a tribute to Simon, in the presence of his family.

Moving forward to 2024 we are looking forward to continuing our educational programme, with hands-on practical courses for medical students and junior doctors at the upcoming Association of Surgeons in Training (ASiT) and Charing Cross conferences. In addition, the association will also be collaborating with the RCSEd on two 'So you want to be a vascular surgeon?' courses. The online ASPIRE Juniors monthly webinar series will return soon and the association are also developing a new revision event for senior trainees in the run up to the November sitting of the FRCS (Vasc) examination (more details soon!). New for 2024 the Rouleaux Club are delighted to be working with the VS to develop a 'Trainer of the Year' Prize, to recognise excellence in teaching and training, with the aim of announcing the winner at the 2024 ASM.

The year will also see on-going debate about the function and make-up of the 'Extended Surgical Team' in vascular surgery, particular considering the results from the recent ASiT report into the role of physician associates. This issue has already seen fierce debate on social media and is a cause for concern for many trainees. The Rouleaux Club will be working closely with the VS, as well as ASiT and other stakeholders to represents the views and interest of trainees with this issue.

Andrew Nickinson
Rouleaux Club President

Society of Vascular Nurses (SVN)

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SVN
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Feedback from the ASM in Dublin has so far been very positive – the venue was fantastic and the social events were fabulous. The riots in the city on Thursday evening proved challenging, but certainly made for some interesting stories. Inside the venue there was no rioting but the depth of feeling around nurse delivered venous intervention services generated some passionate discussion. The SVN continue to support our members who are currently delivering this service and are encouraging them to publish outcome data. We continue to support members who are in the process of developing these services as part of service expansion and quality improvement.

We are delighted to have elected three full time members to the committee and welcome

Melissa Hughes, *Advanced Clinical Practitioner, Lancashire Teaching Hospitals*

Jayne Snellgrove, *Vascular Nurse Specialist, Liverpool University Hospital Foundation Trust*

Nadine Lawrence, *Vascular Nurse Specialist, Bedfordshire Hospitals NHS Foundation Trust.*

They bring with them a wealth of knowledge, experience and perhaps most importantly enthusiasm.

We have also welcomed one seconded member for the year.

Chiamaka Igbokwe, *Advanced Clinical Practitioner, Manchester Royal Infirmary.*

We hope she finds her year useful and may indeed wish to become a full committee member at the end of it.

We are sorry to lose Claire Thomson who will step down in February 2024. She has ably run the membership side of the society and will and over this role now to Jayne Snellgrove. We are running slightly short of our full complement of 15 committee members and will be re-advertising.

One of the aims of the SVN this year is to promote education among our members and the wider nursing community. We are in the process of negotiating with NHSE regarding a PAD education module and have aspirations to provide webinars for members on a regular basis.

We are delighted to hear of members using the SVN Capability document to support their roles, develop careers and ensure suitable re-numeration.

The SVN continues to support the Legs Matter campaign.

The committee continue to link in to the APPG on Vascular and Venous Disease and will be represented at the next drop in session in parliament in March 2024.

Jane Todhunter
SVN President

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

www.vasgbi.com
@vasgbi

The VASGBI ASM 2023 took place in Brighton where delegates enjoyed balmy Indian summer weather whilst gaining insights from fantastic speakers. We very much enjoyed hearing about the history of AAA repair from Professor Yusuf and challenged to consider the complexities involved in deciding when to offer (or not offer) AAA repair by Rachel Bell. Local surgeon Mike Brooks entertained us with his opinions about why carotid endarterectomy should be done awake with local anaesthetic blocks; Mark Edwards astonished us with his grasp (as a surgeon) of how communication can be key to influencing outcomes in major vascular surgery. Brighton anaesthetist Abhijoy Chakladar spoke persuasively about how he and colleagues developed a nerve catheter service which has revolutionised the care of patients admitted with CLTI, and Richard Stoddart impressed the audience with his demonstration of how easy it is for anaesthetists to gain competence in focused cardiac echo. We very much hope that in future we will be able to have conferences joint with our surgical and allied professional colleagues, which we anticipate will oil the wheels of communication between us to our mutual benefit and that of our patients.

In January it was announced that our immediate past chair of VASGBI, Dr Ronelle Mouton, was awarded a Macintosh Professorship by the Royal College of Anaesthetists. We are all very proud of her and her achievement. She will be delivering her lecture '*Strategies to optimise outcomes following abdominal aortic aneurysm surgery – challenges and opportunities'* at the RCoA hybrid cardiac disease and anaesthesia symposium in April 2024. To book a place at this meeting click here: Cardiac disease and anaesthesia symposium | The Royal College of Anaesthetists (rcoa.ac.uk)

VASGBI was a key collaborator on the 7th anaesthetic National Audit Project investigating peri-operative cardiac arrest which was published in November 2023. The study showed, not surprisingly, that vascular patients were over-represented in cases of peri-operative cardiac arrest and recommended that clinicians undertake and record pre-operative risk scoring assessments and DNACPR discussions. A summary of the NAP7 report can be read here: https://rcoa.ac.uk/sites/default/files/documents/2023-11/NAP7_Chapter%204_FINAL.pdf

On March 15th 2024 VASGBI will host the biennial CPD in vascular anaesthesia meeting which is being organised by Dr Dan Taylor and his team from Guys and St Thomas'. The programme promises a challenging, informative and thoroughly updating day. Click the link to register: VASGBI CPD Meeting - Friday 15th March 2024 - VASGBI

The work of VASGBI focuses on developing the knowledge and skills of our members, in order to support continual improvement in the care provided to patients requiring vascular surgery. We have in partnership with colleagues in the east of England developed an online learning package covering the essentials of vascular anaesthesia for trainee anaesthetists. This was launched late in 2023 and is now accessible from the NHS learning hub website: Resource (learninghub.nhs.uk). This is free to access but you will need to log in. An account is free and easy to set up.

The next VASGBI ASM will be held at the Queen's hotel in Leeds on 9th and 10th September 2024. The committee will be finalising the programme in March, after which registration will open. Please visit our website for more details: VASGBI

The Vascular Society for Great Britain and Ireland

www.vascularsociety.org.uk
@VSGBI

The Dublin ASM was hugely successful and one of the best attended ASMs in recent years. The Society would like to thank Ciaran McDonnell for championing Dublin as a venue, Douglas Orr who chairs the ASM Committee and Executive Business Support (EBS) for delivering such a fantastic ASM. The feedback received has been overwhelmingly positive and planning has started to welcome everyone to Brighton for Andy Garnham's Presidential meeting.

The themes for the ASM 2024 will be *'building complex teams' and 'sustainability'*. The Society has already published an Editorial in this Journal on the journey to greener vascular surgery (J.Vasc.Soc.G.B.Irel. 2023;2(4):197-199) and will be building on this work through this year.

The extended surgical team, with a specific focus on superficial venous interventions, proved a highly emotive subject at the Dublin ASM. Trainees are deeply concerned about the impact of any changes in the delivery of superficial venous interventions on their training. Much work since at the Executive and in Elected Council has been looking closely at the survey findings, working with the Presidents of the Allied Societies and the Rouleaux Club, and developing a strategy to move forward. This strategy will be based around a joint society working group chaired by Patrick Coughlin.

The Vascular Society published a statement to members regarding the role of Medical Associate Professionals (MAPs) within vascular multi-disciplinary teams in December:

https://www.vascularsociety.org.uk/_userfiles/pages/files/News%20resources/VS%20Statement%20on%20Medical%20Associate%20Professionals%20-%20December%202023.pdf

This statement recognised the role of Physicians Associates (PAs) within the extended surgical team but not their role as surgical practitioners. We felt this distinction is important for patient safety until regulation is in place. The drive for the recognition of vascular surgery as a speciality came from the need to improve patient outcomes though access to specialist care. We should not now move away from this principle. We must, however, acknowledge that people living with venous disease in the UK are not receiving good care. Change is needed, and it is right that we should lead on this work.

Returning to the theme of people and teams, RCS England published the findings of the UK Census of the Surgical workforce in January. We are grateful to members who took the time to complete the survey. The findings highlight changes that are needed include increased productivity, a sustainable workforce and changing the way we work. https://www.rcseng.ac.uk/standards-and-research/surgical-workforce-census/

Concerningly half of respondents had considered leaving the surgical workforce in the last year and 61% cited burnout and stress as key challenges. The Provision of Vascular Services (POVS) is due its triannual update this year. POVS 2024 will take a different approach from POVS 2021 as the Society feels that the 2021 standards still apply. This year will focus on seven key themes and the first of these will be '*people and teams*'.

Last, but no means least, the Society is proud to have launched a publication entitled *All you need to know about Vascular Surgery* co-edited by Patrick Coughlin and Lasantha Wijesinghe. The book has been developed to provide a guide for medical students, early year doctors and allied healthcare professionals. However, whilst this book has a surgical emphasis, it is also aimed at all the professionals that make the vascular community – specialist nurses, surgical care practitioners and therapists. Please encourage your students and colleagues to use this fantastic resource.

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

News from the Circulation Foundation

www.circulationfoundation.org.uk **@CircFoundation**

Firstly, I would like to thank you all for continuing to actively support the Circulation Foundation. We are pleased to start 2024 in a positive position, excited about the year ahead.

We continue work to support our 3 main aims:

- To support vital research into vascular disease
- To support individuals living with vascular disease
- To raise the awareness of the impact vascular disease has on our patients, their carers and the wider NHS

We have had our first joint CF committee meeting since the confirmed partnership agreement with the Rouleaux Club, SVN and SVTGBI. The meeting had a renewed energy with wider participation from across the MDT, a patient's relative, trainees, and other colleagues who wish to join as ambassadors. The meeting brought lots of new ideas and we will utilise the larger team to further develop the work and reach of the CF. We are so grateful for the participation of all colleagues and organisations in this.

We continue to work on the wholesale refresh of our website. This will create something more modern that we can all be proud to signpost patients, relatives, MDT colleagues, partner organisations, and corporate organisations to. In anticipation of the new website, we are well into the process of refreshing the current patient information leaflets and creating some new ones. Clearly this will be an excellent resource for all vascular units, but most importantly, our patients. The CF are extremely grateful to all colleagues who are giving their time to undertake this work.

With respect to our patient support activity, we know the self-directed exercise Infographic for Intermittent Claudication created in COVID, also relevant with a scattered provision of Supervised Exercise Programmes, is very valuable. We also know we serve an ethnically diverse population across our respective catchments. Therefore, to reduce health inequalities, this has being translated in to 15 different languages so we can support patients to self-care from a range of diverse backgrounds. They are already available as a free resource for you to use on our website and we would also encourage you to share them with your primary care colleagues.

We are grateful that we have 11 runners in the London Marathon in April and will be advertising 5 places for the Great North Run soon. Thanks to the awesome individuals involved in the London Marathon, and do consider running for the CF in the Great North Run.

I will finish with some requests for all colleagues, which are:

- Please continue to help raise our awareness and profile.
- Please do follow us on our social media platforms if you engage with them.
- The amazing CF hoodys and T-shirts are available to purchase.
- If you, or someone you know, would be willing to participate and fundraise on behalf of the CF in our events (Ride London, Great North Run, Swim Serpentine, London Marathon and Big Vitality) please do approach us.
- We have created some backgrounds for virtual meetings, so feel free to use them.

Enjoy the newsletter - all new ideas and suggestions always welcome at info@circulationfoundation.org.uk

Neeraj Bhasin
Chair, Circulation Foundation