2 DATA RETURNED AND THE STUDY POPULATION

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.

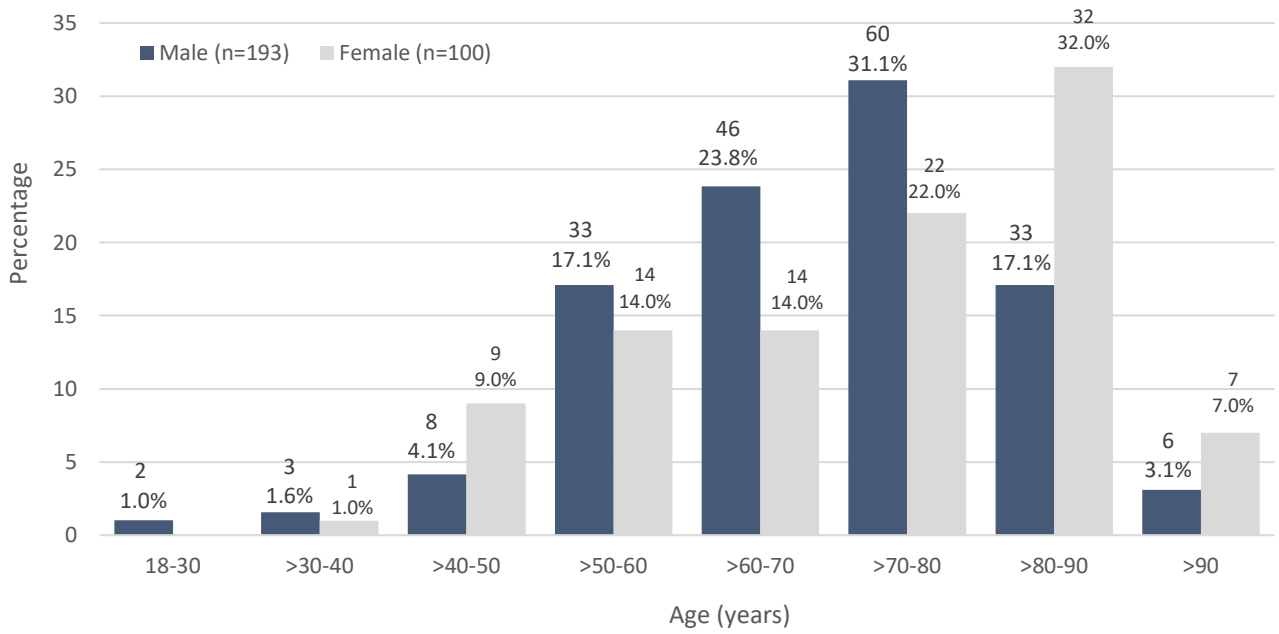

Figure 2.1 Age and sex of the study population; *n=293, mean=71, median=72, mode=86*
Clinician questionnaire data

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]

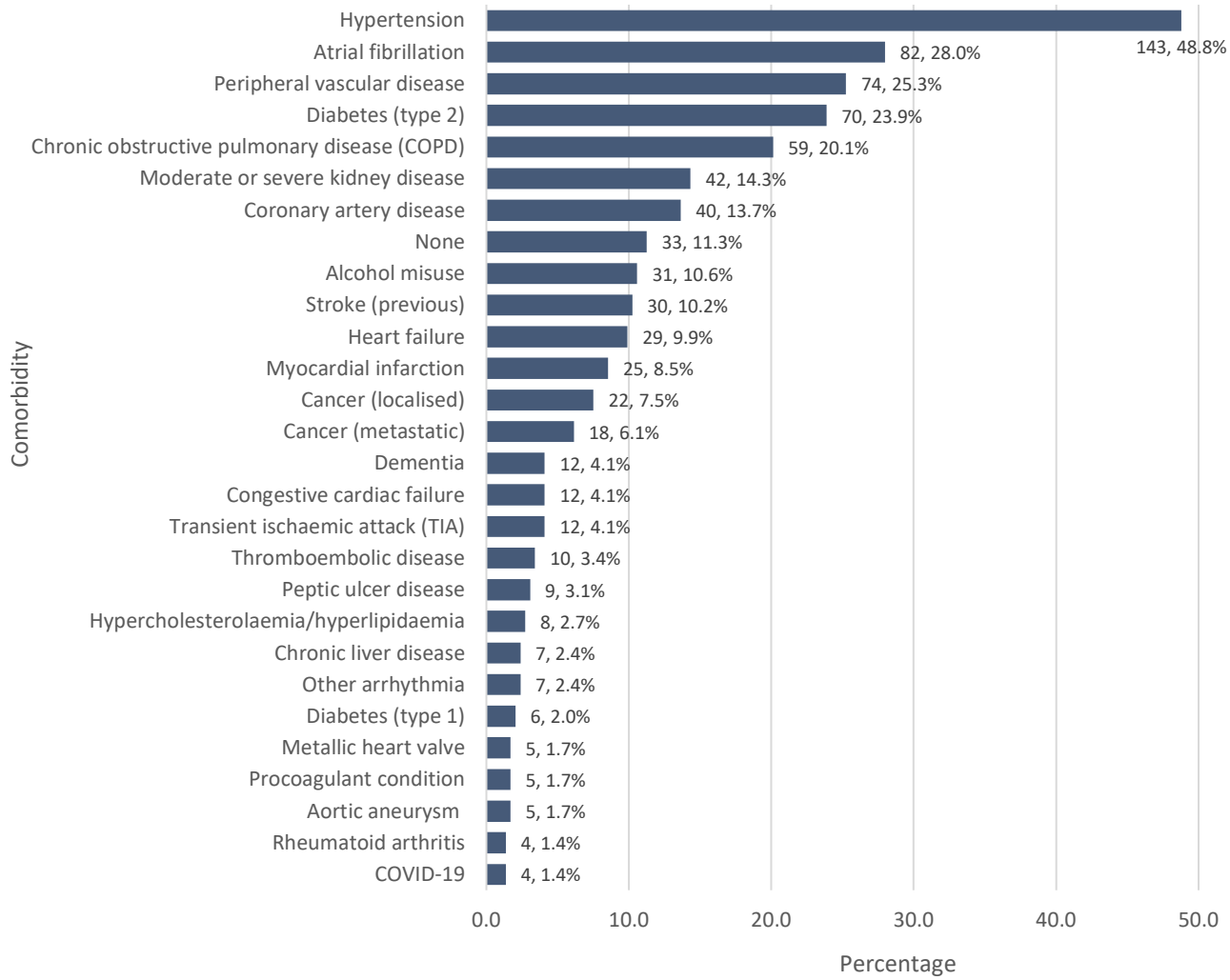

Figure 2.2 Comorbidities in the study population. *Answers may be multiple*; *n=293*

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.

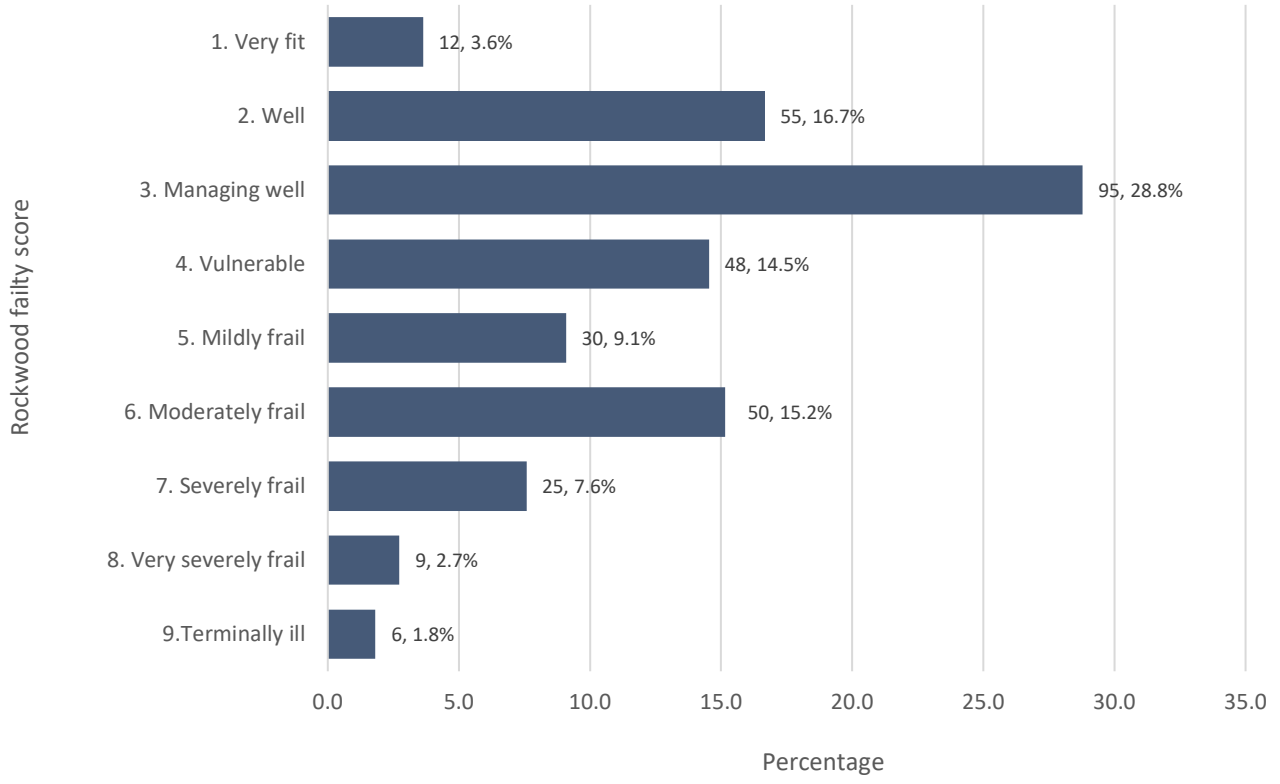

Figure 2.3 Estimated Rockwood frailty score prior to admission; *n=330*

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

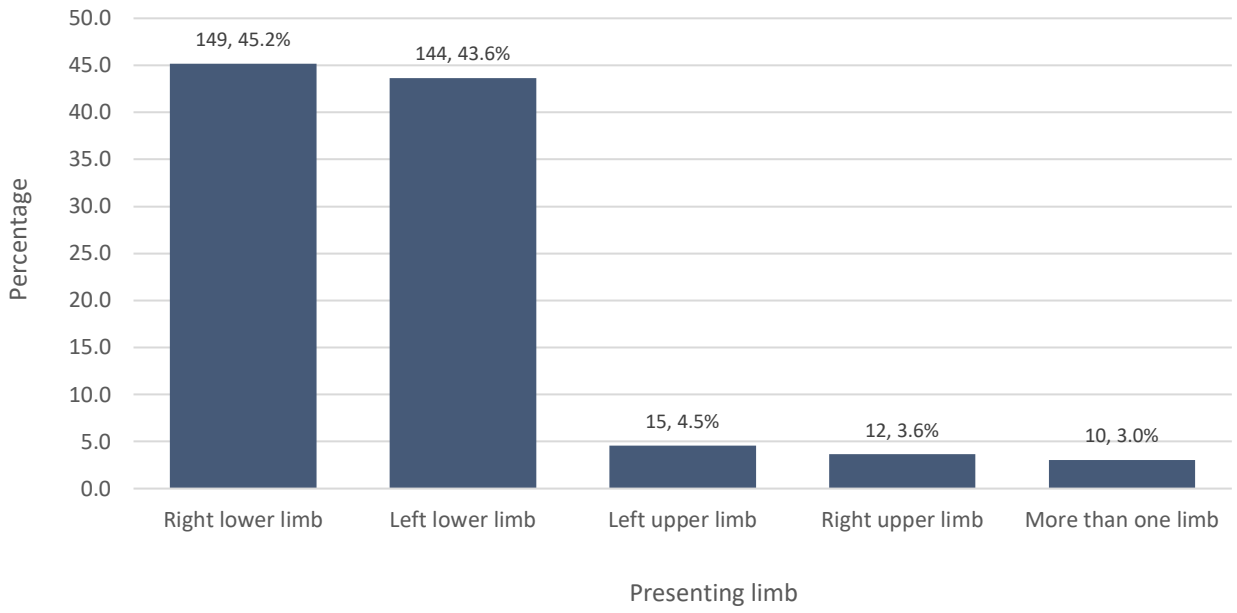

Figure 2.4 Presenting limb*; n=330*

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.