Acute Limb Ischaemia Study

Study Protocol

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Introduction

Acute limb ischaemia (ALI) results from of a sudden blockage to the blood supply of a limb. This results in the limb becoming suddenly starved of oxygen and consequently the limb tissues are at risk of necrosis. The commonest cause was previously a blood clot formed in the heart of patients with atrial fibrillation, which passes through circulation and becomes lodged in arteries supplying the limb; this has become less common with improved medical management of atrial fibrillation (anticoagulation and rate/rhythm control). Local occlusion of diseased (narrowed or dilated) or previously operated on limb arteries is now more common. Other causes include clots from other sources, cancer and iatrogenic. COVID-19 infection and the side-effects from COVID-19 vaccination may also be associated with ALI. ALI is very different to chronic limb threatening ischaemia (CLTI), leading to major amputations previously studied by NCEPOD[1]

The precise incidence of ALI is difficult to pinpoint, due to the lack of precise coding for the condition, but in a UK population-based study over 10 years[2], the incidence was 10 per 100,000 per year (compared to 22 CLTI events), with a 30-day survival of 74%. The incidence is likely to be higher than estimated and therefore a higher number of patients are potentially coming to harm.

ALI is a limb- and life- threatening emergency with catastrophic ramifications if treatment is delayed. The impacts of ALI on patients, their relatives and health care systems are significant.

There are 10-15% of patients who require major amputation and 26% of patients die within 30-days of presentation. Of those patients with amputation, the subsequent loss of function and associated disability often requires intensive therapy, social care and other support. A third of patients who are discharged require ongoing nursing care. Ethnic minority patients have worse outcomes, which may stem from difficulty with diagnosis at presentation[3].

Urgent diagnosis is central to the care of ALI patients. The blocked artery needs to be unblocked to restore flow of oxygenated blood to the affected tissues. This needs to happen within six hours for those with the highest risk but still viable limbs. Delay increases the risk of tissue death, requiring amputation, and the risks of associated organ failure and death.

The National Institute for Health and Care Excellence (NICE) did not include the management of ALI in their clinical guideline on peripheral arterial disease (CG147) in 2012[4] nor is ALI a component of the recent 2022/23 Commissioning for Quality and Innovation for peripheral arterial disease[5].

The 2018 Getting it Right First Time (GIRFT) report for vascular surgery recommended an increase in the early availability of revascularisation surgery where lower limb ischaemia is present, to help reduce amputation rates[6]. However, the GIRFT report did not specifically address ALI either.

Similarly, The Vascular Society has focussed on Chronic Limb Threatening Ischaemia (CLTI) in Provision of Vascular Services (2018)[7] and a quality improvement framework (PAD-QIF) 2019 (A Best Practice Clinical Care Pathway for Peripheral Arterial Disease, 2019)[8].

An NCEPOD study will highlight where there are improvements needed in the processes of care throughout the pathway of care. Areas where an NCEPOD study may identify where improvements can be made would include:

- Lack of awareness: It is expected that there may be limited diagnostic awareness and resource constraints at spoke sites, compounding delays. With only six hours to save a limb, every minute counts. NCEPOD evaluation will facilitate campaigns to increase awareness akin to other 'high-profile' cardiovascular conditions (such as 'central chest-pain' in heart attacks or 'FAST' for strokes) and provide valuable resources for awareness and detection among ethnically diverse populations.
- Regional variation: NCEPOD is likely to reveal extensive geographic disparity, ethnic background variation, resource inequality and discrepancies in treatment. Patients should not be disadvantaged because of where they live or their ethnicity.
- Dissimilarity in 'arterial hub' facilities and infrastructure: It is likely that each arterial hub hospital has differing set-up and facilities. Every hub should be able to provide the full breadth of limb saving care, which is an unknown at present.

Therefore, the management of ALI remains an unmet need not served by any existing care bundle, registry, or quality improvement initiative.

Guidelines and standards

National Institute for Health and Care Excellence (NICE) Scenario: Acute Limb Ischaemia.
Available from: https://cks.nice.org.uk/topics/peripheral-arterial-disease/management/acute-limb-ischaemia/

European Society for Vascular Surgery (ESVS) 2020 Clinical Practice guidelines on the Management of Acute Limb Ischaemia
Available from: https://www.ejves.com/action/showPdf?pii=S1078-5884%2819%2931515-1

Update of the European Society for Vascular Surgery (ESVS) 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia in Light of the COVID-19 Pandemic, Based on a Scoping Review of the Literature.
Available from: https://www.ejves.com/article/S1078-5884(21)00688-2/fulltext

2016 American Heart Association (AHA) and American College of Cardiology (ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines
Available from: https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000470

Aims and Objectives

Overall aim

To explore current care pathways for patients with ALI; identify remediable clinical and organisational factors that can improve the delivery and quality of the required care.

Objectives

Organisational

To review:

1. Provision of services in “hub” and “spoke” hospitals and their relationship to other hospitals
2. Policies, guidelines, and care pathways relating to ALI
3. Staff availability to treat patients with ALI
4. Theatre/ interventional radiology access and priority for patient with ALI
5. Local capabilities and limitations
6. Learning and network sharing.

Clinical

To identify and examine remediable factors in a cohort of patients with ALI
To explore/map the pathway from admission to discharge (including death)
To review:

1. Pre-hospital care (GP, 111, vascular nurse, planned OP), including the referral process, the role of primary care and delay in presentation
2. Initial emergency department/ hospital assessment, including delays and assessment of risk, causation, and co-morbidity
3. Decision making process: Investigations undertaken and multidisciplinary team involvement
4. Timeliness and documentation of the transfer process
5. Pharmacological/non-pharmacological management including analgesia
6. Quality of preoperative care, including pre-/peri-operative optimisation
7. The timeliness of surgery
8. Quality of the initial treatment provided
9. Management of complications and/or ongoing ischaemia and any further interventions/surgery
10. Discharge planning/follow-up and reduction of long-term risks
11. Outcomes from surgery (including avoidable outcomes)
12. Communication with patients and their families.

Methods

Population

Patients 18 years or older admitted to hospital with acute limb ischaemia.
Patients will be identified using the following ICD10 and OPCS codes, highlighted in the appendix.

Inclusions

I70.20	Atherosclerosis of arteries of extremities (without gangrene)
I70.80	Atherosclerosis of other arteries (without gangrene)
I70.90	Generalized and unspecified atherosclerosis (without gangrene)
I72.1	Aneurysm and dissection of artery of upper extremity
I72.3	Aneurysm and dissection of iliac artery
I72.4	Aneurysm and dissection of artery of lower extremity
I72.8	Aneurysm and dissection of other specified arteries
I72.9	Aneurysm and dissection of unspecified site
I74.2	Embolism and thrombosis of upper extremities
I74.3	Embolism and thrombosis of lower extremities
I74.4	Embolism and thrombosis of arteries of extremities, unspecified
I74.5	Embolism and thrombosis of iliac artery
I74.8	Embolism and thrombosis of other arteries
I74.9	Embolism and thrombosis of unspecified artery
I77.1	Stricture of artery

Exclusions

- Chronic limb ischaemia without acute limb ischaemia
- Acute limb ischaemia due to trauma
- Iatrogenic causes of acute limb ischaemia

Data sampling timeframe

Patients for inclusion will be sampled from a timeframe starting on 1st January 2023 to 31st December 2023 inclusive.

Participating providers of healthcare

All acute hospital providers in England, Wales, Northern Ireland and Jersey where patients with ALI might be admitted will be expected to participate in the study.

Incidence and prevalence of the exemplar conditions

Table 1. Nationally collated hospital admission data

Hospital Episodes Statistics (HES) 2022/23; Patient Episode Database for Wales (PEDW) 2022/23; Department of Health (NI)

ICD-10	Description	HES	PEDW	DOH NI
I702	Atherosclerosis of arteries of extremities	6,236	390	
I708	Atherosclerosis of other arteries	449	17	171
I709	Generalized and unspecified atherosclerosis	15	-	
I721	Aneurysm and dissection of artery of upper extremity	110	5	
I723	Aneurysm and dissection of iliac artery	164	4	
I724	Aneurysm and dissection of artery of lower extremity	850	41	83
I728	Aneurysm and dissection of other specified arteries	318	-	
I729	Aneurysm and dissection of unspecified site	19	-	
I742	Embolism and thrombosis of arteries of upper extremities	502	17	
I743	Embolism and thrombosis of arteries of lower extremities	2,837	279	
I744	Embolism and thrombosis of arteries of extremities, unspecified	61	6	198
I745	Embolism and thrombosis of iliac artery	396	40	
I748	Embolism and thrombosis of other arteries	116	-	
I749	Embolism and thrombosis of unspecified artery	40	-	
I771	Stricture of artery	874	114	132
		12,987	913	584

NB: this is high level data that will include a number of patients who did not have ALI

Study promotion

Prior to data collection, NCEPOD will contact all acute hospital and primary care providers. The study will be promoted to via patient groups, third sector organisations, NCEPOD Local Reporters (sending the study poster on to the relevant departments), via any study contacts recruited, and via the relevant medical royal colleges and associations.

Study method test

The data collection methods and data collection tools will be tested to ensure they are robust before the full study is run.

Methods of data collection

There will be five main ways of collecting data for the study.

1. Anonymous online patient survey and/or patient interviews

The survey and interviews will gather data on the patient views around the care they received when they had ALI. The data will not be linked to any other aspects of data collection. We will work with Local Reporters, and relevant charities to encourage involvement. The data will not be linked to any other aspects of data collection. The survey will be anonymous online using Qualtrics and the link disseminated with the help of relevant charities.

2. Anonymous online healthcare professional survey

The survey will gather data on clinician views of how care is provided to patients admitted with ALI. The data will not be linked to any other aspects of data collection. The survey will

be created using Qualtrics and the link disseminated with the help of our local reporters and specialty associations.

3. Organisational questionnaire

Data collected will include information around the organisation of services, the use of protocols, training, networks of care, transfer arrangements, the availability of staff and facilities, emergency surgery access, information for patients and families and follow-up arrangements. Questionnaires will be sent to all hospitals participating in the study via the online questionnaire system.

4. NHS 111 and Ambulance Trust Survey

Data will be collected from NHS 111 and the Ambulance Trusts to ascertain details of the pathway prior to arrival in hospital.

5. Clinical data collection

Patient identification

A local contact, either the NCEPOD local reporter or a specific study contact will be asked to identify all patients admitted as an emergency to their hospital during the study time period, with the included ICD10 and OPCS codes. For this group the admission details will be checked at the hospital to remove as many patients as possible from the data pool who did not have ALI. A patient identification spreadsheet will then be returned to NCEPOD identifying patients suitable to sample for inclusion in the study.

The spreadsheet will include the following data fields: NHS number, hospital number, date of birth, date of admission, source of admission, primary ICD10 code, all ICD10 codes, all OPCS codes, discharge destination, date of discharge, clinician code and specialty, the details of the transferring hospital (if applicable) and the primary care details.

Having identified the patient cohort in secondary care, we will track each patient back to the hospital transferred from / GP practice and any other providers of care and we will collect data on those patients from these organisations.

Clinician questionnaires

Two questionnaires will be used to collect clinical data for this study:

1) Clinician questionnaire - hospital
2) Clinician questionnaire – primary care

Clinician questionnaires - hospital

The clinician questionnaires will be sent to the NCEPOD Local Reporter for dissemination via the online questionnaire system. Reminder letters will be sent at six weeks and ten weeks where the data is outstanding. Up to 15 patients per hospital will be sampled for inclusion in the study.

Clinician questionnaire – primary care

This will be short to encourage submission. The primary care clinician questionnaire will be sent for those patients identified as being referred for the admission by the GP. The

questionnaire will be sent directly to the GP for completion either as a hard copy questionnaire or via the online questionnaire system. Reminder letters will be sent at six weeks and ten weeks where the data is outstanding.

Case note review

The case notes relating to the index admission for the included sample will be requested:

- GP referral letters
- Prior clinic letters
- Ambulance patient report form (PRF)
- Clinical notes from clerking to discharge – medical, nursing and allied health professional
- Imaging reports
- Operation notes
- Anaesthetic chart
- Consent forms
- Critical care charts
- Transfer documentation
- Discharge summary
- Follow-up clinic letters

Upon receipt at NCEPOD the case notes will be redacted if not already done so prior to sending.

Reviewer assessment form

A multidisciplinary group of reviewers (detailed below) will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the process of transition via the reviewer assessment form.

Table 2 summarises the data sources for significant points along the pathway.

Area of enquiry	**Method of data collection**	**Confidentiality**
Primary care	Clinician questionnaire	Identifiable
	Online surveys and focus groups/interviews	Anonymous
Ambulance / NHS 111	Survey	Anonymous
Acute hospital care	Case notes, clinician questionnaire, organisational questionnaires	Identifiable
	Online surveys and focus groups/interviews	Anonymous

Sample Size

Data source	**Target number**
Patient online survey (non-identifiable)	Unlimited (engagement uncertain)
Clinician online survey (non-identifiable)	~300
Organisational questionnaire	~250
Clinician questionnaires (acute hospital care)	Up to 15 per hospital
Case note review	Up to 15 per hospital

Analysis and review of data

Reviewers

A multidisciplinary group of reviewers will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the admission. The reviewer group will comprise vascular surgeons, physicians (general, cardiologists, diabetologists, geriatricians) emergency medicine physicians, interventional radiologists, vascular nurses, anaesthetists, intensivists and general practitioners.

An advert will be sent to Local Reporters to disseminate throughout the relevant departments. It will also be placed on the NCEPOD website. Successful applicants will be asked to attend a training day where they will each assess. A number of meeting dates will be arranged, and each reviewer will then be asked to attend a minimum of a further four meetings. NCEPOD staff will ensure there is a mix of specialties at each meeting from across the UK. Each meeting will be chaired by an NCEPOD clinical co-ordinator who will lead discussion around the cases under review. The meetings will either be held in person in the NCEPOD office, or over Microsoft Teams with secure and temporary access to the case notes for review (not downloadable or printable by the case reviewer). Towards the end of the study the reviewers will be invited to attend a meeting where the data will be presented to and discussed with them. The reviewers will also be sent two copies of the draft report for their comment as this is developed.

Confidentiality and data protection

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 251 approval has been obtained to perform this study without the use of patient consent in England and Wales.

Study outputs

On completion of the study a report will be published and widely disseminated to all stakeholders to encourage local quality improvement (QI). In addition to the report, supporting tools will be made available which may include:

- A summary report and summary sheet
- Infographics
- The recommendation checklist
- An audit tool
- A slide set
- A guide for commissioners
- Fishbone diagrams
- Driver diagrams
- Useful links for patients

Examples of good practice will be shared, and additional QI tools will be developed where appropriate. Key messages from the report will be shared via social media.

Following publication, the report findings will be shared at national and local conferences, study days and other events; and papers may be submitted to journal for consideration for publication.

Data sharing

Post publication of the study there is the potential to share anonymised data sets with interested parties working in the same field. This will be undertaken following a strict process and will ensure the data does not become identifiable in their nature due to small numbers.

References

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3. Gandjian M, Sareh S, Premji A, Ugarte R, Tran Z, Bowens N, Benharash P. Racial disparities in surgical management and outcomes of acute limb ischemia in the United States. Surg Open Sci. 2021 Sep 10;6:45-50.
4. National Institute for Health and Care Excellence (NICE) Scenario: Acute Limb Ischaemia. Available from: https://cks.nice.org.uk/topics/peripheral-arterial-disease/management/acute-limb-ischaemia/
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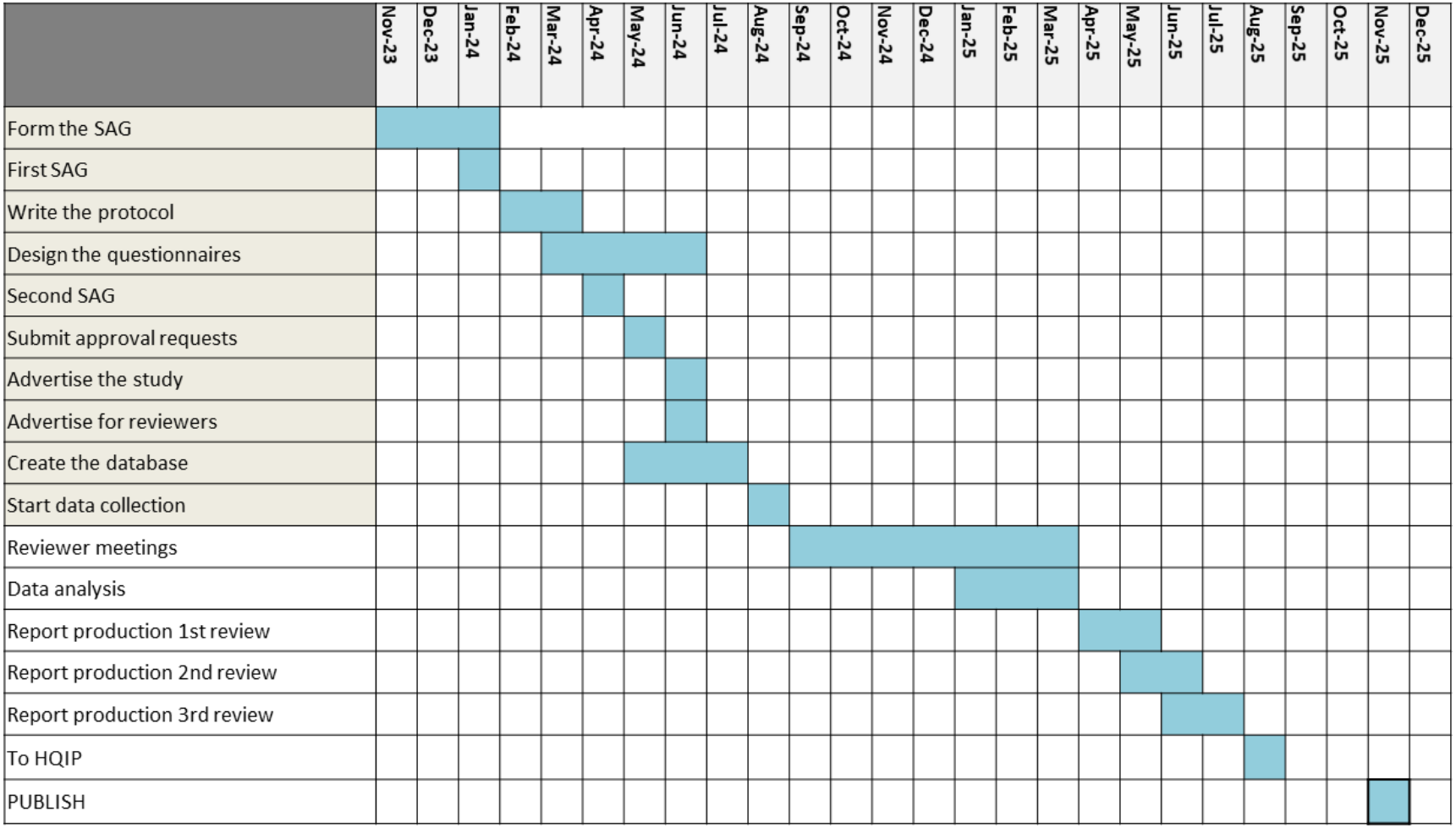
8. J.Vasc.Soc.G.B.Irel. 2022;1(Supp3):S1–S13 http://doi.org/10.54522/jvsgbi.2022.017

Timescale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Advertise the study
Advertise for reviewers
Create the database
Start data collection
Reviewer meetings
Data analysis
Report production 1st review
Report production 2nd review
Report production 3rd review
To HQIP
PUBLISH