9 PROCEDURES UNDERTAKEN

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.

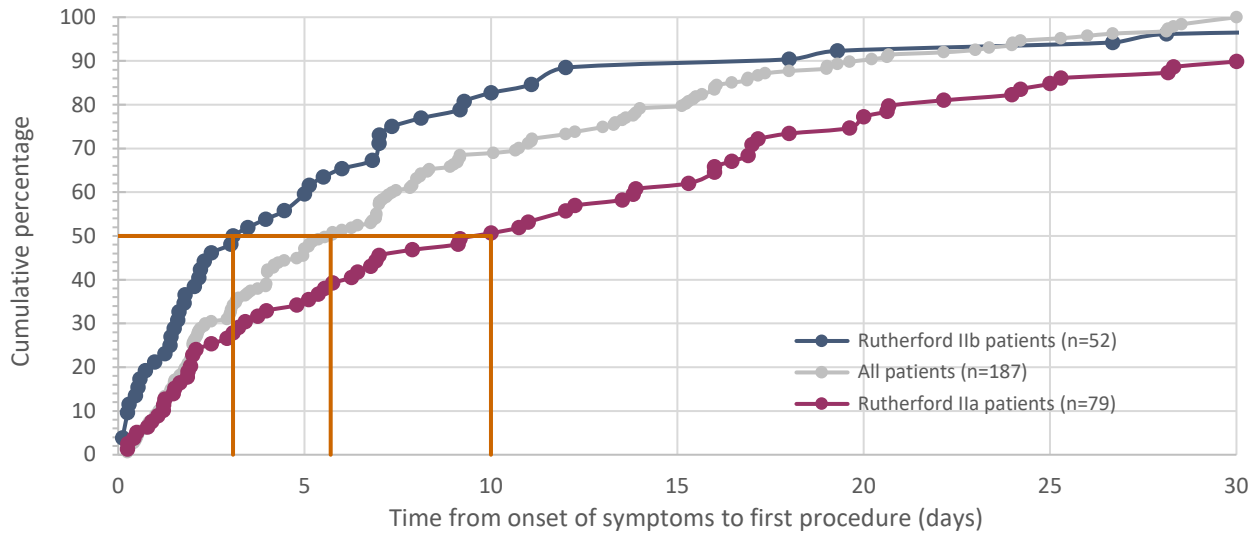

Figure 9.1 Time from onset of symptoms to procedure
Case review data

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.

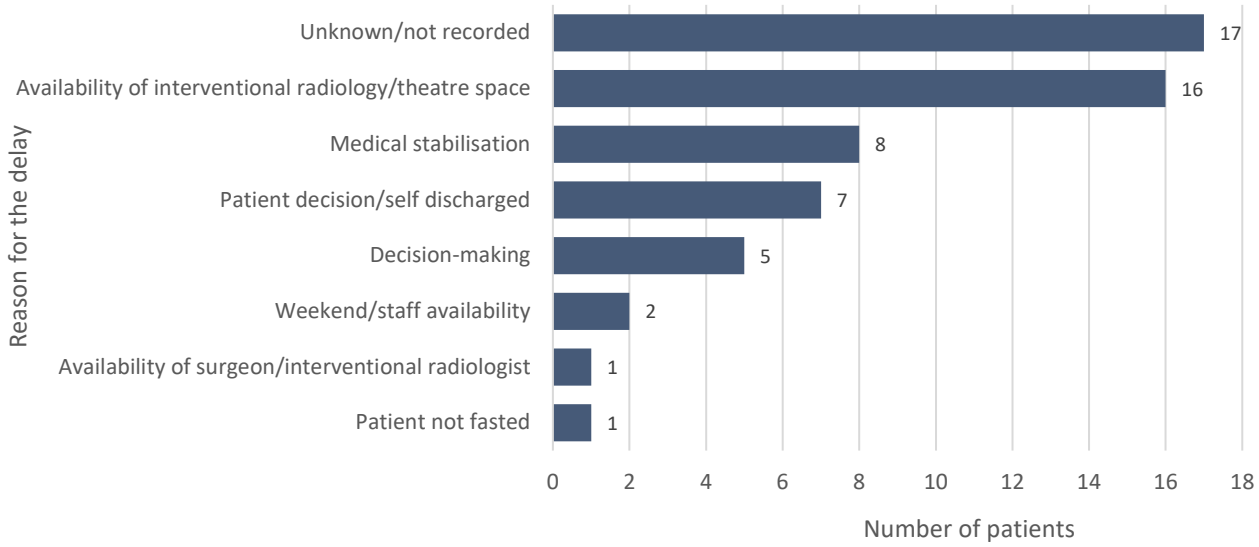

Figure 9.2 Reasons for delays in procedure being performed*; n=50*
Case review data

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 (11/14) (F9.4). Overall, there were 55 patients in the sample who had an amputation (55/330; 16.7%) and nine patients who had multiple amputations.

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.

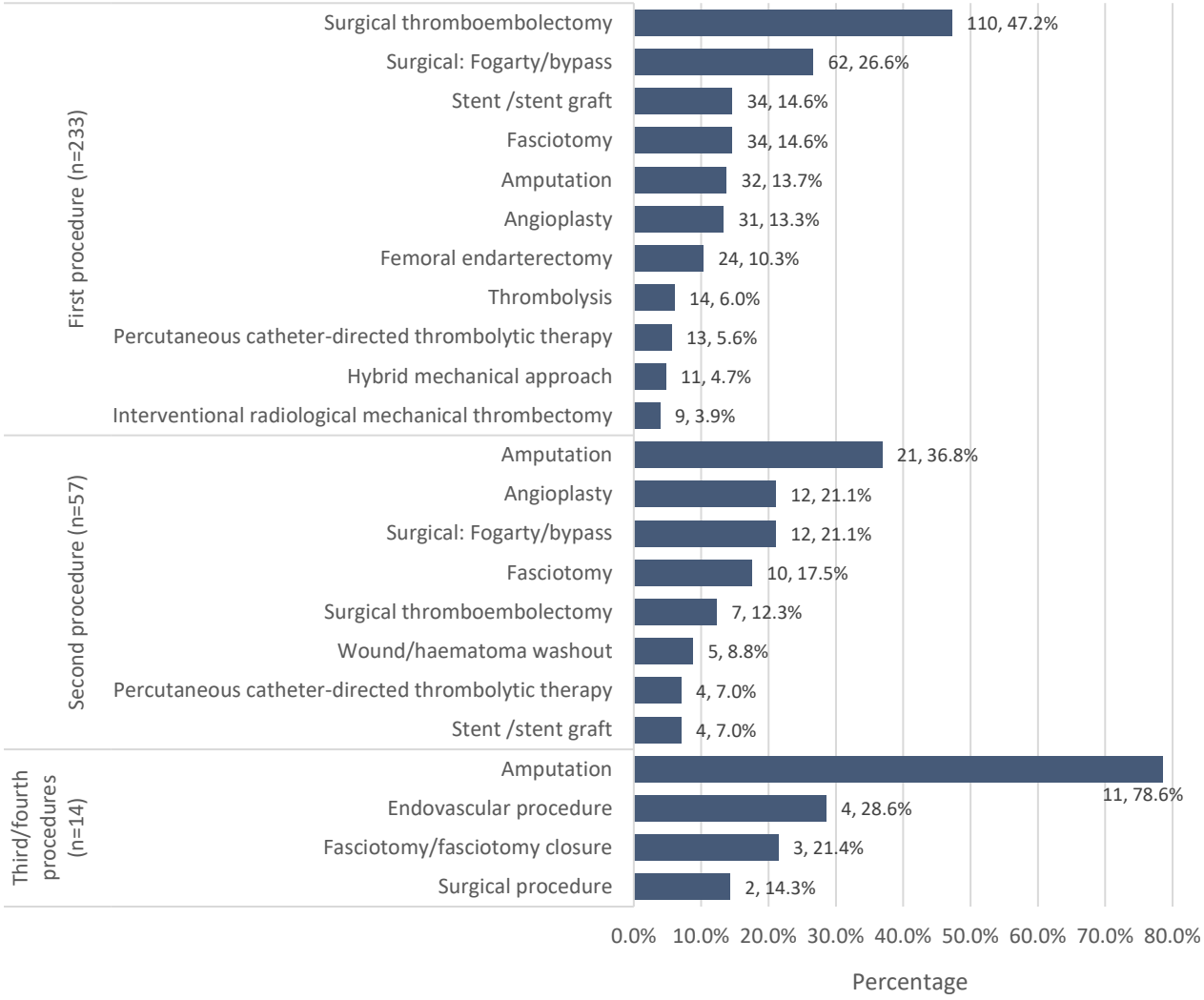

Figure 9.4 Procedures performed
Answers may be multiple; n=230
Clinician questionnaire data

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.