Risking Life and Limb

A review of the quality of the care provided to adults with acute limb ischaemia

ADDITIONAL INFORMATION IN CHAPTERS 1 to 11 AS ONE DOCUMENT

CONTENTS

1 METHODS

(BACK TO CONTENTS)

Study advisory group

A multidisciplinary group of clinicians was convened to steer the study from design to completion, define the objectives of the study and advise on the key questions. The group comprised lay and patient representatives and healthcare professionals in vascular surgery, interventional radiology, vascular nursing, general nursing, anaesthesia, diabetes care, emergency medicine, haematology and general practice.

Study aims and objectives

The objectives of the study were to explore the current care pathways for patients with acute limb ischaemia (ALI) to allow the identification of the remediable clinical and organisational factors that would lead to improvements in the care of ALI.

Hospital participation

Data were included from NHS hospitals in England, Wales, and Northern Ireland.

Study population and case ascertainment

Inclusion criteria

Adults over the age of 18 years who were admitted to a vascular hub as an emergency, between 1st January 2023 and 31st March 2023 for treatment of ALI.

Exclusion criteria

Patients who received only anticoagulation or palliative care at a spoke hospital.

Identification of a sample population

The incidence of ALI is unknown as there is no unique ICD-10 code for ALI. The identification of ALI cases is made more challenging by its heterogeneous modes of presentation and breadth of treatment options, with the same treatments also being used to treat chronic limb ischaemia.

A pre-set spreadsheet was provided to every local reporter in vascular hub hospitals to populate with patients admitted as an emergency in the three months between 01/01/2023 and 31/03/2023, using a range of ICD-10 codes and mode of presentation as a surrogate initial marker for patients who may have ALI.

A local study contact (vascular surgeon or vascular radiologist) then screened the listed patients to separate those with acute limb ischaemia from those with chronic limb ischaemia. Patients were then randomly selected from this sample.

Data collection

From the listed patients up to 10 per hub hospital were randomly selected to be included in the case review. For these patients data were collected from the following sources:

A clinical questionnaire was assigned to the named vascular surgeon for completion. This had questions detailing the care received following the pathway of care from pre-admission to discharge.

Case notes

Copies of the case notes from the hub hospital were requested for the included episode of care for each patient identified, for peer review.

Where transfer from a spoke hospital was identified, a request was sent to the spoke hospital for case note extracts from the emergency department presentation or episode of care if the patient was admitted to the spoke hospital.

For each patient identified, a request was also made to their GP for any case notes relating to the index admission to the hub hospital.

A list detailing the elements of the case notes that were required was provided to the NCEPOD local reporters who collated the notes from each participating trust/health board. For patients transferred from a spoke hospital, a request was made to the spoke hospital to return all notes for that attendance/admission.

Primary care questionnaires were disseminated to the listed GP surgery for each patient identified for the study. This short questionnaire had general organisational questions on the protocols and process of treating patients who have a suspected ALI and questions about what was done for the listed patient at the time of the hospital admission for ALI.

Hub or spoke organisational questionnaires were disseminated to the NCEPOD local reporter for completion, with assistance from relevant local clinical leads. These detailed the organisational structures in place in hub and spoke hospitals to deliver the service to patients who have an ALI.

Surveys

Our survey questionnaires were not linked to the data from patients selected for case review. They were designed using Microsoft Forms to be completed anonymously by patients who have had an ALI and clinicians treating these patients, respectively.

Patient survey

The patient survey (PS) was designed to collect data on the lived experience of patients regarding the care they have received in the treatment of ALI. The link to the patient survey was promoted online by the Vascular Society, the royal colleges and charities, including Legs Matter, and was also circulated to vascular consultants and nurses, who were involved in the study, to circulate to the patients they treat.

Clinician survey

This was designed using Microsoft Forms to collect the views of clinicians, particularly in emergency medicine, who may treat patients with ALI in spoke hospitals. The link to the online survey was promoted online with the help of the royal colleges and the Vascular Society.

Ambulance services survey

A short survey was disseminated to each ambulance service with questions on the service provided for patients with a suspected acute limb ischaemia.

Peer review of the case notes and questionnaire data

A multidisciplinary group of case reviewers comprised consultants and trainees from vascular surgery, interventional radiology, nursing, anaesthesia, acute medicine and emergency medicine.

Using a semi-structured electronic questionnaire **(reviewer assessment form)**, each set of case notes was reviewed by at least one reviewer within a multidisciplinary meeting. A discussion, chaired by an NCEPOD clinical co-ordinator, took place at regular intervals, allowing each reviewer to summarise their cases and ask for opinions from other specialties or raise aspects of the case for further discussion.

Data analysis

Following cleaning of the quantitative data, descriptive data summaries were produced. Qualitative data collected from the case reviewers' opinions and free-text answers in the clinician questionnaires were coded, where applicable, according to content to allow quantitative analysis. As the methodology provides a snapshot of care over a set point in time, with data collected from several sources to build a national picture, denominators will change depending on the data source, but each source is referenced throughout the document. This deep dive uses a qualitative method of peer review, and anonymised case studies have been used throughout this report to illustrate themes. The sampling method of this enquiry, unlike an audit, means that data cannot be displayed at a hospital/trust/health board/regional level.

Data analysis rules

- Small numbers have been suppressed if they risk identifying an individual (usually <3-5)
- Any percentage under 1% has been presented in the report as <1%
- Percentages were not calculated if the denominator was less than 100 so as not to inflate the findings, unless to compare groups within the same analysis
- There will be variation in the denominator for different data sources and for each individual question as it is based on the number of answers given.

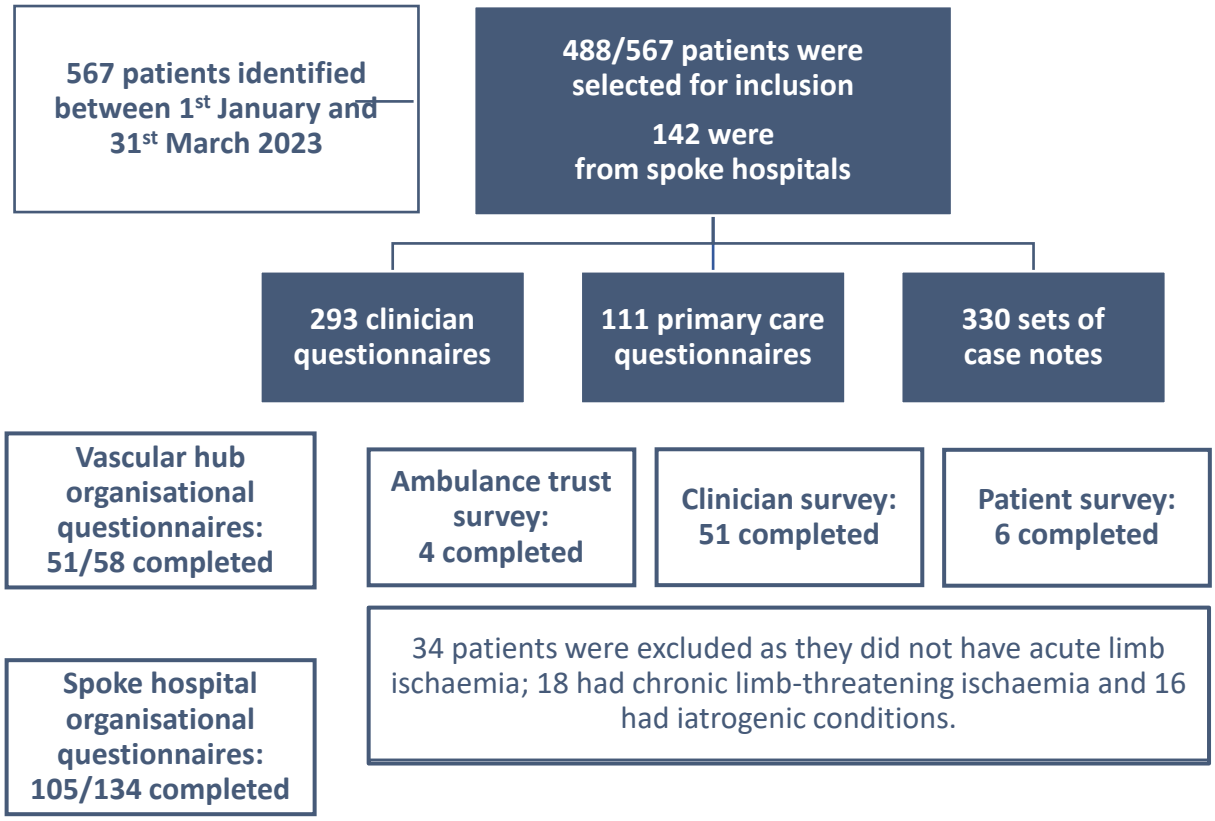
Information governance

All data received and handled by NCEPOD complied with all relevant national requirements, including the General Data Protection Regulation 2016 (Z5442652), Section 251 of the NHS Act 2006 14 (PIAG 4-08(b)/2003, App No 007), and the Code of Practice on Confidential Information. Each patient was given a unique NCEPOD number.

2 DATA RETURNED AND THE STUDY POPULATION

(BACK TO CONTENTS)

Data returned



Age

It is widely believed that acute limb ischaemia (ALI) predominantly occurs in older people. The European Society for Vascular Surgery (ESVS) 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia states that the large majority of ALI occurs in people over 80 years of age,[1,2] while the NICE clinical knowledge summary advises that ALI usually affects people aged over 60 years.[3]

The mean age for patients included in this study was 71 years. The effect of selection bias due to the exclusion of patients who received palliative care in spoke hospitals was thought to be minimal by the study advisory group.

In total, 70/290 (24.1%) patients were 60 years or younger and 92/290 (31.7%) were of working age (65 or younger) (F2.1). These data highlight that age should not be a factor to exclude ALI in any adult with an acutely painful limb and highlights the need for a national registry for ALI to better understand the population and their needs

There were 193/293 (65.9%) men in the study sample and 100/293 (34.1%) women.

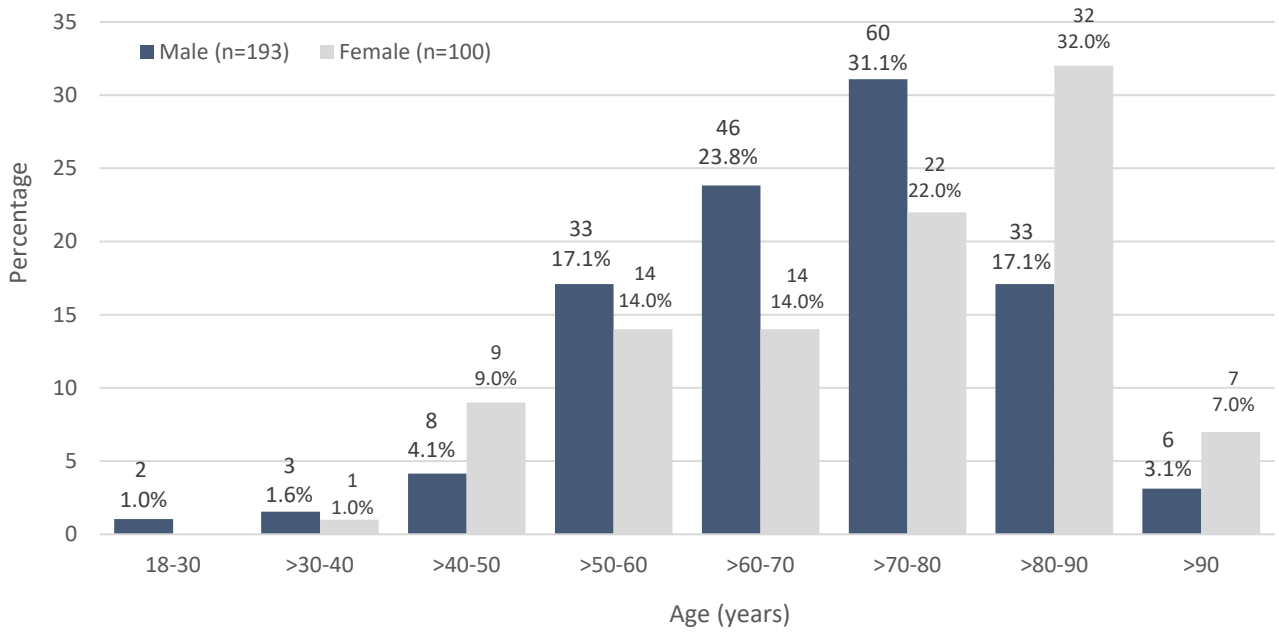


Figure 2.1 Age and sex of the study population; *n=293, mean=71, median=72, mode=86*
Clinician questionnaire data

Ethnicity

There were 260/268 (81.7%) patients in the study sample who were White, which was higher than the national population of 81.7%.[4] However, this is consistent with the population in a similar vascular review of lower limb bypass grafts[5] and was confirmed by the healthcare professionals involved in the study, so it is not believed that our dataset has under recorded the incidence of ALI in Black and ethnic minority patients (T2.1). However, it is recognised that training for healthcare professionals may be required to help diagnose ALI in patients with darker skin, where pallor, one of the '6Ps' can be harder to identify.[6-8]

Table 2.1 Ethnicity of the study population	Number of patients	%	National Census Data 2021
White British/White - other	260	97.0	81.7
Asian/Asian British (Indian, Pakistani, Bangladeshi, Chinese, other Asian)	4	1.5	9.3
Black/African/Caribbean/Black British	2	<1	4.0
Other ethnic group	2	<1	2.1
Mixed or multiple ethnic groups	0	0	2.9
Subtotal	**268**		
Unknown	25		
Total	**293**		

Clinician questionnaire data

Ethnicity is not currently recorded in registries such as the National Vascular Registry nor in hospital episode statistics recorded in secondary care but is available from primary care datasets. Recording of national comprehensive data including ethnicity or linkage to primary care datasets (at patient level - NHS number) would allow future assessment of any biases in study population.[4]

Furthermore, as it is well documented that Black and ethnic minority groups can experience lack of access to healthcare, delayed interventions, worse outcomes, and racial discrimination in all areas of healthcare, recording of ethnicity in national datasets would ensure that all patients with ALI, irrespective of ethnicity or socio-economic group are identified and treated promptly.[5,9-12]

Comorbidities

Comorbidities (coexisting medical conditions) associated with an increased risk of ALI, or which might contribute to delayed presentation, were present in 257/290 (88.6%) patients, with 212/290 (73.1%) patients having more than one (F2.2).

Almost a quarter of patients presenting with ALI had type 2 diabetes mellitus, while type 1 was much less associated. Excessive alcohol use, illicit drug use, mental health issues or dementia are likely to affect compliance with medication or delay presentation to healthcare providers (F2.2). One or more of these factors was identified in 46/293 (15.7%) patients.

A total of 40/293 (13.7%) patients had cancer. Arterial thrombosis, often linked to cancer or its treatment, is associated with poor limb salvage rates and a survival of less than six months for most patients.[13]

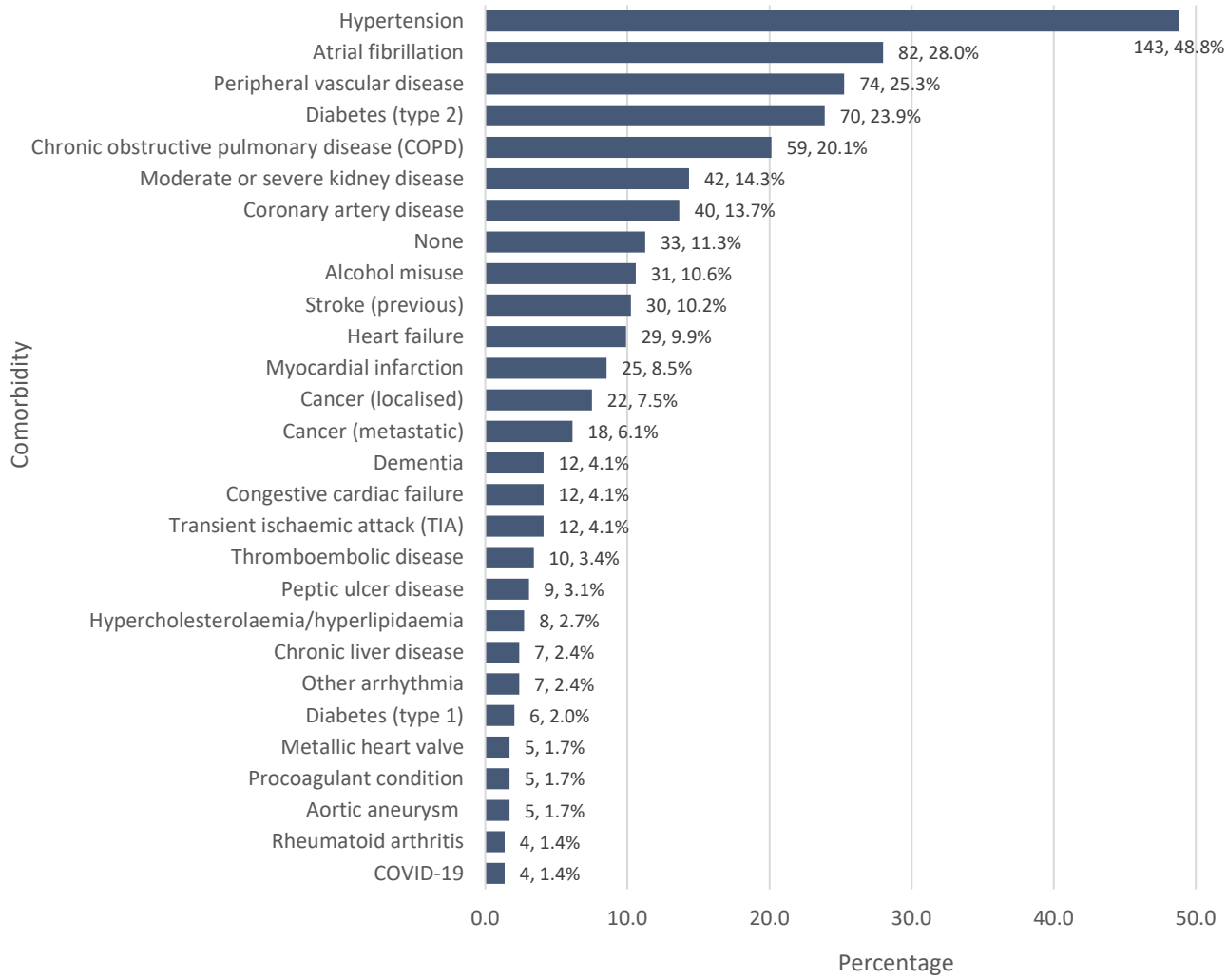


Figure 2.2 Comorbidities in the study population. *Answers may be multiple*; *n=293*
Clinician questionnaire data

Medications

In total, 211/293 (72.0%) patients were taking one or more than one medication, including 24.9% (73/293) who were taking anticoagulants (T2.2).

Table 2.2 Medications on admission	Number of patients	%
Anti-hypertensives	128	45.4
Lipid-lowering drugs	117	41.5
Single anti-platelet	90	31.9
None	56	19.9
Direct oral anticoagulants (DOAC)	44	15.6
Dual anti-platelet	16	5.7
Warfarin	16	5.7
Other anticoagulants	14	5.0
Hormone treatment	2	<1%

Answers may be multiple; n=282, unknown in 11

Clinician questionnaire data

More than a third (33/81; 40.7%) of patients with pre-existing atrial fibrillation (AF) were not receiving anticoagulants, This suggests an area where care could be improved while recognising that some patients may have not been offered an anticoagulant after a risk-benefit assessment, declined it or, if at high risk of anticoagulation complications, been offered antiplatelet treatment. There were 10/81 (12.3%) patients with AF who were receiving a single antiplatelet agent. A single antiplatelet was prescribed in addition to anticoagulation in 5/81 (6.2%) patients with AF.

Smoking status

Smoking rates in the UK have fallen from 46% in 1974 to 12.9% in 2022. In 2023, 11.9% of adults aged 18 years or over (6.0 million people) were current smokers, according to the Office for National Statistics (ONS).[14] In this study 117/266 (44.0%) patients were current smokers and 94/265 (35.5%) were ex-smokers, underscoring the importance of smoking as a risk factor for ALI (T2.3).

Table 2.3 Smoking status of the study population	Number of patients	%
Current smoker	117	44.2
Ex-smoker	94	35.5
Never smoked	54	20.4
Subtotal	**265**	
Unknown/vaper	28	
Total	**293**	

Clinician questionnaire data

This study did not actively collect data on heated tobacco products and e-cigarettes (vapes). Use was noted only when incidentally recorded. E-cigarettes (vapes) are advocated as an alternative to smoking, including the 'Swap to Stop' campaign. The Office for National Statistics estimates that 5.9% of adults in the UK used an e-cigarette daily in 2023, up from 5.2% in 2022.[15] E-cigarettes are regulated under the Tobacco and Related Products Regulations 2016, and are not subject to any of the safety studies required for medical devices and drugs before they can be used.

The Medicines and Healthcare products Regulatory Agency (MHRA) recommends recording e-cigarette use in medical records similar to smoking, to facilitate future studies on their long-term effects. However, it recommends recording details of the brand(s), active components and strength(s), which might not be practical to collect.[16] While the long-term effects of vaping are not known, research has identified negative impacts on the cardiovascular system.[17,18] Specific to peripheral arterial disease (PAD) and ALI, there is evidence of short-term harmful effects on normal peripheral vessels similar to those caused by smoking, even in products containing no nicotine.[19] The recording of e-cigarette use is not yet embedded in medical training and while there is an increasing recognition of the harmful effects, understanding remains limited.

Social situation

Prior to the hospital admission with ALI, 261/282 (92.6%) patients were living in their own home (T2.4). Where the data were available, the majority of patients were managing without additional social support or care (189/261; 72.4%).

Table 2.4 Usual place of residence	Number of patients	%
Own home	261	92.6
Residential home	12	4.3
Nursing home	5	1.8
Other/homeless	4	1.4
Subtotal	**282**	
Unknown	11	
Total	**293**	

Clinician questionnaire data

Frailty

A Rockwood Clinical Frailty Score at admission was estimated by the reviewers where one was not recorded in the notes (F2.3). The Rockwood Clinical Frailty Scale was originally validated in the assessment of frailty in those aged 65 years or older.[20]

It has been routinely used in recent NCEPOD reports and has been shown to be a better predictor of outcomes than age for all adults.[21] Frailty has also been recognised as having a greater impact than age across older age ranges.[22]

Reflecting on their place of residence and social support needs, 162/330 (49.1%) patients were fit, well or managing well prior to their admission (F2.3). While severe frailty was recorded in 40/330 (12.1%), it should be noted that this might have been higher if patients who received palliative care in spoke hospitals had been included.

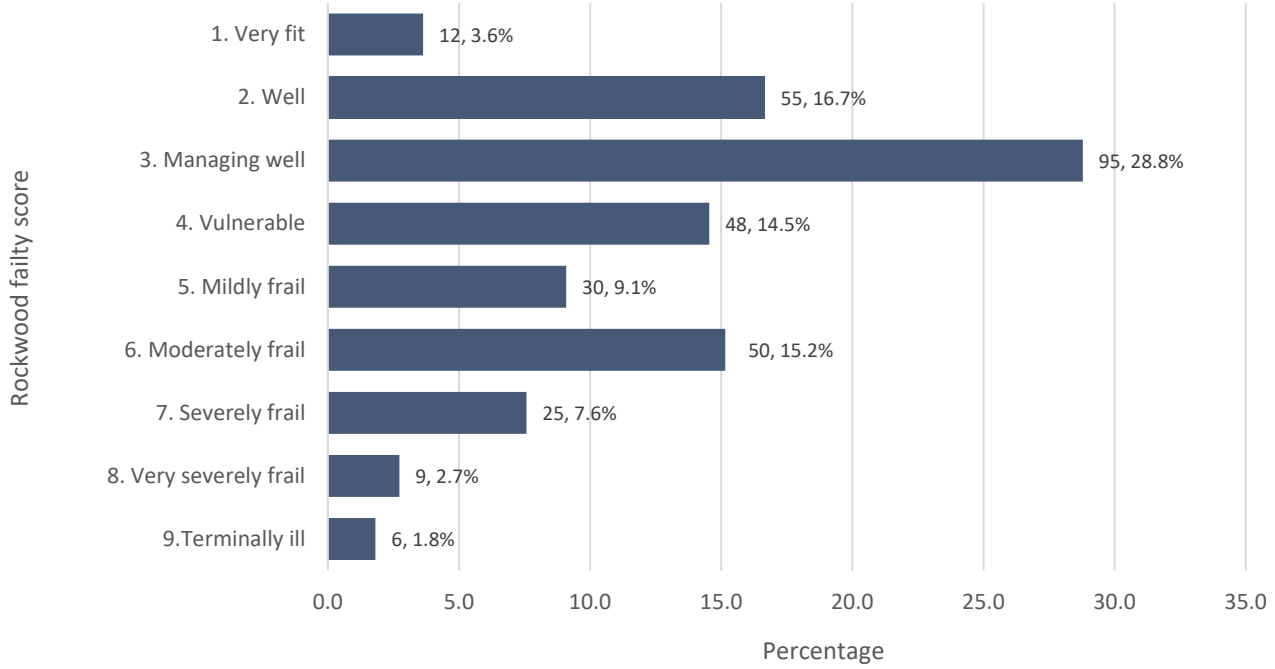


Figure 2.3 Estimated Rockwood frailty score prior to admission; *n=330*

Case review data

Communication difficulties

In total, 34/305 (11.1%) patients had communication difficulties comprising language (10), hearing (8), learning disability/difficulties (5) and post-stroke impairments (4), which may make it harder to communicate symptoms of ALI quickly (T2.5).

Table 2.5 The patient had communication difficulties	Number of patients
Language	10
Hearing difficulties	8
Dementia	5
Learning difficulties/disability	5
Dysphasia/cognitive impairment post-stroke	4

Answers may be multiple; n=34

Case review data

Presentation of symptoms

The majority of patients in the study had a lower limb affected with ALI (303/330; 91.8%) (T2.6). Most patients had only one limb affected, but a small number had more than one limb affected (F2.4). The involvement of multiple limbs suggests a proximal embolic source. All the patients who had atrial fibrillation and multiple limbs affected had been prescribed an anticoagulant prior to their admission. However, the patients' compliance with, and the effectiveness of their anticoagulant prescription, was unknown.

Table 2.6 The presenting limb	Number of patients	%
Lower limb	303	91.8
Upper limb	28	8.5

Answers may be multiple; n=330

Case review data

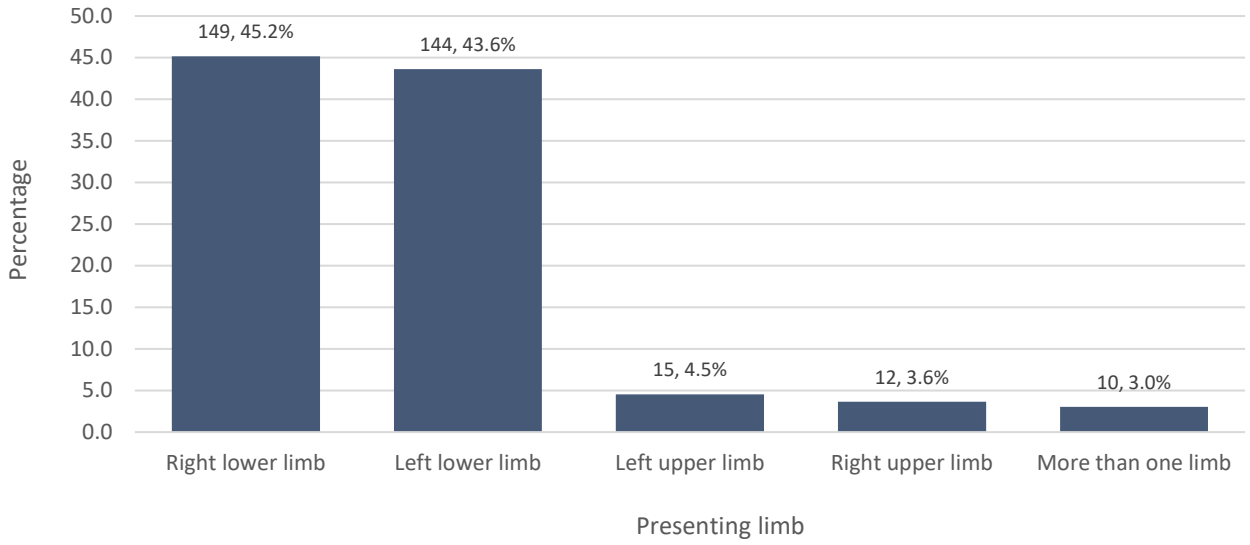


Figure 2.4 Presenting limb*; n=330*

Case review data

An arterial aneurysm is a recognised source of material that can cause a blockage in a limb. In this study 27/290 (9.3%) patients were known to have an aneurysm in the affected limb or at an earlier point in the blood supply to the limb.

This admission was the first episode of ALI for 241/293 (82.3%) patients, but 25/293 (8.5%) had experienced an episode of ALI in the previous ten years (history of ALI was unknown for 27 patients). There were 60/293 (20.5%) patients who had undergone previous surgical or endovascular revascularisation procedures for ALI or peripheral artery disease (PAD) and 11/293 (3.75%) patients who had undergone a previous amputation. Monitoring ALI procedures and outcomes at a national level would provide a benchmark for assessing readmissions/recurrence of disease.

The majority of patients had no ischaemic symptoms in the presenting limb before this presentation (178/293; 60.8%). Minor chronic PAD may not have any symptoms. When symptomatic chronic PAD causes intermittent claudication or more severely, chronic limb-threatening ischaemia (CLTI) with one or more of rest pain, tissue loss, gangrene or ulceration. The clinicians in the vascular hub identified 109/293 (37.2%) patients with symptoms of chronic PAD in the presenting limb (T2.7).

Table 2.7 Prior condition of the presenting limb	Number of patients	%
Asymptomatic	178	60.8
Intermittent claudication	63	21.5
Rest pain	46	15.7
Tissue loss/gangrene/ulceration	11	3.8
Nothing recorded	5	1.7
Discolouration	3	1.0
Other	3	1.0

Answers may be multiple; n=293

Clinician questionnaire data

The reviewers identified a higher prevalence of CLTI prior to the admission, identifying 111/330 (33.6%) patients as having acute-on-chronic limb ischaemia.

Most patients with CLTI will have sought medical advice for their symptoms. Intermittent claudication is commonly managed conservatively, at least initially, in the UK. In other healthcare systems intervention is common. It is unknown how many patients with intermittent claudication had sought medical advice, but it is likely many will have been seen in primary care, and some will have seen a vascular surgeon. Patients with symptomatic PAD will have widespread atherosclerosis and are at high risk of cardiovascular events, yet they are often undertreated with medical therapies.[23,24]

Lipid-lowering drugs were prescribed to 117/293 (39.9%) patients and to 49/109 (45.0%) patients with symptoms of chronic PAD. Whether these low rates were due to lack of assessment and/or prescription or patient decision or intolerance could not be determined.

In this study, only 11 patients in total and six patients with symptomatic PAD were taking a direct oral anticoagulant (DOAC) and antiplatelet agent.[25] Irrespective of whether intervention is a consideration, patients with chronic PAD should be offered appropriate medical management, in addition to promoting healthy behaviours, to reduce life and limb-threatening events. This study suggests that such simple preventative strategies are not well embedded in the current management of PAD.

Seeing a patient with chronic PAD in clinic offers valuable educational opportunities. These include provision of information on the symptoms of ALI and who to contact, and empowering patients to present rapidly to the vascular hub if they develop loss of sensation and or movement in association with acute limb pain.

The reviewers considered that there was room for improvement in the care of 21/111 (18.9%) patients with CLTI. The reasons (answers may be multiple) included eight who had previously seen a GP with ALI, nine who had delayed treatment of their deteriorating chronic ischaemia and five with lifestyle modifiable factors which were not addressed.

3 THE SEVERITY OF ACUTE LIMB ISCHAEMIA

The first-line treatment for acute limb ischaemia, unless the patient needs palliative care only, is anticoagulation, intravenous (IV) fluids and supplemental oxygen.[26] Analgesia is also essential, with involvement of the acute pain team as needed.[27]

Once a diagnosis has been made, the urgency of treatment is determined by whether there is newly altered sensation and/or movement in an acutely painful limb. This simple assessment can be carried out by all healthcare professionals, including nurses and allied health professionals.

To understand the urgency and quantify the severity of a patient's condition to facilitate communication between healthcare professionals the Rutherford classification is used (T3.1).[27,28]

Table 3.1 The European Society for Vascular Surgery (ESVS) modification of the categories of ALI according to Rutherford's clinical findings

Grade	Category	Sensory loss	Motor deficit	Prognosis
I	Viable	None	None	No immediate threat
IIa	Marginally threatened	None or minimal (toes)	None	Salvageable if promptly treated
IIb	Immediately threatened	More than toes	Mild/ moderate	Salvageable if promptly revascularised
III	Irreversible	Profound, anaesthetic	Profound, paralysis	Major tissue loss amputation. Permanent nerve damage inevitable

The ESVS 2020 ALI guideline made some minor modifications to the original Rutherford classification. [28] The full classification includes the use of handheld arterial and venous Doppler, an assessment tool generally only used by vascular specialists.

Distinguishing between the classifications of Rutherford IIa and IIb, and between IIb and III, can sometimes be challenging.[1] Not all patients with ALI require revascularisation or amputation. Some will be appropriately treated with anticoagulation alone (primarily those with ALI, Rutherford I).

The Rutherford category may deteriorate, particularly with delays to treatment, as the lack of blood supply causes tissue and nerve damage. Without treatment Rutherford IIa ALI will usually progress to IIb and then III. Patients with ALI categorised as Rutherford IIb the accepted plan is that patients require revascularisation as soon as possible and ideally within six hours for fully functional limb salvage.

Compartment syndrome where swollen muscles compress the arterial supply and venous drainage is related to the severity and duration of ALI.[29] It may be aggravated by revascularisation and increases the risks of amputation, muscle necrosis and nerve damage. Performing a fasciotomy can relieve the compartment pressure[30] but should be performed within two hours;[1] waiting longer than six hours is not acceptable practice[28] as fasciotomies are not without risk and compilations can include infection, and the need for skin grafts.[31]

4 TIME FROM FIRST SIGNS AND SYMPTOMS TO PRESENTATION

(BACK TO CONTENTS)

CASE STUDY – GOOD CARE

A patient who developed acute calf and foot pain overnight called 999 the following morning. The emergency ambulance paramedic crew who attended, suspected ALI with decreased ankle movement and sensory impairment. The patient was transferred directly to a vascular hub where they were seen within two hours of the initial presentation and underwent revascularisation within four hours of the initial presentation.

The reviewers considered that this was good care with exemplary communication between primary care and the vascular hub.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient with a history of chronic limb-threatening ischaemia, smoking and excessive alcohol use presented to their local emergency department (ED) after five days of sudden onset severe pain in their left leg. The assessment in the ED took over three hours. They were initially misdiagnosed, and it took a further 12 hours before a referral was made to the nearest vascular hub, and a further delay of four hours waiting for an ambulance to transfer them.

The reviewers considered that there were too many delays in all stages of this pathway.

Initial symptoms

Determining the time from the onset of acute limb ischaemia (ALI) symptoms to the first presentation to any healthcare professional is challenging. It relies on the patient's recollection of events, the level of detail recorded in the medical history, and the combination of medical records that may be on more than one healthcare system. For the 283 patients where the reviewers were able to make an assessment, the median time from symptoms to presentation was 1.1 days (F4.1).

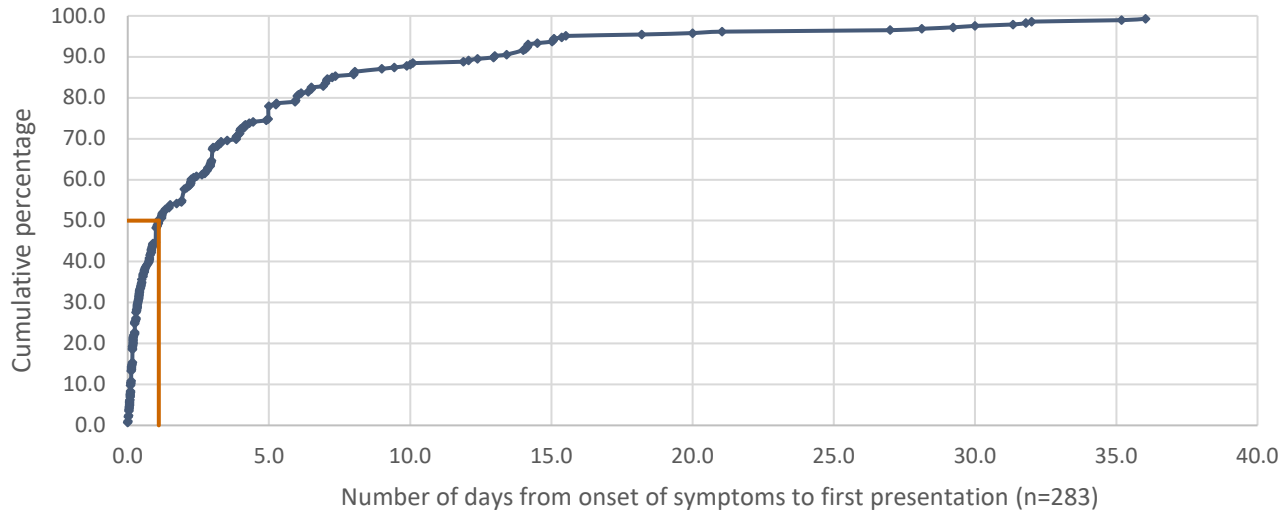


Figure 4.1 Time from onset of symptoms to first presentation to healthcare*; n=283*
Case review data

There were only 65/283 (22.9%) patients who presented within six hours of their symptoms starting. A further 38/283 (13.4%) patients presented between six and 12 hours and 36/283 (12.7%) between 12 and 24 hours (F4.2). Delays to presentation were common, with 144/283 (50.9%) patients

presenting more than 24 hours after the onset of their symptoms. National data on delay to presentation would help target education and patient awareness campaigns.

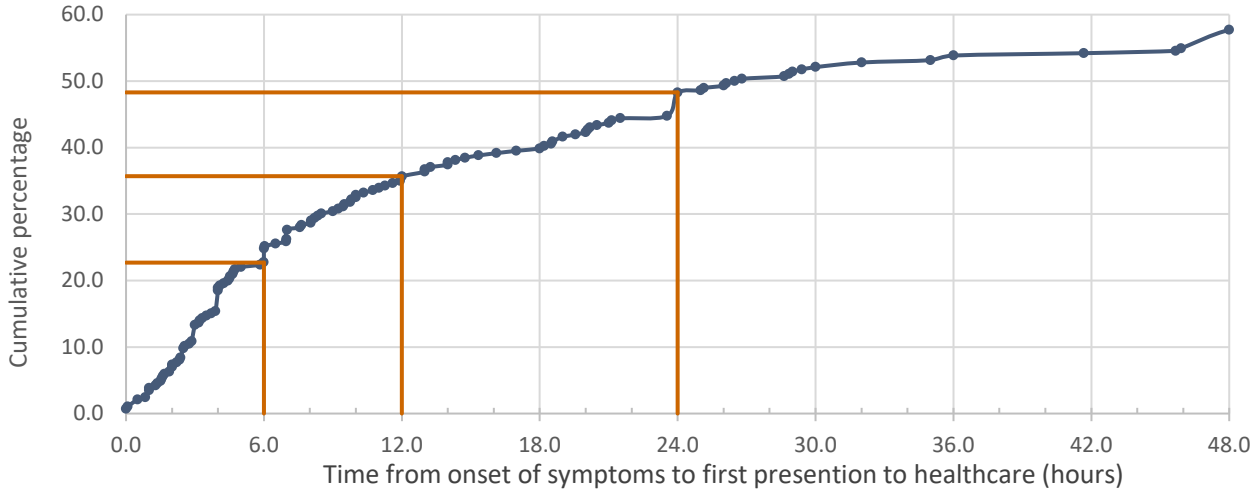


Figure 4.2 Time from onset of symptoms to first presentation to healthcare in hours; *n=283*
Case review data

When time to presentation was assessed against the Rutherford classification (in the vascular hub), 20/62 (32.2%) patients with a Rutherford IIb category first presented to healthcare within six hours and 43/62 (69.3%) presented within 24 hours (F4.3).

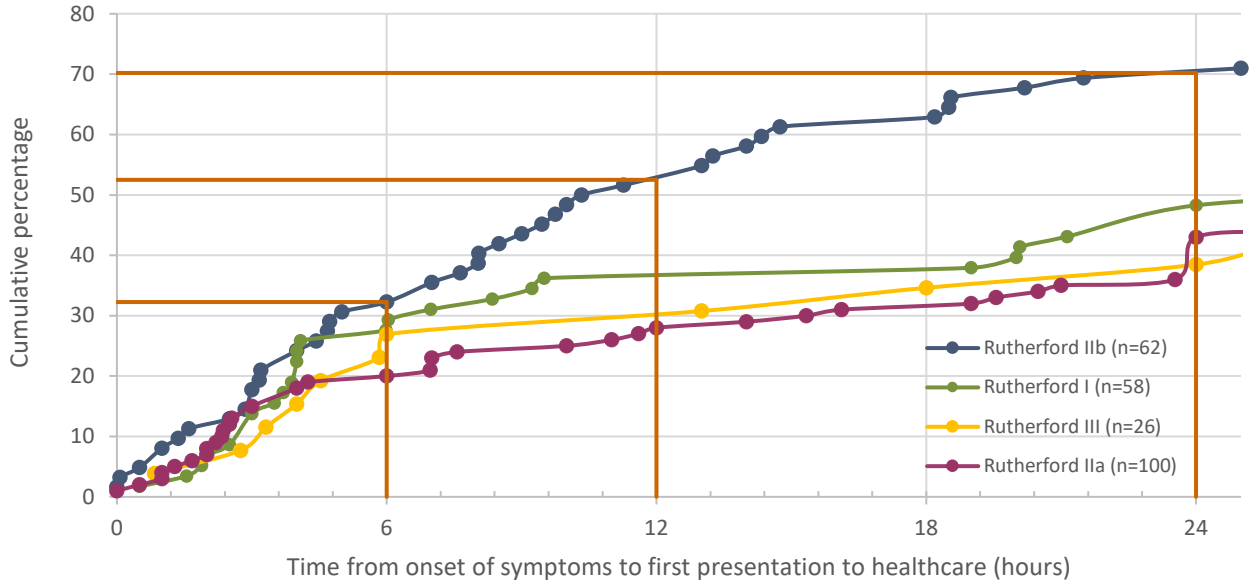


Figure 4.3 Time from onset of symptoms to first presentation to healthcare split by Rutherford category
Case review data

The group of patients with a Rutherford IIa category presented later than those with Rutherford IIb. While it is unknown if the patient's limbs would have been salvageable had they presented earlier, improvements in limb salvage can only occur if there are opportunities to assess and treat earlier. This underscores the need for greater awareness and consideration of the symptoms of ALI.

NHS 111, whose advice algorithm directs patients to attend their local emergency department, was rarely used (or rarely recorded in the notes) (12/325; 3.7%) (T4.1) but when it was, the median time from onset of symptoms to contact with NHS 111 was 4.8 hours (F4.4).

Table 4.1 Healthcare provider that the patient first presented to	Number of patients	%
Self-presented to a vascular hub emergency department	83	25.5
Self-presented to a spoke hospital emergency department	79	24.3
999 call	69	21.2
Primary care	68	20.9
Presented at an outpatient clinic	14	4.3
NHS 111	12	3.7
Subtotal	**325**	
Unknown	5	
Total	**330**	

Case review data

Patients with ALI who self-presented to a spoke emergency department also had shorter median times to presentation (23.5 hours) than those who presented to a vascular hub emergency department (1.3 days) or primary care (1.9 days) (F4.4). All the groups varied widely with ranges from less than six hours to one month. These differences may reflect the symptoms the patient was experiencing or the relative difficulties in accessing primary healthcare advice, while others may have delayed seeking medical advice due to a lack of awareness of the seriousness of their symptoms or other patient factors that affected their healthcare.

"I was on phone for ages to get GP appointment, then had to wait for my son to take me. I was in a lot of pain. Lots of waiting around and sent from one hospital to another. I didn't really know what was going on." Quote from the patient survey

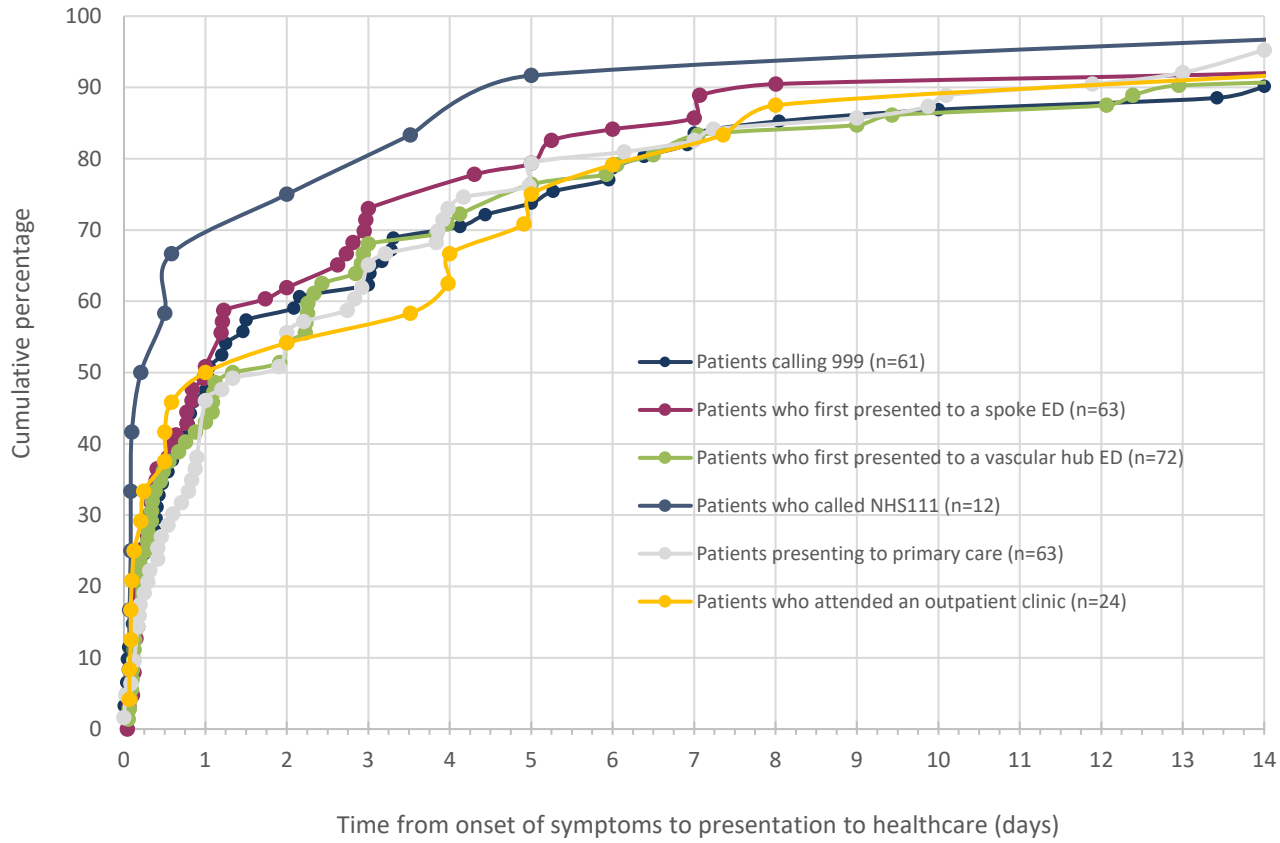


Figure 4.4 Time from onset of symptoms to first presentation to healthcare split by where the patient first presented

Case review data

In 60/330 (18.2%) sets of notes reviewers thought that patient factors delayed their presentation. The commonest reason was lack of patient awareness (25/60) with 'chaotic lifestyle', including not engaging with healthcare in 16/60 and vulnerability/mental health problems in 9/60. Four patients were also noted to have communication difficulties e.g. English as a second language. When patient factors delayed presentation the reviewers considered the outcome was more than likely affected for 11/60 patients.

Where there were missed opportunities to recognise ALI prior to admission, the reviewers found that this was most commonly due to a lack of patient awareness for 82/115 (71.3%). For 24/115 (20.9%) patients there were missed opportunities to recognise ALI in primary care. The reviewers noted that there was also a missed opportunity to recognise ALI by NHS 111. These findings support a public and pre-hospital services awareness campaign, similar to that for stroke.

5 PRESENTATION TO PRIMARY CARE

(BACK TO CONTENTS)

CASE STUDY – GOOD CARE

A patient presented to their GP with a cold, pale, numb painful, pulseless foot that had developed overnight. The GP took a complete history, performed an examination and diagnosed suspected acute limb ischaemia, noting the '6Ps', which included sensory-motor deficit, then organised an emergency transfer by ambulance to the nearest vascular hub where the patient underwent an embolectomy and was discharged home one week later.

The reviewers stated that the GP's recognition of the symptoms of acute limb ischaemia and immediate referral the patient to the vascular hub hospital was exemplary care and likely contributed to the good outcome for this patient.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient with type 2 diabetes presented to their GP with a two-day history of severe leg pain. The leg was pale and painful, yet foot pulses and a pain score were not recorded. The patient went home with a prescription for low-dose aspirin. The next day they called NHS 111 and attended their local emergency department with worsening leg pain, numbness and weakness. They were transferred to a vascular hub, where they were diagnosed with ALI (Rutherford IIb) and required an amputation.

The reviewers stated that there was a missed opportunity to intervene earlier and save the limb. If the patient had been aware that their symptoms were serious and presented earlier, or if the GP had referred them directly to a vascular hub.

Of the 249 patients who had a procedure (revascularisation and/or amputation), the majority presented to a hospital, contacted their GP or called 999 (188/249; 75.5%). Those who presented directly to a hospital had a median time to procedure of 1.2 days compared with those patients who went to primary care first. Their median time to procedure was longer at 2.3 days (F5.1). There were 16/58 vascular networks where it was reported that a referral service/pathway was integrated with primary care.

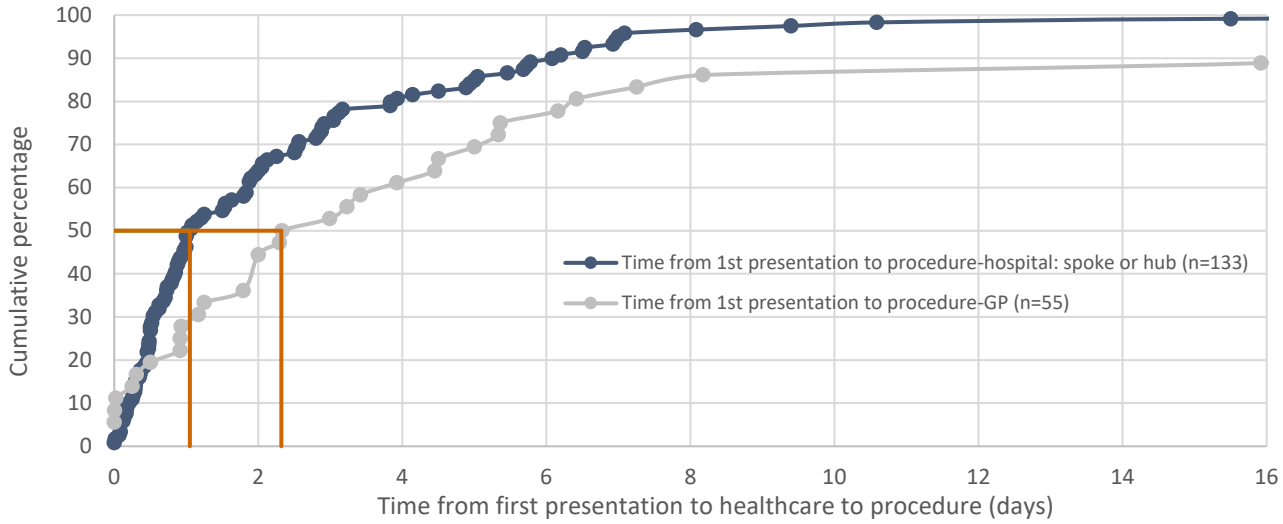


Figure 5.1 Time from first presentation to healthcare to time of first procedure
Case review data

The NICE clinical knowledge summary on peripheral arterial disease (PAD) is available to all healthcare professionals.[3] In the section 'What are the clinical features of ALI', it documents the '6Ps' of ALI, which every medical student is taught:

Pain constant, usually unrelieved by over-the-counter analgesics
Pallor (or cyanosis or mottling)
Paraesthesia or reduced sensation or insensate limb
Paralysis or reduced power
Perishingly cold (poikilothermia)
Pulselessness ankle pulses are absent

What is less well taught or remembered, is that not all of the '6Ps' need to be present to make a diagnosis of ALI and that it is rare to have all of them even in cases of severe ischaemia.[3,27] Detailed local written guidance to assist in the recognition and initial management of ALI was available in 36/111 (32.4%) primary care organisations. It was noteworthy that in 41/111 (36.9%) this was unknown. There are additional NICE resources available to primary care, such as the ALI template produced by Arens/Emis (medical software used in primary care).

Details of what the local guideline covered were not sought but GPs were asked "*What would you expect to happen in your practice if a patient presented with ALI?*"
There were 79/111 (71.2%) primary care organisations where it was expected that the '6Ps' would be recorded, yet they were recorded in only 21/48 (43.8%) patients. Other aspects of clinical assessment were inconsistently performed or recorded, e.g. examining the limb in 30 patients and documenting a pain score in fewer than five patients. A Rutherford category was not recorded for any patients in primary care. Most GPs predicted that the patient would be referred to the nearest emergency department or vascular hub, but this occurred in 27/48 patients and 12/48 patients respectively, demonstrating some disconnection between expected standards and the reality of clinical practice (F5.2).

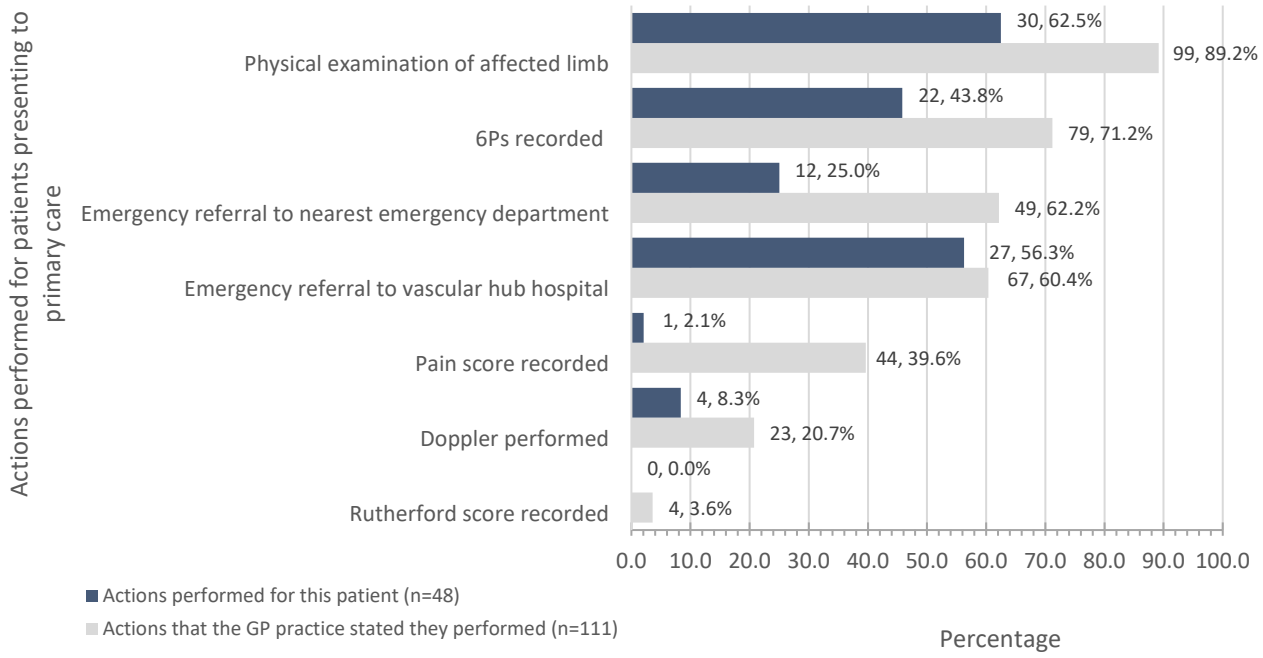


Figure 5.2 Primary care: assessment, diagnosis and actions. Actions that this GP practice stated they performed for patients with ALI; *n=111*, patients with ALI seen at this GP practice; *n=48*
Primary care questionnaire data

Pain was the most frequently recorded of the '6Ps' (42/48) (T5.1). It is important to record the absence as well as the presence of the '6Ps' as not all will be present in every patient. Review of the case notes did not allow differentiation between information not collected and symptoms that were not present.

Table 5.1 Signs of ALI at presentation to primary care	Number of patients	%
Pain	42	87.5
Pallor	17	35.4
Pulseless limb	15	31.3
Perishingly cold (poikilothermia)	15	31.3
Paraesthesia	10	20.8
Swollen limb	6	12.5
Paralysis	3	6.3
Unknown	2	4.2

Answers may be multiple; n=48

Primary care questionnaire

Acute limb ischaemia was diagnosed or suspected in 21/48 patients attending primary care. In 27/48 ALI was not diagnosed, but other vasculitis, cellulitis, or deep vein thrombosis were.

Patients with these conditions often present with painful, swollen limbs. Limb swelling is not usually described as a feature of ALI; however, leg swelling was present in 6/48 patients in our study including two who had no other symptoms.

Making a correct diagnosis of ALI in primary care is not essential, provided it is recognised that the patient requires urgent assessment. Most patients (41/45) had an emergency transfer to hospital, including two thirds (28/45) who were sent directly to the vascular hub from primary care. The need to expedite care was not identified in 4/45 patients, who were advised to return home and go to the emergency department if their symptoms deteriorated (T5.2).

Table 5.2 Directions given following attendance in primary care	Number of patients
Emergency transfer to a vascular hub	28
Emergency transfer to the nearest emergency department	13
Advice to return to place of residence and to attend the nearest emergency department if symptoms got worse	4
Subtotal	**45**
Unknown	3
Total	**48**

Primary care questionnaire

6 PRESENTATION TO A SPOKE HOSPITAL

(BACK TO CONTENTS)

CASE STUDY – GOOD CARE

A patient with acute limb ischaemia (Rutherford category IIa) presented to a spoke hospital following NHS 111 advice. The patient was reviewed rapidly in the emergency department and ALI was diagnosed. There was good communication with the vascular hub, and the patient was transferred within two hours and had an operation two hours later.

The reviewers thought this was an example of good pathway organisation.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient was taken to their local hospital by ambulance with a non-viable leg (Rutherford III), pneumonia, chronic renal failure and severe frailty. They were transferred to the vascular hub where they received palliative care and died three days later.

The reviewers considered this to be an unnecessary transfer to the vascular hub with the patient dying away from their family.

In total, 138/330 (41.8%) patients had attended a spoke hospital before being transferred to a vascular hub. There were 72/138 (52.2%) patients taken by ambulance and ALI was mentioned on the patient report form (PRF), where it was available, for 29 patients. For 22 patients ALI was not mentioned on the PRF. This suggests that ambulance bypass protocols for ALI are not universal or that existing protocols are not being followed. More importantly, it highlights a simple opportunity to reduce delays in the ALI patient pathway. Case reviewers believed that 31/72 patients would have benefited from being taken directly to a vascular hub.

In the organisational questionnaire, 21/55 vascular hubs reported that an ambulance bypass protocol was in use, but only one ambulance trust that responded stated a bypass protocol was used. However, it should be noted that clinical assessment and discussion with the patient should be considered to prevent transfers that offer no clinical benefit.

The clinicians at the hospital also identified delays in the patient presenting to their local hospital in 31 instances, with patients delaying seeking help being the most common reason (T6.1).

Table 6.1 Reasons for the delay in the patient presenting to a hospital	Number of patients
Patient delayed seeking help	22
Patient sought help from primary/ambulatory care was misdiagnosed and discharged home	5
Patient presented to primary care - referred to spoke hospital	5

Answers may be multiple; n=31

Clinician questionnaire data

In the view of the reviewers there was a delay in the triage/streaming process for 18/138 (13.0%) patients and a delay in the initial assessment in 21/138 (15.2%). Misdiagnosis (6/19) was the most common reason for delay. This highlights the need for further information for patients as well as for the healthcare professionals involved in assessment/triage.

A brief education document describing ALI assessment, management and differential diagnoses was made available to all healthcare professionals in 2022 by the Royal College of Emergency Medicine.[27]

In the spoke hospital, 113/138 (81.9%) patients had all necessary assessments completed. Where omissions were identified, they were in the recording of limb power and/or pulses (six) and imaging/Doppler ultrasound in nine patients.

Delays were reported in the examination/investigations in 17/138 (12.3%) patients. Imaging should not delay a transfer but if it can be performed quickly without causing a delay, it can be beneficial for planning treatment in advance. Although, this applies only if imaging can be shared electronically; otherwise, it may pose an unnecessary risk of repeated imaging at the vascular hub.

Rutherford classification

A Rutherford category was recorded in the notes of only 6/138 (4.3%) patients, indicating either a lack of awareness of it or a lack of confidence in using it by non-vascular specialists. According to the clinician survey, 31/32 emergency medicine/acute care physicians recorded the '6Ps' but only 1/32 routinely recorded a Rutherford category, despite 31/32 receiving postgraduate or workplace training in the assessment of ALI. When a Rutherford category was not recorded, the reviewers estimated the Rutherford category based on the patient history and examination in the hospital notes (where they were able).

The Rutherford category for the patients attending the spoke hospital indicated that 30/106 (28.3%) required revascularisation within six hours of their development of sensory-motor symptoms, while 8/106 (7.5%) probably required a primary amputation (T6.2). In total, at least 38/106 (35.8%) patients were in a hospital where the treatment they required could not be provided, suggesting that many vascular networks are missing the organisational opportunities to improve the care of ALI.

Table 6.2 Rutherford category in the spoke hospital (combination of recorded in notes and estimated by reviewers)	Number of patients	%
Rutherford I	13	12.3
Rutherford IIa	55	51.9
Rutherford IIb	30	28.3
Rutherford III	8	7.5
Subtotal	**106**	
Unable to calculate	32	
Total	**138**	

Case review data

A total of 36/138 (26.1%) patients were admitted to a medical ward in the spoke hospital before they were transferred to the vascular hub, including 3/36 patients initially misdiagnosed as having a deep vein thrombosis. Admission to a ward did not appear to be influenced by those with viable limbs or inevitable amputations.

Patients with threatened but salvageable limbs accounted for 25/36 ward admissions. Emergency transfer to a vascular hub was indicated in these patients. The decision to admit a patient or keep them in the emergency department pending transfer should always be clinically driven. It is likely that transfer from a ward would be slower than from the emergency department. Patients with ALI who require care in a vascular hub should receive that care as quickly as possible and not be admitted to a ward.

A record of the discussion with the vascular hub was evident in 118/138 (85.5%) cases reviewed, while 9/23 (39.1%) respondents in the clinician survey identified difficulties contacting the vascular surgical team as a barrier to care.

7 TRANSFER FROM A SPOKE HOSPITAL TO A VASCULAR HUB

(BACK TO CONTENTS)

CASE STUDY – GOOD CARE

A patient attended a spoke hospital with a threatened but viable acutely ischaemic arm. Documentation of the examination and decision-making was excellent. Anticoagulation therapy was started and the patient transferred to a vascular hub without delay. Surgical embolectomy took place within four hours of arrival, and the patient was discharged home two days later.

The reviewers considered that this was good use of an ALI proforma in the spoke hospital.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient presented to a spoke hospital and was initially seen quickly but misdiagnosed as having had a stroke. Once they had been correctly diagnosed, following a senior review, and a referral made to the vascular hub, it took a further four hours for an ambulance transfer.

The reviewers stated this to be an unnecessary delay.

In total, 7/78 spoke hospitals described a network where they referred to two or more vascular hubs. A more complicated picture emerged with the number of spoke hospitals from which the vascular hub received referrals. This ranged from zero to 22, with a mean of 3.54 and mode of two. The total number of spoke hospitals this was based on was 170, suggesting that there are 36 spoke hospitals referring to more than one vascular hub. Since the first stage of defining a vascular network is determining the hospitals it includes, this variation suggests some confusion in network boundaries.

All the patients in this study were admitted to a vascular hub. In 16/50 vascular hubs, at least one spoke hospital within the network was more than an hour away by blue light ambulance in working hours. The median time from arrival at the spoke hospital to arrival at the vascular hub was 8.16 hours, exceeding the recommended target for treatment of immediately threatened limbs (Rutherford IIb) from relevant sensory-motor symptom onset.

For 34/138 (24.6%) patients the reviewers reported that the time spent at the spoke hospital was too long. Waiting for an ambulance was the most common reason for the delay (11/34) (T7.1).

Table 7.1 Details of the delay in the transfer to a vascular hub	Number of patients
Waiting for an ambulance for the transfer	11
Decision-making in the spoke hospital	9
Referral/acceptance at the vascular hub	7
Distance needed to travel to the vascular hub	2
Unclear	4

Answers may be multiple; n=34

Case review data

There were 13/81 (16.0%) patients who had a delay of greater than 24 hours (F7.1). The nine patients who had a deterioration in their Rutherford category in the spoke hospital had a mean transfer time

of ten hours (range 3.9 to 19.4 hours). Reviewers stated that eight patients would have benefited from being admitted directly to the vascular hub.

All responding ambulance trusts stated that a Category 2* transfer would be booked if the clinician booking the transfer considered that there was a risk to a limb. It appears that the existing vascular network and ambulance pathways and protocols are not fulfilling the needs of patient networks for those with ALI. **Category 2 is a target response time average of 18 minutes, with 90% of calls being responded to within 40 minutes. For 2023/24 and 2025/26, the national target is an average of 30 minutes.*

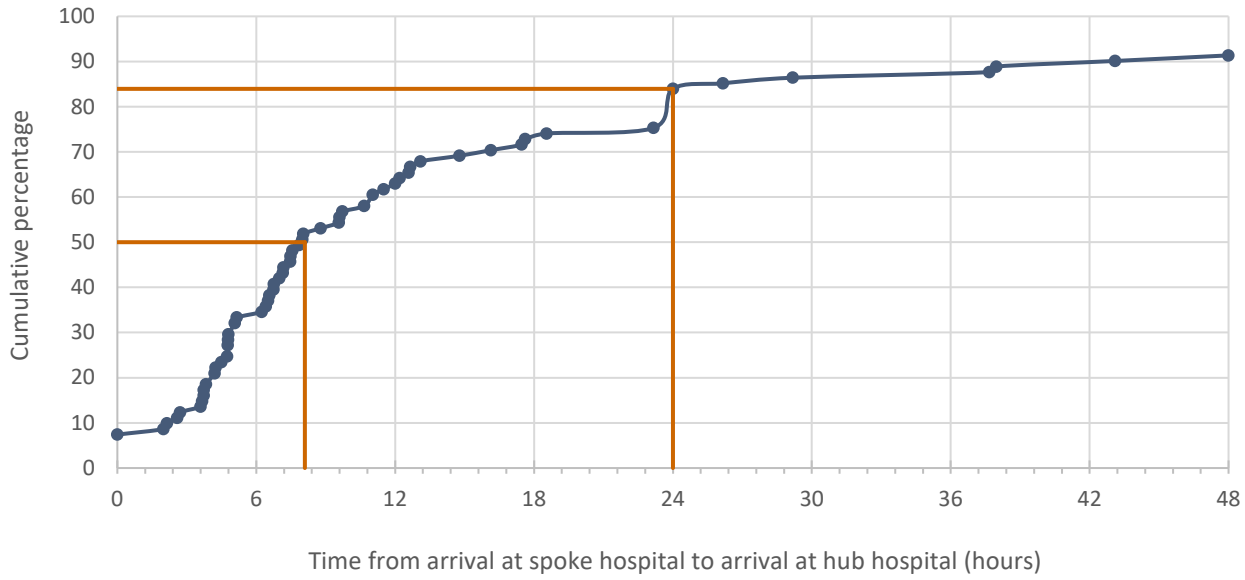


Figure 7.1 Time from presentation to spoke hospital to arrival in vascular hub; *n=81*
Case review data

A well-organised vascular network should be able to reduce the issues that have been identified with presentations to spoke hospitals. Written guidance specific to the management of suspected ALI was available in only 56/91 spoke hospitals (T7.2), and where it existed key components were often missing. In 18/56 there was no single referral contact point at the vascular hub and 16/56 had no description covering the referral. The urgency of the ambulance transfer was not documented in 31/56 and expected timeframes were only documented in nine. The Rutherford category was included in only 8/56 spoke hospital guidelines which may explain why it was so infrequently used.

Table 7.2 Details of ALI guidance in spoke hospitals	Number of hospitals
A protocol covering the process of referring the patient to the vascular hub	40
Referrals to the vascular hub via a defined vascular surgical single point of contact	38
A protocol for the assessment and recognition of ALI	31
Category/urgency of ambulance transfer	25
Preferred imaging modalities for patients with symptoms of ALI	24
A transfer protocol covering the patient transfer to the vascular hub	24
A protocol covering medical treatment of patients who are not transferred	13
Recommended timeframes for the completion of required steps on the pathway	9
A protocol covering the discharge of repatriated patients ensuring all necessary onward referrals and follow-up appointments are made	9
Inclusion of a 'Rutherford' or other severity scale	8
A protocol/standard operating procedure covering the process of repatriating the patient to the spoke hospital following treatment at the vascular hub	8

Answers may be multiple; n=56

Spoke hospital organisational data

When patients are transferred between hospitals sharing their medical records and imaging is essential for safe and expeditious treatment. There were 34/91 spoke hospitals in which medical records could be shared electronically and 56/91 in which images could be shared immediately (T7.3). All other systems that were described, such as email and paper copies, risk delays or other harm.

Table 7.3 Record sharing in vascular networks for patients treated for ALI	Number of spoke hospitals
The spoke hospital and the vascular hub are on the same electronic imaging archiving system, which allows immediate sharing of image reporting	56
The patient case notes sent to the vascular hub are primarily on paper and travel with the patient	42
The spoke hospital and the vascular hub are on the same electronic patient record system, allowing immediate sharing of written case notes	34
Patient case notes are normally emailed to the vascular hub	6

Answers may be multiple, n=91

Spoke hospital organisational data

8 CARE AT THE VASCULAR HUB

(BACK TO CONTENTS)

CASE STUDY – GOOD CARE

A patient with suspected acute limb ischaemia (Rutherford IIb) was transferred from a nearby spoke hospital by ambulance. The patient was admitted and assessed and underwent a femoral endarterectomy within one hour of arrival. They stayed in the vascular hub for four days then were repatriated back to their local hospital allowing their family to visit and support them in their recovery.

The reviewers felt that this was a good example of a vascular network working well with good communication between hub and spoke hospitals, good decision making at each stage of the pathway, and excellent patient-centred care.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient with a history of alcohol excess, smoking and type 2 diabetes presented to the emergency department (ED) of a vascular hub, with a painful leg. They initially refused any examination or treatment and left the ED on one occasion. They were eventually examined by the resident emergency doctor, misdiagnosed as having a deep vein thrombosis and admitted to a medical ward. After review by a consultant physician later that evening they were transferred to the vascular surgery department and diagnosed with acute limb ischaemia, with an embolectomy undertaken within 12 hours.

The reviewers felt that the lack of protocolised care, the lack of awareness of the emergency medicine resident doctors, the delays in senior review and the lack of input from the alcohol or psychiatric liaison teams all contributed to the delays in the care for this patient.

The 2018 Vascular Society Provision of Vascular Services (POVS) did not include ALI in its time critical conditions or in amputation avoidance.[2] There are around 5,000 to 6,000 major amputations annually in the UK and the focus has been on chronic limb-threatening ischaemia (CLTI) to reduce amputation rates. Opportunities to reduce amputations and improve overall care for those who develop ALI as a new condition or as consequence of CLTI, have been overlooked until now.

The 2021 POVS included ALI,[32] and recommends that vascular networks have a written clinical pathway for its management, that ambulances should bypass local emergency departments (spoke hospitals) to avoid delays in presenting to the vascular hub. However, ALI was not included in the time critical conditions in the updated 2024 POVS.[33]

There were 192/330 (58.2%) patients who presented directly to a vascular hub. The most common route was via presentation to an emergency department (82/192; 42.7%), followed by primary care referrals (30/192; 15.6%) and blue light ambulance (34/192; 17.7%) (T8.1).

Table 8.1 Mode of presentation to the vascular hub	Number of patients	%
Transfer from a spoke hospital	138	41.8
Emergency department (within the vascular hub)	82	24.8
Ambulance attendance, blue light to the emergency department	34	10.3
Referral from a GP/primary care transfer	30	9.1
Referral from another inpatient unit	17	5.2
Other ambulance attendance	10	3.0
Referral from another clinic	9	2.7
Referral from a vascular surgery clinic	8	2.4
Referral from NHS 111	2	<1
Total	**330**	

Case review data

Time to surgery

Patients diagnosed and transferred from a spoke hospital were referred directly to vascular surgery. This was supported by their median time from arrival at the vascular hub to procedure of 15.4 hours (F8.2). The median time from presentation at the vascular hub to procedure was 28.4 hours. Attendances at the vascular hub were a more varied group of patients, with some attending the emergency department at a vascular hub because it was their local hospital and some who called an ambulance and required triage and assessment before referral to vascular surgery.

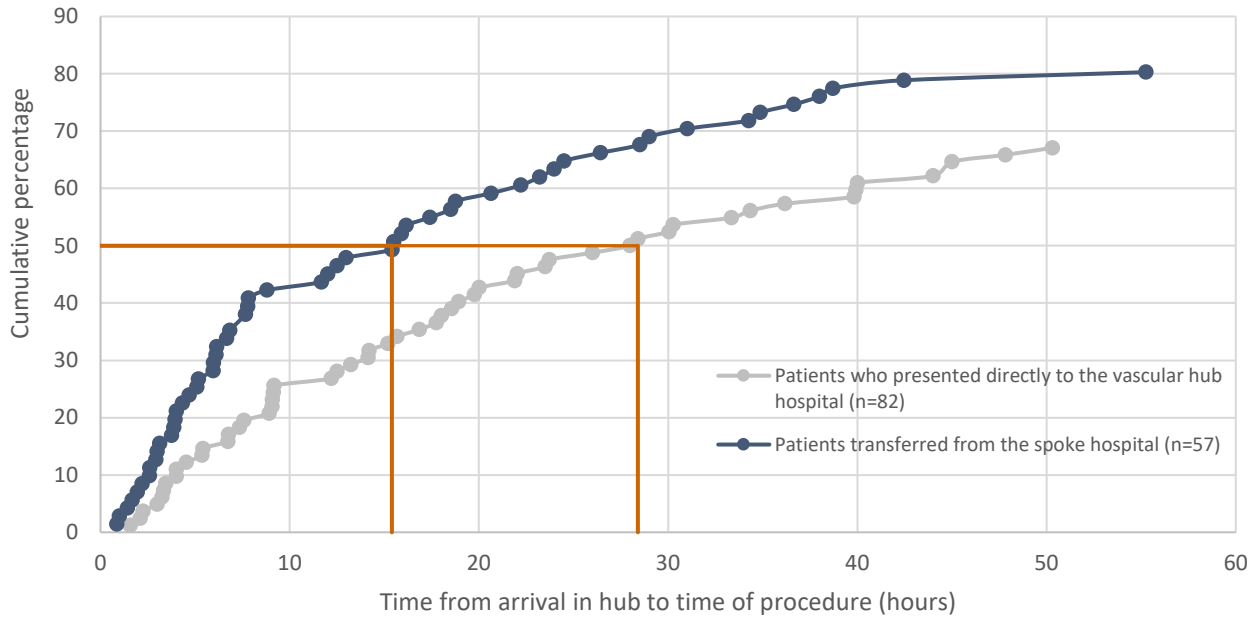


Figure 8.1 Time from arrival in vascular hub to time of procedure - patients admitted directly to vascular hub and those transferred from spoke hospital

Case review data

When ALI is diagnosed in primary care or when the patient is known to be under the care of vascular surgery for chronic ischaemia, there are opportunities to accelerate the care by referring directly to vascular surgery if the network links primary care with the hospitals.

The '6Ps' were inconsistently recorded at the first assessment in the vascular hub (T8.2). Limb pulses (276/293; 94.2%) and pain (253/293; 86.3%) were most recorded. Paraesthesia was recorded in 177/293 (60.4%) patients. Paraesthesia affecting the toes only is categorised as Rutherford IIa ALI, i.e. it is not an indicator of an immediately threatened limb. As noted in the primary care section, it is not uncommon for an ALI limb to be swollen. Limb swelling was present in 27/293 (9.2%) patients. This may cause some diagnostic confusion with deep vein thrombosis and cellulitis if it is not recognised as being present in some patients with ALI.

Table 8.2 Symptoms recorded in the vascular hub	Number of patients	%
Limb pulses	276	94.2
Pain	253	86.3
Cold limb	204	69.6
Paraesthesia	177	60.4
Pallor	146	49.8
Paralysis/weakness	110	37.5
Swollen limb	27	9.2

Answers may be multiple; n=293

Clinician questionnaire data

A Rutherford category was documented in the vascular hub for 69/330 (20.9%) patients (T8.3). When a Rutherford category was not recorded, reviewers estimated the category based on the patient history and examination in the hospital notes.

Table 8.3 Rutherford category	Recorded on admission in the vascular hub notes	Estimated by reviewers	Combination of recorded/estimated
Rutherford I	16 (23.2%)	52 (22.4%)	68 (22.6%)
Rutherford IIa	24 (34.8%)	100 (43.1%)	124 (41.2%)
Rutherford IIb	21 (30.4%)	56 (24.1%)	64 (21.2%)
Rutherford III	8 (11.6%)	24 (10.3%)	32 (10.6%)
Subtotal	**69**	**232**	**301**
Unable to calculate	261	98	29
Total	**330**	**330**	**330**

Case review data

In 81/105 (77.1%) sets of case notes, reviewers stated that there was no change the patient's limb condition between presentation to the spoke hospital and transfer to the vascular hub. Nine patients' limbs improved from Rutherford IIa to I with three on anticoagulation alone. In 15 patients there was a deterioration in their limb with 8/15 deteriorating to a Rutherford category IIb, an immediately threatened limb that required urgent revascularisation for salvage, and 3/15 to an unsalvageable limb requiring amputation (T8.4 and T8.5).

Table 8.4 The Rutherford category changed between the spoke hospital and the vascular hub	Number of patients	%
Stayed the same	81	77.1
Deteriorated	15	14.3
Improved	9	8.6
Subtotal	**105**	
Unknown	33	
Total	**138**	

Case review data

Table 8.5 Detail of the deterioration in Rutherford category	Number of patients
Rutherford I to Rutherford IIb	4
Rutherford IIa to Rutherford IIb	8
Rutherford IIb to Rutherford III	3
Total	**15**

Case review data

Despite the limitations in the documentation of clinical findings, the reviewers considered the initial assessment satisfactory in 290/330 (87.9%) patients and all necessary investigations performed in 307/330 (93.0%).

There was a delay in making the diagnosis of ALI in the vascular hub in 25/297 (8.4%) patients, including 18/25 emergency department attendances (T8.6). This reinforces the need for effective emergency department initial assessment of acutely painful limbs to correctly diagnose and accelerate the care of those with ALI. The most common reasons for the delay were misdiagnosis in 12 patients, deep vein thrombosis in six and chronic limb-threatening ischaemia in six (T8.7).

Table 8.6 Delay in the diagnosis of ALI in the vascular hub	Number of patients	%
Yes	25	8.4
No	272	91.6
Subtotal	**297**	
Unknown	9	
N/A - diagnosis already made in spoke hospital	24	
Total	**330**	

Case review data

Table 8.7 Reasons for the delayed diagnosis in the vascular hub	Number of patients
Misdiagnosed as deep vein thrombosis	6
Misdiagnosed as chronic limb-threatening ischaemia	6
Diagnosis missed	3
Delay in imaging	3
Referred to the stroke team	2
No details provided	5
Total	**25**

Case review data

Once ALI was diagnosed, or at least considered, a timely review by a vascular surgeon of sufficient seniority to plan their care occurred in 270/330 (81.8%) patients. Using an ALI pathway in the vascular hub appeared to have a positive impact on care by reducing review delays: 3/46 (6.5%) experienced a delay on an ALI pathway compared to 18/165 (10.9%) not on a pathway.

This view of care was not supported by the emergency and acute care physicians in the clinician survey, who reported that delays were frequently attributed to vascular surgical refusal to see patients before imaging had been performed and a failure to advocate for imaging acceleration.

The clinician survey supported the use of an ALI pathway across spoke hospitals and vascular hubs, which included decision-making tools, reliable lines of communication with vascular surgery and advice on imaging and its urgency. Of the emergency and acute medicine respondents who worked in a vascular hub, 4/11 reported having such a document, which dropped to 3/21 in spoke hospitals.

ALI care pathways should include a preferred imaging modality (CT, MRI or ultrasound, depending on local access/clinical preference) and a process to prioritise an agreed multidisciplinary treatment plan. A delay in treatment planning occurred in 34/330 (10.3%) patients (T8.8). Current NICE guidance states that patients should be assessed for risk factors for iodinated contrast-induced acute kidney injury but that this should not delay emergency CT scans.[34]

Table 8.8 Reasons for delay in treatment planning	Number of patients
Awaiting imaging	11
Awaiting multidisciplinary input	8
Reviewers unable to determine a reason from the records	8
Awaiting senior surgical review	6
Awaiting anticoagulation	1
Total	**34**

Case review data

Training

This study found delays in the triage, assessment, and diagnosis of patients with ALI in all clinical settings, including vascular hubs. Survey responses indicated that 21/41 vascular hubs provided work-based training in the recognition and management of ALI. In the majority this was focused on vascular surgical residents, with 6/21 extending it to the emergency department and/or foundation/core surgical residents. We did not ask about education on ALI provided in spoke hospitals or primary care. There are opportunities to improve ALI care with better and broader education and improved triage/initial assessment tools.

9 PROCEDURES UNDERTAKEN

(BACK TO CONTENTS)

CASE STUDY – GOOD CARE

Two years after an endovascular aneurysm repair a patient developed a painful calf and foot. After 24 hours they attended the emergency department in a spoke hospital. Evaluation was quick and the suspected acute limb ischaemia confirmed, which revealed that all three calf arteries were badly damaged. Within an hour of arrival in the hub a successful hybrid operation was followed by a calf embolectomy and thrombolysis, and stent insertion.

Reviewers believed the delayed presentation did not affect the outcome and the care was good.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient presented to hospital with a numb foot. The emergency department diagnosis was a suspected stroke. The patient was in a corridor for ten hours until they were seen by the stroke team, who found the patient to h a pale non-salvageable leg requiring an above knee amputation.

Reviewers stated that the patient had presented in time for their leg to be salvaged but the misdiagnosis, and delays in review, including the stroke review likely contributed to the patient's outcome.

There were 249/330 (75.5%) patients in this study who underwent one or more procedure with 78/330 (23.6%) treated with an anticoagulant alone or with palliative care.

Overall, in the 249 patients who had a procedure, the median time to treatment was four days (F4.9). These included 35/249 (14.1%) patients who had a primary amputation, where delaying surgery to optimise the patient or define the required level of amputation can reflect good practice.

Rutherford category IIb patients require revascularisation unless palliative care is more appropriate. Delays from symptom onset to anticoagulant administration and/or the first procedure may contribute to poorer outcomes. The identification of significant sensory and/or motor compromise and absent arterial Doppler signals (Rutherford category IIb) should trigger immediate revascularisation. This limb- and potentially life-saving procedure should be prioritised over all except lifesaving operations, particularly since such cases represent only a quarter of ALI admissions.

Of the 52 patients classified as having Rutherford category IIb ALI, only 5/52 (9.6%) achieved the six-hour target, with a median time of 3.1 days (F9.1). Delays to revascularisation in Rutherford category IIb ALI not only puts the limb at additional risk, but may result in additional interventions such as fasciotomies, that could have been avoided with earlier treatment. Of those who had a procedure more than six hours from the onset of symptoms, 17 patients had an amputation and eight had fasciotomies. Prompt treatment is indicated in patients with Rutherford category IIb ALI; the median time to treatment for the whole population was ten days.

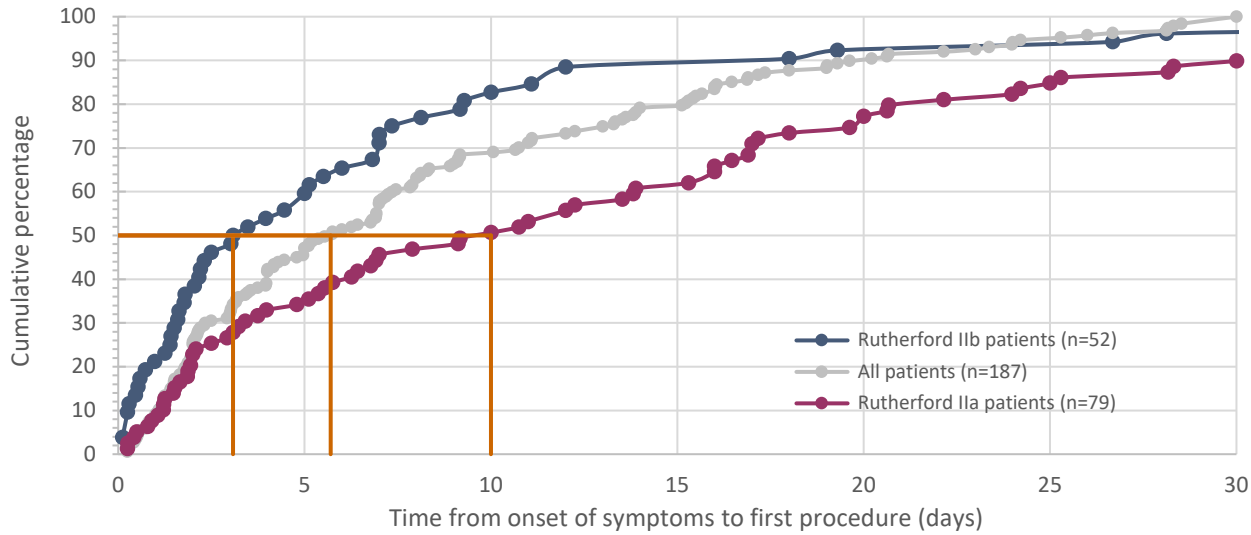


Figure 9.1 Time from onset of symptoms to procedure

Case review data

There were three patients with Rutherford category III ALI who had a revascularisation procedure. The lines between the Rutherford categories may not be distinct in an individual and intra-operative assessment of limb viability can be indicated in some patients.

First procedure

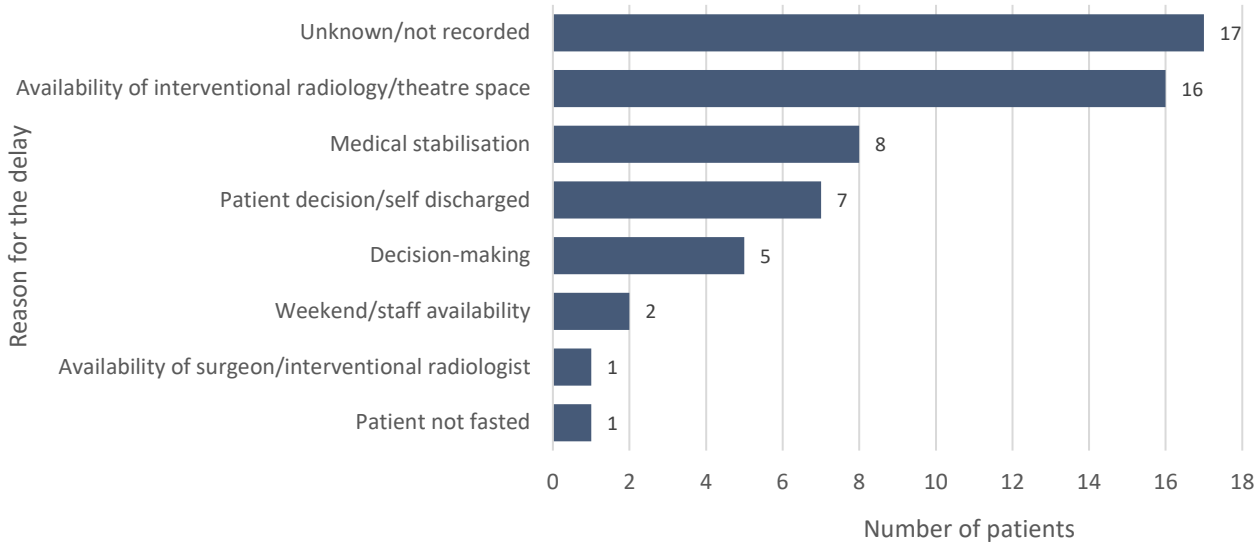
There is known variation in how doctors treat ALI, often based on their experience and available resources rather than strong clinical evidence.[35] Open surgical revascularisation was more commonly performed (159/249; 63.9%) than endovascular (28/249; 11.2%) as the primary revascularisation procedure (T9.1). Whether this was influenced by clinical preference or theatre/interventional radiology capacity is not known. However, it appears likely that interventional radiology availability played a role, as 51/52 (98.1%) vascular hubs had a 24/7 consultant vascular surgeon rota, while only 38/52 (73.1%) had a 24/7 interventional radiology rota. Data collection in a future national ALI registry would inform service planning (including staffing) and optimal revascularisation strategies. Primary amputations were performed in 35/249 (14.1%) patients and 20/249 (8.0%) required fasciotomies.

Table 9.1 First procedure performed	Number of patients	%
Surgical revascularisation procedure	159	63.9
Amputation	35	14.1
Fasciotomy	34	13.6
Endovascular revascularisation procedure	28	11.2
Hybrid revascularisation procedure/surgical and endovascular	22	8.8

Answers may be multiple, *n=249*

Case review data

Hybrid operations require two teams or high-level dual competency (combined open and endovascular). These were less commonly performed (22/249; 8.8%). Simpler hybrid procedures can be performed in an interventional radiology theatre with theatre-quality air exchanges, but



complex hybrid procedures require a hybrid theatre.[36] It is recommended that vascular hubs have at least one hybrid theatre to allow combined open and endovascular treatment.[2] In the organisational questionnaire 18/48 vascular hubs reported that they did not have any hybrid theatres.

Among patients categorised as having Rutherford IIb ALI, open surgery was the more common approach (45/69). Of these, eight patients underwent fasciotomies and 11 required amputations. A further seven patients had an endovascular procedure and six had a hybrid procedure.

Delays to revascularisation or amputation were observed in 50/249 (20.1%) patients, including 11 with Rutherford category IIb ALI. The delay was considered to have altered the outcome in three patients. The reason for the delay was not recorded in 17/50 patients and not all the delays were within the control of the clinicians or the hospital (F9.2). In 7/50 instances it was the patient's decision, while eight patients required medical stabilisation before proceeding. National data would provide greater oversight of the delays impacting on patient outcome.

Figure 9.2 Reasons for delays in procedure being performed*; n=50*
Case review data

A patient with sensory-motor deficit (Rutherford category IIb) has an immediate threat to limb and life. Prioritisation should be based on the duration of the sensory-motor impairment rather than the time of theatre booking. If symptoms have already persisted beyond four hours, it is important to treat the patient more urgently – by placing them at the top of an emergency (CEPOD) list, opening a second emergency theatre or interrupting an elective list, whichever is the quickest. Theatre booking systems and emergency theatre co-ordination are processes designed to facilitate appropriate prioritisations. When conflicts arise, these must be resolved quickly, with senior clinical decision-makers taking responsibility. Generally, life- or limb-saving surgery should proceed even if the patient is not fasted.

Patients with Rutherford category IIa ALI should be treated as soon as reasonably possible and within 24 hours of theatre booking to avoid deterioration. However, individualised prioritisation is indicated, e.g. a patient who cannot be safely anticoagulated should receive earlier intervention.

Postoperatively, ward care was considered appropriate for 232/237 (97.9%) patients. A record of the limb condition postoperatively was found in 172/190 (90.5%) sets of notes and the limb had improved in 134/159 (84.3%) patients (19 amputations excluded).

The reviewers highlighted several areas of good quality care postoperatively including appropriate analgesia in 215/220 (97.7%) patients and appropriate anticoagulation in 228/233 (97.8%).

Complications occurred in 69/243 (28.4%) patients, of which three were considered avoidable and affected the patient's outcome.

Despite complications being managed appropriately in 64/69 patients, they affected the outcome of 25 patients, including two deaths. In 7/25 patients there were ALI specific complications and non-specific complications including cerebrovascular events (4) and respiratory complications (4).
There was room for improvement in the postoperative monitoring/escalation plans with a complete plan documented in the notes for only 82/249 (32.9%) patients (T9.2). No monitoring/escalation plan was documented for 57/249 (22.9%) patients and 108/249 (43.4%) had key components for safe postoperative care missing.

Patients who were on an ALI pathway/proforma were more likely to have a complete monitoring plan (23/39; 59.0%) than those not managed on an ALI pathway/proforma (43/159; 27.0%). While this may reflect the positive impact of an ALI pathway/proforma, it may also be that units that have developed a pathway/proforma are better organised.

Table 9.2 An appropriate monitoring/escalation plan for deterioration was documented	Number of patients	%
Yes, a complete plan documenting frequency of monitoring	82	32.9
Yes, but an incomplete plan	53	21.3
Monitoring plan without escalation protocols	45	18.1
Escalation plan but no monitoring plan	10	4.0
No plan documented in notes	57	22.9
Total	**249**	

Case review data

Additional procedures

In 57/233 (24.5%) patients, one or more subsequent procedure(s) were performed (11 patients had more than two). Surgery was the most common approach for second procedures (29/57) (T9.3).

Table 9.3 Overall number of procedures performed	Number of patients	%
1	176	75.5
2	46	19.7
3	8	3.4
4	3	1.3
Total	**233**	

Clinician questionnaire data

Amputations were included in 22/57 of second procedures (seven below-knee and 12 above-knee amputations). Fasciotomies were performed in fewer than five second procedures, reflecting their time-critical nature and the limited benefit of performing them after eight hours, unless there is a deterioration in the limb indicating the need for a fasciotomy. Haematoma/wound collection drainage were the reason for 5/57 second procedures.

Endovascular revascularisation treatments comprised a greater proportion of second procedures (13/57; 22.8%) than the primary procedure (37/233; 15.9%). The second-stage surgical revascularisations included 19 thromboembolectomies with 12/19 requiring a bypass graft.

Although endovascular (IR) mechanical thrombo-aspiration/thrombectomy is widely discussed and promoted, it was rarely utilised in this snapshot of practice in 2023. It was included in nine primary procedures. While recent publications have reported encouraging findings[37,38] there is no outcome data comparing it with open surgical revascularisation, and the devices (excluding those for stroke) are not currently reimbursed through the Specialised Services Devices Programme,[39] so the financial cost for these expensive systems for ALI will likely delay their adoption into day-to-day UK practice.

The second procedure was inappropriately delayed in 8/57 patients due to theatre availability, patient decision, and delayed recognition of recurrence of ALI. Three or more procedures were uncommon (14) and when they did occur, they most commonly included an amputation (10/14) (F9.4).

There were some indicators that the care provided after the second procedure was less good than after the first procedure. The limb condition was not assessed in 9/65 patients postoperatively and analgesia and anticoagulation were inappropriate in others.

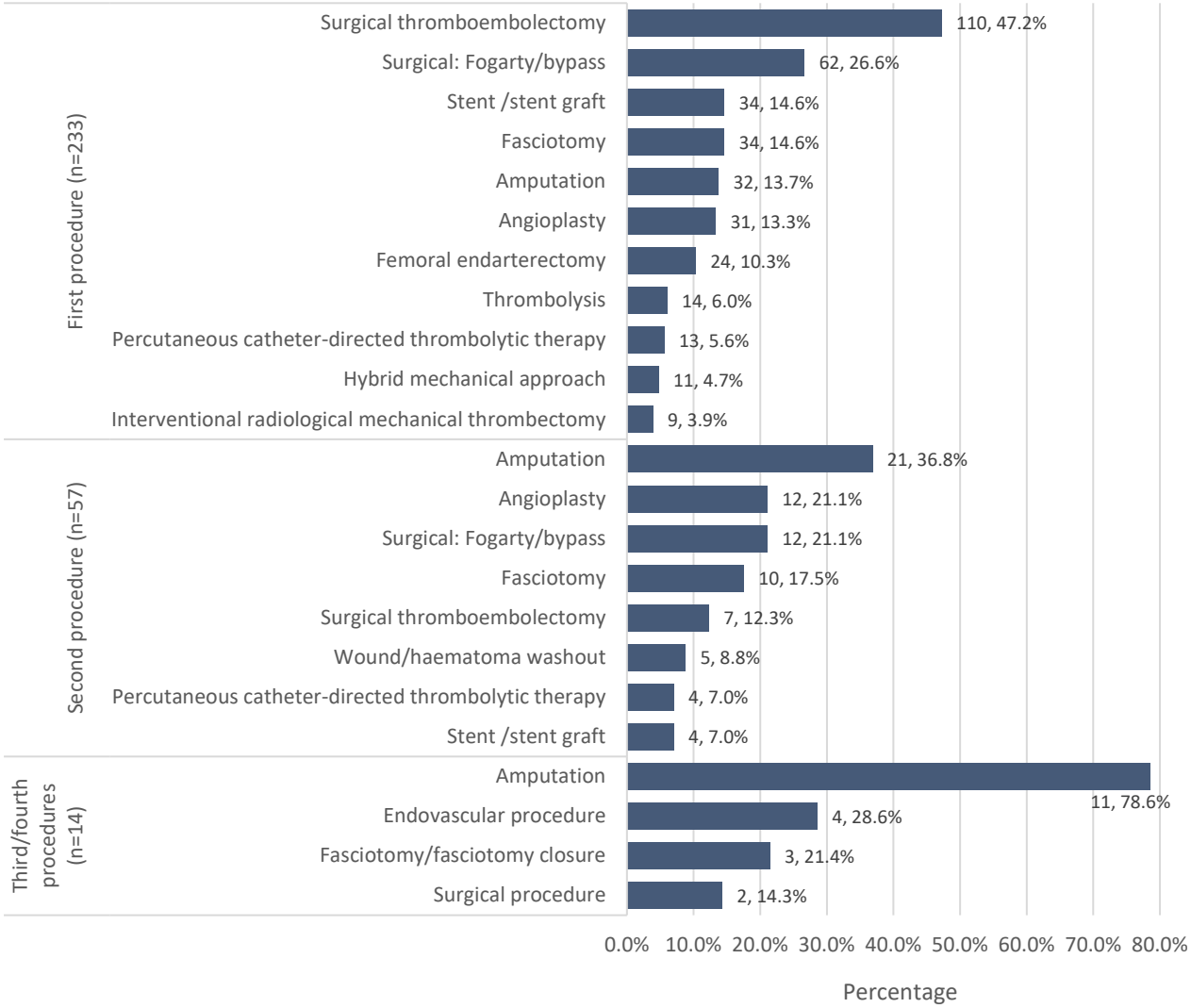


Figure 9.4 Procedures performed

Answers may be multiple; n=230

Clinician questionnaire data

Where an assessment could be made, communication with the patient and/or their family was considered to be good (185/204; 90.7%), but in 19/204 (9.3%) it could have been improved. In a larger number (126/330; 38.2%), the reviewers could not make an assessment, indicating that the documentation of communication needs to be improved.

10 DISCHARGE AND OUTCOME

(BACK TO CONTENTS)

CASE STUDY – GOOD CARE

A patient with type 2 diabetes and a history of smoking had acute-on-chronic limb ischaemia and was discharged two days after the hybrid iliac thrombectomy and iliac stent operation. At discharge, they were given information about how to recognise worsening symptoms of acute limb ischaemia and what to do. In addition to the follow-up with the vascular team, they were referred for follow-up at the diabetic clinic and the smoking cessation team.

The reviewers believed this represented good discharge planning and follow-up.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient with a cold painful foot was treated with heparin for three days in a vascular hub. The condition improved and they went home. The pain recurred 12 hours later. NHS 111 advised attendance at the local (spoke) emergency department which led to a transfer to the vascular hub 12 hours later. The patient's foot improved again with heparin treatment, and six weeks of anticoagulation therapy was prescribed.

The reviewers highlighted the lack of safety-netting, the inappropriate advice from NHS 111, poor use of resources and the omission of any anti-thrombotic treatment at the first discharge.

The median length of stay was 19 days for the whole study population and 28 days for patients who had an amputation (F5.1). Patients who have an amputation typically require longer admissions. The mean number of dedicated vascular surgery beds in vascular hubs was 26.4 (range 15-60) with two stating that they had no dedicated beds. Vascular hubs must have the infrastructure and staffing necessary to support their commissioned services.

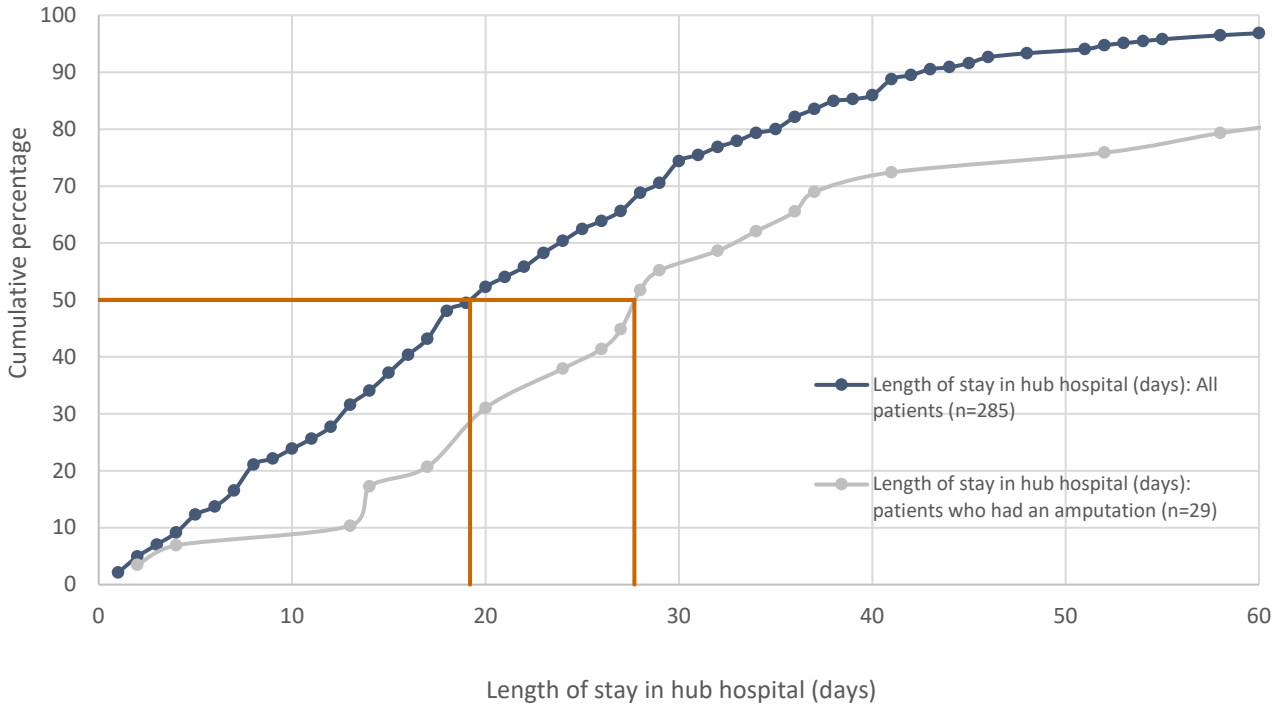


Figure 10.1 Length of stay in hospital for the study population; *n=285* and for patients who had an amputation; *n=29*

Case review data

Where possible and appropriate, networks can improve access to services by using other facilities when vascular hub care is no longer required. However, this process currently appears to be under-developed as only 10/291 (3.4%) patients who survived were discharged back to a spoke hospital and 13/291 (4.5%) were transferred to a step-down or rehabilitation unit.

The 'Provision of Vascular Services 2018' describes repatriation 'rules' as "*making or breaking the capacity of an arterial centre to deliver good, timely care ....this needs to be at executive level because of the implications it has on the wider functioning of all hospitals concerned.*"[2] Only 18/58 vascular hubs returning an organisational questionnaire stated that they had a policy or standard operating procedure for repatriating patients to their referring hospital. Care closer to a patient's home also makes it easier for friends and relatives to visit, assisting recovery.[40]

Discharge planning

NCEPOD reports frequently identify issues with the quality of discharge summaries which results in incomplete communication between hospital services and primary care, affecting continuity of care and safety-netting.

The reviewers identified a discharge summary for 262/291 (90.0%) patients who survived to discharge. Information was missing in 44/262 (16.8%), and the discharge planning was considered inadequate in 19/257 (7.4%) (T10.1). The most common omission was details of the vascular follow-up (27/44; 61.4%). Referrals to community services, including diabetic clinics, were missing in 26/44 (59.1%). The diagnosis was not recorded in 23/44 (52.3%) patients. Of note was the fact that just 6/61 (9.8%) patients who had recently undergone an amputation were referred for psychological support. ALI-specific discharge proformas may help to improve oversight of the discharge process and communication.

Table 10.1 Information missing from the discharge summaries	Number of patients	%
Details of a follow-up appointment with the vascular surgeon	27	61.4
Referrals to community services	26	59.1
Diagnosis	23	52.3
Referral for psychological support	6	13.6
Risk of return of symptoms	5	11.4
Telephone number to call if the patient has problems	4	9.1
Medications prescribed at discharge	4	9.1
Care plan	4	9.1
Details of the procedure/s performed	3	6.8
Wound care advice	2	4.5
Case worker's details	1	2.3

Answers may be multiple; n=44

Case review data

Currently, there is no standardised risk management package for people with ALI. Risk management is individualised based on the cause of ALI and patient risk factors.[28]

Anticoagulants were prescribed in 148/291 (50.9%) patients and antiplatelet medication in 114/291 (39.2%) (F10.2). Any medications not documented on a discharge plan with a specified duration of prescription may be discontinued at the first primary care review. Although published studies show that 25% of patients with ALI have evidence of thrombophilia, there is no consensus on what, if any, therapy is indicated after an ALI.[28]

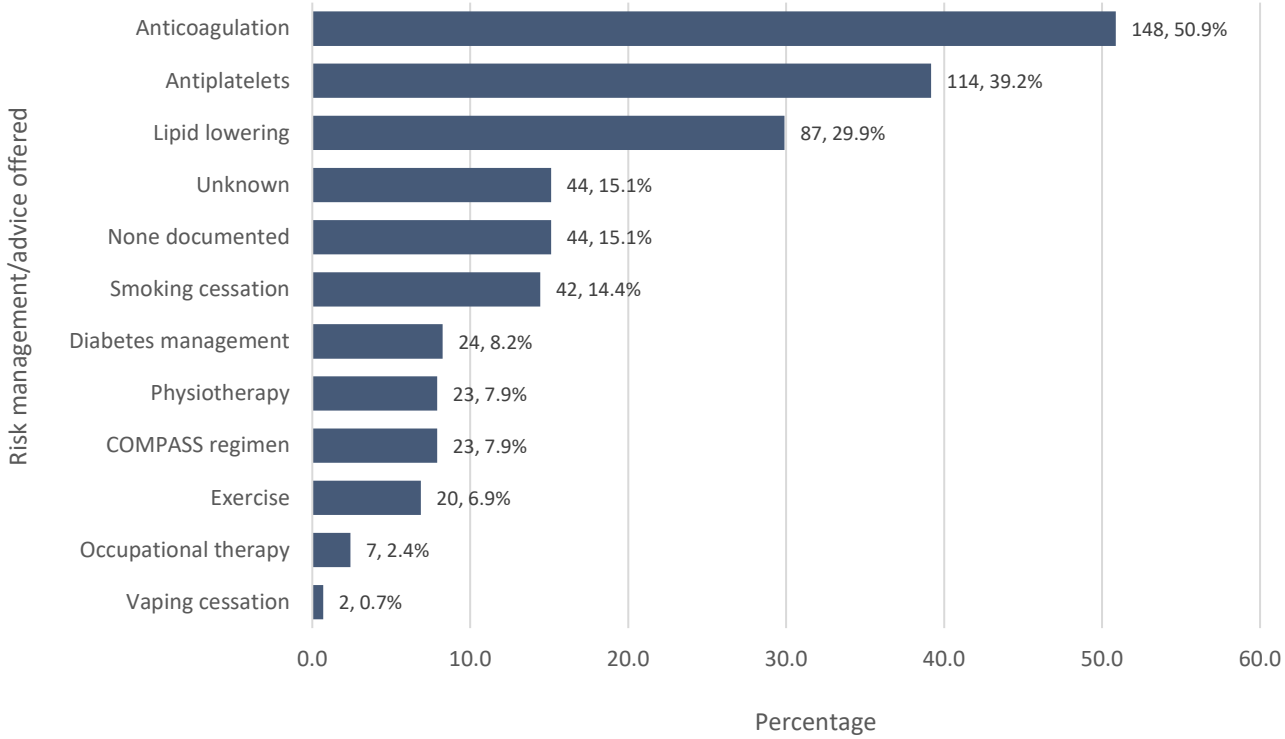


Figure 10.2 Long-term risk management/advice at discharge *Answers may be multiple; n=291*
Case review data

In the broader population of people with peripheral arterial disease (PAD), there is good evidence that low-dose rivaroxaban (2.5 mg twice a day) plus low-dose aspirin once a day improves outcomes compared to aspirin alone. In the Cardiovascular Outcomes for People Using Anticoagulation Strategies (COMPASS) trial this combination reduced major adverse limb events (including ALI and major amputation) by 46% and major adverse cardiovascular events by 28%, with no increase in severe bleeding.[25]

In total, 166/330 (50.3%) patients in this study had a revascularisation procedure and were discharged with an intact limb. For patients in the VOYAGER PAD trial who had undergone revascularisation, the combined medications significantly lowered the composite incidence of ALI, major amputation, myocardial infarction, ischaemic stroke, or death. However, the effects on major bleeding were mixed, with one measure showing no increase and another showing a significant increase compared to aspirin alone.[24]

Only 23/291 (7.9%) patients were documented as being commenced on the 'COMPASS/VOYAGER PAD regimen', with a possible additional 55/291 (18.9%) patients (those taking a DOAC and antiplatelet medication) being prescribed it without naming it. It is unknown if alternative focused strategies may be more effective in specific causes of ALI or patient subgroups. The role of

antiplatelets, the various available anticoagulants or a combination of the two requires evaluation across the various causes of ALI. Future national guidance should include a consensus and data-based best practice post-ALI pharmacological regimen until data specific to ALI become available.

Of the 76 patients with known diabetes prior to their ALI, 70/76 (92.1%) had type 2 and 6/76 (7.9%) had type 1. In 43/76 (56.6%) a need for improved diabetes management was identified.

A follow-up appointment was not arranged for 45/291 (15.5%) patients. The reviewers considered that this was inappropriate for 16/45 patients.

No risk management was documented for 44/291 (15.1%) patients and where documentation existed, it was considered inadequate in 20/291 (6.9%) cases, including 15 patients who should have had smoking/vaping cessation advice. Smoking cessation advice was offered to 58/92 (63.0%) current smokers.

Support and functional status

ALI is a life changing event for many patients. For those who survived, 210/330 (63.6%) patients were discharged home without the need for additional support, whereas at admission this figure was 162/330 (49.1%) (F10.3).

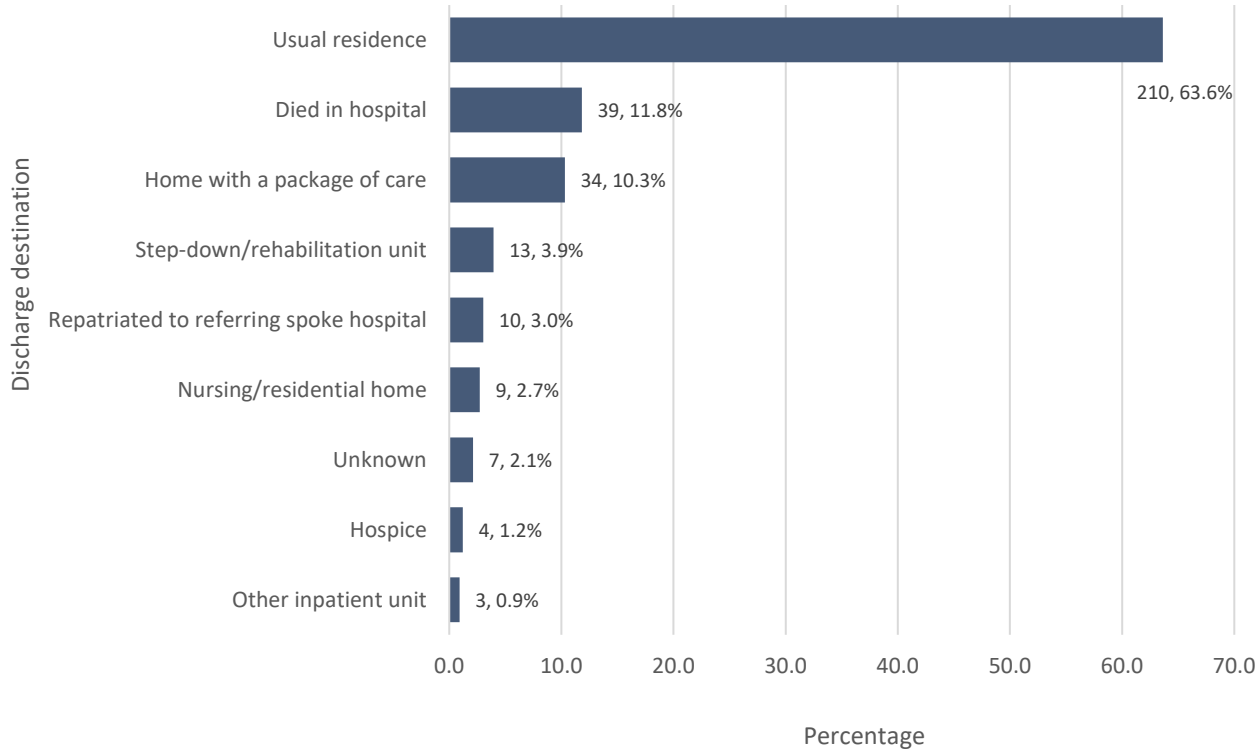


Figure 10.3 Discharge destination of the study population; *n=330*
Case review data

While the Rockwood frailty score for 141/255 (55.3%) patients was unchanged at discharge, a small number showed an improvement (18/255; 7.1%), and the reviewers identified a deterioration in functional status in 68/255 (26.7%) patients (T10.2).

Table 10.2 Change in Rockwood frailty score between admission and discharge	Number of patients	%
No change	141	55.3
Decrease in functionality	68	26.7
The patient died	28	11.0
Increase in functionality	18	7.1
Subtotal	**255**	
Unable to answer	38	
Total	**293**	

Case review data

Readmission

Readmissions within 30 days were uncommon (16/291; 5.5%); 7/16 were for issues with the same limb including infection and/or worsening ischaemia requiring another procedure.

Mortality

The 30-day mortality for this group of patients was 12.7% (42/330), of which the inpatient mortality for patients admitted to a vascular hub was 11.8% (39/330) patients. This included 13 patients who had a revascularisation procedure, nine amputations and 17 who did not undergo a procedure in the vascular hub. The mortality for those who underwent surgery was 6.7% (22/330).

Of the inpatient deaths, 26/39 were considered predictable with all receiving palliative care at some point in their care pathway. There were 16/39 patients who had a medical certificate of cause of death, and ALI was listed in part 1a for seven of these patients.

11 OVERALL QUALITY OF CARE

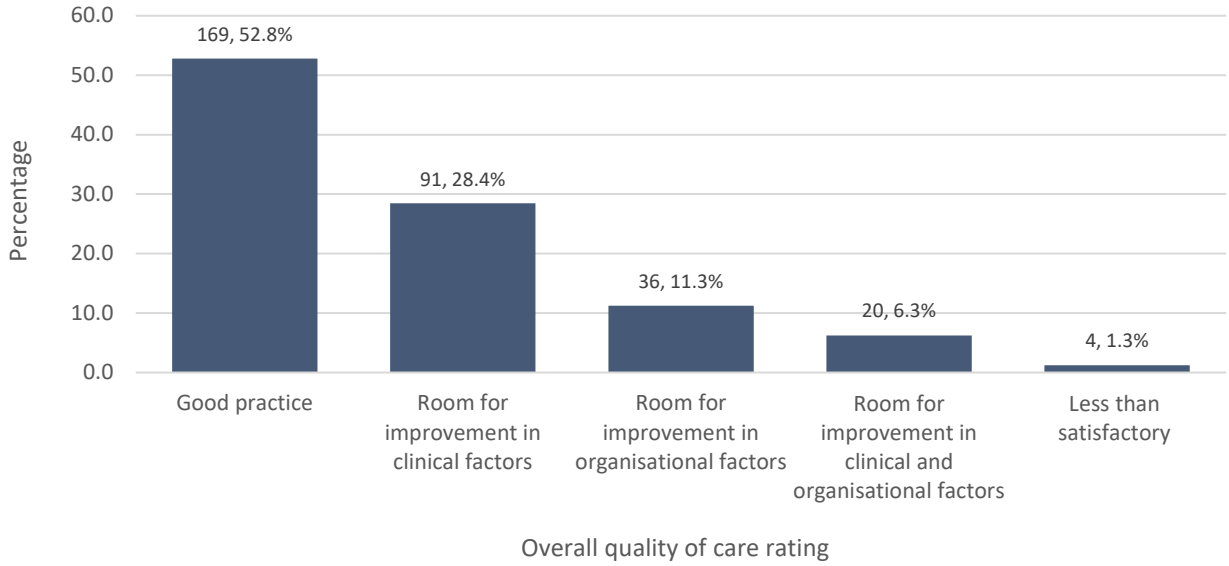


Figure 11.1 Overall quality of care; *n=320*
Case review data

The reviewers were asked to assign a grade to the overall quality of care received by each patient in the study (F11.1). Overall quality of care was rated as good for 169/320 (52.8%) patients. The reviewers reported there was room for improvement in the clinical and/or organisation of care for 151/320 (47.2%). A less than satisfactory rating was assigned to four patients (1.3%). These ratings do not consider the patient factors that have been shown to impact the care in this study.

Measuring performance is crucial for quality improvement. Only 22/47 vascular hubs stated that they recorded data on surgical procedures, while 19/42 collected data on interventional radiological revascularisation procedures for ALI. When asked about shared learning across the ALI network, the use of prospectively collected data was uncommon with most learning occurring in morbidity and mortality meetings or in response to reported adverse events.

Delays were identified as a key area of concern in improving ALI care. Considering the data relating to delays in the pathway, 123/249 (49.4%) individual patients who had a procedure experienced a delay at some stage between their initial presentation and first procedure. Excluding the patient-related delays in presenting, there were 115/249 (46.2%) individual patients delayed at some point in the pathway. National data collection for ALI would aid benchmarking and monitoring of the delays occurring thought the entire ALI pathway. This could focus resources as well as educational opportunities.

The vascular hubs identified delays in patient presentation, initial assessment, recognition of and imaging for ALI as areas requiring improvement, along with transfer delays between vascular hubs and spoke hospitals. Additional challenges included a limited number of vascular surgical beds, the lack of a hybrid theatre, and too few interventional radiologists, limiting the treatment options. Embedding this into a registry would ensure that these factors can be considered beyond this report alone.