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Editor's foreword

Welcome to the fourth issue of the *Journal of Vascular Societies Great Britain and Ireland (JVSGBI)*. We are really delighted with the response to the journal, and the interest that has been demonstrated by the number of articles that are submitted, and the stats and downloads etc. from the website.

This issue includes two editorials, the first by Ms Rachel Bell entitled *How do you solve the problem of aortic dissection?* Which discusses *The Acute Aortic Dissection Pathway Toolkit* which was published in March 2022 and is the result of collaboration between the Cardiac Getting it Right First Time (GIRFT) programme, Surgical Care Improvement Project (SCIP) for Cardiac Surgery, the Vascular Clinical Reference Group, NHSEI Specialised Commissioners and patient groups. The second editorial is by Associate Professor Philip Stather entitled *The future of exercise therapy for people with intermittent claudication?* which reviews the benefits of supervised exercise therapy (SET) for all patients with intermittent claudication. I am sure all readers will find both editorials of great interest.

There are two original research articles which publish the research priorities for the James Lind Alliance Priority Setting Partner from the Vascular Wounds and the Diabetic Food Disease groups. We hope that these priorities will guide vascular research for the future and hope other funders follow NIHR in promoting JLA identified research questions.

Included in this issue there are two further original research articles: Dr Ross Lathan has published results of a survey of surgical site infection prevention practice in UK Vascular Surgery; and Mr Brenig Llwyd Gwilym's article presents *Deprivation and supervised exercise for intermittent claudication.*

Ellis Whorlton-Jones *et al* have written a protocol for a randomised multicentre controlled trial: *Does the level of encouragement affect 6-minute walk test performance in patients with intermittent claudication?*

There is also a case report *Ilio-mesenteric bypass for chronic mesenteric ischaemia where prior endovascular treatment has failed* from Mr Ashraf Elsharkawy *et al*.

This issue is the fourth issue, and we would like to take the opportunity to thank all the reviewers of the articles over the past year – your input and expertise has been really appreciated.

Finally, I hope you enjoy this issue of *JVSGBI* and please do continue to share your work by submitting articles for publication.

Ian Chetter
Editor in Chief JVSGBI
VSGBI Research Committee Chair

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EDITORIAL

How do you solve the problem of aortic dissection?

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"The tragedies of life are largely arterial" – Sir William Osler[1]

Every vascular surgeon can remember stories of patients with aortic dissection having thrombolysis for a presumed myocardial infarction, or a V/Q scan and full anticoagulation for a likely pulmonary embolus. My most memorable story is of an international sports coach who developed tearing intrascapular chest pain during the first week of a grand slam tournament and presented to my hospital's Emergency Department twice and was sent home twice with a prescription for Gaviscon. He felt so unwell he telephoned his physician in the United States who told him he was having an aortic dissection and to immediately go to another hospital and tell the receptionist that he was having an aortic dissection. He survived to tell his story but, given that type A dissection has a 1–2% mortality per hour within the first 24 hours, it was luck rather than excellent healthcare that saved his life.[2] Whilst mortality rates are lower for acute type B dissection, they still reach 10% at 30 days.[3] In short, aortic dissection is dangerous, carries a significant fatality rate and deserves a higher profile.

Stories from patients and relatives about their experience of aortic dissection are often a catalogue of delays in diagnosis, imaging and treatment. Add to that the patients who die from their pathology without ever meeting the specialists who might have been able to help them, and you realise that we have a problem that needs fixing.

Aortic dissection is the commonest aortic emergency, with an incidence of six cases per 100,000 per year. Whilst that might be the case, it seems that we don't educate medical students and doctors in a way that makes them remember that it is one of the differential diagnoses for acute chest pain. The patient charities have worked hard to improve awareness with their 'THINK AORTA' campaign and have badgered and sent mailshots to every emergency department, Member of Parliament and Health Secretary for the last few years to try and get their message across. Aortic Dissection Awareness UK & Ireland and The Aortic Dissection Charitable Trust actively support patients and families affected with this condition and have campaigned tirelessly to drive change in the system to make it safer and more responsive.

As a medical professional who signed up to make people better, I have long thought that we could improve the care for this group of patients by being better educated, more aware and simply organising national pathways for acute aortic syndromes (type A dissection, type B dissection, non-A – non-B dissection, intramural haematoma and penetrating aortic ulcers). I know that the mention of system change in the NHS makes many clinician's blood run cold, mainly because it is damned hard work to effect change and that change is often poorly led and resourced. However, when it is done well, like with the organisation of major trauma services in England, it resulted in a 19% reduction in mortality despite an almost 50% increase in transfer time.[4]

The Acute Aortic Dissection Pathway Toolkit was published in March 2022 and is the result of collaboration between the Cardiac Getting it Right First Time (GIRFT) programme, Surgical Care Improvement Project (SCIP) for Cardiac Surgery, the Vascular Clinical Reference Group, NHSEI Specialised Commissioners and the patient groups mentioned above. The complexity and breadth of aortic dissection mean that you need a multidisciplinary team with participation and input from many specialties to produce a

Key words: acute aortic dissection, type B, type A, clinical pathways, diagnosis, inter-hospital transfer

comprehensive document. The toolkit recognises the main driver for change is published unwarranted variation around the UK in the provision of treatment for conditions of the thoracic aorta.[5] The aim of the toolkit is to help regions work across organisations to ensure equity of access to specialist services and improve outcomes for patients. There are examples in the toolkit of teams that have already redeveloped their pathways and have seen operative mortality halve and length of stay reduce for acute type A aortic dissection.[6]

The document sets out seven important principles for the development and sustainability of a regional pathway for aortic dissection. They are regional governance and leadership, development of a multidisciplinary team and meeting, a published regional rota and single point of contact, timely and reliable image transfer, safe inter-hospital transfer, specialist treatment for all acute aortic dissections and development of a regional education programme. It empowers regions to develop a model for their area that works for their unique geography and workforce, hence the document is not prescriptive. The principles remain important and should underpin any proposed changes, the aims being to improve outcomes for patients by harnessing regional skill mix to benefit the maximum number of patients, improving governance, encouraging regular multidisciplinary team working and educating doctors and paramedics to equip them to diagnose acute aortic emergencies rapidly and consistently. Data collection and audit of performance and outcomes are part of the regional governance and will be the drivers for research and continuous improvement in the development of the service in the long term. One of the positives of the ongoing COVID-19 pandemic is that we are all familiar with video conferenced meetings and this will facilitate regional meetings for discussion and the setup of regional multidisciplinary meetings. Pragmatically, the toolkit comes with many examples of protocols that have been shared by different organisations and it encourages plagiarism and adaptation by regional groups for their own use to take away the pain of writing something from scratch, including the THINK AORTA campaign trigger cards which can be individualised for each aortic centre with the single point-of-contact phone number.

The nay-sayers amongst you will criticise that this is not a service specification, does not mandate the transfer of all patients with acute type B dissection to a specialist centre, comes with no resource and no mechanism for ensuring the maintenance of good standards of care. These are valid points and may lead to further iterations of the toolkit once we have more data, particularly for those patients with type B aortic dissection who are treated medically and are currently difficult to count without a specific OPCS code.

This is a call to arms to ask you all to participate in developing a safe, comprehensive, responsive regional service for the management of patients presenting with aortic dissection. The Vascular Society and the Society for Cardiothoracic Surgery in Great Britain and Ireland fully support this project and are committed to making improving national aortic dissection pathways. So let's make it a good day everyday for these patients and their families. Call me an idealist, but I dream of a day where the patient reaches me within hours of a correct diagnosis, with seamless transfer of images and an ability to have an informed multidisciplinary conversation to determine their optimal treatment. Nirvana you may scoff, but this is a problem worth solving.

Get your copy of the Acute Aortic Dissection Pathway Toolkit here.

Conflict of Interest: None.

Funding: None.

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EDITORIAL

The future of exercise therapy for people with intermittent claudication?

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National Institute for Health and Care Excellence (NICE) guideline 147 recommends supervised exercise therapy (SET) for all patients with intermittent claudication, consisting of 2 hours of SET per week for a 3-month period.[1] This is supported by good evidence from Cochrane reviews[2,3] that SET shows improvement in mean walking performance compared with home-based exercise and walking advice, with an increase of 120–210 metres, and also has comparable results to endovascular revascularisation. Despite this evidence and the guidance from NICE, the provision of SET is variable with <50% of UK hospitals providing SET and <25% meeting the NICE dose recommendation.[4] With centralisation of services into a hub and spoke model, the spokes are likely to have inferior access to SET. Furthermore, attendance and uptake rates to SET are often less than 25%.[5] Barriers associated with provision and uptake include access, time, travel and pain.

To help meet best practice recommendations, reduce unnecessary interventions and improve mobility and quality of life, innovations in practice are required. One example in recent practice is the integration of patients with peripheral arterial disease into cardiac rehabilitation. This helps to make exercise more accessible to a larger number of people. More recently, application of remote monitoring through regular telephone consultations, mobile technology and fitness trackers has become more attractive due to the COVID-19 pandemic. Remote monitoring can help deliver exercise therapy and provide feedback directly to healthcare professionals in order to monitor adherence. It may also help identify people with deteriorating symptoms who may require more invasive intervention. The use of these approaches can provide direct streamlined communication with patients, potentially reducing delays to presentation and minimising the need for outpatient appointments.

Recent work has investigated the potential use of remote monitoring techniques. The REmotely Supervised Exercise Therapy Trial (RESET2) pilot trial[6] is currently recruiting and compares the use of electronic walking logs with and without fortnightly video calls with a physiotherapist. The Motivating Structured walking Activity in people with Intermittent Claudication (MOSAIC) trial[7] compares standard care to a brief physiotherapist-led walking behaviour change programme that includes 2x60 minute face-to-face sessions and 2x20 minute phone calls with pedometers delivered over 12 weeks. Each session is underpinned by a motivational interviewing approach and incorporates behavioural change principles (goal setting, action planning and relapse prevention). The PrEPAID trial[8] investigates the effect of patient-centred education and pain management using electrical stimulation intervention, incorporating motivational interviewing techniques, goal setting, activity tracking and remote monitoring through regular telephone calls.

A recent meta-analysis including 23 studies and 1907 participants compared supervised exercise, home exercise and non-exercise controls.[9] Whilst home-based programmes still appeared to be inferior to supervised programmes in terms of improving maximal walking distance, this was removed when a sensitivity analysis was included to determine the impact of monitoring. It further demonstrates the applicability of using monitoring to deliver successful home-based interventions in this population.

Key words: remote monitoring, exercise therapy, innovation

Accordingly, a number of dedicated mobile applications have also been developed for individuals with peripheral arterial disease. TrackPAD showed an improvement over standard care, and increased walking distance by 83 meters compared with an average reduction of 38.8 metres.[10] JBZetje is a Dutch app that provides remote monitoring with direct feedback to clinicians.[11] The CONTECI programme, aimed at using mobile technology to empower patients through education, reduces time to diagnosis of complications and improves quality of life and patient satisfaction.[12] Lastly, VascTrac is being considered in the USA[13] using iPhones to monitor overall physical activity and also includes specific walk tests. Whilst mobile applications appear promising, the quality and access to digital services may be limited by patient and clinician digital literacy, variable internet connectivity, technological issues such as National Health Service firewalls and data governance. Crucially, some patients may not have access to equipment or internet services, leading to digital exclusion and potentially creating health inequalities.

In conclusion, with healthcare systems promoting patient empowerment, innovations in practice that incorporate remote monitoring and reductions in face-to-face appointments are essential. The use of wearable technology, mobile phone applications and video consultations is increasing, with direct connectivity to healthcare professionals an imperative component of this pathway. These innovative technologies require further development to incorporate behaviour change techniques and supported exercise classes, followed by integration into safe care pathways. The future of exercise therapy is not one size fits all. A range of options including face to face SET, behaviour change interventions, wearable technology and/or mobile phone applications should be provided to incorporate patient preferences, optimise access and improve health outcomes.

Conflict of Interest: PWS has set up Walk-A-Cise Ltd to develop an exercise therapy mobile phone application.

Funding: None.

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ORIGINAL RESEARCH

Research priorities for vascular wounds: results of the Vascular Society GBI/James Lind Alliance Priority Setting Process

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Plain English Summary

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

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

What we found: A total of 481 health care professionals and 373 patients or carers submitted research priorities about vascular conditions, which were consolidated into a final combined list of 15 priorities specifically about vascular wounds. At a final workshop involving patients, carers and clinicians, these priorities were put into a 'top 10' list ranked according to perceived importance. Research priorities relate to: improving wound healing and preventing infection, involving patients more in their own treatment and care, finding better methods for assessing and managing wounds.

What this means: The most important research priorities for vascular wounds have been identified. Researchers and funders are encouraged to focus on addressing these priorities and supporting studies in these areas.

Abstract

Background: The management of vascular wounds is often a complex and prolonged process that impacts individuals' quality of life, is challenging for clinicians and results in a significant financial burden to the NHS. UK wound care practices vary considerably perhaps because guidelines and treatment options are frequently based on low levels of clinical and cost effectiveness evidence. Therefore, further research is required but capacity is limited and funding is highly competitive. To address this issue, the Vascular Society of Great Britain and Ireland (VSGBI) in association with the James Lind Alliance (JLA) undertook a national Priority Setting Process (PSP) for vascular conditions. This paper presents the results of this process, with a focus on the topic of 'vascular wounds'.

Methods: A modified JLA PSP was implemented in three overarching phases: (1) a clinician-led survey to gather clinician research priorities; (2) a patient and carer-led survey to gather patient and carer research priorities; and (3) a consensus workshop to discuss clinician and patient priorities and agree a list of joint research priorities. Consensus was achieved using nominal group technique and a ranked 'top 10' list of research priorities for vascular wounds was established.

Results: In the first phase (clinician-led survey), 481 clinicians submitted 1,231 research questions related to vascular conditions in general. Of these, 36 wound-specific research priorities were reduced to three overarching summary questions recirculated for interim scoring. In the second phase (patient and carer-led survey), 373 patients and carers submitted

582 research priorities. Of these, 12 priorities were identified and recirculated for interim scoring. In the third phase (consensus workshop), clinician and patient priorities were amalgamated into 15 priorities for discussion. The final top 10 list of vascular wounds research priorities relate to: improving wound healing and patient quality of life, prevention of infection, assessment and diagnosis, personalised treatment and improving communication.

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

Key words: vascular, wounds, research, priorities

Background

In the UK, approximately 3.8 million people live with a wound at an estimated cost of £8.3 billion per year to the NHS, with this figure expected to rise in the future.[1,2] Additionally, complications like delayed healing, infection and deterioration of other comorbidities are known to have a detrimental impact on patients' quality of life and increase the overall societal socioeconomic burden related to wounds.[3,4]

Fundamental questions about wound healing and the mechanisms of wound repair remain unanswered, and this has led to inconsistencies in wound care practice across the UK.[5,6] Despite a wide range of treatment options and clinical practice guidelines, evidence to support effectiveness is often limited and under-researched.[7–10] These issues have been recognised by NHS England and NHS Improvement who have established the National Wound Care Strategy Programme.[11]

In order to ensure optimal wound management, more research is needed; however, funding is limited and highly competitive. Funding bodies need to ensure their limited investment is directed to areas with the greatest potential for improving clinical services and health outcomes, whilst avoiding research waste.[12] Priority Setting Processes (PSPs) are an increasingly popular methodology to address this issue. They systematically identify and prioritise research gaps and are seen as an effective way of highlighting important topics for funding consideration.[13]

The Vascular Society of Great Britain and Ireland (VSGBI) initiated a national PSP for vascular conditions in association with the James Lind Alliance (JLA) who specialise in facilitating patient involvement in research.[14] Prior to this there was no agreement for research priorities within the vascular specialist community. A rapid PSP for wound care uncertainties undertaken in 2017 produced a list of 25 wound care uncertainties but did not include any patient or carer perspectives.[15] The aim of the Vascular PSP was to survey vascular health professionals, patients and carers to identify and prioritise the most important research priorities. This paper presents an overview of the vascular condition PSP, focusing on the recommendations for wounds-related priorities and implications for future research in this area.

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

Vascular PSP Special Interest Groups (SIGs)		
Access	Amputation	Aortic
Carotid	Diabetic foot	Peripheral arterial disease
Service organisation*	Venous	Wounds

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

Methods

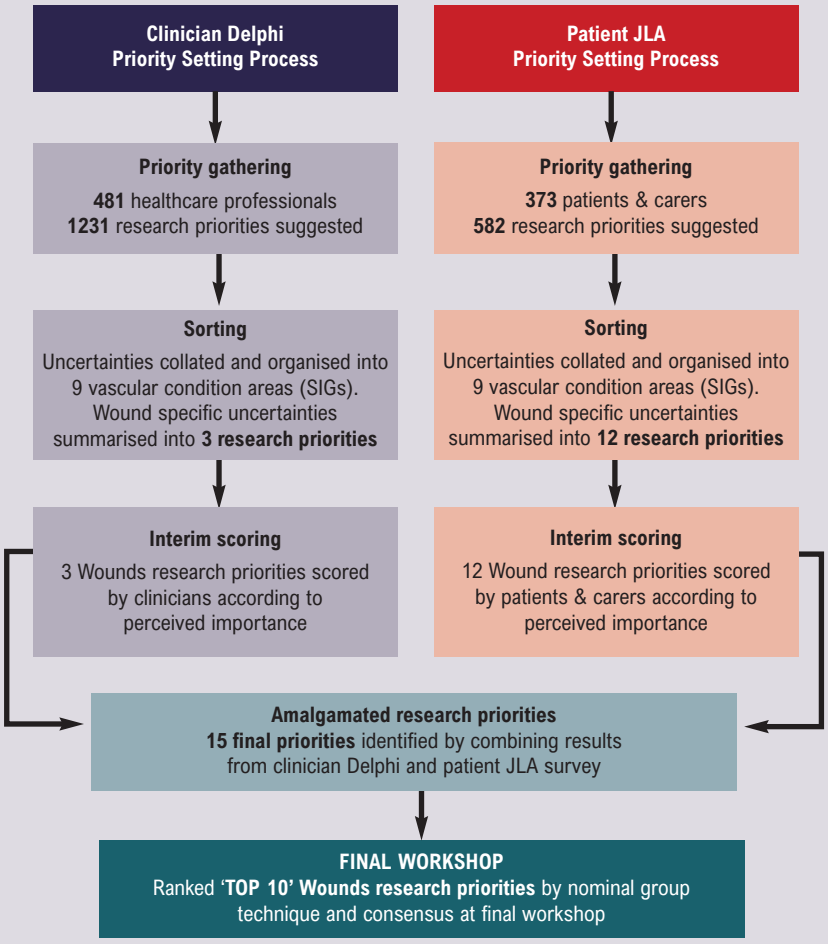
The VSGBI undertook a research PSP in association with the JLA to identify research priorities for vascular conditions. The work was overseen by a steering committee involving representation from all the leading UK Vascular Societies and patients. Nine overarching vascular condition Special Interest Groups (SIGs) were established to help support the process and ensure that each area retained their important research priorities (Table 1). A detailed description of the process has been provided previously.[16–21] A summary of the process is outlined below and presented in Figure 1.

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

Scope of the Wound SIG

The remit of the Wound SIG is to support research into the care of patients living with or affected by vascular wounds and the services that surround treatment and management of wounds. The Wound SIG aims to develop this list of top 10 priorities into funded wounds research studies that address these important areas.

Figure 1 Flowchart of the Vascular Priority Setting Process (PSP).



Clinician-led research Priority Setting Process

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

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

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

Patient/carer-led research Priority Setting Process

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

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

Survey Round Two: The refined list of priorities was redistributed in a second survey for scoring. Participants were invited to rate the importance of research priority using a Likert scale (scores ranged from 'not at all important' to 'extremely important'). This process was completed in 2021 and the results of patient and carer wounds-related priorities are summarised in Table 3.

Special Interest Group Prioritisation Workshops

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

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

Research priority	Mean Score
What is the most effective way to manage mixed aetiology/hard to heal/complex leg ulcers?	8.04
Can we optimise wound healing in vascular patients?	7.77
How can we reduce surgical site infection in vascular surgery?	7.68

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

Research priority	Mean Score
How can we accelerate healing of open wounds?	4.71
How can we improve quality of life in patients with open wounds?	4.56
How can we prevent open wounds becoming infected?	4.33
What is the best way to debride (remove dead or unwanted material) from wounds?	4.25
Which dressings are best for open wounds in specific situations?	4.22
How can we personalise wound care to meet patient circumstances or needs?	4.11
How can we improve consistency in assessment, diagnosis and management in patients with wounds?	4.08
How can we improve patient involvement in the decisions about their wounds?	4.06
How can we improve communication between clinicians in wound care services?	4.09
How can we improve communication with patients with wounds?	3.92
How can we reduce wound odour?	3.81
Which service configuration is associated with the best outcomes in wound patients?	4.09

The final prioritisation workshop for Wounds was conducted virtually on 18 May 2021 using the Zoom platform to accommodate COVID-19 restrictions. All attendees (including healthcare professionals, patients and carers) were recruited via direct contact or were approached if they expressed an interest during the initial prioritisation process. Participants were sent details of the workshop, an agenda and a list of the research priorities to be discussed in advance. Prior to the workshop, participants were asked to consider the combined list of clinician and patient research priorities shown in Table 4 and to rank them in order of importance from 1 (most important) to 15 (least important).

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

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

A	How can consistency in assessment, diagnosis and management in patients with wounds be improved?
B	How can wound odour be reduced?
C	How can communication between clinicians in wound care services be improved?
D	What is the best way to debride (remove dead or unwanted material) from wounds?
E	How can surgical site infection in vascular surgery be reduced?
F	How can wound care be personalised to meet patient circumstances or needs?
G	What is the best way to manage complex, hard to heal leg ulcers?
H	How can wound healing be optimised in vascular patients?
I	How can patient involvement in the decisions about their wounds be improved?
J	How can wounds be prevented from becoming infected?
K	Which service configuration is associated with the best outcomes in wound patients?
L	How can healing of open wounds be accelerated?
M	How can communication be improved with patients with wounds?
N	Which dressings are best for open wounds in specific situations?
O	How can quality of life be improved in patients with open wounds?

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

Second round of discussion: The JLA facilitator presented on screen a potential order of questions based on initial feedback and discussion. Participants had an opportunity to reconsider their initial placement of priorities whilst the facilitator moved priorities on screen, to reflect an agreed order of priorities 1–15.

Third round of discussion: The ranked priorities of the two separate groups were combined by the lead facilitator using a geometric mean of the respective ranked positions. All participants came together as one group and the lead facilitator presented the combined results of the group rankings. Again, participants had an

opportunity to reconsider the order of priorities before reaching a final ranked top 10 list of wounds research priorities.

Results

Clinician research priority identification and prioritisation

A total of 481 clinicians submitted 1,231 research priorities relating to vascular surgery in general. Thirty-six wounds-related research priorities were submitted, 17 of which were excluded outright as they were too specific to single patient experience or there was no apparent question (eg. nonsensical or broad statement). The remaining 19 priorities were combined and summarised into three clinician priorities for scoring, the results of which are shown in Table 2.

Patient/carer research priority identification and prioritisation

A total of 373 patients/carers suggested 582 research priorities related to vascular surgery in general, of which nine responses were specific to wounds. After data cleaning (eg, removing nonsensical suggestions, separating out submissions with multiple suggestions and combining overlapping priorities), 12 research priorities were redistributed for scoring and the results are shown in Table 3. Prior to the workshop, the SIG team pooled clinician and patient/carer research priorities, resulting in a list of 15 for discussion (Table 4). In order to reduce risk of bias, these priorities were randomly ordered and each assigned a letter (rather than a number).

Final prioritisation workshop

The final prioritisation process was conducted via a virtual online meeting on 18 May 2021. It was attended by three patients and carers and five healthcare professionals (specialist vascular nurses, podiatrist, vascular surgeon) with four observers. The final prioritisation resulted in a final top 10 research priority list (Table 5). The priorities are ordered according to importance as determined at the workshop. There was general consensus that the list correctly represented the discussions and viewpoints which occurred in the breakout groups. Results from the participant feedback indicated that 100% agreed or strongly agreed that the process for determining the top 10 priorities was robust and fair.

Discussion

The top 10 research priorities for UK vascular wounds research have now been established. Using a modified JLA methodology, vascular healthcare professionals and patients with lived experience of wounds have jointly agreed the most important priorities for future research in this area. The five priorities that did not make the ranked top 10 list are still considered important.

Overarching themes within the final top 10 list relate to improving wound healing, patient quality of life, prevention of infection, assessment and diagnosis, personalised treatment and better communication with clinicians.

Table 5 Final ranked top 10 list of vascular wounds research priorities.

Ranking	Question
1	How can patient involvement in the decisions about their wounds be improved?
2	How can healing of open wounds be accelerated?
3	How can quality of life be improved in patients with open wounds?
4	How can wound care be personalised to meet patient circumstances or needs?
5	Which service configuration is associated with the best outcomes in wound patients?
6	How can communication between clinicians in wound care services be improved?
7	How can consistency in assessment, diagnosis and management in patients with wounds be improved?
8	How can wounds be prevented from becoming infected?
9	How can wound healing be optimised in vascular patients?
10	How can communication be improved with patients with wounds?

Strengths and limitations

The Vascular PSP used well established methodologies throughout, with oversight from a multidisciplinary steering committee. The Delphi method, often used in PSPs, is regarded as a flexible research technique but one that tends to focus on the identification of expert opinion.[22] To mitigate this, the Vascular PSP sought the input of the JLA who provide a transparent and structured framework that emphasises patient participation in PSPs, with patients having an equal voice to clinicians and researchers in influencing the research agenda.[23,24] It is possible that the modified approach of having two separate processes before bringing the clinician and patient views together may have resulted in a different top 10; however, during the amalgamation process there was already plenty of overlap with similar questions and the format of the final workshops did establish shared priorities.

Due to the nature of survey data collection there is potential for responder bias,[25] and consideration was given to whether responses would be adequately reflective of the opinions of people with lived experience of wounds and those treating them. Underrepresentation is a well-recognised limitation of many PSPs,[26,27] and the implications are that there may be potentially relevant priorities not submitted and consequently not considered within the analysis. The Vascular PSP sought to minimise this risk in a number of ways. The survey was made available in electronic and hardcopy format (with freepost address), and it was promoted via a number of platforms with the help of affiliated charity groups and organisations who regularly work with the population targeted for input. Furthermore, the introduction of SIGs meant that each vascular condition area had a dedicated review of responses by a group of interested professionals and patients who could highlight if there were any expected topic areas missing.

KEY MESSAGES

- A total of 15 research priorities relating to vascular wounds were considered by a group of patients, carers and healthcare professionals.
- Working with the James Lind Alliance, a final list of the 'top ten' most important wounds research priorities for patients and vascular health professionals have been established.
- Wounds priorities broadly encompass research aimed at improving wound healing, prevention of infection and better methods of and diagnosis and communication.

Most workshop participants found the use of a virtual platform acceptable, although it is recognised that potentially lack of access to IT may have limited participation and altered representation. On the other hand, the virtual platform meant patients did not have to travel, and this may have made the workshop more accessible for some patients. Positive comments collected from the feedback survey following the final workshop demonstrated that clinicians and patients found the process of discussing priorities in mixed groups a positive and worthwhile experience. It gave participants an opportunity to hear about the experiences of others and to reassess their initial judgements.[28] Although the mixed discussion groups were not strictly balanced in terms of patient attendance, this was carefully moderated through the skilled JLA facilitators who ensured that patient participants were regularly included and asked for their views. Some participants expressed a preference for a different ranking order of the priorities, but this is not uncommon for PSPs and is a known factor of a consensus approach.

Implications for future research

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

Conclusion

The Vascular PSP has established a top 10 list of priorities for UK wounds research, from the shared perspective of vascular patients, carers and health professionals. Researchers and funders can confidently invest resources into these areas of wounds research with reassurance that they are clinically relevant and of practical importance.

Conflict of Interest: ICC is the Editor-In-Chief of the *JVSGBI*. Co-author TG was the lead JLA advisor for the Vascular PSP and was paid to Chair the Steering Committee for the project.The other authors declare no conflicts of interest.

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ORIGINAL RESEARCH

A survey of surgical site infection prevention practice in UK vascular surgery

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Plain English Summary

Why we undertook the work: Wound infections after surgery cause a multitude of problems for patients ranging from minor to major illness, including death in some instances. Understandably, this affects one's ability to function day to day both physically and mentally. Further, all these unwanted problems incur additional costs to the NHS. Various measures can be taken to potentially reduce the chances of an infection after surgery, but the strength of the evidence supporting these measures is inconsistent. Previous research highlighted that the preventive measures varied from one hospital to another, and since this work, several guidelines have been produced to try to standardise these preventive measures. However, it is not known whether these guidelines have led to conformity between hospitals. We therefore aimed to survey vascular surgeons to understand their current practice for implementing measures to prevent wound infection.

What we did: We identified 15 interventions aimed at reducing wound infection after surgery from the three guidelines published from international bodies (the World Health Organisation, National Institute for Health and Care Excellence, and Centers for Disease Control and Prevention). A focus group consisting of experts in vascular surgery then constructed a questionnaire survey that would capture practice pertaining to these 15 areas. The survey underwent two rounds of validity testing in one hospital with 10 consultants in vascular surgery, before being sent to all the membership of the Vascular Society's.

What we found: Responses were received from 109 surgeons from 47 hospitals across the UK, giving a response rate of 24%. Surgeons estimated that 7.5% of patients get wound infections after surgery. Operations involving arteries in the legs or major lower limb amputation were identified as at highest risk of infection. About half (52% of respondents) diagnose infections using their experience alone rather than recognised criteria. When cleaning the skin before an operation, more than half (57%) use chlorhexidine and 78% prefer to use an alcohol-based solution. However, the majority of surgeons (79%) prefer to use an aqueous-based solution to clean their own hands before surgery. After surgery, 74% of surgeons do not have a dedicated programme in place to monitor wounds in case of infection.

What this means: Despite three international bodies producing guidance to prevent wound infections after surgery, the practice in vascular surgery remains varied, perhaps reflecting inconsistency between guidance recommendations. Further high-quality evidence is needed to assess the effectiveness of individual interventions to reduce the incidence of wound infections after vascular surgery. The impact of this evidence should then be maximised to develop up-to-date guidance and minimise variability in practice.

Abstract

Background: Surgical site infections (SSI) have a significant impact on morbidity and mortality within vascular surgery. Despite the publication of several guidelines, there is a lack of consensus regarding the most effective perioperative practice to minimise the incidence of SSI. This study aimed to assess the current practice of SSI prevention among UK vascular surgeons.

Methods: An online survey developed using the current National Institute for Health Care and Excellence (NICE), Centers for Disease Control and Prevention (CDC) and World Health Organisation (WHO) SSI prevention guidelines was piloted in a tertiary vascular centre before being distributed by email to the members of the Vascular Society of Great Britain and Ireland. The survey contained 15 question domains across preoperative, perioperative and postoperative phases to establish current SSI prevention practice. The survey was open for 1 month with reminder emails at 2 and 3 weeks.

Results: A total of 109 respondents from 47 UK hospitals completed the survey, 90 of which were consultants (82.6%). The median reported SSI rate was 7.5% (IQR 5–10%). Lower limb

arterial and major limb amputations were highlighted as the highest risk procedures of SSI. Empirical criteria are used by 67.2% of respondents to diagnose SSI, and over half (52.2%) of surgeons used this alone. Most respondents use alcoholic chlorhexidine gluconate (69.6%) skin preparation and basic wound dressings (67.6%). Around half (52.5%) of respondents reported that they would use negative pressure wound therapy for closed wounds. Formal wound surveillance was not undertaken by 73.7% of respondents.

Conclusions: There is little agreement in current guidelines on the best practice to prevent SSI. Unsurprisingly then, clinical practice follows suit and continues to show little consensus on prevention measures used. There also appears to be a disparity in registry level, clinical perception and literature data for SSI rates. Well-designed high-quality trials are needed to provide evidence-based recommendations in this field.

Key words: surgical site infections (SSI), vascular, survey

Introduction

Surgical site infections (SSI) are a common complication following vascular surgery, with significant detrimental effects for patients and healthcare providers.[1] Reported SSI rates vary, but may be as high as 40%.[2] This high rate is due to vascular surgical patients often being elderly, smokers and diabetics, frequently having multiple long-term conditions. Undesirable physical sequelae of SSI include pain, immobility, scarring, prolonged hospital stays and additional visits to clinics or from community services.[3] SSI also inflict a heavy psychological burden, such as with social isolation due to odour and weeping being reported by patients as 'embarrassing' and leaving them in 'utter despair'.[4] Unsurprisingly, SSI are associated with depressive features, particularly with the chronicity of SSI-related illness.[4,5] Vascular patients suffering from SSI incur greater length of stay, with those with infected amputation sites residing on average for 21 days compared with 3.3 days for those with infected abdominal hysterectomy.[6] This concomitant increase in morbidity and prolonged hospitalisation has an adverse impact on health-related quality of life[7] and survival. Furthermore, postoperative wound infections are detrimental to the surgeon-patient relationship.[8] Moreover, healthcare systems sustain substantially elevated costs.[9,10] Recent cost analysis in patients undergoing vascular surgery estimated the additional cost at £3,776 per SSI event.[11]

Prior research has demonstrated a significant variation in reported SSI rates and perioperative management of patients undergoing major lower limb amputations.[12] In recent years, key organisations have published updated guidelines on SSI prevention.[13–15] It is unclear whether the introduction of these SSI prevention recommendations has resulted in widespread implementation.

Aiming to establish current clinical practice in the prevention of SSI within UK vascular surgery, our group designed, validated and distributed an online questionnaire regarding SSI prevention practice to the membership of the Vascular Society of Great Britain and Ireland. The insights gained from expert responses are reported in this paper.

Methods

The steering group for this study consisted of a professor, a consultant vascular surgeon, an academic clinical lecturer, a specialty trainee and a research fellow. The steering group coordinated the questionnaire development, validation, distribution and analysis.

Questionnaire development

SSI prevention guidelines from the National Institute for Health and Care Excellence (NICE), Centers for Disease Control and Prevention (CDC) and World Health Organisation (WHO) were analysed to identify 15 preventive measures forming the basis of survey question synthesis. Each guideline was also evaluated as to the level of recommendation for all SSI prevention measures to establish a rudimentary utility of the current strategies (Table 1). Survey questions for each of the 15 SSI prevention domains were discussed with the steering group, resulting in the addition of two further domains (type of sutures and post-discharge wound surveillance) and the removal of a single domain (surgical gloving) as little variation was anticipated. All decisions required unanimous agreement amongst the steering group members. Additionally, questions were reviewed to ensure wording was succinct, clear and unambiguous.

Questionnaire validation

A preliminary survey of 34 questions across 16 SSI prevention domains, including a range of binary, multiple choice and free-text open-ended questions, was validated through two rounds of piloting at a tertiary vascular centre with 10 consultants. After round 1, major (questions removed or added) and minor alterations (wording alterations) were made based on the feedback from the consultant body. Major alterations included two questions rationalised into one on three occasions, the removal of six questions and the addition of five questions. The reasons for major alterations included a lack of utility, repetition, a desire to minimise respondent fatigue, and an attempt to ensure all SSI prevention strategies were addressed. Ten minor alterations were made to wording or responses of questions. After the second pilot, no further changes were suggested.

Table 1 Recommendations from current surgical site infection prevention guidelines.

SSI prevention measure	WHO 2018	CDC 2017	NICE 2019
Pre-operative bathing	Research needed	Research needed	Recommends use
MRSA eradication/testing	Research needed	Recommends against use/not mentioned	Research needed
Surgical antibiotic prophylaxis (SAP)	Research needed	Research needed	Recommends use
Surgical site hair removal	Research needed	Recommends against use/not mentioned	Recommends against use/not mentioned
Surgical site preparation	Research needed	Research needed	Research needed
Surgical handwashing	Research needed	Recommends against use/not mentioned	Recommends use
Enhanced nutritional support	Research needed	Recommends against use/not mentioned	Recommends against use/not mentioned
Normothermia	Research needed	Research needed	Recommends use
Blood glucose	Research needed	Research needed	Recommends against use/not mentioned
Incisional wound irrigation	Research needed	Research needed	Recommends against use/not mentioned
Prophylactic NPWT	Research needed	Recommends against use/not mentioned	Recommends against use/not mentioned
Antimicrobial sutures	Research needed	Recommends against use/not mentioned	Research needed
Prolonged SAP	Research needed	Recommends against use/not mentioned	Recommends against use/not mentioned
Dressings	Research needed	Recommends against use/not mentioned	Recommends use
GICS	Recommends against use/not mentioned	Recommends against use/not mentioned	Research needed

CDC, Centers for Disease Control and Prevention; GICS, gentamicin impregnated collagen sponge; NICE, National Institute for Health and Care Excellence; MRSA, methicillin-resistant *Staphylococcus aureus*; NPWT, negative pressure wound therapy; SSI, surgical site infection; WHO, World Health Organisation.

Questionnaire distribution

The online survey was disseminated using Qualtrics XM platform™ software. Demographic data collection included background information (working grade and current hospital of practice) and the presence of a generic SSI policy within the unit (National Vascular Registry (NVR) submission, diagnostic criteria, infection rates, high-risk procedures and active SSI prevention policy). Participants were advised their responses would be anonymised.

The final survey was distributed between 15 March and 12 April 2021 via email, inviting surgeon and trainee members of the Vascular Society of Great Britain and Ireland to participate. One month was allowed for responses with reminder emails circulated at 2 and 3 weeks.

Questionnaire analysis

Responses were scrutinised by the lead researcher and non-response questionnaires removed. Partially completed questionnaires were included. Only answers submitted within the response window were included in the analysis. Completed questionnaires were exported into Microsoft Excel Version 16.59. Binary responses were reported as percentages and multiple-choice answers were expressed as percentages of the specific question's respondents. Median reported SSI estimates are presented alongside interquartile ranges. Responses including 80% or more in one item were taken as good levels of agreement for use of that practice. A χ^2 test was completed where appropriate in SPSS version 27 (IBM Corp, Armonk, New York, USA) to determine the impact of variables on estimated SSI rates and a regression analysis performed. In the interest of the statistical analysis, infection rates were subdivided above and below the median reported infection rate. Estimated SSI rates collected from the survey were compared with the nationally reported rates from the NVR 2019 (with permission).

Results

Survey responses

A total of 109 respondents completed the survey, with the majority (n=90, 82.6%) identifying they were in a consultant role. Other positions included specialty registrar (n=14, 12.8%), core trainee (n=3, 2.8%) and not specified (n=2, 1.8%). Based on numbers of consultants registered with the Vascular Society (n=376), this is approximately a 24% response rate. Survey responses came from a total of 47 hospitals with a wide distribution across the UK, as shown in Figure 1. The majority of respondents (58.7%, n=62) primarily worked in a university hospital and 41.3% (n=43) in a district general hospital.

Infection rates

The median estimated SSI rate was 7.5% (IQR 5–10%). Twenty respondents (18.3%) reported SSI rates ≥10%. Empirical criteria alone were used to diagnose SSI by 35 (52.2%) respondents (Figure 2). Lower limb arterial and major limb amputation were identified as high-risk procedures for SSI (n=58, 92.1% and n=47, 74.6% of responses, respectively). All units routinely submitted data to the NVR and 62.7% (n=47) had a dedicated SSI prevention protocol.

Preoperative measures

Preoperative bathing

Preoperative bathing was recommended to patients by 67.1% (n=49) of clinicians, with the majority indicating standard soap as the agent of choice (54.9%, n=28). Chlorhexidine gluconate (CHG) soap, CHG cloths and other agents (Betadine, n=1; Hibiscrub, n=1; Octenisan, n=2; Stellisept, n=1) were recommended by 29.4% (n=15), 5.9% (n=3) and 9.8% (n=5), respectively. Reasons given for not advocating preoperative bathing include: not necessary (14.7%), a lack of evidence base (50.0%) and a lack of capacity to provide (23.5%). Four surgeons indicated that they used to recommend preoperative bathing but, as they now admit elective patients on the day of surgery, this is not possible.

Methicillin-resistant Staphylococcus aureus (MRSA) screening

Preoperative MRSA screening was practised by 93.3% (n=56) of vascular surgeons. Reasons for not screening patients included a lack of supportive evidence and a lack of staff or time resource capacity. For patients colonised with MRSA, the majority of responders provide treatment with both intranasal mupirocin and CHG body wash (66.1%, n=39). Intranasal mupirocin alone is used in 16.9% (n=10) and CHG body wash alone in 5.1% (n=3) of cases.

Figure 1 Distribution of survey responses.

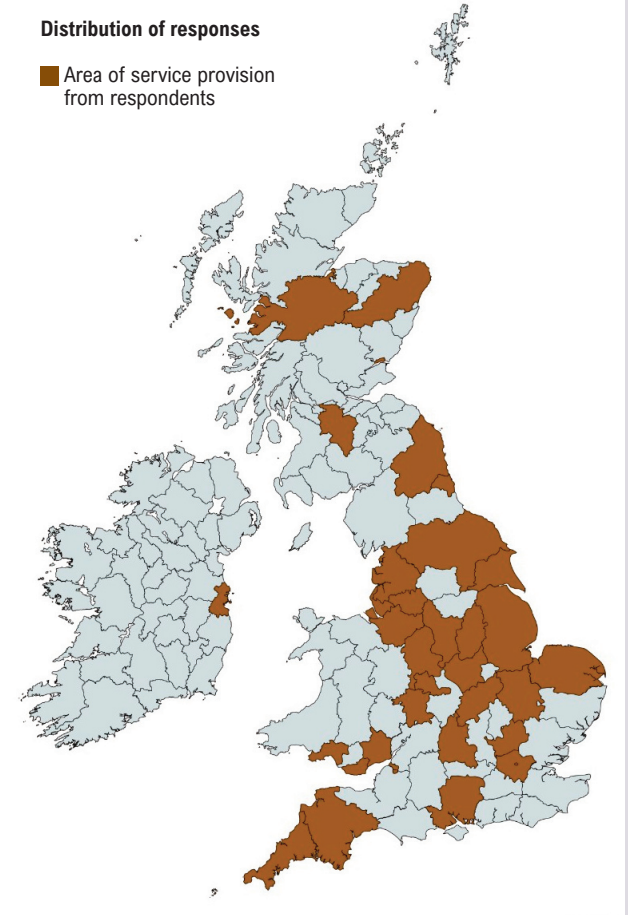
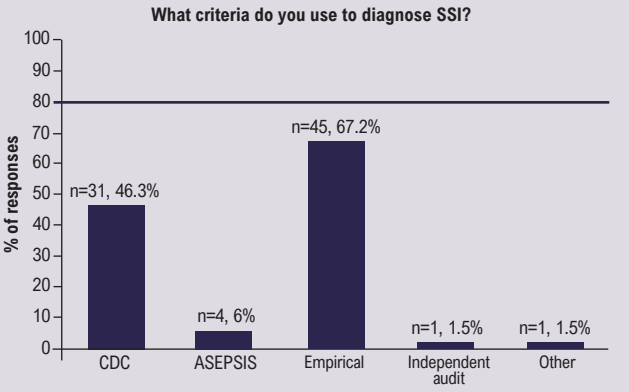


Figure 2 Surgical site infection (SSI) diagnostic criteria used.



CDC, Centers for Disease Control and Prevention

Surgical antibiotic prophylaxis (SAP)

The majority of surgeons use SAP for open abdominal aortic aneurysm (AAA) repair (95.5%, n=64), lower limb arterial disease (94.0%, n=63), major limb amputation (92.5%, n=62), endovascular aortic aneurysm repair (89.6%, n=59), carotid endarterectomy (89.6%, n=58) and minor limb amputation (77.6%, n=52) procedures. Antibiotic prophylaxis is used by less than one-third of surgeons in peritoneal dialysis catheter (26.9%, n=18), open venous (20.9%, n=13) and arteriovenous fistula (13.4%, n=7) procedures. This was a multiple response question; some respondents did not indicate use of antibiotics prior to open AAA repair, lower limb arterial disease or major limb amputation, which prevented these from reaching 100% use. SAP is given at incision by 21.3% (n=16) and within two hours preoperatively by 77.3% (n=58).

Hair removal

Only 13 responses were available for this question. Hair removal typically takes place in theatre (84.6%, n=11), with a clipper (100%, n=13). Reasons that necessitate this are to avoid hair in the closure site (84.5%), to facilitate postoperative dressings (58.6%) and for ease of skin preparation (55.2%). Only 1.7% (n=1) did not remove hair covering the incision site, although a reason was not specified.

Surgical site preparation

Most responders reported using alcoholic skin preparations (78.3%, n=54), whilst 11.6% (n=8) used aqueous and 10.1% (n=7) used both aqueous and alcoholic solutions. Chlorhexidine skin preparation was preferred by 56.5% (n=39) of respondents, povidone iodine-based solutions by 15.9% (n=11) and 27.5% (n=19) used both preparations.

Hand preparation

The majority of surgeons used an aqueous-based solution for surgical scrubbing (79.2%, n=61), 18.2% (n=14) used alcohol-based solutions and 2.6% (n=2) would use either.

Perioperative measures

Nutrition

Less than half of the respondents routinely carry out perioperative nutritional assessments (45.6%, n=26), 33.3% (n=19) do not undertake this practice and 21.1% (n=12) would do so for targeted groups (empirical decision, n=5; elective open procedures, n=2; amputation, n=1; low albumin, n=1; frailty, n=1). Reasons for not undertaking nutritional assessments included lack of time (33.3%) or staff (36.7%) to assess every patient. Furthermore, 30.0% indicated they had no nutritional service to refer to.

Temperature regulation

Methods to maintain perioperative normothermia included standard blankets (53.7%, n=36), forced air warming (86.6%, n=58), heated mattress (46.3%, n=31) and warmed fluids (50.7%, n=34).

Blood glucose

Just over half of surgeons monitor blood glucose perioperatively in patients without diabetes (57.4%, n=39).

Wound irrigation

Wound irrigation prior to closure of clean wounds was practised by 31 (49.2%) respondents, with saline (50.0%, n=22), povidone iodine (31.8%, n=14) and hydrogen peroxide (16.9%, n=7) being the most commonly used wound irrigation agents.

Gentamicin impregnated collagen sponge (GICS)

GICS was used by 71.6% (n=48) of respondents. Indications for usage included prosthetic implants (62.5%), venous implants (10.4%), biosynthetic implants (18.8%), re-intervention surgery (70.8%), contamination or known infection (12.5%) and groin wounds (2.1%).

Triclosan-coated sutures

Most respondents did not use triclosan-coated sutures (77.9%, n=53), whereas 14.7% (n=10) regularly used them and 7.4% (n=5) were unsure if antimicrobial sutures were used. Reasons for not using these sutures included a lack of evidence base (27.3%), cost (9.1%), personal choice (13.6%), being unavailable (45.5%) or an unawareness of the sutures (3.0%).

Dressings

Following primary skin closure, 96.4% (n=84) of respondents indicated they used a wound dressing. A basic wound dressing was most commonly used (52.9%, n=46), while advanced dressings (14.9%, n=13) and skin glue (20.7%, n=18) were also used.

Negative pressure wound therapy (NPWT)

Negative pressure wound therapy (NPWT) was also commonly used in specific situations following primary wound closure (52.5%, n=31). Reasons provided for the use of NPWT included re-intervention surgery (31.0%), groin surgery (51.7%), high body mass index (16.7%) and long wounds (3.4%). Reasons cited for non-use of NPWT included a lack of guidelines (34.6%), a lack of evidence base (38.5%), cost (19.2%), limited resources (3.8%) and difficulty of application (3.8%).

Postoperative measures

Prolonged surgical antibiotic prophylaxis

Prolonged surgical antibiotic prophylaxis (>24 hours) was used by 22 (37.3%) respondents, most commonly after major limb amputation (73.9%) and lower limb arterial procedures (69.6%).

Wound surveillance

Formal wound surveillance programmes were not undertaken by 73.7% (n=42) of respondents. Methods of monitoring wounds included face-to-face (85.0%), community nurse follow-up (23.3%), wound photograph at discharge (10.0%), paper questionnaire (8.3%), automated remote follow-up (5.0%), specialist vascular nurse (3.3%) and other not specified (5.0%).

Impact of SSI prevention practice on estimated SSI rates

Participants were asked to estimate SSI rates for the period January to December 2019. The results were investigated against SSI practices for potential influencing practices, as shown in Table 2. Blood glucose monitoring in non-diabetic patients appeared to be significant in the reduction of postoperative infections.

NVR data

Data submitted to the NVR indicated a lower overall vascular SSI infection rate of 1.92% compared with the median estimated SSI rate of 7.5% (based on submissions for all AAA surgery, carotid endarterectomy, lower limb surgical revascularisation and major limb amputation).[16]

Discussion

This survey corroborates guideline recommendations for further well designed RCTs to evaluate the impact on SSI rates of preoperative bathing, MRSA screening, surgical site preparation solutions, perioperative blood glucose management, wound irrigation solutions, antimicrobial sutures, NPWT, gentamicin impregnated substrates, postoperative dressings and prolonged surgical antibiotic prophylaxis.[13–15] This survey also highlights the disparity in reported SSI rates between registries, clinical practice and the literature. High-quality RCTs are needed to provide evidence on which to base practice and inform future versions of guidelines.

Lower limb revascularisation and amputation are both reported as high-risk procedures for SSI, which is supported by NVR data and this current survey.[16,17] There is, however, little consensus on

Table 2 Impact of SSI prevention practice on estimated infection rates.

	SSI estimate ≤7.5%	SSI estimate >7.5%	P value	OR	95% CI
SSI policy					
Yes	34	13	0.296	1.690	0.700 to 2.684
No	17	11			
Non-diabetic glucose monitoring					
Yes	17	8	0.030	0.134	0.330 to 0.542
No	4	14			
Wound irrigation					
Yes	9	11	0.639	0.750	0.225 to 2.496
No	12	11			
GICS					
Yes	16	13	0.232	0.451	0.121 to 1.682
No	5	9			
Dressings					
Basic	16	17	0.728	0.784	0.121 to 1.682
Other	6	5			
NPWT	10	12	0.650	1.320	0.398 to 4.378
No NPWT	11	10			
Antibiotic prophylaxis					
≤24 hours	13	14	0.907	0.929	0.270 to 3.199
>24 hours	8	8			
Wound surveillance programm					
Yes	8	6	0.449	0.609	0.168 to 2.207
No	13	16			

GICS, gentamicin impregnated collagen sponge; NPWT, negative pressure wound therapy; SSI, surgical site infection

which criteria should be used to diagnose these infections, with most respondents basing diagnosis on clinical experience. Given the inconsistency in the use of diagnostic criteria, there is a need for standardisation of a robust measure to accurately diagnose SSI. CDC criteria have widely been accepted as the gold standard, but seemingly they are not uniformly used. The recently validated Bluebelle Wound Healing Questionnaire provides a promising prospect in this area, particularly given its patient reported element; however, it is not yet widely used in clinical practice.[18] Current SSI prevention practice in vascular surgery varies considerably, with little consensus on many measures. Despite increasing awareness and uptake of strategies to prevent SSI, there is a clear lack of concurrence on their implementation. There is a lack of unanimity on nutritional assessment, blood glucose monitoring in non-diabetic patients, clean incisional wound irrigation, optimal wound dressings and the use of prophylactic NPWT. This seems to be recognised in the recently published CDC, NICE and WHO guidelines, which all highlight the paucity of evidence in key areas of SSI prevention.[13–15] Further, not one of the 15 SSI prevention measures identified by the three regulatory bodies has a unanimously agreed recommendation for use in practice, indicating a significant need for high-quality research streams in these avenues.

There was over 80% agreement from respondents in several measures including MRSA screening, procedures requiring SAP, preoperative hair removal and use of forced air warming. However, there are aspects within those measures with little agreement in best practice, such as eradication methods for MRSA colonisation and other strategies to maintain normothermia. Although surgeons seemingly agree for which procedures to give antibiotic prophylaxis (open and endovascular AAA, lower limb arterial disease, major and minor amputation and carotid endarterectomy), only 19.4% indicated using antibiotic prophylaxis in open venous surgery. The HARVEST trial demonstrated a significant reduction in SSI with antibiotic prophylaxis in open varicose vein surgery.[19] The optimal SAP regimen for vascular procedures is variable and does not appear to be evidence based. It is particularly troublesome in the lower limb arterial patient group, given the confounding issue of tissue loss and ischaemia alongside wound infection. The majority of surgeons (76%) indicated use of alcohol-based skin preparations compared with 48% reported in a 2014 survey.[12] This is in line with a growing body of evidence supporting the use of alcoholic chlorhexidine over aqueous povidone iodine, although evidence from the recent FALCON trial may alter this practice.[20,21] A meta-analysis of almost 12,000 participants showed that triclosan-coated sutures were clinically and cost effective in significantly reducing the risk of SSI.[22,23] Despite this, our survey found that most respondents did not use these sutures for reasons of lack of evidence and expense.

The median reported surgeon SSI rate was considerably greater than the nationally reported average (7.5% vs 1.92%); however, both are significantly lower than SSI rates in the vascular literature, which can be up to 40%.[2,24,25] This presents a worrying disparity between registry data, clinical practice and research findings. This survey suggests factors contributing to under-reporting may include lack of consensus regarding SSI diagnosis and lack of formal wound surveillance. Given the substantial cost identified per SSI, under-reporting misconstrues the true clinical and socioeconomic burden of this problem.[11]

The impact of SSI policy, non-diabetic blood glucose monitoring, wound irrigation, GICS, dressings, antibiotic prophylaxis and presence of a wound surveillance programme on estimated infection rates was investigated. The significance of blood glucose monitoring in non-diabetic patients in this survey is likely to be a type 2 error given the small sample size, although further exploration would be needed to determine the true significance of this.

Limitations

The survey achieved a response rate of almost 25% from consultant members registered with VSGBI, providing a snapshot of opinions from an extensive geographical spread of UK vascular units. It was also conducted during the COVID-19 pandemic, which may have influenced response rates. As with most surveys of this nature, it is open to responder and recall bias and results may have changed if there were more participants. In order to minimise bias, the focus group meticulously considered question wording (to ensure unambiguity) and survey length during development. A panel of experts reviewed the questions at each stage before piloting within the consultant body of a tertiary vascular unit.

Response fatigue is a common issue and levels of participation did drop towards the end of the survey questions. Even with attempts to address this as made during survey development, all remaining questions were felt to be relevant to comprehensively ascertaining current practice. To preserve structure and enable ease of organisation for respondents to follow, questions were categorised into SSI-related preoperative, perioperative and postoperative themes. Additionally, not every SSI prevention measure was included in the survey – for example, surgical technique and laminar flow theatres can impact infection rates. To include all aspects of SSI prevention measures would have extended the duration of the survey and risked drop out or respondent fatigue further.

Conclusion

There is little agreement in current guidelines on the best practice

KEY MESSAGES

- There is little consensus on the practice of surgical site infection prevention in vascular surgery.
- Current guidelines have conflicting recommendations.
- There is a disparity in clinical estimate, registry and research figures regarding surgical site infection rates.

to prevent SSI. Unsurprisingly then, clinical practice follows suit and continues to show little consensus on prevention measures used. There also appears to be a disparity in registry level, clinical perception and literature data for SSI rates. Well-designed high-quality trials are needed to provide evidence-based recommendations in this field.

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ORIGINAL RESEARCH

Research priorities in diabetic foot disease

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Plain English Summary

Why we undertook the work: More research is needed to help improve treatment and delivery of care for people with vascular conditions but funding is limited. The Vascular Society of Great Britain and Ireland (VSGBI) ran a Priority Setting Process (PSP) to find out the most important research questions. This helps researchers to better focus their work and helps funders to direct their support to projects that aim to answer these important questions. This paper presents the results of this process, focusing on research priorities related to diabetic foot problems.

What we did: We asked vascular patients and healthcare professionals in separate surveys to suggest their own priorities for vascular research. Responses were summarised and organised into nine overall vascular condition areas. Summary questions were then sent out to the same participants for scoring. The lists of patient and professional priorities were then combined into a shared list for discussion at a final workshop meeting where a mix of patients and their carers with lived experience of diabetic foot problems and healthcare professionals agreed the 'Top 12' research priorities for preventing and managing diabetic foot problems research in the UK.

What we found: A total of 481 healthcare professionals and 373 patients or carers submitted research priorities about vascular conditions, which were consolidated into a final combined list of 12 priorities specifically about preventing and managing diabetic foot problems. At a final workshop involving patients, carers and clinicians, these priorities were put into a 'Top 12' list ranked according to perceived importance. There was a notable difference between participants who thought risk assessment and prevention of diabetic foot disease was most important and those who felt treating diabetic foot disease and improving outcomes was key. Many participants individually remarked that there was significant overlap between research questions.

What this means: The most important research priorities for the prevention and management of diabetic foot problems have been identified. Researchers and funders are encouraged to focus on addressing these priorities and supporting studies in these areas.

Abstract

Introduction: Diabetic foot disease is a life-changing event for patients and is associated with high burdens to society in terms of cost, mortality and morbidity. The Vascular Society Diabetic Foot Specialist Interest Group (VSDFSIG), in association with the James Lind Alliance (JLA), aimed to identify and develop key research priorities for preventing and managing diabetic foot disease.

Methods: A modified JLA Priority Setting Partnership was undertaken. Two separate processes to identify research priorities were undertaken with healthcare professionals and patients and carers, led by the VSDFSIG. This exercise produced a list of 12 research priorities. The final workshop was attended by patients, carers and healthcare professionals from a variety of backgrounds involved in the care of people with diabetes and foot pathology. The research priorities were graded to produce a final list of ranked priorities. A final sandpit event addressed the priorities to generate research projects or programmes of research.

Results: A total of 481 healthcare professionals and 373 patients and carers submitted over 100 research priorities relating to diabetic foot disease. These related to diabetic foot disease prevention (including prevention of recurrence and amputation), improving foot outcomes (treatment, risk assessment, blood flow, health promotion) and determining factors that affect healing time (delays in referral, foot infection, antibiotics, larval therapy). Four themes were discussed at the sandpit event relating to potential research projects.

Conclusions: The top 12 research priorities in the prevention and management of diabetic foot disease and potential research projects that will inform researchers, clinicians and funders on the direction of future research priorities are presented.

Key words: diabetic foot disease, research priorities

Introduction

Diabetic foot disease is among a number of serious complications of diabetes mellitus.[1] In the UK there are over 7,000 diabetes-related lower limb amputations each year.[2] Diabetic foot ulceration (DFU) precedes diabetes-related lower limb amputations in 80% of cases, with studies reporting a prevalence of DFUs as between 1%[3] and 2%[4] in people living with diabetes in the UK. Fifty percent of people with diabetes who have suffered a foot ulceration will not live beyond five years.[5]

The Global Burden of Disease study ranked diabetes mellitus-related lower extremity complications as 10th on a scale of leading causes of global years lived with disability in 2015.[6] In 2014–2015, the estimated cost attributed directly to DFU and lower limb amputation in the National Health Service (NHS) in England was between £972 million and £1.13 billion.[7] Increased personal and societal costs in terms of psychosocial and physical behaviours[8] and reductions in quality of life[9,10] are also important.

In an attempt to improve the health outcomes and reduce the burden of diabetic foot disease, the Vascular Society of Great Britain and Ireland (VSGBI) created the Vascular Society Diabetic Foot Specialist Interest Group (VSDFSIG) in October 2019. The VSDFSIG comprises a multi-disciplinary team of health professionals alongside patients and/or their carers with an interest in furthering research activity in the field of preventing and managing diabetic foot disease.

One of the first objectives of the VSDFSIG was to establish the research priorities in the prevention and management of diabetic foot disease in the UK. However, there is frequently a mismatch between patients and carers with lived experience of diabetic foot problems and health professionals in selecting and deciding the most relevant research priorities.[11] Bridging this divide is essential to ensure any research is impactful and of relevance to policy makers and research funders.[12]

The James-Lind Alliance (JLA) Priority Setting Partnership (PSP) is one such approach to overcome the divide by bringing together patients, their carers and health professionals to identify and prioritise 'evidence uncertainties' in specific conditions or areas of healthcare.[13] The PSP methodology aims to make patients and carers as empowered as health professionals in all stages of the process. Using the modified JLA PSP, we aimed to identify and prioritise the most important clinical research priorities in the field of diabetic foot disease, to guide the future research objectives of the VSDFSIG.

Methods

Using a modified version of the JLA PSP methodology, the aim was to identify and prioritise the most important diabetic foot disease prevention and management research questions. There were also questions about treatment, communication, education, assessment, service provision and diabetic foot clinical pathways. There was no formal requirement for ethics approval as the JLA PSP methodology is considered public and patient involvement in research and is not research in itself.

The VSDFSIG is a multidisciplinary team comprised of: vascular surgeons and trainees; diabetes physicians; podiatrists; podiatric surgeons; orthopaedic foot and ankle surgeons; vascular nurse specialists; and trial methodologists, all with experience of delivering diabetic foot research, in combination with patient representatives. The VSDFSIG combined with a support team from the Vascular Society and JLA to deliver the research prioritisation partnership.

A health professional-led priority setting process had previously been undertaken by the VSGBI to identify specific research priorities associated with diabetic foot disease prevention and management, details of which have been published previously.[14] A Delphi consensus methodology was used and this process was completed in 2018.

Patient/carer-led research question identification process

A VSDFSIG and JLA-led priority setting partnership was delivered as part of a wider VSGBI initiative, details of which have been published previously.[15] In brief, a first round of survey was open from August 2019 to March 2020 and invited any patients and carers who had been affected by vascular-related disease to submit their priorities for research (Figure 1). The survey was made available in electronic and paper format and was publicised via the following membership bodies; VSGBI, The Society of Vascular Nurses, The Society of Vascular Technicians of Great Britain and Ireland, the Rouleaux Club, BACPAR and BSIR. The survey was also promoted via twitter and in affiliated organisation group newsletters and websites. Similar responses were amalgamated, summarised and duplicates removed. A second round of prioritisation took place from November 2020 to January 2021 and asked participants to rate the importance of the summary list of research priorities using a Likert scale (scores ranged from 'not at all important' to 'extremely important').

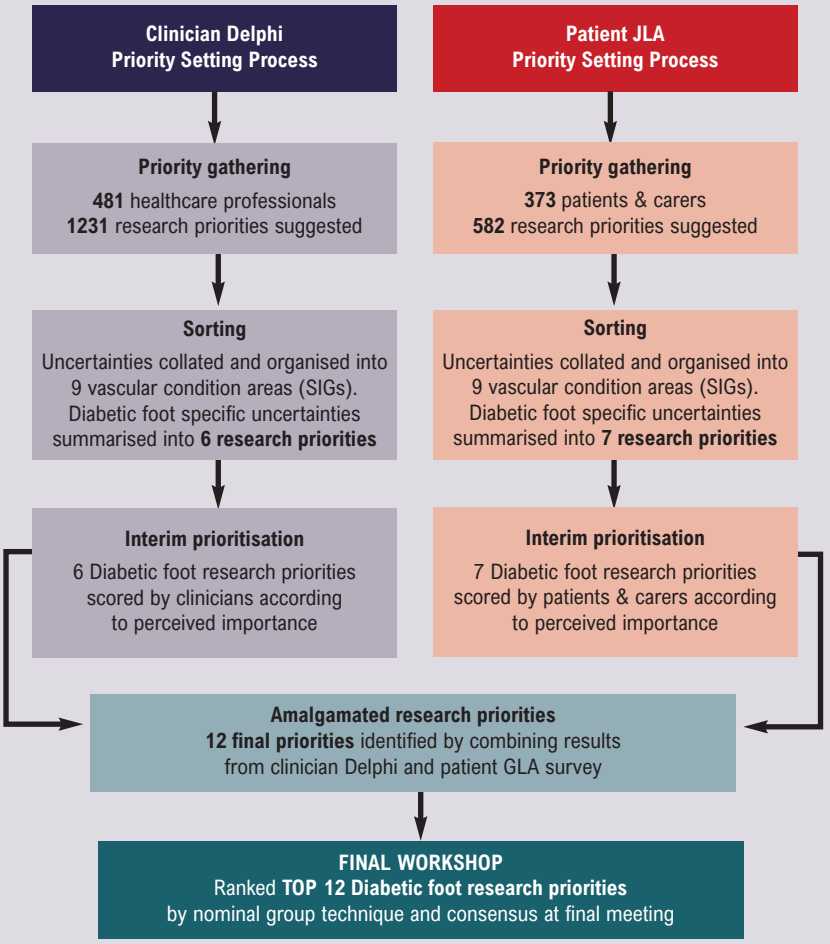
Final consolidation workshop

The final prioritisation process was conducted via a virtual online meeting on 14 June 2021. Nine patient and carer attendees with lived experience of diabetic foot problems were recruited via direct contact from members of the VSDFSIG. Nine healthcare workers were recruited via direct communication with national bodies (eg, VSGBI, Royal College of Podiatry) and via direct links with members of the VSDFSIG.

The workshop was facilitated by the JLA and VSGBI. Members of the VSDFSIG (DR, JS, RC, LA) provided general support during the process, but had no influence over the process of priority setting, observed all sessions (muted with cameras off) and noted key points arising from the discussion.

The seven patient and carer research priorities from the JLA PSP were merged with the six priorities from the health professional PSP, and after removal of a duplicate question, 12 were taken forward to the final prioritisation workshop. One week prior to the

Figure 1 Flowchart of the Vascular Priority Setting Partnership for diabetic foot disease



workshop, the 12 research priority questions were circulated to attendees. Attendees reviewed and ranked the research questions in order of importance prior to the meeting.

The workshop commenced with an overview of the JLA process. Attendees were divided into three 'breakout' groups, each comprising a mix of patients/carers and healthcare professionals. Each breakout group was led by an experienced facilitator skilled in the JLA process.

In the first breakout session, each participant presented their 'top 3' and 'bottom 3' of the final research priorities. In the second breakout session, having heard a range of perspectives, the same groups were asked to arrange the priorities into a ranked order (numbered 1–12) by mutual discussion. The JLA facilitators collated the priority rank order from each group to generate a combined priority rank order of the research questions.

In the third breakout session, attendees were assigned to different groups for a third round of discussion based on the combined priority rank order, and encouraged to review the order in light of new perspectives. The results of each group's rank orders were again combined to create a final ordered list. The finalised list of top 12 research priorities was presented to participants in the final workshop plenary to facilitate for reflection and comment.

Results

Results from the clinician-led research priority identification and prioritisation

A total of 481 clinicians submitted 1,231 research priorities relating to vascular surgery in general, of which 75 diabetic foot-related research priorities were submitted. These were reduced to six overarching summary priorities that were recirculated for scoring in the second round of the Delphi consensus.

Patient/carer-led research priority identification and prioritisation

There were 26 priorities related to diabetic foot submitted among 582 research priorities from 373 participants in the first round. Of these, five were excluded as they were individual patient specific and six were moved to other Vascular Society SIGs (3 wound, 3 amputation). The remaining 15 priorities were consolidated into seven overarching research priorities by the VSDFSIG chair and PPI representatives.

Final consolidation workshop

As part of the JLA PSP process, the VSDFSIG agreed a list of 12 research priorities (Table 1), derived from the initial survey responses prior to the workshop. The priorities were ordered randomly to reduce the risk of influencing bias and each was assigned an identifying letter (rather than a number).

Following drop-outs on the day, the final consolidation workshop was attended by eight patients/carers and eight healthcare professionals, with an additional four observers from the VSDFSIG. The final top 12 research priority list, in rank order of importance, was defined (Table 2). The third priorities both scored the same score and are therefore ranked equal. Although the original aim was to determine the top 10 priorities, the group felt that all 12 research priorities merited inclusion in the final list.

A number of key points were prominent during the discussions in the workshop. There was a notable difference between participants who thought risk assessment and prevention of diabetic foot disease was most important (priorities 1, 2, 3a, 6, 7 and 10) and those who felt treating diabetic foot disease and improving outcomes was key (priorities 3b, 8, 5, 11, 12). Many participants individually remarked that there was significant overlap between research priorities. For example, priorities 1 and 7 concerned prevention of DFU.

Throughout the discussion, patients/carers expressed

Table 1 List of research questions entered into the final prioritisation exercise

ID	Question
A	What is the most effective way of preventing further amputation after toe amputation for diabetic foot disease?
B	What is the most effective way of preventing diabetic foot ulcers?
C	What is the best way of improving blood flow to the leg in people with diabetes?
D	Can risk assessment be improved in patients with diabetic foot complications?
E	Is larval therapy effective in diabetic foot ulcer healing?
F	What is the most effective way of preventing recurrence of diabetic foot ulcers?
G	How can outcomes in diabetic patients with foot infection be improved?
H	Could more patients learn to self-administer antibiotics if needed/required?
I	How can awareness of diabetic foot complications be promoted?
J	Why are there delays in referral for diabetic foot disease?
K	Is an annual foot check for diabetic foot problems worthwhile?
L	What factors affect healing time in diabetic foot disease?

Table 2 Final ranked diabetic foot research priorities

Rank order	Research question
1	What is the most effective way of preventing diabetic foot ulcers?
2	What is the most effective way of preventing further amputation after toe amputation for diabetic foot disease?
3a	Why are there delays in referral for diabetic foot disease?
3b	How can outcomes in diabetic patients with foot infection be improved?
5	What is the best way of improving blood flow to the leg in people with diabetes?
6	Can risk assessment be improved in patients with diabetic foot complications?
7	What is the most effective way of preventing recurrence of diabetic foot ulcers?
8	What factors affect healing time in diabetic foot disease?
9	How can awareness of diabetic foot complications be promoted?
10	Is an annual foot check for diabetic foot problems worthwhile?
11	Could more patients learn to self-administer antibiotics if needed/required?
12	Is larval therapy effective in diabetic foot ulcer healing?

Table 3 Themes and key discussion points from sandpit discussion event

Theme	Key points discussed
Role of podiatry in the prevention of DFU	• The role of podiatry was dependent upon risk assessment and use of the annual foot check • Foot health professionals versus podiatrists specifically • NHS versus the private sector • Community versus hospital-based podiatry • Levels of clinical expertise • Frequency of surveillance • Structure of the foot assessment and if/how this can be further standardised • Evidence for the role of podiatry in intact feet
Reduction in further amputation following a minor amputation	• The role of biomechanics • Considering a selected group of patients, eg. those with isolated medial column arch collapse • Minor foot surgery for biomechanical correction • Is there sufficient knowledge on changes pre- and post-intervention (pressure assessment and clinical outcomes • Materials science research in foot offloading • Non-weight bearing versus early mobilization to prevent deconditioning • Prehabilitation and enhanced recovery following surgery in the diabetic foot patient • Access to community therapies pathways • Prophylactic revascularisation
Improving referrals into DFU MDTs	• Awareness of DFU MDTs • Clarity of pathways of care • Single points of contact • Role of technologies, telehealth and remote surveillance • Role of a 7-day service • Patient self-referral • Need to separate out patient delays and service/pathway delays
Risk assessment and the annual foot review	• Risk scores and risk stratification – how should we manage patients differently? • Psychological interventions • Role of technology to objectify the annual foot check

DFU, diabetic foot ulcer; MDT, multi-disciplinary team.

frustration with medical terminology, whilst also highlighting a desire to introduce specific timelines into priorities (eg, How long will it take a diabetic foot ulcer to heal?).

After prolonged discussion, the two research priorities numbers 11 ('Could more patients learn to self-administer antibiotics if needed/required?') and 12 ('Is larval therapy effective in diabetic foot ulcer healing?') were also included. Participants felt that both priorities remained important and are available to be researched.

Sandpit event

Six weeks following the final consolidation workshop, a sandpit event was organised to kick-start the process of generating research projects or programmes of research to address the priorities. This was again conducted online and attended by 16 participants, a mix of clinicians and patients with lived experience of diabetic foot problems. Furthermore, the former comprised a mix of clinical disciplines including vascular surgery, orthopaedic surgery, podiatry and diabetology. Prior to the meeting a mapping exercise was performed by VSDFSIG members to identify past, current and planned research against each research priority to identify the research gaps. Participants split into two groups of similar composition to independently discuss four themes (Table 3) which consider both the priorities and research gaps. Following discussions within the two groups, all participants reconvened and

the emerging points were shared and discussed further amongst the complete group. Some of the key points are summarised in Table 3. It was clear that there was overlap and inter-dependence of the themes.

Discussion

Using a modified JLA PSP methodology, we identified and ranked the principal 12 research priorities in the prevention and management of diabetic foot disease. A two-round process produced 12 priorities for final ranking. Following discussion, consensus was reached with patients, carers and healthcare professionals to produce a top 12 ranked list of clinical research priorities in the prevention and management of diabetic foot disease.

Strengths and limitations

The strengths of this process include the use of the structured and modified JLA PSP process to integrate patients, carers and health professionals' perspectives on the research priorities in the prevention and management of diabetic foot disease. Facilitation by skilled JLA advisors ensured that all participants contributed actively to the workshop and discussions.

Whilst the VSDFSIG attempted to include a range of participants from different geographical, socioeconomic and different lived experiences of diabetic foot disease, it is recognised that participants might not be truly representative of all stakeholders. However, this was mitigated by implementing the role of VSDFSIG who were able to provide a dedicated review of survey responses and highlight if there were any expected topic areas that could have been missed. Secondly, the risk of responder bias is prominent in this type of research that can limit the generalisability of any findings.

Implications for future research

Establishing the top 12 clinical research priorities will inform the future strategy of the VSDFSIG in contributing to the evidence base for the treatment and management of diabetic foot disease. These priorities will influence researchers and funders to ensure that the most important research priorities for both healthcare professionals and patients are considered. Furthermore, the themes and key points distilled through the subsequent sandpit event are available to the diabetic foot research community as key elements to take forward. The VSDFSIG are available to support any researchers interested in developing research proposals to answer these priorities.

Vascular Society Diabetic Foot Specialist Interest Group: Frank Bowling, University of Manchester, Manchester UK; Andy Cowan, Diabetes UK; Jonathan Cohen, PPI representative; Catherine Gooday, Norfolk and Norwich University Hospitals NHS Foundation Trust; Venu Kavarthapu, King's College Hospital, London; Sandip Nandhra, University of Newcastle; Pasha Normahani, Imperial College Healthcare NHS Trust, London; Jane Nixon, University of Leeds; James Pickard, Mid Yorkshire NHS Trust; Nung Rudarakanchana, London North West University Healthcare NHS Trust

KEY MESSAGES

- The top 12 clinical research priorities for the treatment and management of diabetic foot disease are established.
- Key themes on the prevention of foot ulceration and reduction of further amputations were identified.

Data availability: Derived data supporting the findings of this study are available from the corresponding author on reasonable request.

Conflict of Interest: None.

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ORIGINAL RESEARCH

Deprivation and supervised exercise for intermittent claudication

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Plain English Summary

Why we undertook the work: Supervised exercise therapy can help improve the symptoms of persons who suffer from pain in the legs as a result of narrowing or blockages in the arteries. Previous studies have found that patients' attendance with supervised exercise programmes is not as good as it could be, but the reasons for this are not clear. We wanted to find out how many patients with arterial leg pain attended a supervised exercise programme after being invited, and how many went on to finish the programme. We also wanted to find out if patients living in deprived areas were more or less likely to attend the supervised exercise programme. Additionally, we wanted to see if there were any factors that made it more likely that patients went on to attend or complete the programme, and whether patients reported feeling better after finishing the programme.

What we did: We looked at the medical records of patients who were invited to a supervised exercise programme to treat arterial leg pain between January 2017 and December 2018. We looked at data on deprivation in different areas of Wales produced by the government and analysed the data to answer our questions.

What we found: We found that 28 out of 164 patients (17.1%) attended the first appointment and 12 out of 164 (7.3%) completed the programme. There was no evidence that living in a deprived area made any difference to whether patients would attend or complete the programme, but the numbers are small.

What this means: The number of patients attending and completing the programme was low in this study. Our next aim is to find out why this is so that we can hopefully help more people with this treatment.

Abstract

Introduction: Supervised exercise is the first-line management for intermittent claudication and researchers must demonstrate that it is acceptable to patients and sustainable. Non-compliance with supervised exercise is an incompletely understood issue. It is unknown whether living in a more socioeconomically deprived area is associated with non-compliance with supervised exercise.

Methods: Consecutive patients referred to the National Exercise Referral Scheme (NERS) for intermittent claudication from a single centre from January 2017 to December 2018 were eligible for inclusion. The Welsh Index of Multiple Deprivation (WIMD) was used as a measure of deprivation for small areas in this study. The primary outcome was number of patients attending the NERS programme after referral. Secondary outcomes were number of patients completing the NERS programme, factors associated with attending and completing the NERS programme, and quality of life scores (EQ-5D-5L).

Results: Of the 164 patients in our cohort, 28 (17.1%) attended the exercise programme and 12 (7.3%) completed the full programme. Living in a more socioeconomically deprived area was not associated with attending the programme or completing the programme. There was insufficient quality of life score data for meaningful analysis.

Conclusions: The uptake and completion rate for supervised exercise in this cohort was low. There was no association between living in a more socioeconomic deprived area and either of these outcomes. Further qualitative research is needed to understand patients' perspective of barriers to compliance with exercise programmes and how to overcome them.

Key words: intermittent claudication, supervised exercise, deprivation

Introduction

Intermittent claudication is ischaemic muscle pain resulting from impeded arterial blood flow that is precipitated by exercise and relieved by rest. It is thought to have a prevalence of up to 10%.[1] National and international guidelines recommend supervised exercise, in conjunction with risk modification through lifestyle changes and best medical therapy, as first-line management for intermittent claudication.[2,3] There is a well-supported consensus that exercise – specifically supervised walking exercise – is a cornerstone of intermittent claudication management.[4–7]

Supervised exercise often comes at a cost to the patient, and previous research has identified that uptake and compliance with exercise programmes could be improved.[8,9] Identifying how compliance with supervised exercise can be maximised directly addresses the top two peripheral arterial disease research priorities from the perspective of patients/carers and clinicians/healthcare professionals.[10] Factors associated with not engaging with supervised exercise are incompletely understood. Some of the potential barriers that have been identified include lack of education/understanding about intermittent claudication and the role of exercise, timing of the programme, cost of travel to the programme and other medical issues.[11] However, previous studies have not explored whether socioeconomic depression could be a barrier to engaging with supervised exercise. It is unknown whether socioeconomic deprivation is associated with supervised exercise non-compliance.

The primary objective of this study was to determine the proportion of patients referred to a national supervised exercise scheme from one health board in Southeast Wales that go on to attend the programme. Secondary objectives were to determine the proportion of patients that complete the exercise programme, to determine whether living in a more socioeconomically deprived area was associated with not attending and not completing the exercise programme, and to determine whether quality of life scores improved by completing the programme.

Methods

This study is reported in accordance with recommendations from the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).[12] Local approval for service evaluation was obtained prior to starting data collection (reference number: SA/958/19). Funding required to access data from the supervised exercise programme was provided by the Gwent Vascular Institute, Aneurin Bevan University Hospital.

Patient identification and baseline demographic data collection

Consecutive patients referred to the National Exercise Referral Scheme (NERS) for the management of intermittent claudication from a single centre in South Wales over a two-year period (from January 2017 to December 2018) were eligible for inclusion. Patients were referred to the NERS from vascular outpatient clinics by consultants, registrars or vascular nurse practitioners. Referrals were made following a diagnosis of intermittent claudication if the patient indicated willingness to engage in supervised exercise and agreed to the referral after discussion with the healthcare professional. Contraindications to referrals included recent myocardial infarction, uncontrolled severe hypertension, uncontrolled arrhythmias and unstable acute heart failure. A copy of every referral is stored in the vascular department. Patients were retrospectively identified using copies of the NERS referrals from electronic records in the vascular surgery department. Baseline demographic data were collected from hospital electronic health records. The following baseline data were collected: age at time of referral, postcode data, diabetes mellitus, hypertension, chronic kidney disease, ischaemic heart disease, stroke, transient ischaemic attack, chronic obstructive pulmonary disease, smoking status (current, ex, never) and body mass index.

National Exercise Referral Scheme (NERS) and deprivation data

NERS provides tailored supervised exercise for patients referred by healthcare professionals in both primary and secondary care. The scheme is funded by the Welsh Government and managed by the Welsh Local Government Association and Public Health Wales. The scheme aims to provide supervised exercise for patients with varying chronic health issues including cardiovascular health issues. Patients presenting with intermittent claudication are eligible for referral to the scheme; tailored supervised exercise for this group includes walking exercise activities aiming to increase participants' walking distance. Patients can attend twice a week for a total of 16 weeks. The activities are delivered as group sessions and last 1 hour each. Patients have a choice of available locations and times to attend and are required to pay £2.00 for each session. The cost is fixed regardless of location or reason for referral.

Data regarding NERS appointments are not immediately available to secondary care teams since they are not on hospital electronic health records. These data are stored by Secure Anonymised Information Linkage (SAIL), a databank funded by the Welsh Government and Care Research Wales. The application for access to data was approved by SAIL's Information Governance Review Panel (project number: 0897). Data on patients identified on local hospital electronic health records were submitted for linkage with SAIL data. Additional data provided by SAIL in an anonymous format were: Welsh Index of Multiple Deprivation ranks, NERS attendance (first appointment, withdrawal/completion) and quality of life questionnaire EQ-5D-5L (at start and end of programme).[13]

The Welsh Index of Multiple Deprivation (WIMD) is the Welsh Government's official measure of deprivation for small areas in Wales and was used in this study.[14] The index is based on multiple measures of deprivation: income, employment, health, education, access to services, housing, community safety and physical environment. The index ranks all small areas in Wales from 1 (most deprived) to 1,909 (least deprived). WIMD was used in this study to

represent the deprivation experienced in the small area (with an average population of 1,200 people) in which each patient resided.

Outcomes

The primary outcome was the number of patients attending the NERS programme after referral. Secondary outcomes were the number of patients completing the NERS programme (attending weekly sessions for 16 weeks total), quality of life and multivariate analysis results to identify factors associated with attending and completing the NERS programme.

Statistical analysis

Each patient was assigned a WIMD rank based on postcode data and the cohort was split into quartiles for describing demographic and comorbidity data. The WIMD rank was used as a continuous variable for regression analyses (as opposed to using the quartiles as categorical data). Categorical data were compared between the quartiles using the χ^2 test and continuous data were analysed for normality and parametric or non-parametric tests used as appropriate.

Multiple imputation was performed to handle missing data using the Markov chain Monte Carlo method with 25 imputation sets and 25 iterations prior to regression analyses. Binary regression analyses were used to identify predictors of attending the NERS programme, predictors of completing the NERS programme, and predictors of withdrawing from the NERS programme. Univariate analysis was performed, with variables reaching a statistical significance threshold of $p<0.1$ carried forward to multivariate analysis. Results were presented as odds ratios (ORs) with corresponding 95% confidence intervals (95% CI). Statistical significance was defined as $p<0.05$. Regression analyses were conducted on imputed data followed by analysis using case-wise deletion as sensitivity analyses. Data were analysed using SPSS version 26 (IBM, New York, USA).

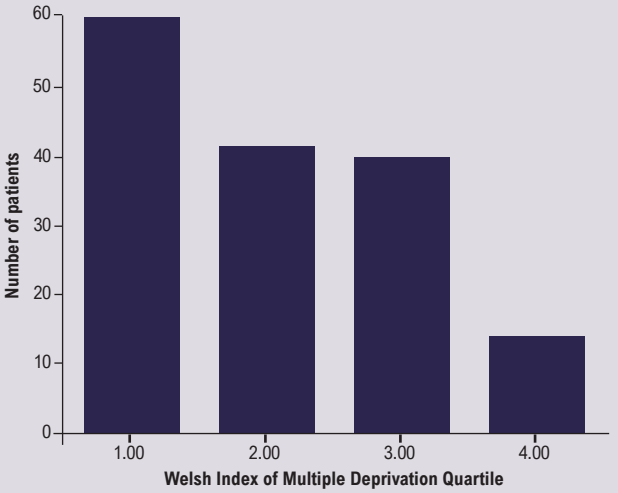
Results

The total number of referrals to NERS between 1 January 2017 and 31 December 2018 was 268. All 268 referrals were for intermittent claudication. Following exclusions for no matches on the SAIL database and those patients still on the waiting list for their first NERS appointment, 164 patients were included in the analyses.

Demographic and comorbidity data

The median age at time of referral was 68.3 years (interquartile range (IQR) 60.4–73.5). Males accounted for 68.9% (113/164), 42/164 (25.6%) had type 2 diabetes, 111/164 (67.7%) had hypertension, 15/164 (9.1%) had chronic kidney disease, 36/164 (22.0%) had ischaemic heart disease, 12/164 (7.3%) had a previous stroke or transient ischaemic attack and 20/164 (12.2%) had chronic obstructive pulmonary disease. Most patients were current smokers (84/163; 51.5%) and 55/163 (33.7%) were ex-smokers. Median (IQR) body mass index was 26.7 (24.0–30.2) kg/m^2.

Figure 1 Graph showing the number of patients in each Welsh Index of Multiple Deprivation quartile.



The median (IQR) WIMD rank was 644 (319–1183). WIMD rank was not available for nine patients. The cohort was split into quartiles based on the total range of WIMD ranks in Wales (1–1909). Quartile 1 (least deprived areas) had 60/155 (38.7%) patients, quartile 2 had 41/155 (26.5%) patients, quartile 3 had 40/155 (25.8%) patients and quartile 4 (most deprived areas) had 14/155 (9.0%) patients (Figure 1). The quartiles were equivalent in terms of demographics and comorbidities (Table 1).

Imputed data (multiple imputation) addressed the nine patients with missing WIMD data and the two patients with missing smoking status data.

NERS outcomes

Of the 164 patients in our cohort, 28 (17.1%) attended the exercise programme and 12 (7.3%) completed the 16-week programme.

The variables reaching the threshold of $p<0.1$ on univariate analysis to predict whether patients attended the NERS programme were type 2 diabetes (OR 0.304 (95% CI 0.087 to 1.070), p=0.064) and WIMD rank (OR 0.999 (95% CI 0.998 to 1.000), p=0.093). Sex, age at time of referral, body mass index, type 1 diabetes, hypertension, chronic kidney disease, ischaemic heart disease, stroke/transient ischaemic attack, chronic obstructive pulmonary disease and smoking status were not significant. Neither type 2 diabetes (OR 0.348 (95% CI 0.097 to 1.241), p=0.104) nor WIMD rank (OR 0.999 (95% CI 0.998 to 1.000), p=0.144) were significant on multivariate analysis (Table 2). Sensitivity analysis results using case-wise deletion were similar to results from analyses conducted on imputed data (Appendix 1 online at www.jvsgbi.com).

The only variable to reach the threshold of $p<0.1$ on univariate analysis to predict whether patients would not complete the NERS programme after starting was smoking status (ex-smoker): OR

Table 1 Demographic data for each quartile of the Welsh Index of Multiple Deprivation (WIMD).

	Categorical data									
	Quartile 1		Quartile 2		Quartile 3		Quartile 4			Missing
Variable	N	%	N	%	N	%	N	%	P value	N
Male	39/60	65.0	30/41	73.2	27/40	67.5	13/14	92.9	0.209	<5
Diabetes type 1	<5/60	n/a	<5/41	n/a	<5/40	n/a	<5/14	n/a	0.179	<5
Diabetes type 2	12/60	20.0	11/41	26.8	10/40	25.00	7/14	50.0	0.179	<5
Hypertension	41/60	68.3	22/41	53.7	31/40	77.5	10/14	71.4	0.140	7
Chronic kidney disease	<5/60	n/a	<5/41	n/a	5/40	12.5	<5/14	n/a	0.137	<5
Ischaemic heart disease	14/60	23.3	5/41	12.2	11/40	27.5	<5/14	n/a	0.315	<5
Stroke/TIA	<5/60	n/a	5/41	12.2	<5/40	n/a	<5/14	n/a	0.396	<5
Chronic obstructive pulmonary disease	7/60	11.7	5/41	12.2	6/40	15.0	<5/14	n/a	0.512	<5
Current smoker	32/60	53.3	20/40	50.0	22/40	55.0	6/14	42.9	0.858	<5
Ex-smoker	19/60	31.7	16/40	40.0	11/40	27.5	5/14	35.7	0.858	<5
Continuous data										
	Quartile 1		Quartile 2		Quartile 3		Quartile 4			
Variable	Median	IQR	Median	IQR	Median	IQR	Median	IQR	P value	
Age	67.9	59.1–74.2	68.6	60.8–75.8	67.4	60.0–72.1	70.4	65.6–73.7	0.603	
Body mass index	26.1	23.3–30.8	26.3	24.0–31.2	27.4	25.0–29.2	26.9	25.2–33.3	0.498	
Welsh Index of Multiple Deprivation rank	284	180–343	661	570–783	1240	1127–1295	1587	1524–1772	n/a	

0.130 (95% CI 0.013 to 1.317), p=0.084 (Table 3). WIMD rank did not meet the threshold (OR 0.999 (95% CI 0.998 to 1.000), p=0.156). Sensitivity analyses results using case-wise deletion were similar to results from analyses conducted on imputed data (Appendix 2 online at www.jvsgbi.com).

The number of patients who completed the EQ-5D-5L questionnaire at the beginning and after completing the 16-week programme (n=12) was deemed too low to allow for meaningful statistical analysis due to the high risk of a type 2 error.

Discussion

The overall rate of supervised exercise uptake in our cohort was 17.1% (28/164) and the completion rate was 7.3% (12/164). Living in a more socioeconomically deprived area reached the threshold of p<0.1 on univariate analysis to predict taking up the programme. However, it was not an independent predictor of taking up the programme on multivariate analysis. Smoking status (ex-smoker) was the only variable to reach a threshold of p<0.1 on the secondary univariate analysis, and was associated with a lower likelihood of withdrawing from the programme. The mean scores for the mobility, usual activities, pain/discomfort and anxiety/depression domains of the EQ-5D-5L demonstrated a non-significant trend of improvement after completing the programme.

The rate of supervised exercise uptake, adherence and completion reported in the literature is variable,[9,15–17] ranging from 24% to 78%. The uptake and completion rate in this cohort is lower than the majority of that reported in the literature.[15–17] One possible reason for the discrepancy is that trial conditions may report over-optimistic rates,[9,18,19] but other factors such as differences in prior education/expectations of supervised exercise for intermittent claudication,[20] transport provision, cost of enrolment[21,22] and lack of standardisation to supervised exercise are unknown variables that may account for the lower rates in our cohort.[23] The NERS programme allows for patients to choose between different venues that provide the exercise sessions; however, we are not able to make conclusions about the patients' perceived convenience of attending. It is possible that patients in this cohort have difficulty using suitable transport, especially if reliant on public transport that may require them to walk distances far greater than their claudication distance to reach stations. Similarly, the cost of attending the sessions is likely to be far greater than the £2.00 fee charged by NERS for patients that rely on public transport or taxis. Delays from referral to first session is another unknown variable that may have influenced the low uptake observed in this cohort.

Living in areas with more socioeconomic deprivation has been shown to be associated with lower levels of physical activity and utilisation of local facilities for exercise.[24–26] This is not seemingly replicated when socioeconomic deprivation and supervised exercise for intermittent claudication are considered based on findings from this cohort. Other factors such as lack of understanding of the pathology of intermittent claudication, pain,[27] motivation,[28] other (non-PAD) health issues,[9,27,28] cost[29] and

Table 2 Univariate and multivariate regression analyses to identify independent predictors of attending the first appointment.

	Univariate analysis		
Variable	OR	95% CI	P value
Male	0.644	0.277 to 1.497	0.306
Age (years)	1	0.967 to 1.034	0.990
BMI: normal weight (18.5–24.9 kg/m^2) (reference)			
BMI: underweight (<18.5 kg/m^2)	n/a	n/a	n/a
BMI: overweight (25–29.9 kg/m^2)	0.989	0.344 to 2.841	0.984
BMI: obese (≥3.0 kg/m^2)	1.161	0.367 to 3.677	0.799
Diabetes: none (reference)			
Diabetes: type 1	n/a	n/a	n/a
Diabetes: type 2 *	0.304	0.087 to 1.070	0.064
Hypertension	1.010	0.423 to 2.412	0.983
Chronic kidney disease	1.240	0.326 to 4.717	0.752
Ischaemic heart disease	0.375	0.106 to 1.321	0.375
Stroke/TIA	0.421	0.052 to 3.399	0.417
Chronic obstructive pulmonary disease	0.504	0.110 to 2.309	0.378
Smoking status: never smoked (reference)			
Smoking status: current smoker	0.600	0.202 to 1.780	0.357
Smoking status: ex-smoker	0.511	0.155 to 1.678	0.268
WIMD rank*	0.999	0.998 to 1.000	0.093
	Multivariate analysis		
Variable	OR	95% CI	P value
Diabetes: none (reference)			
Diabetes: type 1	n/a	n/a	n/a
Diabetes: type 2	0.348	0.097 to 1.241	0.104
WIMD rank	0.999	0.998 to 1.000	0.144

*Statistically significant.
BMI, body mass index; WIMD, Welsh Index of Multiple Deprivation; TIA, transient ischaemic attack.

Table 3 Univariate analyses to identify variables associated with withdrawing from the programme.

	Univariate analysis		
Variable	OR	95% CI	P value
Male	1.646	0.496 to 5.458	0.415
Age	0.984	0.945 to 1.024	0.422
BMI: normal weight (18.5–24.9 kg/m^2) (reference)			
BMI: underweight (<18.5 kg/m^2)	n/a	n/a	n/a
BMI: overweight (25–29.9 kg/m^2)	0.524	0.132 to 2.077	0.358
BMI: obese (≥3.0 kg/m^2)	0.422	0.077 to 2.316	0.321
Diabetes: none (reference)			
Diabetes: type 1	n/a	n/a	n/a
Diabetes: type 2	n/a	n/a	n/a
Hypertension	1.471	0.381 to 5.671	0.575
Chronic kidney disease	2.138	0.423 to 10.818	0.358
Ischaemic heart disease	0.694	0.145 to 3.321	0.648
Stroke/TIA	1.165	0.138 to 9.876	0.888
Chronic obstructive pulmonary disease	1.489	0.302 to 7.344	0.625
Smoking status: never smoked (reference)			
Smoking status: current smoker	0.736	0.179 to 3.019	0.670
Smoking status: ex-smoker*	0.130	0.013 to 1.317	0.084
WIMD rank	0.999	0.998 to 1.000	0.156

*Statistically significant.
BMI, body mass index; WIMD, Welsh Index of Multiple Deprivation; TIA, transient ischaemic attack.

family/work/transportation issues may be more relevant barriers.[28,29] Ex-smoking status was associated with a lower likelihood of withdrawing from the programme; it is possible that since these patients had a previously positive experience of lifestyle change, they were more likely to go on and complete the programme.

There were insufficient data to undertake meaningful statistical analyses using the EQ-5D-5L quality of life measure following completing the 16-week programme in this study. Findings from other studies have been in favour of improved quality of life following supervised exercise.[19,30] However, it is worth noting that, despite there being a consistent finding of improved disease-specific quality of life measures (such as the walking impairment questionnaire) with supervised exercise,[19,30,31] results are conflicting when generic quality of life measures are evaluated.[7,19,30] Disease-specific quality of life measures should be considered by NERS in the future.

The results from this study highlight the poor uptake and compliance with supervised exercise for intermittent claudication in Southeast Wales and suggest that efforts to improve this should focus on known barriers, regardless of the socioeconomic deprivation in the area in which patients reside. The demographics of our cohort are as would be expected for a cohort with intermittent claudicants, increasing the generalisability of the results.

There are several questions that remain to be addressed by further research. Further studies should evaluate socioeconomic deprivation and supervised exercise uptake/compliance in other geographical areas. Despite having a strong evidence base demonstrating the short-term benefits of supervised exercise, longer-term outcomes require further evaluation,[32] and evidence suggests that sustained engagement in physical activity is needed to maintain the improvements in outcomes.[15] It is unknown whether the barriers to supervised exercise attendance/compliance in the short term will pose the same challenges following completing a supervised exercise programme. A recent systematic review

identified that "lack of motivation", "health reason not related to supervised exercise therapy", and "patient choice" were the three most frequent reasons for incomplete adherence to an exercise programme for intermittent claudication.[9] Further qualitative research is needed to understand these issues from the patients' perspective and to identify whether they would also influence long-term engagement in physical exercise. Reducing key barriers by increasing provision and accessibility should also increase acceptability to patients.

There are limitations to this study. Firstly, some patients were excluded due to their records being unable to be linked with data on the SAIL platform, potentially introducing bias. There was potential confounding in our regression analyses from unknown variables such as patients' depth of knowledge about the pathology and of supervised exercise, access to transport and psychological factors that may influence attendance. Similarly, there is a limitation to regression analyses since there were relatively low numbers of patients included. We used the WIMD in our analysis as we did not have patient level deprivation data available, therefore our results cannot be extrapolated to make assumptions about how individual socioeconomic deprivation influences uptake and completion of supervised exercise. Several patients could not be included in the analyses because the data could not be linked with SAIL records or they were still waiting to be invited for their first appointment. Long delays (unknown to us) could be a confounder when evaluating compliance. There were far fewer patients in the fourth quartile (most deprived areas) compared with the other quartiles. It is possible that patients living in the most deprived areas have unequal access to healthcare and may not have presented to the vascular service, introducing potential bias. There were insufficient data to allow for analyses of quality of life outcomes and no disease-specific quality of life measures were recorded. The NERS programme does not meet the National Institute for Health and Care Excellence (NICE) recommendations for supervised exercise for intermittent claudication,[33] meaning our results may not be applicable to programmes that do meet the recommendations.

Conclusion

The uptake and completion rate for supervised exercise in this cohort was low. There was no association between living in a more socioeconomic deprived area and either of these outcomes. Further research is needed to understand the patients' perspective of barriers to access, uptake and compliance with exercise programmes and how to overcome them.

Conflict of Interest: None.

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KEY MESSAGES

- The number of patients with intermittent claudication who attend a supervise exercise programme in this cohort was very low.
- Socioeconomic deprivation was not associated with attending at least 1 supervised exercise session.
- Socioeconomic deprivation was not associated with completing a 16 week supervised exercise programme.

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TRIAL PROTOCOL

Does the level of encouragement affect 6-minute walk test performance in patients with intermittent claudication? A protocol for a randomised multicentre controlled trial

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Plain English Summary

Why we are undertaking the research: Peripheral artery disease is a common problem where the blood vessels in the leg are narrowed by fatty build-ups. These fatty deposits may restrict blood flow which causes pain during exercise and limits how far people can walk. To assess a patient's maximal walking distance, clinicians may use a 6-minute walk test whereby patients are asked to walk as far as possible in six minutes. Currently, encouragement is recommended during the test to ensure the patient walks as far as possible. However, the optimal frequency of this encouragement is still debated and may prove an important factor to guarantee the patient performs to the best of their ability.

What we aim to do: We plan to run an investigation to assess whether the frequency of encouragement delivered by an exercise professional affects how far a patient can walk during a 6-minute walk test. People with peripheral artery disease will be asked to enrol in a 6-minute walk test every week for six weeks. During each of their six tests they will receive standardised encouragement at either 1-minute or 2-minute intervals. Following all the tests, the two groups will have their average maximal walking distances compared. At the end of the study we hope to gain an insight into how often standardised encouragement should be delivered during a 6-minute walk test. We also hope to be able to inform future guidelines of the best way to conduct this highly utilised test in people with peripheral artery disease.

Key words: intermittent claudication, six-minute walk test, encouragement

Trial registration: ClinicalTrials.gov (NCT04586725)

Introduction

Peripheral artery disease (PAD) is characterised by atherosclerotic lesions of the arteries in the lower limbs, resulting in a reduction of blood flow.[1] Globally, it is estimated that 236 million people are living with PAD, with the number of cases increasing by 24% from 2000 to 2010.[2,3] A classic symptom of PAD is intermittent claudication (IC), characterised by ischaemic muscle pain precipitated by exertion and relieved by rest.[4,5] IC is associated with various comorbidities such as diabetes mellitus, hypertension and dyslipidaemia as well as reductions in physical function, quality of life and balance.[4,6,7] Pertinently, symptoms cause patients to stop walking, leading to reductions in walking capacity.

To assess symptomatic responses to an intervention, maximal walking capacity is typically the primary outcome in randomised controlled trials (RCTs).[8,9] This involves a patient walking for as long as possible until ischaemic leg symptoms or fatigue prevents them from continuing. This is assessed by treadmill[10,11] and corridor exercise testing protocols such as the 6-minute walk test (6MWT);[8,12] however, inconsistencies remain in their application.[13] The American Thoracic Society provides guidelines for performing a standardised 6MWT including verbal phrases that are conducted every minute. Conversely, when the test is applied in PAD, Montgomery and Gardner[14] suggest encouragement every two minutes. Encouragement has been shown to significantly affect maximal walking distance (MWD) by as much as 30 metres in heart failure and respiratory disease populations.[15] However, the effect of encouragement on walking performance in people with IC is yet to be investigated.[16] Therefore, the primary aim of this trial is to assess the impact of different levels of encouragement on MWD during a 6MWT in patients with IC.

Methods and analysis

The study is a multicentre parallel RCT. Patients will be blinded to the trial aims and randomly allocated to one of two 6MWT groups: encouragement at 1-minute intervals following current guidelines (control) or encouragement at 2-minute intervals, on a 1:1 allocation ratio. Adapted from previously published methods,[15] patients will conduct six 6MWTs one week apart with MWD recorded at each visit. All sessions will be supervised by a qualified exercise professional or member of the research team. Data will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[17]

Trial setting

The trial will be conducted at four centres in the UK: University of Central Lancashire, Atrium Health in Coventry, Coventry University and the University of Salford. Data will be collected at each site.

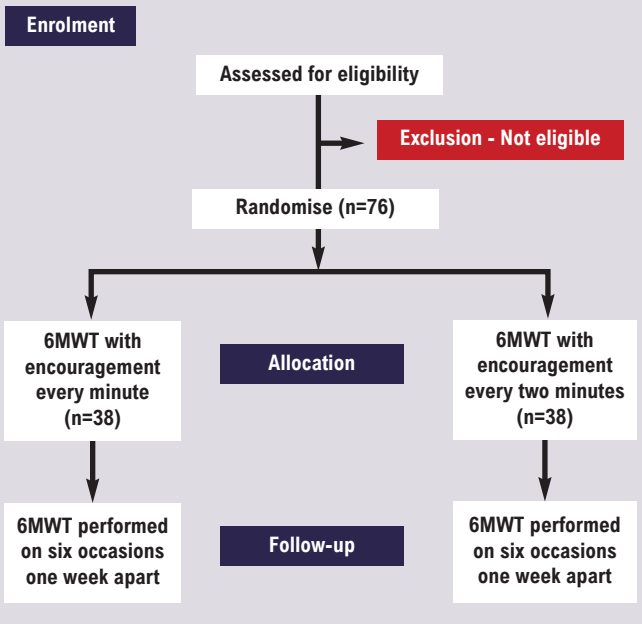
Trial registration

The trial was prospectively registered on ClinicalTrials.gov (NCT04586725). Any amendments required to this protocol will seek approvals from the research ethics committee before implementation and will be fully reported in the final trial report.

Trial procedures

An outline of the patient pathway for the trial is presented in the trial flow chart (Figure 1). Patients will be made aware of the trial at an exercise programme or vascular clinic. Recruitment will be either prior to SEP entry or on completion of the programme depending on site. If they wish, patients will receive a paper copy of the participant information sheet from a clinical or exercise professional. The contact details of the research team will be on the information sheet; therefore, it is the patient's choice to contact the research team. Once confirmed, patients will be contacted by a member of the research team to determine eligibility. Informed consent will be obtained at the baseline assessment/first 6MWT visit. Eligible participants will subsequently be randomised to the following groups: encouragement at 1-minute intervals or encouragement at 2-minute intervals. Clinical examination will take place prior to the first 6MWT visit and will include a review of medical history, current medications, stature (cm), body mass (kg) and cardiovascular risk factor assessment (resting blood pressure, resting heart rate and smoking status). At all subsequent visits and prior to testing, participants will be verbally screened against the exclusion criteria.

Figure 1 Trial flow chart.



Inclusion criteria

1. Patients recently diagnosed with IC who have been screened by a vascular specialist nurse, clinician or podiatrist will be eligible.
2. >18 years of age.
3. Resting ankle brachial pressure index (ABPI) <0.9 or a reduction of ≥20 mmHg following exercise testing.
4. Able to walk unaided.
5. English speaking and able to follow exercise instructions.
6. Able to provide informed consent.

Exclusion criteria

1. Those who have critical limb-threatening ischaemia (rest pain and/or tissue loss).
2. Unable to provide consent.
3. Those presenting with any significant comorbidities or contraindications to exercise testing or training in accordance with the American College of Sports Medicine.[18]

Intervention

All 6MWTs will be conducted in accordance with American Thoracic Society guidelines with the frequency of encouragement the only deviation.[12] In brief, the walking test will be conducted over a 30 metre (100 ft) flat enclosed corridor, with patients instructed to walk as far as possible within 6 minutes. Prior to each test, patients will rest in a chair at a quiet location for at least 10 minutes. A qualified, experienced exercise professional will conduct the tests and deliver standardised verbal phrases of encouragement. These will be delivered at the allocated time points during the test (Table 1). Patients are allowed to rest during the test, but the clock will continue to run and the phrases will be delivered at the allocated time points. Total metres walked will be calculated at the end of each test. To be regarded as having sufficiently adhered to protocol, patients must attend on six occasions, one week apart, and complete all six tests. To verify the safety of the 6MWT, adverse and serious adverse events will be carefully monitored, recorded and reported in line with the principles of Good Clinical Practice (GCP).

Table 1 Standardised verbal phrases of encouragement.

Minute	Phrases at 1-minute intervals	Phrases at 2-minute intervals
1	'You are doing well. You have 5 minutes to go'	
2	'Keep up the good work. You have 4 minutes to go'	'Keep up the good work. You have 4 minutes to go'
3	'You are doing well. You are halfway done'	
4	'Keep up the good work. You have only 2 minutes left'	'Keep up the good work. You have only 2 minutes left'
5	'You are doing well. You have only 1 minute to go'	
6	15 seconds before the end state 'In a moment I'm going to tell you to stop right where you are, and I will come to you'. When the 6 minutes end, say 'stop' and mark the spot where they stopped	15 seconds before the end state 'In a moment I'm going to tell you to stop right where you are, and I will come to you'. When the 6 minutes end say 'stop' and mark the spot where they stopped

Adapted from American Thoracic Society.[12]

Randomisation and blinding

The random allocation sequence of patients will be generated by a trial statistician on a 1:1 basis using a computer program random number generator (https://www.studyrandomizer.com/). To ensure allocation concealment, researchers will request randomisation from the chief investigator on completion of all baseline assessments using a sealed, opaque, sequentially numbered envelope. The concealment will not be created by the researchers who recruit. Researchers and clinicians conducting the assessments will not be blinded; however, they will not be involved in data analysis. The trial statistician will be blinded to the interventions. Under no circumstances will the trial statistician be unblinded.

Outcome measures

The primary outcome is to assess the impact of the frequency of encouragement on MWD performance (difference in metres walked) across six 6MWTs. The secondary outcome is to assess the learning effect of the 6MWT (metres) across six tests, one week apart.

Sample size

Based on recently published work, a minimal clinical important difference of 46 metres[16] and standard deviation of 61 metres resulted in an effect size of 0.754. With a power of 80% and a significance level of 5%, a sample size of 58 patients will be recruited would be needed to attain statistical significance. A drop-out of approximately 30% will be allowed, yielding a required sample size of 76 patients to be randomised into the two groups.

Data collection and management

Data will be collected and retained in accordance with the Data Protection Act 2018. The protocol and subsequent trial will adhere to the Standard Protocol Items: Recommendations for Clinical Trials (SPIRIT) and adopts the SPIRIT checklist.[19] Trial data will be collected on a case report form by the research team at each 6MWT visit. All patients will be given a study code along with the abbreviated hospital title to ensure anonymity. The anonymised data will be stored using a password protected file on the University of Central Lancashire staff OneDrive system and processed using an institutional Surface Pro. Only named investigators will have access to the patient data. Study documents (paper and electronic) will be retained in a secure location during and after the trial has finished for a minimum period of 5 years.

KEY MESSAGES

- The 6MWT is a key tool to assess walking capacity in patients with intermittent claudication.
- The frequency of encouragement has shown to affect walking capacity in other clinical populations, however it is yet to be investigated in patients with intermittent claudication.
- We hope to highlight the impact of different levels of encouragement during a 6MWT.

Data analysis

To examine differences in metres walked between the two encouragement groups at each of the six time points, linear mixed models will be used with 'group' modelled as a fixed factor and random intercepts by participants. Furthermore, to examine differences in walking performance between the six time points, repeated measures linear mixed models will be used for each group, with 'time' modelled as a fixed factor and random intercepts by participants. Assumptions of normality will be assessed by a Kolmogorov–Smirnov test. Skewness and kurtosis will be visually examined. All analyses will be conducted using SPSS v27 (IBM, New York, USA). For linear mixed models, the mean difference (b), t-value and 95% confidence intervals of the difference will be presented and statistical significance for all analyses is accepted as $p<0.05$. All data will be summarised and reported in accordance with the CONSORT guidelines.[17]

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

Funding: The authors received no financial support for the research, authorship and/or publication of this article.

Ethics and dissemination: Ethical approval for this multicentre randomised controlled trial was granted by North West – Greater Manchester East Research Ethics Committee (21/NW/0296) on 29 October 2021. On completion, the study results will be published in peer-reviewed journals and presented at scientific meetings. The expected impact for this study is to inform future national and international guidelines for the assessment of patients with IC.

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CASE REPORT

Ilio-mesenteric bypass for chronic mesenteric ischaemia where prior endovascular treatment has failed: a case series

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Abstract

Background: Symptomatic chronic mesenteric ischaemia is a rare but debilitating disease, and its diagnosis is often delayed by the time taken to rule out underlying malignancy or other abdominal pathology. Once diagnosed, definitive revascularisation should not be delayed to avoid future bowel infarction. There is no consensus on the best treatment option, but most centres use angioplasty as the first choice, leaving open surgery for those who are unsuitable for or failed endovascular treatment. Failure of endovascular treatment does not seem to preclude open surgical bypass.

Methods: This series includes four patients who presented with symptomatic chronic mesenteric ischaemia in whom endovascular treatment failed and who were then managed successfully with ilio-mesenteric bypass, with average follow-up of 4 years.

Results: The average age of the patients was 57 years; three of the four patients were female. Two patients had initial successful angioplasty but required bypass later for recurrent symptoms. In the other two cases the endovascular approach failed immediately, with one developing acute ischaemia requiring bowel resection followed by mesenteric bypass.

Conclusion: Mesenteric bypass for symptomatic chronic mesenteric ischaemia is feasible after failed angioplasty. Immediate or delayed failure of endovascular treatment does not seem to preclude future surgery.

Key words: chronic mesenteric ischaemia, mesenteric angioplasty, mesenteric bypass

Introduction

Symptomatic chronic mesenteric ischaemia (CMI) is a relatively rare condition with an incidence thought to be in the range of 2–3 per 100,000.[1] It is characterised by substantial morbidity, mortality and a decreased quality of life.[2] The typical presentation includes postprandial abdominal pain, weight loss and/or unexplained diarrhoea. Mesenteric duplex ultrasound is an effective screening tool for mesenteric artery occlusive disease,[3] while CT angiography is most often used for mapping the disease prior to any intervention, although magnetic resonance imaging is an alternative.[4]

Treatment targets for CMI are aimed at improving quality of life, restoration of normal weight and avoiding bowel infarction. The endovascular treatment of CMI has largely replaced open surgical management over the last two decades. The appropriateness of this shift has in part been validated by the findings of a recent meta-analysis.[5] Open surgical revascularisation (OSR) was found to result in significantly more in-hospital complications and a trend towards a higher 30-day mortality compared with endovascular revascularisation (ER).[5] However, these findings were balanced by superior long-term outcomes with primary and secondary patency rates being significantly higher for OSR according to further review articles.[6,7]

Current guidelines conclude that the reduction in short-term mortality and morbidity of ER outweigh the superior long-term results of OSR, particularly in view of the older population affected (mean age 69 years).[8] Most centres, including our own, offer endovascular treatment as the first approach, leaving OSR for those who are not ER candidates or have failed ER. In this series we present two patients where initial ER was unsuccessful requiring OSR, and another two patients where previously successful ER failed, requiring OSR.

Methods

This was a retrospective review of patients who

Table 1 Patient characteristics and intervention outcome.

Case	Age	Sex	Past history	Complaint	Initial scan	Previous endovascular therapy	Preoperative CTA	Surgical procedure	Outcome
1	73	Female	Hypertension, hyperlipidaemia, RAS to solitary functioning kidney (Figure 1)	Post-prandial abdominal pain, weight loss for 15 months	MRA: occlusion of CA and SMA origins	Stenting of CA (BMS) Redo angioplasty of CA stent (after 3 years)	Occlusion of CA stent and SMA origin	Left CIA–SMA bypass using GSV	Recurrent symptoms 3 years after bypass MRA: bilateral CIA stenosis (Figure 2a), managed by iliac stenting (Figure 2b). Remained asymptomatic for 6 years under surveillance
2	53	Female	Smoker, hypertension	Post-prandial abdominal pain, diarrhoea for 18 months	CTA: occlusion of CA and SMA	Failed trial of angioplasty due to heavy calcification	Occlusion of CA and SMA origins	Left CIA–SMA bypass using GSV	Recurrent symptoms 12 months after bypass DU: stenosis in distal anastomosis (PSV=812 cm/s), underwent successful angioplasties. (Figure 3) Remained asymptomatic for 4 years under surveillance
3	53	Female	Smoker, retroperitoneal fibrosis, debulking surgery and bowel resection, open cholecystectomy	Abdominal pain, severe weight loss for 9 months	CTA: occlusion of CA and tight stenosis of SMA	SMA stenting (BMS)	Occluded SMA stent. Stent fractured and displaced distally (Figure 4)	Left CIA–SMA Dacron graft (Figure 5a–c)	Remained asymptomatic for 3 years under surveillance
4	49	Male	DM, familial hyperlipidaemia	Post-prandial abdominal pain, diarrhoea for 6 months	CTA: occlusion of both CA and SMA origins	Failure to cross the lesions after multiple wire and catheter combinations. Complicated with acute intestinal ischaemia	Occluded CA and SMA origins	Small bowel resection then left CIA–SMA and CHA b ypass using bifurcated rifampicin-bonded Dacron graft	Remained asymptomatic with patent graft for 4 years under surveillance

BMS, bare metal stent; CA, coeliac artery; CHA, common hepatic artery; CIA, common iliac artery; CTA, computed tomography angiography; DM, diabetes mellitus; DU, duplex ultrasound; GSV, great saphenous vein; MRA, magnetic resonance angiography; RAS, renal artery stenosis; SMA, superior mesenteric artery.

underwent intervention for CMI at Manchester Vascular Centre over the last decade. Those who had primary surgical bypass were excluded. From about 46 patients who had endovascular treatment, four patients who had failed angioplasty and required surgical bypass were included in this report. Hospital records for patients' demographic characteristics, presentation, co-morbidities, intervention and re-intervention, outcomes and follow-up were analysed (Table 1).

All patients underwent left common iliac artery (CIA) to superior mesenteric artery (SMA) bypass through a midline laparotomy incision. After inspection of bowel viability, exposure of the SMA was done by a longitudinal incision over the root of the mesentery facilitated by retraction of the transverse colon cranially and the small bowel medially. The left CIA was exposed by division of the retroperitoneum lateral to the sigmoid, avoiding injury of the ureter as it crosses the CIA. After administration of 5000 IU heparin intravenously, the inflow and outflow arteries were clamped sequentially and the graft was tunneled retroperitoneally in a wide C-shaped configuration to avoid kinking. Afterwards, the proximal anastomosis to the CIA was constructed first, followed by the distal one to the SMA. We used the greater saphenous vein (GSV) as a conduit in cases 1 and 2 (Table 1) and a prosthetic graft in the other two cases.

Postoperatively, all patients were prescribed antiplatelet and statin medications and were kept under surveillance protocol of combined clinical and ultrasound surveillance at 6 weeks, 3 and 6 months postoperatively, then every 6 months for 2 years and annually thereafter. The follow-up periods for our cases were 7, 4, 2 and 3 years, respectively.

Informed consent was obtained from all patients after explaining

Figure 1 Computed tomography angiography with three-dimensional volume reconstruction showing heavily calcified supracoeliac aorta and solitary functioning right kidney.

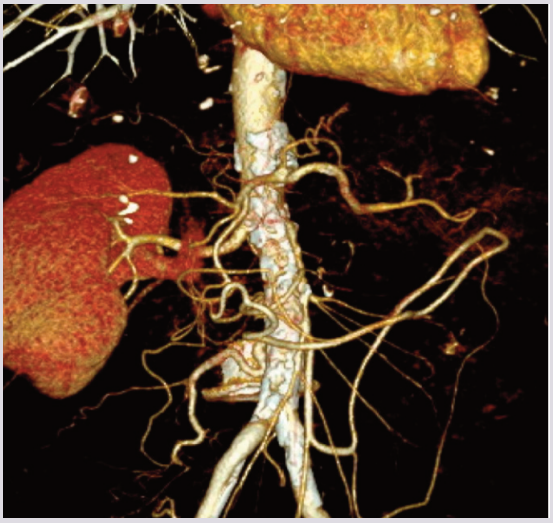


Figure 2 Development of bilateral iliac artery stenoses in patient with patent superior mesenteric artery (SMA) bypass. (a) Magnetic resonance angiography shows iliac artery stenoses and (b) angiography post-stenting shows patent both iliac arteries and SMA bypass (red arrow).

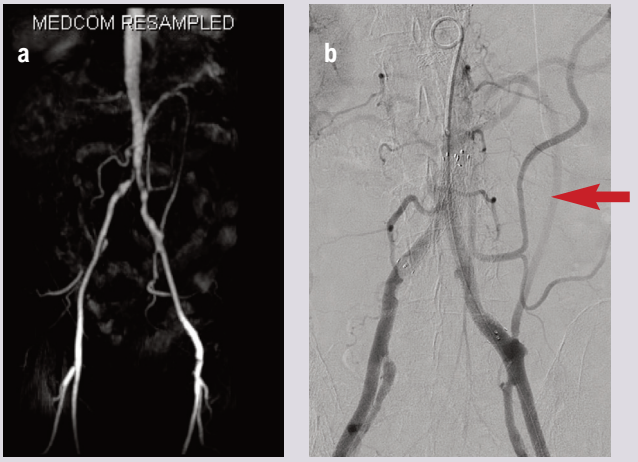


Figure 3 Completion angiogram post-angioplasty of distal anastomotic stenosis of superior mesenteric artery (SMA) bypass shows wide patent graft.

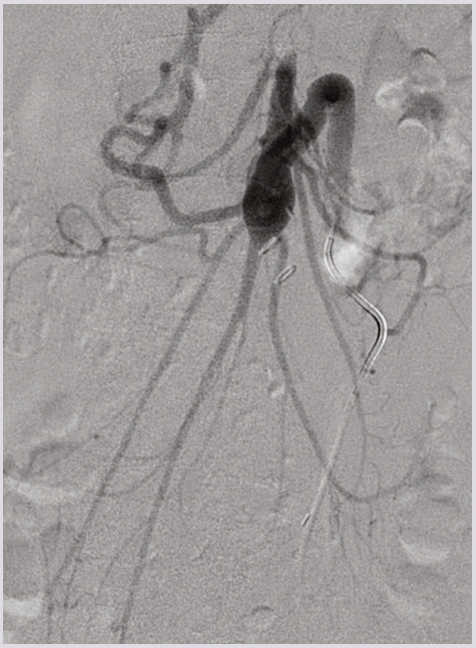
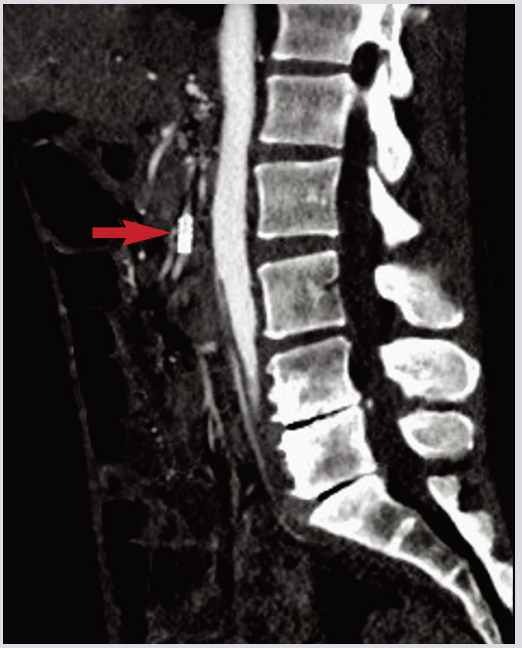


Figure 4 Computed tomography angiography (sagittal view) shows occluded superior mesenteric artery (SMA) stent. The stent is fractured and displaced distally in the artery (red arrow).

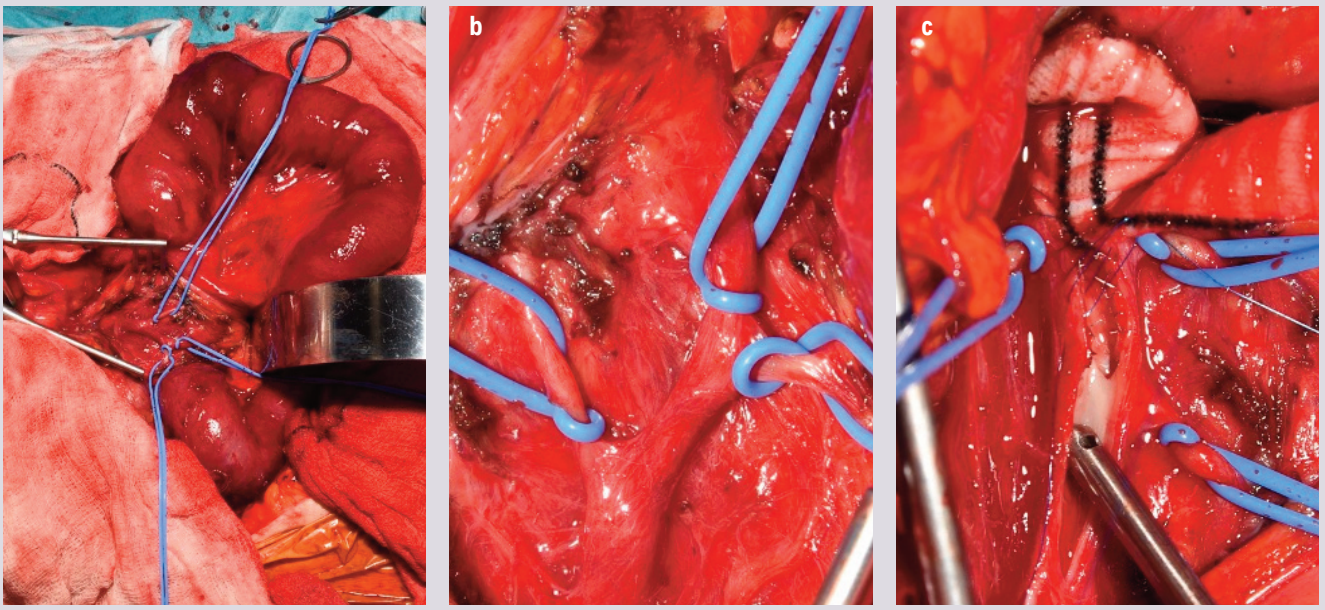


to them the nature and benefit of the study and thereby authorised reproduction of anonymised images.

Results

Four patients with an average age of 57 years (three women and one man) were included. All patients had occlusion of both the SMA and CIA origins on the initial scan (Table 1). In the first group (two patients) initial angioplasty was successful but required open bypass after 3 years from first angioplasty in case 1 and after 4 years in case 3 for recurrent symptoms. In the second group (two patients) initial trial of angioplasty failed. One patient was treated electively with OSR and the other patient suffered acute on chronic ischaemia with bowel infarction as a result. This necessitated exploration, bowel resection then OSR. There was no record of any

Figure 5 Intraoperative images show (a) superior mesenteric artery (SMA) exposure, (b) control of SMA and its branches to allow construction of anastomosis, and (c) construction of distal anastomosis between end of Dacron graft and side of SMA. Note the long SMA arteriotomy and the fractured stent incorporated into the anastomosis.



major complications or mortality after OSR, and all bypasses remained patent for 8, 5, 3 and 4 years, respectively, until the time of writing this paper.

Discussion

In symptomatic patients with CMI, a conservative approach has no role in treatment and delayed revascularisation has been associated with clinical deterioration and bowel necrosis.[9] Although there are no randomised controlled trials comparing the different treatment modalities for CMI, most centres advocate mesenteric angioplasty as the first option given the possibility of less perioperative morbidity and mortality.[8]

The results from a recently published large cohort of 245 cases from Denmark showed that endovascular treatment as the first option for CMI carries a 3-year mortality rate of 25% and a low risk of symptom recurrence.[10] A meta-analysis by Alahdab *et al*[5] comparing mesenteric ER with OSR, which included 100 observational studies and 18,726 patients, showed that OSR was associated with a statistically significant increased risk of in-hospital complications and a trend towards a higher 30-day mortality. In addition, the 'endovascular first' approach may lengthen the total successful revascularisation duration. One of our patients benefitted from a total of 4 years of primary and secondary patency of CA stent before having her bypass. There is evidence in the literature of more complications and a higher mortality rate in patients who required surgical bailout after failed ER,[11] which raises the question whether an endo-first approach is appropriate for allcomers. Further research is needed to clarify this. However, in our series failed ER either immediately or late did not preclude successful OSR.

These early benefits of ER should be balanced against the superior long-term outcomes of OSR. Our series reports excellent patency rates for OSR with one bypass remaining patent for more than 8 years. This is consistent with meta-analyses comparing OSR and ER for CMI. In a systematic review of 1,795 patients by Pecoraro *et al*,[6] the open surgical group has superior primary and secondary patencies. Also, Gupta *et al*[7] concluded that the 5-year primary and assisted primary patencies were significantly higher in the OSR group, as well as freedom from symptoms at 5 years which was 4.4 times higher in the OSR group compared with the ER group.

We could argue that, in the setting of the 'endovascular-first' era, surgeons are performing fewer open mesenteric bypasses probably due to subspecialisation and centralisation of the service and the need for two surgeons to be present for open surgery. That might lead to a selection bias in the multidisciplinary team meetings for ER in patients whose disease pattern may be better served by OSR as the first approach. These patients would benefit from the longer patency rates and freedom of symptom recurrence that OSR offers. In addition, ER attempts for unsuitable lesions could result in devastating complications. In one of our patients an ER attempt complicated by distal embolisation down the mesenteric arcades required emergency exploration and bowel resection.

Secondary interventions to maintain the patency of mesenteric bypass, particularly when the GSV is used, are not uncommon. In the first case (Table 1) the patient developed recurrence of

KEY MESSAGES

- Surgical bypass is feasible after failed angioplasty for chronic mesenteric ischaemia.
- Immediate or delayed angioplasty failure doe does not preclude successful open surgical revascularisation.
- Close surveillance of the mesenteric bypass is required to keep patency of the graft.

symptoms together with bilateral lower limb claudication 3 years after the bypass. Both duplex ultrasound and MRA confirmed development of bilateral CIA stenoses proximal to the mesenteric bypass which were treated successfully with bilateral iliac stenting (Figure 2a and b). Over the following 2 years, recurrence of symptoms confirmed with raised velocities on duplex ultrasound at the proximal anastomosis was managed with balloon angioplasty on two different occasions. In case 2 (Table 1), recurrent symptoms after 12 months of bypass and velocity of 812 cm/s detected by duplex ultrasound at the distal anastomosis were successfully treated with angioplasty (Figure 3). This emphasises the importance of close clinical and duplex ultrasound surveillance for these patients.

Conclusion

The series presented shows that OSR for symptomatic CMI is safe and effective following failed endovascular treatment. All patients may require strict clinical and radiological surveillance to ensure patency of the bypass.

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Authors' contributions: All authors read and approved the final version of the manuscript.

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Reviewer acknowledgement (Volume 1)

As we publish our fourth issue of *JVSGBI*, we would like to thank our reviewers for taking the necessary time and effort to review the manuscripts published in Volume 1. We appreciate their valuable comments and suggestions, which have helped us to improve the quality of the articles we have published online at www.jvsgbi.com

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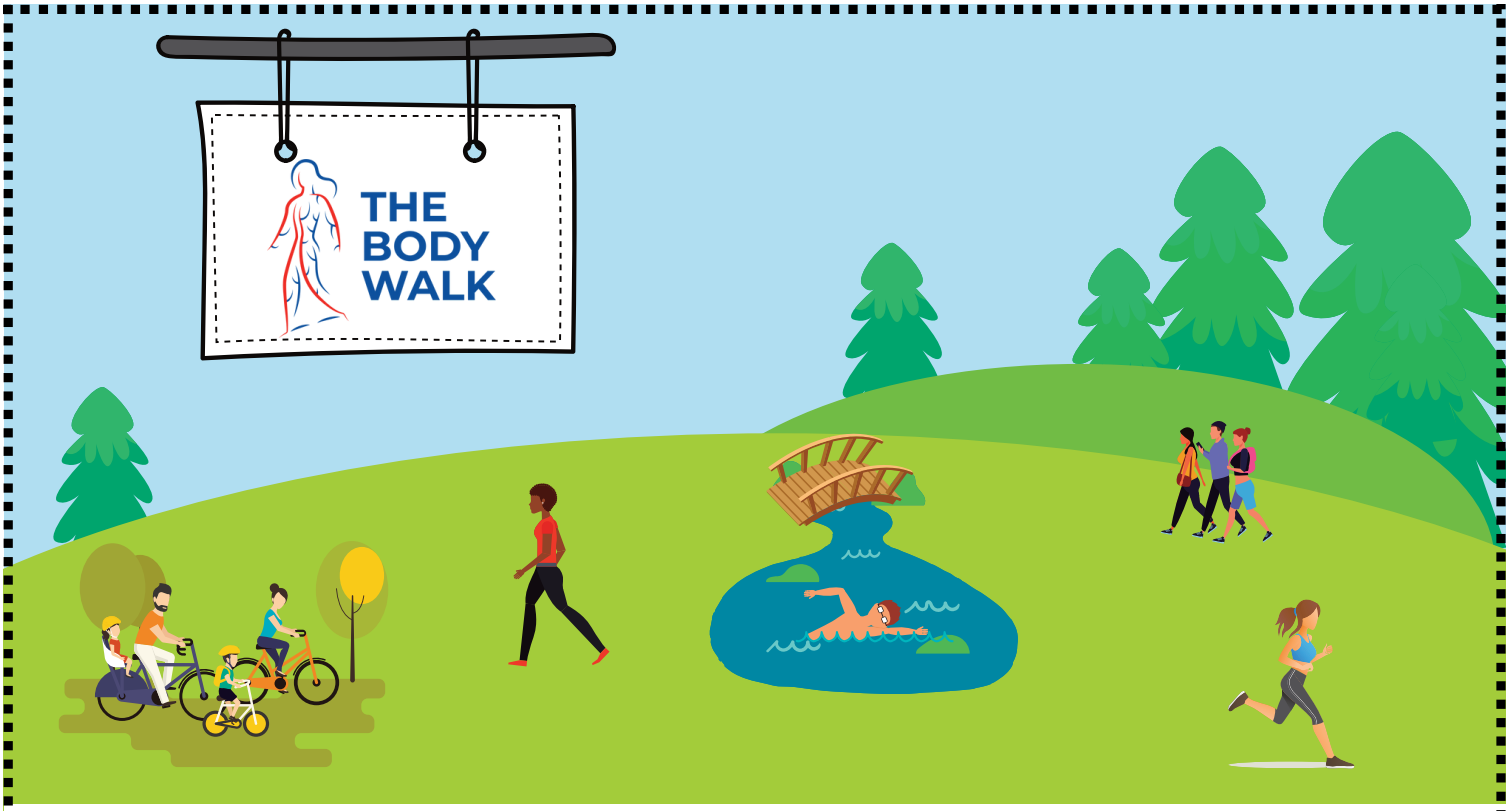

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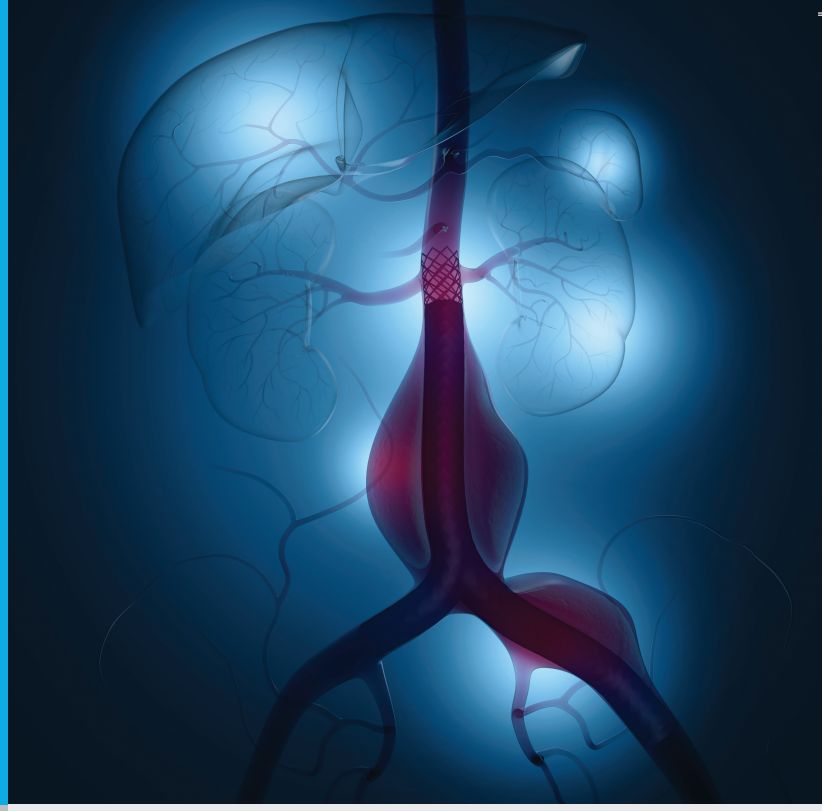

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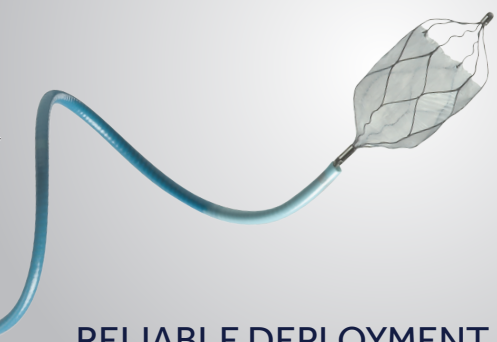

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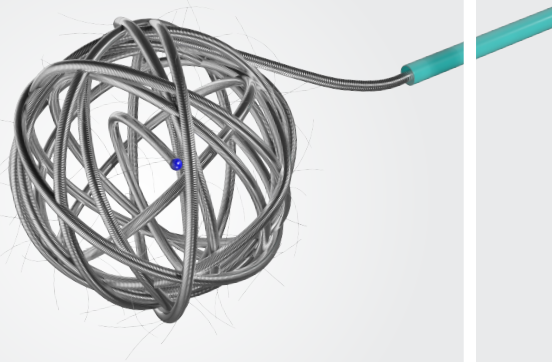

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