9 Peripheral Vascular Disease

Gerald Fowkes

1 Summary

Introduction and statement of problem

This chapter is concerned with two peripheral vascular diseases:

- peripheral arterial disease, defined as atherosclerosis of the distal aorta and/or lower limb arteries causing arterial narrowing and disruption of blood flow to the legs
- abdominal aortic aneurysm defined as abnormal dilatation of the aorta distal to the renal arteries.

Peripheral arterial disease commonly presents as intermittent claudication, which is pain in the calf that occurs on walking and which is relieved by rest. More severe forms of peripheral arterial disease present as rest pain, gangrene or ulceration, occasionally leading to amputation.

Abdominal aortic aneurysms commonly remain asymptomatic but sometimes rupture with a high risk of death. Symptomatic aneurysms and large asymptomatic aneurysms require surgical repair because of an increased risk of rupture.

Health service issues that are currently important in meeting the needs of patients with these peripheral vascular diseases are, in primary care, the appropriate management of cardiovascular risk factors and referral of patients with intermittent claudication. In secondary care, key issues are the centralisation of services around major vascular units at regional and supra-district level and the minimum facilities that should be provided in these units. In the clinical management of patients, the diagnosis and treatment of claudication, the use of interventional radiology and reconstruction surgery, and the management of asymptomatic aneurysms are important. Also, the value of screening, particularly for asymptomatic aneurysms, has been debated in recent years.

A key problem for purchasers at present is the specification of the minimum requirements for providing a vascular service at secondary care level. Whether or not to screen for aortic aneurysms is another important issue.

Sub-categories

The sub-categories of disease used throughout this chapter are:

- peripheral arterial disease
  - intermittent claudication
  - critical limb ischaemia
  - asymptomatic peripheral arterial disease

- abdominal aortic aneurysm
  - ruptured aneurysm
  - asymptomatic aneurysm.

Prevalence and incidence

Intermittent claudication occurs rarely in men and women under 55 years of age but affects 5% of those aged 55 to 74 years. Prevalence increases rapidly with age and it is slightly more common in men than women. It is more frequent in the lower social classes, mostly due to higher levels of smoking. Only one quarter of claudicants have a deterioration in symptoms. The main risk for claudicants is a two to threefold higher mortality than non-claudicants, mostly due to associated coronary heart disease. The time trends in claudication are unknown.

Critical limb ischaemia is rare, with an estimated incidence of 500–1000 per million population per year. Twenty-five percent have an amputation and 50% are dead within 5 years.

Asymptomatic peripheral arterial disease causing a major disruption to blood flow in the legs is common, affecting 8% of 55- to 74-year-olds; a further 17% have minor asymptomatic disease. These individuals are also at increased risk of acute coronary events and stroke.

The most important form of symptomatic aneurysm is rupture. The annual incidence is about 17 per 100 000. The death rate due to aortic aneurysm in 1996 was 24.1 per 100 000 in men and 13.8 per 100 000 in women.

The prevalence of asymptomatic aneurysm is about 5% in men aged 65 to 74 years. The male:female ratio is about 3:1 and the prevalence increases steeply with age.

Services available and their costs

For peripheral arterial disease the consultation rate in general practice is low, accounting for only 1 in 420 of total consultations, and thus specific services are not provided at that level. The services available at secondary level have been documented in detail in Scotland, and less so in England, and show that around 80% of vascular work is performed outside specialist units and that two thirds of 'vascular surgeons' are general surgeons with a special interest in vascular surgery. Access to intensive care units and vascular laboratory support is not available in 50% of hospitals providing vascular surgery.

In 1995/96, the number of patients discharged in England with a primary diagnosis of peripheral atherosclerosis was 36 000, mostly from general surgical units. Diagnostic angiography was performed on 39 000 occasions; 10 600 patients had an arterial bypass operation and 4400 had a vascular amputation. Relatively few angiographies and angioplasties were carried out as day cases. Since the mid-1980s, a steep increase has occurred in the use of angioplasty, but the effects on amputation and reconstruction rates are unclear. The mean hospital cost of amputation is about £6000 and of reconstructive surgery about £5000, whereas angioplasty costs about £1500.

Over 11 000 discharges in 1995/96 were due to aortic aneurysms. More than 5000 aortic aneurysm repairs were carried out, with around one quarter performed as emergencies. The hospital cost of an aneurysm repair is about £4500. Operations per head of population showed little regional variation. Screening for abdominal aortic aneurysms in the community is not carried out routinely in the UK.

Effectiveness of services and interventions

Smoking cessation in patients with intermittent claudication is associated with better results following surgery, lower amputation rates and improved survival. The most effective health service methods to achieve smoking cessation are advice from a health professional and nicotine replacement therapy. Exercise can improve walking distance by 150%, but lipid-lowering therapy has an inconsistent effect on symptoms. Most patients with peripheral arterial disease can benefit from treatment with statins. Good control of blood pressure and glycaemia are also appropriate in relevant patients.

Antiplatelet therapy is important in reducing cardiovascular risk in claudicants. Cilostazol and naftidrofuryl are the only specific drugs that can be recommended to possibly improve walking distance. Percutaneous transluminal angioplasty may have a short-term benefit but this is unlikely to be sustained by 2 years. Likewise, the long-term results of bypass grafting are quite variable, depending greatly on the location and extent of disease and type of intervention.

For critical limb ischaemia, the success of arterial reconstruction is also variable with 2-year patency rates between 30% and 70%. For below-knee amputation, 80% of patients achieve reasonable mobility compared to only 40% having above-knee amputations.

For ruptured abdominal aortic aneurysms, the peri-operative mortality is between 40% and 60%. On the other hand, almost 100% would die without surgery. Asymptomatic aneurysms of diameter > 6 cm are generally operated on but the latest evidence, from the recently published UK Small Aneurysm Trial, indicates that aneurysms < 5.5 cm should simply be observed using ultrasound surveillance. The mortality of elective surgery is 5.8%. Trials are currently in progress investigating the effectiveness of endovascular repair and have recently shown benefits of aneurysm screening in the general population.

Models of care/recommendations

National guidelines are required on the management and referral of patients with intermittent claudication in primary care. Several recent reports in the UK have indicated that vascular services at secondary care level need to be centralised in major vascular units serving populations of at least 500 000. Minimum staffing requirements and facilities can be specified to ensure that such a unit can provide a high-quality vascular service round the clock. This specification includes provision of at least three full-time vascular surgeons and an equivalent number of full/part-time interventional radiologists, a 30-bed vascular unit plus 10 beds for rehabilitation of amputees, a fully equipped vascular laboratory, appropriate radiological facilities and access to intensive care beds on site.

This major vascular unit should be the focus for an integrated regional or supra-district vascular service in which some services are provided in other hospitals in a 'hub and spoke' arrangement. Hospitals on the 'spoke' would provide outpatient clinics, some diagnostic facilities including Duplex scanning, pre-operative assessment, day surgery, post-acute care and rehabilitation. In a few geographically remote areas, smaller hospitals may require to provide a more substantial range of vascular services, including emergency surgery and more straightforward elective procedures.

2 Introduction and statement of the problem

Definition of peripheral vascular diseases

The term peripheral vascular disease does not have a precise and agreed meaning. When used in the plural, peripheral vascular diseases normally refers to all diseases that affect the arteries, veins and lymphatics of the peripheral vasculature.[1] When used in the singular, peripheral vascular disease normally refers to only those diseases that affect arteries; these include atherosclerosis, aortic aneurysm, Buerger's disease, Raynaud's syndrome and others.[1] The most common is atherosclerosis, in which lipid is deposited in the arterial wall; sometimes peripheral vascular disease refers to this condition only. 'Peripheral' refers to the location of disease. Usually peripheral vascular disease includes conditions that affect the arteries serving the lower limbs, sometimes the upper limbs, and less commonly the carotid, renal and other extra coronary arteries.

In this chapter, two peripheral vascular diseases will be evaluated. These are atherosclerosis that affects the lower limb, which will be referred to as 'peripheral arterial disease', and aneurysms of the lower abdominal aorta, referred to as 'abdominal aortic aneurysm'. These conditions have been chosen because they are common and have a major impact on the use of health service resources. Precise definitions of these conditions are as follows:

- Peripheral arterial disease: atherosclerosis of the distal aorta and/or lower limb arteries causing arterial narrowing and disruption of blood flow in the legs.
- Abdominal aortic aneurysm: abnormal dilatation of the aorta distal to the renal arteries.

Aetiology and pathology

In peripheral arterial disease, the pathological condition of atherosclerosis is identical to that which occurs in the coronary arteries, causing ischaemic heart disease. The deposition of atheroma, comprising mostly lipid in the media of the arterial wall, may begin in childhood, and by late middle age most adults have evidence of atheroma in their peripheral arteries.[2] Atheroma has a predilection for certain sites in the arterial tree, notably at bifurcations and bends, and may lead to stenosis (narrowing) or occlusion (complete blockage) of the artery. The pattern, severity and effects of the disease vary greatly, so that some individuals remain asymptomatic while in others, the arterial narrowing leads to inadequate muscle blood flow (ischaemia) with resulting pain.

As the underlying pathology of peripheral arterial disease and coronary heart disease are the same, it is not surprising that the aetiological risk factors for the two conditions are similar.[3] The classic cardiovascular risk factors of cigarette smoking, hypercholesterolaemia and hypertension are implicated in peripheral arterial disease. Likewise, more recently investigated risk factors for coronary heart disease, such as lack of physical exercise, alcohol consumption, diabetes mellitus, low high density lipoprotein (HDL) cholesterol, hyperhomocysteinaemia, thrombophilia and hypercoagulable states, are also associated with an increased risk of peripheral arterial disease.[4] Cigarette smoking would appear to be a more important risk factor for peripheral arterial disease than coronary heart disease, with over 90% of patients with intermittent claudication stating that they are current or ex-smokers.[5] Diabetes mellitus is often believed to be a more important risk factor for peripheral arterial disease than coronary heart disease but the evidence for this is inconsistent. There is no doubt that diabetes mellitus is very important in the later stages of peripheral arterial disease in which diabetic neuropathy and small vessel disease, as well as atherosclerosis in large vessels, may cause gangrene and ulceration.[6]

Aortic aneurysm affecting the lower abdominal aorta is the result of a weakening and thinning of the aortic wall leading to dilatation and ballooning of the aorta.[7] It is believed to result from a change in the composition of the collagen and elastin matrix in the media of the arterial wall. This matrix is affected by the activity of certain enzymes, including the metalloproteinases. The presence of an aneurysm often coincides with the occurrence of significant atherosclerosis in the aortic wall, and population studies have shown the two conditions to be inter-related. However, the extent to which atherosclerosis may be involved in the pathogenesis of aneurysms is not well established.[8]

The only risk factor that has been shown conclusively to be involved in the aetiology of aortic aneurysm is cigarette smoking, with some smokers having a two- to threefold increased risk compared with non-smokers.[9] Aneurysms have been shown in some studies to occur more frequently in the close relatives of cases,[10] but to date, a mode of inheritance has not been demonstrated.[5] Nor has a specific gene affecting, for example, enzyme activity in the arterial wall been identified. However, future research is likely to lead to greater understanding of the role of inheritance and genes in the aetiology of this condition.

Clinical presentation, diagnosis and treatment

The most common clinical presentation of peripheral arterial disease is intermittent claudication, in which pain occurs in the calf on exercise and is relieved by rest. The diagnosis can often be made on the clinical history alone but may be confirmed by measurement of the ankle brachial pressure index (ABPI). This is the ratio of the ankle to brachial systolic pressure and can be measured easily using a sphygmomanometer and Doppler ultrasound machine. In the presence of symptoms, a ratio of < 0.9 is over 90% sensitive and specific in identifying peripheral arterial disease.[11] A treadmill exercise test may be useful to document pain-free walking distance and a Duplex scan may be used to locate significant atherosclerotic lesions. Angiography, which involves injection of an opaque dye into the arterial system, may be required for the accurate identification of lesions, pending interventional treatment.

The clinical course of patients with intermittent claudication is very variable. Most patients either improve or stay about the same; deterioration leading to amputation is uncommon.[12,13] In mild claudication, 'stop smoking and keep walking' is standard advice;[14] drug therapy is of limited value.[15] Interventional treatment may be warranted when patients perceive the handicap as severely limiting their quality of life. In such cases, balloon angioplasty or bypass surgery may be carried out, although there have been few controlled trials examining the cost-effectiveness of these procedures. Balloon angioplasty involves passing a catheter through the skin into the artery and inflating a balloon to crack and obliterate the atheromatous plaque. Bypass operations, which are the main type of reconstructive surgery, involve the insertion of a graft comprising vein or synthetic material, such as Dacron. This graft allows blood to bypass the narrowed or obstructed artery. In most cases of intermittent claudication, risk factor management and antiplatelet therapy is also warranted.

The intermittent pain may worsen and be present when the patient is stationary (rest pain). Gangrene and ulceration of the foot may also occur. In such severe forms of peripheral arterial disease (critical limb ischaemia), bypass surgery, angioplasty or amputation are usually required.

An aortic aneurysm may present either as an emergency following rupture or with symptoms such as a pulsating abdominal mass or back pain.[1,7] The diagnosis can rarely be made on clinical examination alone and usually requires confirmation by ultrasound or computed tomography (CT) scanning of the abdomen. Sometimes asymptomatic aortic aneurysms are found when an abdomen is being scanned for other purposes or as part of an aneurysm screening programme.

Treatment of an aneurysm is highly dependent on the presenting features. Ruptured aneurysms require emergency surgical repair, which is associated with a high mortality of 40–60%.[16] Symptomatic aneurysms also require surgical treatment, usually elective, to relieve the symptoms and reduce risk of rupture. Management of asymptomatic aneurysms is dependent on their size – larger aneurysms are operated on while smaller aneurysms, in which the risk of rupture is low, are surveilled routinely using ultrasound, and only operated on if the aneurysm grows substantially and is at increased risk of rupture.

Diagnostic and treatment codes

The International Classification of Diseases (ICD-10), Office of Population Censuses and Surveys (OPCS-4) operation codes, and Healthcare Resource Group (HRG-3) codes relevant to peripheral arterial disease and aortic aneurysm are shown in Table 1.

As a general rule, the diagnostic codes for peripheral arterial disease are not very helpful because they are not specific enough to identify individual clinical conditions, and the same condition may occur under different codes. For example, a patient with intermittent claudication may be categorised as 170.2, 170.8, 170.9 or 173.9 (Table 1). The codes for aortic aneurysm are probably more accurate, although there may be misclassification of ruptured/non-ruptured. The operation codes are more precise, although under-reporting is likely, particularly of more minor procedures such as diagnostic angiography and angioplasty.

In addition to the HRGs as shown in Table 1, the National Casemix Office set up in 1998 a process of developing Health Benefit Groups (HBGs). These are groups of people: (a) with similar healthcare need; (b) who require similar healthcare interventions; and (c) who, given those interventions, would have a similar range of outcomes. For any condition, HBGs are classified within four stages of the natural history: 1, at risk of the condition; 2, presenting with the condition; 3, confirmed disease requiring initial care; and 4, consequences of disease requiring continuing care and/or rehabilitation. Each of these HBG categories is placed together with relevant HRG categories, such as prevention and promotion, investigation and diagnosis, into a matrix format. These matrices enable disease morbidity, health service activity and finance data to be turned into information on a condition-specific and a case group basis.

Health service issues

In primary care, the appropriate indications and threshold for referral of patients with peripheral arterial disease are not well established. Practice undoubtedly varies between different parts of the UK and it is likely that many referrals to vascular units do not benefit from additional investigations or receive more effective treatment than was advised in general practice. Another important issue for primary care is that it has become increasingly recognised that patients with peripheral arterial disease are at greatly increased risk of cardiovascular and cerebrovascular events and that risk-factor management in such patients is often lacking.

In secondary care, a major issue that has been of concern in recent years is the appropriate location and organisation of vascular units so that a comprehensive vascular service can be provided with adequate emergency cover, technological facilities and ancillary services. In considering the organisation of services, an important issue is the minimum specification required for a vascular unit in order to provide a high-quality service. Such a specification will include the required surgical, radiological, anaesthetic and other staff per head of population, number of inpatient beds, range of diagnostic facilities, intensive care and high dependency units, rehabilitation and other services.

Another issue relevant to secondary care is that the diagnosis and management of patients with intermittent claudication referred to hospital is extremely variable. The appropriate sequence of investigations and indications for treatment, particularly angioplasty or surgery, is not well specified. Precise guidelines are required on the most cost-effective strategies. In particular, indications for appropriate diagnostic

Table 1: International Classification of Diseases (ICD-10), Office of Population Census and Surveys (OPCS-4) operation codes, and Healthcare Resource Groups (HRG-3) for peripheral arterial disease and aortic aneurysm.

ICD-10	
I70.2	Atherosclerosis of arteries of extremities
I71.3	Abdominal aortic aneurysm, ruptured
I71.4	Abdominal aortic aneurysm, without mention of rupture
I71.8	Aortic aneurysm of unspecified site, ruptured
I71.9	Aortic aneurysm of unspecified site, without mention of rupture
I73.9	Peripheral vascular disease, unspecified (includes intermittent claudication)

I70.0 atherosclerosis of aorta, I70.8 atherosclerosis of other arteries, I70.9 generalised and unspecified atherosclerosis, and E10-E14 diabetes with .5 (peripheral circulatory complications) may also include some cases of peripheral arterial disease.

OPCS-4	
L16.-, L18.-, L19.-, L25.4	Aortic aneurysm repairs*
L50.-, L51.-, L52.-, L53.2, L58.- L59.-, L60.1, .2, L62.2	Iliac and femoral bypass/ endarterectomy/embolectomy
X09.3, .4, .5, X11.-	Amputations – knee/toe**
L26.1, .2, .3, .8, .9, L31.1, .8, .9 L39.1, .2, .3, .8, .9, L43.1, .2, .3, .8, .9 L47.1, .2, .8, .9, L54.1, .2, .8, .9 L63.1, .2, .3, .8, .9, L71.-	Transluminal operations including angioplasty
L26.4, L31.2, L39.4, L43.4, L47.3 L54.3, L63.4, L72.1	Diagnostic angiography

* Includes only those cases that have diagnosis of abdominal aortic aneurysm (in any position).
** Includes only those cases that have diagnosis of atherosclerosis or peripheral vascular disease (in any position).

HRG-3	
Q01	Emergency aortic surgery
Q02	Elective abdominal vascular surgery
Q03	Lower limb arterial surgery
Q04	Bypasses to tibial arteries
Q12	Therapeutic endovascular procedures
Q13	Diagnostic radiology – arteries or lymphatics with comorbidity/complications
Q14	Diagnostic radiology – arteries or lymphatics without comorbidity/complications
Q15	Amputations
Q16	Foot procedures for diabetes or arterial disease, and procedures to amputation
Q17	Peripheral vascular disease > 69 years or with comorbidity/ complications
Q18	Peripheral vascular disease < 70 years without comorbidity/ complications

imaging need to be specified. Also, interventional radiological techniques, such as balloon angioplasty and stenting, are being widely used and undergoing continuing development and refinement, so that ongoing guidance on their use is required.

For patients with severe peripheral arterial disease requiring surgery, the indications for when arterial reconstruction, especially bypass grafting, or amputation should be performed are not clear-cut. Decisions are affected by the availability of resources, because reconstructive surgery is often more time-consuming and demanding than amputation. Appropriate organisation of services and adoption of surgical guidelines would ensure more uniform practice and higher rates of limb salvage in patients with severe peripheral arterial disease. Also, for patients having amputation, the availability of rehabilitation services varies greatly. It is well known that early rehabilitation has a major effect on outcome for amputees, but unfortunately limb-fitting services are not always easily accessible.

The management strategy of aortic aneurysms is generally straightforward, except that some doubt exists as to the appropriate treatment for smaller, asymptomatic aneurysms, with a choice of elective aneurysm repair or routine ultrasound surveillance in which the size and growth of the aneurysm is monitored. The recently published results of the UK Small Aneurysm Trial, however, indicate that it is generally not cost-effective to operate on aneurysms < 5.5 cm diameter, and that Trusts would be better to invest in ultrasound surveillance.

In the prevention of peripheral vascular disease, the value of screening for aortic aneurysms is currently under consideration by the Department of Health following a recommendation by the National Screening Committee. The costs and organisation of a district-based screening service is considerable although trials have shown that screening and then management of aneurysms, either by surgery or surveillance, is cost-effective. For the prevention of peripheral arterial disease, the risk factors, such as cigarette smoking and hyperlipidaemia, are essentially the same as for coronary heart disease, although smoking appears to be more important. Primary prevention programmes for coronary heart disease are therefore applicable to peripheral arterial disease and separate initiatives are not required.

Key problems for purchasers

The key problems currently facing purchasers are first, to ensure that the minimum service requirements for the management of peripheral vascular diseases are in place at secondary care level in order to ensure provision of a high-quality service. Also, methods of monitoring need to be established to ensure that the process and outcome of care is satisfactory. The second key problem concerns screening for aortic aneurysms, an area in which professional groups have put pressure on authorities but on which national guidance is awaited. Finally, purchasers need to try and ensure that an efficient and consistent programme exists for the management of intermittent claudication in both primary and secondary care.

3 Sub-categories

The following sub-categories of peripheral arterial disease and aortic aneurysm are used in this chapter because they reflect different severities of disease and approaches to management.

Peripheral arterial disease

(a) *Intermittent claudication* is the most common condition and the only condition that many patients experience. Mild symptoms are likely to be treated conservatively, whereas more severe symptoms might be treated with angioplasty or bypass surgery.
(b) *Critical limb ischaemia* is a more severe form of peripheral arterial disease in which the patient has rest pain, gangrene or ulceration. These patients normally require urgent hospital admission and are treated by means of surgical reconstruction, amputation or, occasionally, angioplasty in the first instance.
(c) *Asymptomatic peripheral arterial disease* is now being increasingly recognised as a high-risk group for future cardiovascular and cerebrovascular events, requiring appropriate risk factor management.

Abdominal aortic aneurysm

(a) *Ruptured aneurysm* is managed by surgical repair where appropriate. This will be carried out as an emergency procedure and requires that a skilled vascular team is available out of hours.
(b) *Asymptomatic aneurysm*, on the other hand, may be managed either using an elective surgical repair or by ultrasound surveillance. Population screening for asymptomatic aneurysms may also be carried out.

4 Prevalence and incidence

Intermittent claudication

The prevalence of intermittent claudication in the general population has been measured by questionnaire. Table 2 shows the prevalence by age and sex found in three population surveys[17–19] carried out in the UK during the 1980s and 1990s using the WHO/Rose questionnaire on intermittent claudication.[20] These studies came to broadly the same conclusions. Under the age of 55 years intermittent claudication is uncommon, affecting less than 1% of men and women. Over the age of 55 years, the prevalence increases steeply with age and overall in 55- to 74-year-old men and women the prevalence is almost 5%.[17] At younger ages the prevalence of claudication is almost twice as high in men as in women, but at older ages the sex difference narrows, in keeping with the findings in other forms of atherosclerotic disease. The WHO/Rose questionnaire is known to lack sensitivity (60–70%)[21–22] and more recent adaptations, such as the Edinburgh Claudication Questionnaire,[23] are now recommended for use. However, despite the low sensitivity of the WHO/Rose questionnaire, the prevalence figures in Table 2 are probably only a slight underestimate because of the inclusion of false positives. In the Scottish Health Survey,[24] which used the Edinburgh questionnaire, the prevalence was measured over a wide range from 16 to 64 years. In men, the prevalence at age 16–24 years was 0.4% rising consistently to 1.9% at age 45–54 years and 5.0% at age 55–64.

Reliable information on the geographical variation in prevalence of intermittent claudication in the UK is not available, but the distribution by social class and the strong relationship with cigarette smoking would suggest that there is a north–south divide as is found for coronary heart disease. In the Edinburgh Artery Study of 55- to 74-year-old men and women[17] a consistently increasing trend in the prevalence of claudication was found with lower social class (3.6% in Class I to 5.9% in Classes IV+V). Likewise, an

Table 2: Prevalence (%) of intermittent claudication by age in general population surveys in the UK in the 1980 and 1990s.

Age group	Men			Women	
	SHHS	SS	EAS	SHHS	EAS
40–44	0.4			0.2	
45–49	1.0			0.4	
50–54	0.8	0.8		0.4	
55–59	2.2	1.8	2.2	1.0	2.3
60–64		2.4	4.6		5.0
65–69		3.9 (65–72)	3.6		5.5
70–74			8.4		6.6

EAS: Edinburgh Artery Study.[17]
SS: Speedwell Study.[18]
SHHS: Scottish Heart Health Study.[19]
EAS, SS and SHHS used WHO/Rose questionnaire[20] and included Grades I and II claudication.
EAS also included 'probable' claudication (increasing figures by around one quarter).
SS included men only.

inverse trend occurred with educational attainment: those who left school and did not proceed to further education had a twofold higher prevalence than those entering college or university. Also, using the Carstairs deprivation score, which classifies households in postcode sectors according to a combination of four variables (men unemployed, overcrowded housing of more than one person per room, households without a car and household heads in semi- or unskilled/manual occupations), a higher prevalence of peripheral arterial disease was associated with greater deprivation, especially in men.[25] Although peripheral arterial disease in this analysis[25] was measured using hospital discharge data and the ABPI, it would be very surprising if the relationship did not also hold true for intermittent claudication. In the Edinburgh Artery Study, much of the association with deprivation appeared to be related to cigarette smoking.[25]

Limited information is available on the incidence of intermittent claudication in the UK. In the Speedwell Study, 4% of men aged 45–63 years developed claudication during 10 years of follow-up, with the incidence increasing consistently with age.[18] In the Edinburgh Artery Study among men and women aged 55 to 74 years, 9% developed claudication during 5 years of follow-up – a figure equivalent to 1.8% per annum or 15.5 per 1000 person years.[26] Overall, the 5-year incidence was higher among men (8.7%) than among women (6.6%). The higher incidence rate in the Edinburgh Artery Study compared to the Speedwell Study was due to the older population and inclusion of 'probable' claudicants.

Since atherosclerosis is the cause of peripheral arterial disease, coronary heart disease and ischaemic stroke, it is not surprising that concomitant heart disease and a history of stroke occurs commonly in subjects with intermittent claudication. In the general population, around 40% of claudicants have angina.[17] The prevalence of concurrent coronary heart disease in claudicants is between two and four times that in non-claudicants.[27] In patients presenting to hospital, between 38% and 58% have evidence of coronary heart disease diagnosed by history and electrocardiogram (ECG), but if patients are investigated intensively by, for example, coronary angiography, 90% have evidence of coronary atherosclerosis.[12] A history of stroke occurs in about 15% of claudicants but depends on the age, sex and other features of the population studied.[27] This high prevalence of other manifestations of atherosclerosis in claudicants emphasises the importance of total patient management and not just treatment of the claudication in these patients.

In patients developing intermittent claudication, the natural history of their leg ischaemia is relatively good.[12] In claudicants referred to hospital, around one third will become symptom-free during their lifetime without intervention; around one third to one half remain about the same; and in only one quarter will the symptoms deteriorate, resulting in a lifetime amputation rate for hospital referrals of less than 7%.[28] This prognosis is even better among claudicants identified in community surveys. In the Edinburgh Artery Study, 50% of claudicants became symptom-free during 5 years of follow-up,[26] and the lifetime incidence of amputation in claudicants in the general population, as shown in the Framingham Study in the USA, is only about 1–2%.[29]

However, a major concern in patients with intermittent claudication is the high risk of mortality. The 5-year mortality among claudicants referred to hospital is around 25–50%[12] and the relative risk of dying is two to three times that of individuals without claudication.[13] Similar relative risks occur in claudicants in the general population.[26,30] Given that many individuals with peripheral arterial disease in the legs have evidence of widespread vascular disease, not surprisingly over 60% of deaths are due to coronary heart disease and about 10% are due to stroke.[31] Very few deaths are due directly to complications of leg ischaemia.

Patients with intermittent claudication are also at greatly increased risk of major non-fatal cardiovascular and cerebrovascular events. Long-term follow-up studies of claudicants in the general population in Scotland,[26] USA,[30] Sweden[32] and other Western countries have found a twofold relative risk of non-fatal myocardial infarction compared with non-claudicants. In typical claudicants referred to hospital, roughly 15% will have a non-fatal coronary event within 5 years.[12] Likewise, non-fatal stroke occurs more commonly in claudicants than in healthy subjects. In the Edinburgh Artery Study the 5-year incidence of stroke or transient ischaemic attack (TIA) in claudicants was 6.8% with a twofold increased relative risk compared to non-claudicants.[26] Even when adjusted to take account of the higher levels of cardiovascular risk factors in claudicants (cigarette smoking, hypercholesterolaemia and elevated blood pressure), the increased risks of future coronary heart disease and stroke were reduced only slightly.[26,30,32]

Valid information on time trends in the prevalence of intermittent claudication in the UK would need to be based on repeated large cross-sectional surveys in the general population. Such repeat surveys have not been carried out. Data on trends in claudication, however, are available from the Reykjavik Study in Iceland.[33] Between 1970 and 1986, both the prevalence and incidence of claudication decreased in men at all ages between 40 and 70 years. The decline in prevalence was about 55% and in incidence 66%. No data were collected for women. Interestingly, the decline in claudication was greater than that for coronary heart disease in men during the same period and started a few years earlier.[34] In the UK, claudication has been measured sequentially in two cohort studies, the Speedwell Study[18] and the Edinburgh Artery Study.[17,26] The numbers within the specified age groups were small but neither study suggested that there had been a decline in prevalence of claudication. Results for the Speedwell Study are shown in Table 3.

The trends in prevalence and incidence of intermittent claudication in the UK are thus unknown. The expectation would be that trends in claudication would closely mirror those for coronary heart disease and, as was found in the Reykjavik Study, be influenced particularly by trends in cigarette smoking in the general population.[33] The decline in the incidence of coronary heart disease[35] and smoking prevalence[36] would point to a decreasing frequency of claudication. On the other hand, a possible lower case fatality rate for myocardial infarction[37] would lead to increasing survival of those with severe atherosclerotic disease and perhaps an increased occurrence of chronic manifestations such as intermittent claudication.

Table 3: Age specific prevalence of intermittent claudication at baseline and at subsequent examinations in the Speedwell Study.

	Sample number and % prevalence claudication							
	50–54 yrs		55–59 yrs		60–64 yrs		≥ 65 yrs	
Examination								
Baseline	727	1.0	852	1.8	318	2.2	–	–
3-year	598	0.8	686	1.2	695	3.5	45	2.2
6-year	205	0	639	1.6	646	2.9	472	3.8
9–10-year	–	–	440	1.4	575	2.4	741	3.9

Baseline examination conducted in 1979–82.
Source: adapted from Bainton *et al.*[18]

Critical limb ischaemia

The frequency of critical limb ischaemia in the general population is difficult to estimate because it is too rare to measure reliably in population surveys. Although most patients are admitted to hospital, diagnostic coding is too imprecise to identify such patients reliably. However, in a multicentre study in the UK in the mid-1980s, of 409 patients with critical limb ischaemia, 25% had major amputations within 12 months.[38] An expert European consensus group utilised this information, together with reasonably valid data on the frequency of amputation and knowing that the vast majority of these amputations were for ischaemia, to calculate an overall incidence of critical limb ischaemia in the range 500–1000 per million population per year.[39]

The natural history and survival of patients with critical limb ischaemia is poor. The UK Joint Vascular Research Group found that 1 year after presentation with critical ischaemia 20% of patients were dead and only 53% were alive with both legs intact.[38] Of the 25% having major amputation, the 5-year survival rate was less than 50%.[40] As might be expected, amputation or reconstructive surgery on the ischaemic leg has little effect on survival. In one study of patients with rest pain who did not have surgery, the 5-year mortality was over 50%.[41] The poor survival in patients with critical limb ischaemia is undoubtedly related to the widespread atherosclerotic disease which is invariably present.

Asymptomatic peripheral arterial disease

Asymptomatic peripheral arterial disease causing a severe disruption to blood flow occurs commonly in the general population. In the Edinburgh Artery Study, 8.0% had evidence of major asymptomatic disease (Figure 1) and the results of Duplex scanning indicated that at least one third of these subjects had occlusion of a major artery.[17] A further 16.6% were classified as having minor asymptomatic disease. Asymptomatic disease has not been investigated in other population studies in the UK, but comparable findings have been reported in surveys overseas. In the Basle Study, conducted some years ago on workers in the pharmaceutical industry, the prevalence of occlusion confirmed by arteriography was 0.4% at age 20–24 years, increasing to 7.5% at age 60–64 years.[41] Surveys in Denmark[42] and Israel[43] found that 14% and 5% respectively had low ankle brachial systolic pressure ratios (< 0.9). The Lipid Research Clinics study in the USA used a combination of non-invasive tests and found that the prevalence of large vessel disease

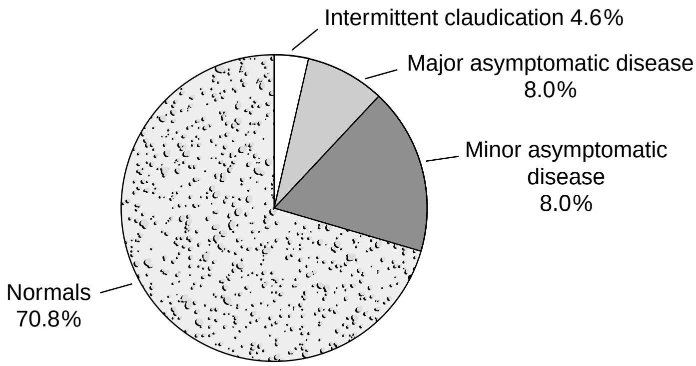


Figure 1: Prevalence of symptomatic and asymptomatic peripheral arterial diseases in the general population aged 55 to 74 years: Edinburgh Artery Study.

affecting the lower limb increased progressively with age from 3% at less than 60 years to more than 20% in those aged 75 years and over.[44]

Individuals in the general population with demonstrable asymptomatic peripheral arterial disease are at increased risk of developing intermittent claudication. In the Edinburgh Artery Study, over a 5-year follow-up period, 15.2% with major asymptomatic disease developed claudication, compared with 7.1% of those with minor asymptomatic disease and 3.2% of normals.[26] A low ABPI, irrespective of the presence of ischaemic symptoms, is indicative of a higher prevalence of concomitant coronary heart disease, history of stroke or TIA, and carotid stenosis.[45] It is not surprising therefore that subjects with lower limb arterial disease, as measured by a low ABPI, have an increased mortality mostly due to coronary heart disease and stroke. There is a two- to threefold increased risk of cardiovascular mortality in both men and women without symptoms of any vascular disease but an ABPI < 0.9 compared with those with an ABPI ≥ 0.9.[26,30,32,46] Also, those with a low ABPI are at increased risk of non-fatal myocardial infarction and stroke.[26,32] Interestingly, these risks associated with a low ABPI occur independently of those due to risk factors such as cigarette smoking, hypercholesterolaemia and hypertension,[47] so that the ABPI may be a useful marker of vascular risk in supposedly healthy individuals.

Ruptured aneurysm

Aneurysms may cause minor symptoms such as backache, but the most important symptomatic phenomena are those due to rupture. Rupture is often catastrophic and causes sudden death before the patient is admitted to hospital. The incidence of rupture in the population therefore requires tracing of all ruptures causing sudden death in the community as well as those in patients admitted to hospital. In a study in Swansea in 1983, the annual incidence was found to be 17 per 100 000 population, and of these, 60% died outside hospital.[48] Of those admitted to hospital well over half die during that admission. As the mortality rate from rupture is extremely high and because there are no valid figures on incidence of rupture per se, mortality rates from aortic aneurysm are the best routine measure of community burden.

In England and Wales in 1996, 6163 men and 3663 women died due to an aortic aneurysm[49] resulting in a mortality rate of 24.1 and 13.8 per 100 000 men and women respectively (Table 4). The majority of the deaths were due to abdominal aneurysms, with thoracic aneurysm accounting for about 7% of deaths. Dissecting aneurysms, in which only the inner wall of the artery is ruptured leading to blood flowing between the inner and outer walls, accounted for about 20% of deaths. The death rate due to aortic aneurysms was negligible below 45 years of age and the rate increased at successive ages. At all ages the mortality was higher in men than in women.

Table 4: Mortality due to aortic aneurysm by age and sex in England and Wales, 1996.

Age group (yrs)	Deaths due to aortic aneurysm Rate per 100,000 (n)	
	Male	Female
0–14	0.0 (1)	0.0 (1)
15–44	0.4 (40)	0.1 (14)
45–64	10.9 (644)	2.5 (148)
65–74	103.3 (2,128)	34.4 (835)
75+	254.7 (3,350)	108.6 (2,665)
Total	24.1 (6,163)	13.8 (3,663)

Deaths due to aortic aneurysm include thoracic ($n \sim 700$) and dissecting ($n \sim 2{,}000$) aneurysms.
Source: Office for National Statistics[49]

Asymptomatic aneurysm

The population prevalence of abdominal aortic aneurysms (which are mostly asymptomatic) can be determined only from community surveys using ultrasound screening. Table 5 shows the results of four such surveys carried out in the UK.[50–53] The prevalence figures are affected by the population studied, definition of aneurysm according to diameter and measurement technique. Overall, roughly 5% of men aged 65–74 years would appear to have an aneurysm ≥ 3.0 cm in diameter. The prevalence of aneurysms in females is much lower, with a male:female ratio of about 3:1. Although comprehensive data on prevalence by age are not obtainable from screening studies, it would seem from the limited data available and from mortality and hospital admission statistics that aneurysms are relatively uncommon below the age of 50 years. The prevalence would appear to rise steeply with age in older subjects, and may be up to 10-fold higher in those over 85 compared to those aged 55.[7,54,55]

As aneurysms may, in part, be genetically determined[7] and would appear to occur more often in the presence of aortic atherosclerosis,[7–9], the prevalence of aneurysms has been shown to be higher in close family relatives of those affected and also in those with various manifestations of cardiovascular disease.[55] Also the prevalence has been found to be higher in those with cardiovascular risk factors, such as cigarette smoking, hypertension and hypercholesterolaemia. The prevalence of aneurysm in these risk categories varies greatly with the exception perhaps of cigarette smokers, in whom prevalences between 10% and 14% have been reported.[55]

Table 5: Population prevalence of abdominal aortic aneurysms in community surveys in the UK.

Author	Location	Age and sex	Number	Aneurysm diameter (cm)	Prevalence (%)
Collin *et al.*[50]	Oxford	65–74 men	824	≥ 3	4.0
O'Reilly & Heather[51]	Gloucester	65–74 men	1,195	≥ 2.5	7.8
Scott *et al.*[52]	Chichester	65–80 men	2,342	≥ 3	7.6
		65–80 women	3,052	≥ 3	1.3
Smith *et al.*[53]	Birmingham	65–75 men	2,669	≥ 2.9	8.2

Magnitude of disease in a UK district

The figures on prevalence and incidence of the different manifestations of peripheral vascular disease are mostly based on the results of ad hoc surveys in different populations in the UK. The following extrapolation of these figures to a typical UK district population must therefore be interpreted with caution.

In a district of 500 000 population with the age and sex distribution of the estimated 1996 population in England and Wales, there would be about 9500 claudicants and around 1000 individuals would develop intermittent claudication each year. (The total number of claudicants in the UK is about 1 million.) Each year around 375 individuals in this district would develop critical limb ischaemia. In addition to the claudicants, almost 20 000 would have major asymptomatic peripheral arterial disease causing severe disruption to blood flow in the legs. About 120 males and 70 females would die each year due to an aortic aneurysm, the majority being caused by rupture of an abdominal aneurysm. Also, the population at large would contain around 4500 individuals with an asymptomatic abdominal aneurysm.

5 Services available and their costs

Peripheral arterial disease

Primary care

In primary care, the main service requirement is to provide adequate diagnosis, referral and risk factor management in patients with intermittent claudication. This is normally part of routine general practice. In the diagnosis of peripheral arterial disease, measurement of the ABPI is a simple, inexpensive and useful test to perform but few GPs have the equipment or skill to perform this test. Otherwise, providing a proper service at primary care level does not require any special facilities or expertise.

Table 6 shows the consultation rates in general practice for the major peripheral vascular disease diagnostic groups in England and Wales in 1991–92. The number of patients consulting and total number of consultations per head of population per year for peripheral arterial disease and aortic aneurysm was extremely low, particularly as many in the 'other peripheral vascular diseases' group would have had neither of these categories of disease. The number of consultations per 10 000 people per annum was 82 and accounted for only 0.24% (1 in 420) of total consultations in general practice. Data from the Continuous

Morbidity Recording system in general practice in Scotland indicates that in 1997 there were 8404 new consultations for peripheral arterial disease in Scotland. This consultation rate is equivalent to 17 per 10 000 person years at risk, a figure comparable to the 25 per 10 000 found in England and Wales (Table 6).

Table 6: Consultation rates for peripheral vascular diseases in general practice in England and Wales, 1991–92.

Diagnostic group (ICD-9)	**Rate per 10,000 person years at risk**		
	New and first ever episodes*	**Patients consulting****	**Consultations with doctor**
Atherosclerosis (440)	1	2	4
Aortic aneurysm (441)	2	3	6
Other aneurysm (442)	0	0	1
Other peripheral vascular diseases (443)	24	40	71
All diseases and conditions	n.a.	7,803	34,785

* Episodes: single or sequence of consultations covering the duration of a continuing illness. A new episode is an episode for a condition for which the patient has previously consulted.
** Patients consulting at least once during the year.
Source: Office of Population Consensus and Surveys. *Morbidity Statistics from General Practice. Fourth national study 1991–1992*. London: Her Majesty's Stationery Office, 1995

Secondary care: availability of services

The services available for the secondary care of peripheral arterial disease in the UK are not comprehensively documented. However, an unpublished survey of vascular services in hospital trusts in Scotland for the recent Acute Services Review[56] revealed a diversity of provision. This survey found the following.

Location

- The vascular service in most hospitals was part of the general surgery service. Three out of 18 hospitals had a unit dedicated to vascular disease only.
- A large number of general hospitals, including teaching hospitals, did not provide any vascular service.

Staffing

- One third of 'vascular surgeons' performed vascular surgery only, whereas two thirds of 'vascular surgeons' were general surgeons with a principal specialty interest of vascular surgery.
- All hospitals providing a vascular service had anaesthetists with a special interest in vascular cases but not all elective vascular lists were covered by vascular anaesthetists.
- Among radiologists performing vascular interventions, less than one third specialised, i.e. 50% or more of their work was in interventional radiology.
- Three out of 18 vascular services were supported by physicians specialising in vascular medicine.
- Four out of 18 vascular services had nursing staff with specialist training in the management of vascular disease.

Facilities

- A vascular laboratory was not available in 50% of hospitals providing a vascular service.
- All vascular units had access to intensive therapy unit beds and two thirds had access to high dependency unit beds and on-site renal dialysis.

Organisation

- Emergency rotas varied greatly from a 1 in 4 rota of specialist vascular surgeons to rotas in which non-vascular general surgeons participated. Occasionally single-handed vascular surgeons were continuously on call for vascular emergencies.
- About 90% of hospitals providing a vascular service had a separate vascular waiting list and around one third had a dedicated vascular theatre.

A previous survey of Trusts in Scotland in 1992 produced very similar findings.[57] Also, the results of a 1995 survey of vascular surgeons in the UK, carried out by the Vascular Surgeons Society of Great Britain and Ireland, suggested that the situation in Scotland was not atypical of the UK as a whole.[58] This latter survey found that around half the surgeons were working in hospitals servicing populations of 250 000–500 000, 40% in hospitals serving 100 000–250 000 and 20% in hospitals serving over 500 000. Around one third of surgeons had specifically allocated vascular beds and about one third had a dedicated vascular list. Half had no access to intensive therapy unit beds. The National Confidential Enquiry into Perioperative Deaths (1994/95) in England and Wales found that one third of cases admitted with vascular emergencies were treated by consultants with no vascular interest.[59] Therefore, the overall picture in the UK is that the majority of vascular surgery is being carried out in general surgery units in district general hospitals and not in tertiary specialist referral centres.

Some limited information is available on the costs of providing a vascular service for the diagnosis and treatment of peripheral arterial disease. Hospital costs for HRGs relevant to peripheral arterial disease obtained from an ongoing survey of a sample of NHS Trusts in 1997/98 are shown in Table 7. The highest mean cost was for amputations (£5994), whereas a bypass to tibial arteries cost £5378. In contrast, a therapeutic endovascular procedure, which would comprise mostly angioplasty, had a mean cost of only £1519. In recent years, costs have been estimated separately in some hospitals. For example, in a survey of patients followed up for one year in one centre, the costs of arterial reconstruction at 1988/89 prices ranged from £6590 per patient for proximal grafts to £11 000 for distal grafts.[60] These included costs of revision of failed grafts, secondary amputation and treatment of the other leg. In contrast, the cost of primary amputation ranged from £10 400–£10 850 per patient. In another hospital, a report published in 1995 indicated that the median inpatient cost of primary amputation was £8000 and for a successful bypass graft was £5300.[61] The average total health and social service costs consumed during, and up to 6 months following, surgery were £12 500 for amputation and £6000 for bypass surgery. Thus the results of these studies show that amputation is, on average, a more costly procedure than reconstructive surgery.

Capital costs for providing a vascular service may be substantial, particularly the equipment required for vascular radiology. A Duplex scanning machine costs £100 000, spiral CT £350 000, digital subtraction angiography (DSA) £500 000 and a fixed theatre C arm £500 000. Magnetic resonance angiography (MRA), which is available in a few centres but is currently not essential for routine practice, costs £500 000–£1 000 000.

Table 7: Reference costs for peripheral arterial disease Health Related Groups (HRGs) in NHS Trusts in 1997/98.

HRG No.	HRG label*	Mean average cost (£)**	Range for 50% of NHS Trusts***	
			Minimum (£)	Maximum (£)
Q03	Lower limb art. surg.	4,024	3,011	4,724
Q04	Bypass to tibial art.	5,378	3,765	6,613
Q12	Therap. endovasc. proced.	1,519	910	1,766
Q13	Diag. radiol. with comorb/complic	2,032	1,377	2,510
Q14	Diag. radiol. w.o. comorb/complic	1,019	651	1,123
Q15	Amputations	5,994	4,449	6,615
Q16	Foot proced. diab. arter.	2,709	1,720	3,516
Q17	PVD > 69 yrs or comorb/complic	1,363	967	1,549
Q18	PVD < 70 yrs w.o. comorb/complic	1,087	642	1,175

* See Table 1 for full text of labels.
** Mean of the average cost of HRG in 249 NHS Trusts.
*** Range from the minimum average cost to maximum average cost of the mid 50% of Trusts, i.e. from bottom of 2nd to top of 3rd percentiles.
Source: *The National Schedule for Reference Costs*. London: Department of Health, 1998

Secondary care: use of services

The use of secondary vascular services in hospitals in England in 1995/96 for the diagnosis and treatment of peripheral arterial disease is shown in Tables 8–10. The number of patients discharged with a primary diagnosis of peripheral atherosclerosis was about 36 000 and, of these, the great majority were in general surgical units (which included specialist vascular centres) (Table 8). Almost an equal number of cases were given a secondary diagnosis of peripheral atherosclerosis. The precise nature of these cases is difficult to determine given the generality of the diagnostic group.

Table 9 shows the number of procedures performed in 1995/96. The commonest was diagnostic angiography (nearly 40 000). Transluminal procedures, which would have been mostly angioplasties, comprised the most frequent interventional treatment, while iliac/femoral bypass was the most common major surgical operation. The number of amputations was about half that of bypass procedures but the mean length of stay of amputations was the highest, at 27.7 days. Most amputations were carried out in general surgery or vascular units (rather than orthopaedic units). The accuracy of this data on number of procedures carried out is not precisely known but is probably an underestimate of the true vascular workload. A recent report comparing the OPCS and local audit figures in five hospitals in England and Wales in 1994/95 found considerable under-reporting.[62] For example, 31% of arterial reconstructions were not reported, ranging from 13% to 68% under-reported in the five hospitals. The figure for angioplasties not reported was 58%.

The number of discharges and mean lengths of stay for the HRGs relevant to peripheral vascular disease are shown in Table 10. The lengths of stay for lower limb arterial surgery (Q03) and amputations (Q15) are comparable to those in Table 9. The mean length of stay for bypass to tibial artery (Q04) was considerably higher than for lower limb arterial surgery as a whole (Q03), 23.1 compared with 14.3 days. As expected, the lengths of stay for peripheral vascular disease in those < 70 years with no complications or comorbidities (Q18) were less than those for peripheral vascular disease in older patients with complications or comorbidities (Q17).

Table 8: Discharges with primary or secondary diagnosis of peripheral vascular disease in England in 1995/96.

	Primary diagnosis			Secondary diagnosis		
	n	% general* surgery	population** rate	*n*	% general* surgery	population** rate
Peripheral atherosclerosis (ICD 170.2 or 173.9)	35,860	88	73.3	34,182	24	69.9
Ruptured aneurysm (ICD 171.3 or 171.8)	3,644	75	7.5	342	34	0.1
Non-ruptured aneurysm (ICD 171.4 or 171.9)	7,656	83	15.7	7,107	31	0.1

* Percentage of vascular discharges that were from general surgical units, including vascular surgery.
** Crude number of discharges per 100 000 population
Source: *Hospital Episode Statistics*. National Casemix Office, 1997.

Table 9: Peripheral vascular procedures and mean lengths of stay in hospitals in England in 1995/96.

Surgical procedure	Number primary or secondary	Population rate*	% General surgery**	Length of stay***
Iliac/femoral bypass	10,636	20.6	95	16.6
Amputation (vascular)	4,458	9.1	93	27.7
Transluminal procedure	15,972	32.7	85	5.4
Diagnostic angiography	39,160	80.1	71	4.9
Aortic aneurysm repair	5,164	10.6	95	12.2

* Crude number of procedures per 100 000 population.
** Percentage of vascular procedures that were carried out in general surgical units, including vascular surgery.
*** Mean length of stay in general surgical units trimming the data at 100 days and weighting day cases as zero length of stay.
Source: *Hospital Episode Statistics*. National Casemix Office, 1997

In England in 1996/97, approximately 10% of diagnostic angiographies and less than 3% of transluminal procedures were performed as day cases (Hospital Episode Statistics, unpublished information). By contrast, in Scotland in 1995, 34% of angiographies and 13% of transluminal procedures were carried out as day cases (ISD, Scottish Office, unpublished information). However, these differences between England and Scotland could be due to differences in recording practices. Linkage of hospital discharge records for individuals in Scotland also permit readmission rates to be calculated. For the period 1989–95, the proportion of patients readmitted within 28 days following an iliac/femoral procedure was 9.8%, amputation 9.6% and transluminal procedure 5.4% (ISD, Scottish Office, unpublished information).

Table 11 shows regional variations in the population rates for major vascular procedures.[63] Femoral reconstructions varied over twofold between 3.2 per 100 000 in South Thames Region to 7.0 per 100 000 in North West Region. The North West Region also had the highest rate of amputations (14.6) and North Thames Region had the lowest rate (9.6). Consistent regional differences in the incidence of femoral

Table 10: Health Related Group (HRGs) for diagnoses of peripheral vascular diseases: number of discharges and mean length of stay for hospitals in England 1995/96.

HRG number	HRG label*	Number discharges with primary PVD diagnoses**	Mean length of stay (days)***	Number discharges with any diagnoses†	Mean length of stay (days)***
Q01	Emergency aortic surgery	1,488	10.4	1,660	10.4
Q02	Elective abdom. vasc.surg.	4,011	12.7	4,973	12.8
Q03	Lower limb art. surg.	4,067	14.3	9,319	14.1
Q04	Bypass to tibial art.	517	23.1	1,038	23.2
Q12	Therap. endovasc. proced.	6,099	3.0	12,270	3.6
Q13	Diag. radiol. with comorb/ complic				
Q14	Diag. radiol. w.o. comorb/ complic	10,312	1.7	18,535	2.0
Q15	Amputations	2,330	29.8	6,290	27.3
Q16	Foot proced. diab. arter.	267	13.4	1,279	12.0
Q17	PVD > 69 yrs or comorb/ complic	5,303	5.8	7,253	6.0
Q18	PVD < 70 yrs w.o. comorb/ complic	2,281	3.9	3,584	4.2

* See Table 1 for full text of labels.
** Number of discharges in general surgery only with primary peripheral vascular disease diagnosis (I70.2, I71.3, –.4, –.8, –.9, I73.9). Majority of discharges for these diagnoses (> 95%) were in general surgery except for Q17 and Q18 in which discharges were also from general medicine, geriatric medicine and other specialties.
*** Mean based on length of stay trimmed at 100 days, day cases weighted as zero length of stay.
† Number of discharges in general surgery only with any diagnosis. This category will include both primary and secondary peripheral vascular disease diagnoses.
Source: *Hospital Episode Statistics*. National Casemix Office, 1997

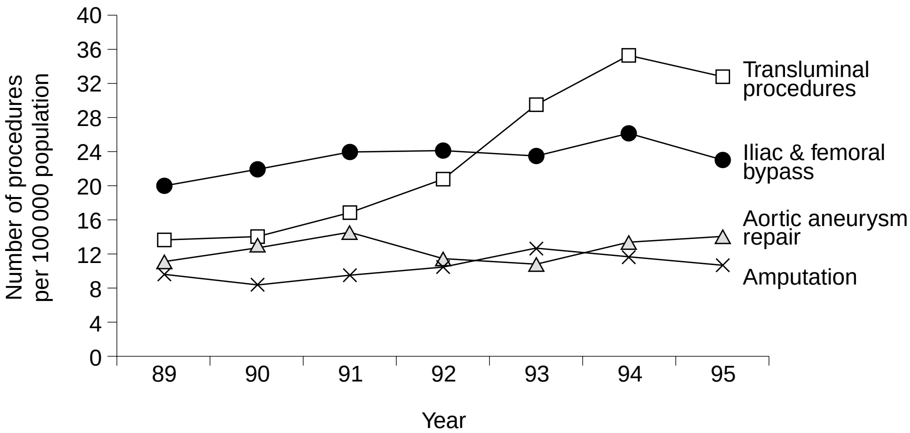
reconstruction and amputation were not apparent. The variations probably reflected a combination of many factors including differences in the age, sex, disease and behavioural characteristics of the populations, the accuracy of reporting and differing surgical practices.

An increase in the use of reconstructive surgery since the 1980s has frequently been associated with some reduction in amputation rates, but the extent to which this might be causally related is unclear.[64] More recently, there has been considerable interest in the increasing trends in the use of angioplasty in the NHS and how this might affect the rate of bypass procedures and amputations carried out. Figure 2 shows that in Scotland from 1989 to 1995, there was a steep increase in the rate of performance of transluminal procedures (angioplasty). There was a less marked rise in the rate of iliac and femoral bypass operations and amputations (and a reduction in all three procedures in 1995, with the fall in amputations beginning in 1994). In England, an increase in the rate of transluminal procedures from 1993 to 1996 was accompanied by a very slight reduction in the amputation rate and no change in the rate of bypass procedures (Figure 3). These rates would have been influenced by changing disease incidence, referral threshold and surgical practice, and it is difficult to know the extent to which angioplasty has reduced the need for surgery.

Table 11: Selected peripheral vascular procedures per population carried out in hospitals in England by region in 1994/95.

	Operations per 100,000 population		
	Abdominal aortic aneurysm repair (L184–186) (L194–196)	**Femoral reconstruction (L294–295)**	**Amputation (X093–95)**
Northern & Yorks	9.2	5.4	13.1
Trent	9.3	3.8	12.3
Anglia & Oxford	9.1	3.3	11.8
North Thames	10.3	4.7	9.6
South Thames	10.2	3.2	11.4
South & West	12.8	6.7	10.4
West Midlands	10.2	4.2	13.6
North West	9.9	7.0	14.6

Source: Hospital Episode Statistics. Office of National Statistics 1994/95. Adapted from Darke[63]



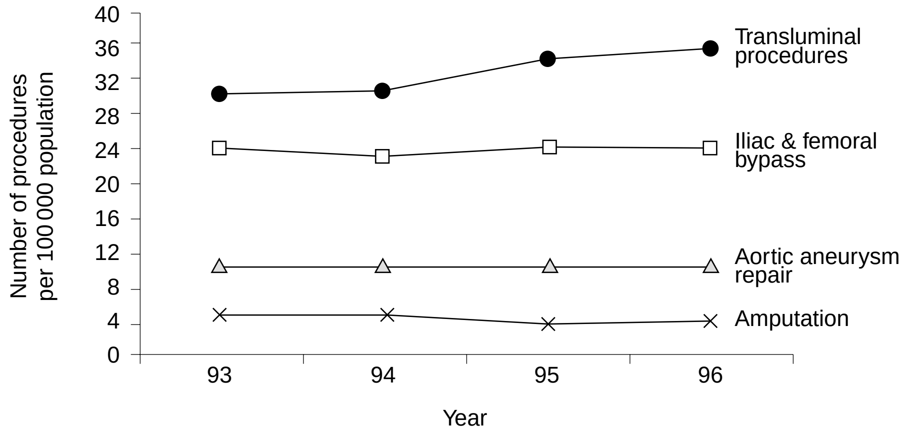
Source: SMRI (linked database), Information Services Division, Scottish Office

Figure 2: Trends in selected peripheral vascular surgical procedures per population in Scotland, 1989–95.

Rehabilitation services

The provision of appropriate and accessible artificial limb and appliance fitting is the main rehabilitation service required for patients with peripheral arterial disease. Although amputation is relatively uncommon in such patients, over 80% of amputations are due to vascular disease.[65] The provision of artificial limb and appliance services in England was reviewed by a Department of Health working party in 1986[66] and, following this, most district health authorities established a local service. In most parts of the country, the local service is complemented by a supra-district or regional service providing more complex needs, such as non-standard electronic control systems. In Wales, there are three centres and in Scotland, there are six centres covering the country with satellite clinics held in local hospitals.[67]

Table 9 shows that in England in 1995/96, 4458 amputations for vascular disease were carried out, giving a population rate of 9.1 per 100 000. An audit of amputations carried out in hospitals in Scotland, found



Source: *Hospital Episodes Statistics*

Figure 3: Trends in selected peripheral vascular surgical procedures per population in England, 1993–96.

that in 1995/96, 60% of lower limb amputations were transtibial and 37% were transfemoral.[65] Fourteen percent of amputees died before discharge, 60% received a prosthesis and 26% did not receive a prosthesis before discharge to home or long-term care. Of those referred to limb fitting centres, 45% were seen within 4 weeks of amputation and 75% within 8 weeks.[68] These referrals comprised 15% < 55 years of age, 55% aged 55–74 years and 20% aged 75 years and over. Among the referrals, 83% received a prosthesis.[68] The total cost of providing the artificial limb and appliance service in the six centres in Scotland in 1995/96, including the cost of prostheses, wheelchairs and other appliances, was £14 million,[67] which is equivalent to a cost of over £160 million for the UK as a whole. In Scotland in 1995/96, the service dealt with 700 new referrals for limb fitting and about 15 000 referrals for provision of a wheelchair. There were also 17 000 other attendances.[67]

Aortic aneurysm

In primary care, the diagnosis of abdominal aortic aneurysm is very rare and the consultation rate is so low (Table 6) that a typical GP is likely to see a patient with this condition only about once per year.

From Table 8, it can be seen that around 4000 ruptured aneurysms were diagnosed in hospitals in England in 1995/96 and that nearly twice that number of primary diagnoses of non-ruptured aneurysms were made. Over 5000 aortic aneurysm repairs were carried out and the mean length of stay for these patients was 12.2 days (Table 9). The figures for emergency aortic surgery (Q01) and elective abdominal vascular surgery (Q02) in Table 10 suggest that around one quarter of the aortic aneurysm repairs were carried out as emergencies. With the exception of South and West Region, which had a high aneurysm repair rate of 12.8 per 100 000 population, there was surprisingly little variation in repair rates between the different regions of England (range 9.1 to 10.3 per 100 000). Figure 2 shows that there has been a slight upward trend in aortic aneurysm repair rates in Scotland in recent years (1989–95) contrasting with a more rapid two- to threefold increase in the 1970s and early 1980s.[68] The same is likely to have been true in England and Wales, where there was also a substantial increase between 1968 and 1983.[54]

The costs of carrying out elective aneurysm repair in the UK have been studied in detail[69] as part of the UK Small Aneurysm Trial. The average cost of carrying out an elective aneurysm repair in the UK in 1996 was estimated to be about £5000. One third of costs were attributable to duration of stay in a standard surgical ward, about 27% to use of intensive care or high dependency beds and about 20% to the cost of the operation. As part of this costing exercise, a survey of over 100 vascular surgeons in the UK indicated that there was considerable variation in the use of these resources between centres, for example mean length of stay in a standard ward varying between 8 and 12 days. It was estimated that the cost of an aneurysm repair for a typical patient in the UK might vary between ± 50% of the national average. Indeed, the HRG mean average reference cost for aneurysm surgery (elective and emergency) was about £4300 in 1997/98 with the average cost for the middle 50% of Trusts varying between about £2800 to £5300.

Screening for abdominal aortic aneurysms is not carried out routinely in the UK. A recommendation from the National Screening Committee that screening should be implemented is under consideration by the Department of Health. Some data are currently available from some local initiatives[50–53] showing that the likely uptake of screening in men aged 65–80 years is likely to be between about 50% and 70%[51,52] depending on the social class, location and targeting of the catchment population. It was estimated that the cost of detecting an asymptomatic aneurysm in a screening programme in the UK would have been about £100 in 1990.[70]

6 Effectiveness of services and interventions

Intermittent claudication

Physical examination

Clinicians have over the years used many different physical signs as aids to the diagnosis of peripheral arterial disease. The clinical utility of these signs has been assessed recently in a systematic review of published studies.[71] Although a statistical meta-analysis was not conducted, the following positive findings were considered to be helpful in diagnosing the presence of peripheral arterial disease: abnormal pedal pulses, unilateral cool extremity and a femoral bruit. Table 12 shows the sensitivities, specificities and likelihood ratios for these tests in the largest study. This was carried out in general practices in Holland.[72] Another test, the venous filling time, was found to be useful in the identification of more severe peripheral arterial disease.[71]

Diagnostic tests

In the diagnosis of intermittent claudication, measurement of the ratio of the ankle to brachial systolic blood pressure, that is the ABPI, using Doppler ultrasound and a sphygmomanometer is the simplest and most commonly used test. In symptomatic patients, the sensitivity and specificity of identifying angiogram-positive disease is up to 95% and almost 100% respectively,[73] and the ABPI is related inversely to the severity of disease. The variability is comparable to that of routine arm blood pressure and a difference of less than 0.15 between sequential readings in a patient is not considered to be clinically significant.[74] The sensitivity of the test may be increased to 97% by conducting an exercise test, usually on a treadmill, in which significant arterial disease invariably results in a fall in ankle pressure.[73]

The severity of intermittent claudication may be assessed by a standard treadmill test in which the maximum distance to claudication and the maximum walking distance may be measured. However, results must be interpreted with caution because of considerable intra-patient variability and the many different ways in which vascular laboratories carry out the investigation.[75] Also many patients are not physically able to be assessed on the treadmill.

Table 12: Sensitivities, specificities and likelihood ratios for abnormal physical findings in detecting peripheral arterial disease diagnosed as ankle brachial pressure index < 0.9.

Physical finding	Sensitivity	Specificity	Likelihood ratio	
			Positive	Negative
Pedal pulse absent or weak	0.73	0.92	9.0	0.3
Femoral bruit	0.29	0.95	5.7	0.7
Unilateral cool extremity	0.10	0.98	5.8	0.9

Pedal pulse comprises pulse at either posterior tibial artery or dorsalis pedis artery.
Study based in general practice. *n*=2,455.
Source: Stoffers *et al.*[72]

The main non-invasive test now used commonly to assess the location of disease is Duplex scanning. The test is good at identifying occlusions and discriminating between large (> 50%) and small (< 50%) stenoses. In a review of evidence comparing Duplex with arteriography, Duplex was found to be 71–98% sensitive and 91–100% specific in discriminating stenoses of greater or less than 50%.[76] Discrimination of more precise degrees of stenosis is less good but may improve with technological developments. In practice, the advent of Duplex scanning has reduced but not eliminated the need for arteriography in the management of patients requiring an interventional procedure.

Angiography (arteriography) is considered to be the gold standard of investigations for peripheral arterial disease, although it is prone to considerable observer variability.[73] DSA has now replaced conventional arteriography in most centres because less contrast is used, radiation dosage is reduced and more detailed images are obtained. Newer imaging modalities, such as MRA, CT, including helical or spiral CT, angioscopy and intravascular ultrasonography are used in a few centres but have not been sufficiently developed or evaluated for widespread routine use in the investigation of peripheral arterial disease.

Risk factor management

The management of cardiovascular risk factors in peripheral arterial disease is an important issue for the NHS because it has become recognised only recently that a high priority must be given to this aspect of patient care.

Smoking cessation

Cigarette smoking is related to the development of peripheral arterial disease and to a worse prognosis[13] and thus smoking cessation would be expected to be beneficial.[14] Randomised controlled trials of the effectiveness of smoking cessation are not available because of the difficulties of ensuring patient compliance. However, two large follow-up studies of patients with intermittent claudication referred to hospital indicate probable benefits.[77,78] In one of these[77] 11% and in the other[78] 27% of the patients complied with the advice to stop smoking. Within 3 years of stopping smoking there was no reduction in limb-threatening complications of the vascular disease. After 7 years, however, rest pain had developed in 16% of persistent smokers, but in none of those who had stopped smoking.[77] After 10 years 53% of persistent smokers suffered a myocardial infarction compared with only 11% of stopped smokers; 54% of persistent smokers died compared with 18% of stopped smokers.[77] In a recent comprehensive review of the literature, abstinence from smoking was found to be associated consistently with better outcomes following revascularisation, lower amputation rates and improved survival.[79] However, smoking cessation had probably only a minimal effect in improving walking distance in claudicants.[79]

The NHS Centre for Review and Dissemination has recently produced a brief report on smoking cessation and concluded that the most effective interventions the health service can provide are advice from a health professional and nicotine replacement therapy.[80] This accords with findings of the US Agency for Health Care Policy and Research.[81] Brief advice to stop smoking given by health professionals, and taking around 3 minutes, achieves a 2% reduction in the number of smokers. This may be increased to up to 5% by lengthening the duration of advice and follow-up.[81,82] Meta-analysis of trials on the efficacy of nicotine replacement therapies indicate that, when accompanied by advice or counselling, a quit rate of around 20% over a minimum period of 6 months can be achieved.[83] All modes of nicotine replacement therapy (gum, patches, sprays and inhalers) appear to be effective, although there is some evidence that higher-dose gum may be more effective in heavily dependent smokers – a common category of smoker in those with peripheral arterial disease.[84] Such smoking cessation interventions are considered to be cost-effective in saving lives and reducing morbidity, and hence a good use of NHS resources.[80]

Little information is available on the effectiveness of smoking cessation programmes in patients with peripheral arterial disease[79] but the assumption is that the measures shown to be effective in the general population also work in the diseased population, although the level of effectiveness may differ. Fortunately, nicotine replacement therapy has been shown to be safe in patients with cardiovascular disease.[85,86] An increase in angina, palpitations or adverse events was not found in patients with coronary heart disease. In these studies, about one third of patients had peripheral arterial disease, but no acceleration of adverse limb events or worsening of symptoms was found.[85,86] Thus, nicotine replacement therapy, along with advice on smoking cessation, can be recommended for patients with peripheral arterial disease.

Exercise

The effectiveness of exercise programmes in the treatment of intermittent claudication has been investigated in a Cochrane systematic review.[87] Exercise therapy significantly improved maximal walking distance by approximately 150% and in one study produced a better result than angioplasty at 6-month follow-up.[88] In another systematic review investigating the components of exercise rehabilitation programmes that were most effective, the optimal programme used intermittent walking to near maximal pain for a minimum period of 6 months.[89] There was also some evidence to suggest that the exercise sessions should be carried out at least three times per week and that each should last a minimum of 30 minutes.[89] However, the cost-effectiveness of different exercise regimens needs to be evaluated.

The long-term effects of exercise in patients with peripheral arterial disease on the incidence of fatal and non-fatal cardiovascular events has not been investigated. In the population as a whole, those who exercise on a regular basis have half the cardiovascular mortality of those who are inactive, and the benefits occur in those who take either moderate or intense exercise.[90] The National Institutes of Health Consensus Conference on physical activity and health concluded that individuals should ideally have 30 minutes of moderate exercise, such as walking, each day.[91] It is likely that patients with peripheral arterial disease would also enjoy longer-term benefits from regular exercise.

Lipid lowering

A Cochrane systematic review has been carried out of lipid-lowering therapy in peripheral arterial disease.[92] In two trials in which disease progression was measured in the femoral artery using angiography,[93,94] there was a significant overall reduction in disease progression in the groups receiving lipid-lowering therapy (OR 0.47, 95% CI 0.29 to 0.76) (Figure 4). In all seven trials, however, the changes in walking distance were inconsistent, although a general improvement in symptoms, which could not be combined in a statistical meta-analysis, was found.[92] The conclusion of the review was that lipid lowering may improve symptoms but the variation in the trials was such that firm conclusions could not be drawn.

Disease progression on angiogram/number in group

Study	Lipid lowering therapy	Control	Peto OR (95% CI Fixed)	Weight %	Peto OR (95% CI Fixed)
CLAS	21/77	30/76		51.3	0.58 [0.30, 1.13]
St Thomas' trial	10/144	27/156		48.7	0.38 [0.19, 0.77]
Total (95% CI)	31/221	57/232		100.0	100.0 [0.29, 0.77]
Chi-square 0.70 (df=1) Z=3.04					

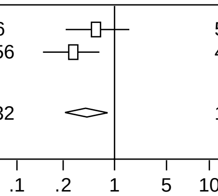


Figure 4: Effect of lipid lowering on angiographic progression of peripheral arterial disease: meta-analysis.

The review also found evidence that lipid-lowering therapy might reduce mortality in patients with peripheral arterial disease (OR 0.21, 95% CI 0.03 to 1.17), but with little change in non-fatal cardiovascular events (OR 1.21, 95% CI 0.80 to 1.83).[92] However, these results need to be interpreted with caution because of the relatively small numbers of events in the studies. On the other hand, the benefits of lipid-lowering therapy, especially with the statin group of drugs, in the secondary prevention of cardiovascular events have been demonstrated in large randomised controlled trials.[95,96] Statins result in a risk reduction of about one third for fatal and non-fatal myocardial infarction and total mortality in patients with coronary heart disease.[95,96] The relative risk reductions are consistent, irrespective of baseline cholesterol, so that the largest absolute benefits are in patients with high risk of cardiovascular events. Since patients with peripheral arterial disease are at high risk, the case for treating such patients with a statin is as strong as the case for treating survivors of myocardial infarction.[97] In the light of this evidence, key messages on lipid lowering in claudicants have been proposed by an expert group in the UK (Davies *et al.*, unpublished information).

- Measure non-fasting serum cholesterol.
- Provide dietary advice if cholesterol > 5.2 mmol/l.
- Prescribe statin if < 70 years of age and cholesterol > 5.2 mmol/l despite dietary measures.

Blood pressure control

Randomised controlled trials have demonstrated that in patients with hypertension, reducing blood pressure decreases morbidity and mortality from cardiovascular and cerebrovascular disease. Guidelines based on the best available evidence on the management of hypertension are readily available.[98,99] Trials on the long-term cardiovascular effects of controlling blood pressure in patients with peripheral arterial disease have not been carried out. However, the control of blood pressure, including the use of anti-hypertensive drugs, is considered to be more beneficial in patients at high risk of future cardiovascular events than in low-risk patients.[98] Indeed the cost-effectiveness of treatment is greater in elderly patients and in those with established cardiovascular disease.[98]

Although control of blood pressure in patients with peripheral arterial disease is warranted, the treatment requires special care because lowering systolic pressure can decrease local perfusion pressure and blood flow to ischaemic muscle and skin. The type of antihypertensive drug used may be important[100] and the reduction in blood pressure needs to be carried out slowly and monitored carefully, particularly in patients with critical ischaemia.[100]

Diabetes control

There is limited evidence from follow-up studies of patients with peripheral arterial disease that those with diabetes have a higher amputation rate and higher mortality.[3,13] However, the extent to which glycaemic control in patients with peripheral arterial disease affects prognosis has not been determined. In diabetics as a whole, good control is likely to reduce the development of microvascular complications, especially retinopathy[101] and nephropathy.[102] However, only borderline support exists for a comparable reduction in macrovascular outcomes, such as myocardial infarction, in both type I diabetes[103] and type II (as shown in the UK Prospective Diabetes Study[104]). There is no reason to believe that these findings would not be relevant to diabetics with peripheral arterial disease. Thus, despite the lack of firm evidence in peripheral arterial disease, good diabetic control, at least to prevent microvascular complications, can be recommended, as specified in European guidelines based on expert consensus.[105]

Drug therapy

For many years there has been considerable debate about the value of drug therapy for intermittent claudication. Four oral drugs have been licensed for use in the treatment of intermittent claudication in the UK: naftidrofuryl, oxpentifylline, inositol and cinnarizine. An expert group of the Scottish Intercollegiate Guideline Network (SIGN) produced an authoritative guideline on drug therapy for peripheral arterial disease in which the recommendations were graded according to the level of evidence.[106]

Naftidrofuryl (Praxilene)

In nine double-blind, placebo-controlled trials of naftidrofuryl in the treatment of intermittent claudication, the placebo response produced an average improvement in pain-free walking distance of 25%, but an additional 30% was achieved with naftidrofuryl at 3 and 6 months post-treatment. These results were confirmed in two meta-analyses.[107,108] The group recommend that: 'Naftidrofuryl may be considered for symptomatic benefit in patients suffering moderate disease but it is not known if it has any effect on the outcome of the disease'.[106]

Oxpentifylline (Trental)

The expert group referred in particular to a meta-analysis of 10 randomised controlled trials which concluded that the limited amount and quality of data precluded an overall reliable estimate of oxpentifylline efficacy.[109] The guideline stated that: 'In the absence of consistent evidence from clinical trials, it is not possible to make any recommendation on the use of oxpentifylline as a treatment for intermittent claudication'.[106]

Inositol nicotinate (Hexopal)

Four double-blind, randomised controlled trials showed no clear evidence of benefit of this drug over placebo. The guideline therefore stated that: 'Inositol nicotinate is not recommended for treatment of intermittent claudication'.[106]

Cinnarizine (Stugeron Forte)

The expert group did not find any studies that were of adequate quality to assess clinical effect and concluded that: 'It is not possible to make a recommendation on the use of cinnarizine in the treatment of intermittent claudication'.[106]

The SIGN guidelines have recently been updated and now include a recommendation that the newly developed drug, cilostazol, be considered as a first line treatment for intermittent claudication.

Antiplatelet drugs

A comprehensive meta-analysis of the effect of aspirin, and other antiplatelet drugs, in reducing the risk of fatal and non-fatal vascular events in patients with various manifestations of atherosclerosis was published in 2002 by the Antithrombotic Trialists' Collaboration.[110] Overall, antiplatelets reduced the risk of myocardial infarction, stroke and death by about 25%. In patients with intermittent claudication, the reduction was similar. The SIGN expert group concluded that: 'Patients with intermittent claudication should receive aspirin long term as prophylaxis against cardiovascular events'.[106] Recently a large multinational trial has shown that clopidogrel, a new antiplatelet agent, has a significant improvement (8.7%) over aspirin in overall efficacy and has fewer side effects, but with a higher treatment cost.[111]

Percutaneous transluminal angioplasty

Dilatation and recannalisation of an artery by percutaneous means (percutaneous transluminal angioplasty) may be carried out as a treatment for intermittent claudication for those with relatively mild symptoms. Its effectiveness needs to be compared with conventional medical treatment, such as smoking cessation, exercise programmes and low-dose aspirin.[112] A Cochrane systematic review[113] of the two completed trials found that at 6-month follow-up, walking distances in the angioplasty group in one trial were greater than in the control group, but in the other trial were no better than an exercise programme. After a minimum of 2 years of follow-up, walking distances and quality of life were no better in the angioplasty groups. The conclusion of the review was that, although angioplasty may have a short-term benefit, it is unlikely to be sustained, and widespread use of angioplasty for mild to moderate claudication cannot be recommended.[113] However, these trials were small and could not examine possible differential effects for lesions at different arterial sites.

In patients with more severe claudication, angioplasty may be used instead of a surgical operation such as thromboendarterectomy or bypass grafting. A well-conducted randomised controlled trial was carried out in the early 1990s in which angioplasty was compared with bypass surgery.[114] Patency rates did not differ significantly between the angioplasty and surgical groups; 4-year patencies were 64.1% and 68.1% respectively (Figure 5). Also limb survival, that is the retention of the treated leg without a major amputation or death, was similar between the two groups. There were, however, three operative deaths (2.3%) in the surgical group and none in the angioplasty group. A formal cost-effectiveness study has not been carried out, but since the cost of angioplasty is in the region of £1500 and of surgery around £5000 (*see* Table 7), in patients with a lesion amenable to angioplasty, this may be the preferred option.

Reconstructive surgery

The treatment of intermittent claudication by means of bypass surgery using a vein or prosthetic graft is a well-established practice in patients who have severe claudication which causes a major disruption in quality of life.[115] It is generally assumed that in such severe cases, conservative treatment is inadequate,

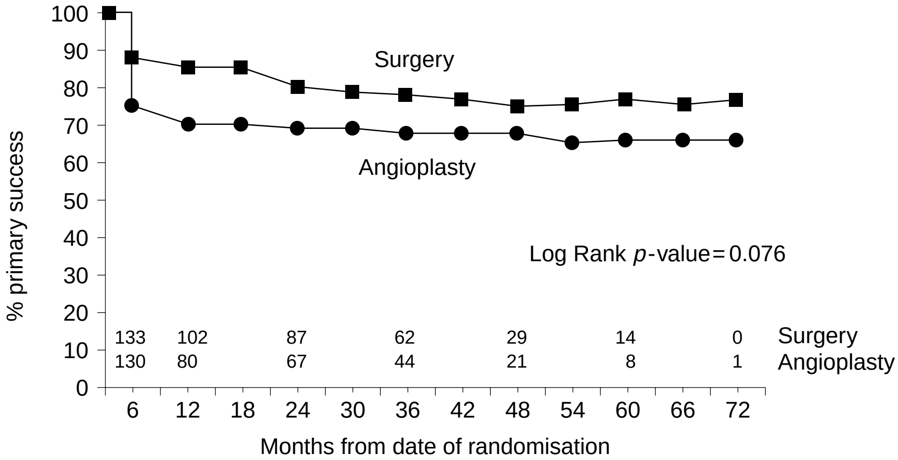


Figure 5: Life-table analysis of primary patency, angioplasty versus surgery.

therefore few randomised controlled trials comparing surgery and conservative therapy have been carried out. In one small trial in which patients were followed up for 1 year, exercise training produced a mean improvement in pain-free walking distance of 120 metres, reconstruction 320 metres, and a combination of reconstruction and training produced an improvement of 489 metres.[116] However, the medium- to long-term patency rates, which vary greatly depending on the location and extent of disease and type of surgical intervention, may be quite poor, for example only about 50% at 4 years for a prosthetic below-knee bypass.[116] Thus, graft surveillance programmes are common and a further surgical intervention is often required. Although the costs of revascularisation procedures have been estimated, formal estimates of the costs per added quality of life are not available.

Critical limb ischaemia

Diagnostic tests

In the diagnosis and assessment of critical limb ischaemia, the validity and variability of Doppler ultrasound measurement of ankle pressures, Duplex scanning and arteriography are comparable to the use of these procedures in severe claudication. A very low ankle pressure (< 40 mmHg) was considered indicative of severe ischaemia and increased risk of limb loss, but this has now been criticised because many patients with critical limb ischaemia have non-compliant vessels resulting in falsely elevated ankle pressures.[39]

Transcutaneous measurement of the oxygen tension in the skin ($TcPO_2$) is used in some centres to assess the degree of ischaemia. It is time-consuming and considerable experience is required to produce reproducible results. However, in combination with other tests $TcPO_2$ measurements can reliably determine the severity of limb ischaemia[118] and may be of use in selection of amputation sites.

Reconstructive surgery

In patients presenting with critical limb ischaemia, around one half undergo arterial reconstructive surgery, one quarter have a major amputation and the remainder are treated conservatively.[119] Partly due to the diverse nature of the presentation of critical limb ischaemia, randomised controlled trials of the effects of these interventions have not been performed.

Observational studies indicate that, as is the case in patients with intermittent claudication, the success rate of arterial reconstruction in patients with critical limb ischaemia is variable with 2-year patency rates varying between 30% and 70%, depending on the procedure carried out.[115] Also technical failures in up to 20% at operation may lead to secondary amputation. The overall effect, as has been shown in Sweden, is that around one third of vascular surgery may be concerned with re-operations, redo surgery and other interventions.[120]

Amputation

Major amputation may be carried out as a primary procedure or secondary to a failed reconstruction. The success of amputation depends especially on the level of surgery: 80% of patients with below-knee amputations end up having reasonable mobility compared with only 40% of those with above-knee amputations.[121] However, only 5% will never require a wheelchair. The long-term survival in such patients is nevertheless poor, with only about 50% alive 5 years after amputation.

Reconstruction or amputation?

Evidence comparing the cost-effectiveness of arterial reconstruction or primary amputation for critical limb ischaemia is limited. In a restrospective survey of patients having amputation or reconstruction for critical limb ischaemia, it was estimated that proximal reconstruction (i.e. surgery involving large arteries only, such as the iliac, femoral and popliteal) resulted in a net saving at 1989/90 prices of £3791 per person compared with amputation, with a net gain of 0.14 quality-adjusted life years per person.[60] On the other hand, distal reconstruction (i.e. surgery involving small arteries in the lower leg, such as the crural) resulted in a net cost of £143 per person compared with amputation and a net gain of 0.10 quality-adjusted life years per person, so that the net cost per quality-adjusted life year gained by distal reconstruction was £1430.

The clinical indications defining which patients with critical limb ischaemia should have arterial reconstruction or primary amputation have not been clear-cut and have partly depended on surgical preference. The Scottish and Northern Vascular Audit Groups reached a consensus using a modified Delphi method on which procedures were appropriate for specified clinical presentations (Table 13),[122] but a subsequent audit of practice found that around one quarter of amputations did not conform to the agreed indications. A decision to amputate or reconstruct may be based on other factors, such as operating resources. It is likely that a higher proportion of legs could be saved,[119] in keeping with some specialist centres, which can achieve success rates of over 80% patency at 5 years following reconstruction.[123]

Percutaneous transluminal angioplasty

Instead of proceeding directly to surgery for the treatment of critical limb ischaemia, in some centres, angioplasty is attempted in the first instance for patients with suitable lesions. A multicentre, randomised controlled trial comparing these two approaches in the UK found little short-term difference between the two approaches. Information from uncontrolled trials and observational studies has produced mixed results. Evaluation of long-term cost-effectiveness is important because many patients having angioplasty

Table 13: Arterial reconstruction or amputation agreed as appropriate for categories of clinical presentation of critical limb ischaemia.

Angiographic findings	Degree of gangrene	Appropriate procedure
SFA or more proximal occlusion	None	Arterial reconstruction
with patient popliteal and distal vessels	Digital	Arterial reconstruction
	Forefoot	Arterial reconstruction
	Midfoot or heel	Arterial reconstruction in most cases
Patent SFA and proximal vessels.	None	Major amputation in most cases
Complete occlusion of tibial, ankle	Digital	Major amputation in most cases
and foot vessels	Forefoot	Major amputation in most cases
	Midfoot or heel	Major amputation
SFA and all distal vessels occluded	None	Major amputation in most cases
	Digital	Major amputation in most cases
	Forefoot	Major amputation
	Midfoot or heel	Major amputation
Inflow and distal vessels occluded,	None	Arterial reconstruction
SFA and PFA patent	Digital	Arterial reconstruction
	Forefoot	Arterial reconstruction
	Midfoot or heel	Arterial reconstruction in most cases
Tibial vessels occluded but	None	Arterial reconstruction (if vein available)
patent segment(s) at ankle or foot	Digital	Arterial reconstruction (if vein available)
	Forefoot	Arterial reconstruction (if vein available)
	Midfoot or heel	Arterial reconstruction (if vein available)

SFA = superficial femoral artery; PFA = profunda femoral artery.
Source: Pell *et al.* on behalf of Scottish and Northern Vascular Groups[121]

are likely to have surgery at a later stage. Recently the new technique of subintimal angioplasty has been carried out in a few centres with apparently impressive outcomes.

Drug therapy

In around 10% of patients with critical limb ischaemia, surgery is not feasible and pharmacological agents have been tried, particularly infusions of vasodilators such as inositol nicotinate and prostanoids.[15] However, evidence on the effectiveness of these preparations in critical limb ischaemia is sparse and stronger evidence is required before they can be recommended for widespread use.[115]

Asymptomatic peripheral arterial disease

Since there is good evidence that a low ABPI measured on subjects in the community is a marker of an increased risk of fatal and non-fatal cardiovascular events, the possibility exists of screening the population in an attempt to detect low ABPI and thus prevent vascular events in previously healthy individuals.[124] In addition to management of cardiovascular risk factors, antiplatelet therapy might be justified, given the benefits in individuals with symptomatic atherosclerotic disease.[110] A randomised controlled trial, the

Aspirin for Asymptomatic Atherosclerosis (AAA) trial, is currently in progress in the UK to test this hypothesis. It will report in 2009.

Ruptured aneurysm

In patients with aneurysms that are symptomatic, whether due to rupture or pressure on surrounding tissues or tenderness on palpation, surgical repair of the aneurysm is warranted in those fit for surgery. This will usually be performed as an emergency or urgent operation. The peri-operative mortality for emergency repair of a ruptured aneurysm ranges between about 40% and 60%.[125] On the other hand, the mortality rate without surgery is for all practical purposes 100%. If surgery is successful, the long-term survival approaches that of the normal population,[126] although it is slightly worse due to a relatively high prevalence of concomitant coronary heart disease and hypertension in patients with aneurysms. The quality of life of survivors following surgery is also good.[125]

Asymptomatic aneurysm

Diagnostic tests

The principal test used to identify and measure the diameter of an abdominal aortic aneurysm is B-mode ultrasound. This examination is easy to perform, and a maximum variation in the diameter measured both between and within observers of $\pm$ 0.2 cm can be achieved.[127,128] However, the most sensitive investigation is a CT scan, which also allows improved visualisation of renal artery origins and can more precisely delineate the relation of the aneurysm to nearby structures.[129] Spiral CT, which provides a three-dimensional reconstruction of an aneurysm, is indispensable prior to endovascular treatment and for postoperative surveillance.

Surgery or surveillance?

In patients with asymptomatic abdominal aortic aneurysms, the risk of rupture rises with increasing aortic diameter. In the UK, surgeons generally recommend prophylactic repair of aneurysms of more than 6 cm diameter and routine surveillance by means of ultrasound of aneurysms < 4 cm diameter. The results of the recent UK Small Aneurysm Trial indicate that aneurysms of 4–5.5 cm diameter should also have routine ultrasound surveillance rather than early surgery.[128] Although 61% of those assigned to surveillance eventually had surgery, there was no difference in mortality after 6 months of follow-up between the early surgery and surveillance groups (Figure 6). The 30-day operative mortality in the early elective surgery group was 5.8%. Furthermore, the mean cost in those allocated surveillance (£4000), was less than those allocated to early surgery (£5000).[130] Health-related quality of life was generally similar in the two groups 1 year post-treatment, but early surgery patients reported positive improvement in current health perceptions and less negative change in bodily pain.[130]

The use of endovascular repair of aortic aneurysms has been introduced in recent years but has been associated with several problems.[131] Like many minimally invasive techniques, it may fail and require conversion to open surgery. This conversion may be associated with a high complication rate such that major complications occur in 10–25% of endovascular repairs. Furthermore, the mortality is surprisingly high, normally around 6–10%.[131] However, there does appear to be a learning curve as centres become more experienced and achieve better results. At present, the overall costs of endovascular repair appear to be no cheaper than open surgery.[132] Randomised controlled trials have been conducted comparing

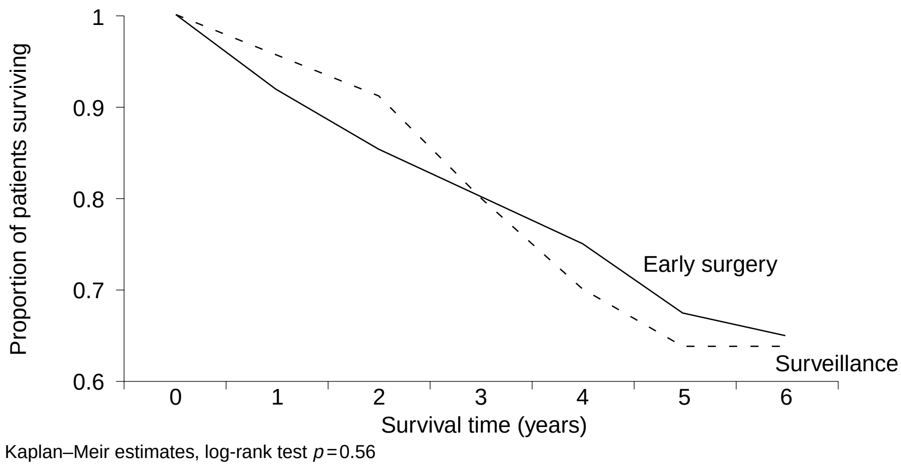


Figure 6: Survival following surgery or ultrasound surveillance for small asymptomatic abdominal aortic aneurysms.[128]

endovascular and conventional aneurysm repair and the National Institute for Clinical Excellence (NICE) has recommended recently that endovascular repair should normally be pursued in the first instance.

Screening

Several pilot studies of screening for asymptomatic abdominal aortic aneurysms have been set up in the UK[49–52] and some health authorities have been encouraged to set up programmes. Although these pilot studies have provided information on uptake and detection rates, they have not provided information on effectiveness compared to no screening. However, the results of the Multicentre Aneurysm Screening Study (MASS) and other trials has led to a recommendation by the National Screening Committee that screening be implemented.

A summary of the size of effects of interventions in the treatment of critical limb ischaemia and aneurysms is shown in Table 14.

Table 14: Principal interventions for peripheral vascular disease: size of effect and quality of evidence.

	Size of effect	Quality of evidence	Size of effect	Quality of evidence
	on claudication		**on cardiovascular events**	
Intermittent claudication				
Risk factor management				
smoking cessation	C	II-1	A	II-I
exercise	C	I-1	Unknown	IV
lipid lowering	C	I-1	A	III
blood pressure control	Unknown	IV	B	III
diabetes control	Unknown	IV	C	III
Drug therapy				
cilostazol	B	I-1	n.a.	n.a.
naftidrofuryl	B	I-1	n.a.	n.a.
oxpentifylline	Unknown	IV	n.a.	n.a.
inositol	D	I-1	n.a.	n.a.
cinnarizine	Unknown	IV	n.a.	n.a.
antiplatelets	n.a.	n.a.	A	I-1
Percutaneous transluminal angioplasty	C	I-2	n.a.	n.a.
Reconstructive surgery	B	I-2	n.a.	n.a.
Critical limb ischaemia	*on critical limb ischaemia*			
Reconstructive surgery	B	II-2	n.a.	n.a.
Amputation	B	II-2	n.a.	n.a.
Percutaneous transluminal angioplasty	C	II-2	n.a.	n.a.
Ruptured aneurysm	*on mortality*			
Surgery	B	II-2	n.a.	n.a.
Asymptomatic aneurysm				
Surgery $\leq$ 5.5 cm diameter	D	I-1	n.a.	n.a.
> 5.5 cm diameter	B	III	n.a.	n.a.
Screening	B	I-1	n.a.	n.a.

n.a. = not applicable.

7 Models of care and recommendations

In recommending models of care for peripheral arterial disease and aortic aneurysm, the two diseases can be considered together because they comprise the bulk of the work covered by a vascular service. This section considers the service required in (i) primary care, (ii) secondary care and (iii) screening, although the major component is at secondary care level.

Primary care

At primary care level, good-quality care requires appropriate diagnosis and referral of patients with peripheral arterial disease and aortic aneurysm. For intermittent claudication, diagnosis is relatively straightforward but clear indications are required for when it is appropriate to refer patients for a specialist opinion. Anecdotal evidence suggests that many patients are referred inappropriately. Furthermore, the management of risk factors and antiplatelet therapy is haphazard in these patients and requires to be standardised. National guidelines are required for the management and referral of patients with intermittent claudication in primary care. Such guidelines might encompass the following.

- Diagnosis: key history including, walking ability and cigarette smoking; clinical examination, including peripheral pulses and blood pressure; investigations, including ABPI, serum cholesterol and urinalysis.
- Treatment: smoking cessation, including advice and nicotine replacement therapy; exercise advice; antiplatelet therapy; management of risk factors such as hypertension, hypercholesterolaemia and diabetes mellitus.
- Referral: minimum duration of claudication, say 3 months; degree of impairment of quality of life; level of diagnostic uncertainty; need for investigation and treatment of hypertension, hypercholesterolaemia and diabetes mellitus; minor injuries to foot, such as abrasions that do not heal.

Although the long-term care of claudicants and management of risk factors should ideally be carried out in general practice, in some districts, a shared care approach between primary and secondary care may be appropriate.

In patients with abdominal aortic aneurysm presenting either with symptoms or rupture in primary care, the main problem is awareness of the diagnosis because of its rarity in the primary care setting. Reinforcement of the existence of the condition in postgraduate education and in shared care arrangements for the management of peripheral vascular disease may be adequate to heighten awareness.

Secondary care: minimum specification for a major vascular unit

As demonstrated in Section 5, there are serious shortcomings in the provision of a 24-hour specialist vascular service throughout the UK. The two key issues that need to be addressed are first, the minimum specification for a major vascular unit, and second, how services should be organised to ensure best possible access by the whole population to this service.

In recent years in the UK, these issues have been addressed by three specialist working groups, which have published the following reports: 'Vascular surgery services' by a Working Group of the National Medical Advisory Committee in Scotland[57]; 'The provision of vascular services' by the Vascular Advisory Committee of the Vascular Surgical Society of Great Britain and Ireland[63]; and 'Vascular services in Scotland' by a subcommittee of the Acute Services Review.[56] In addition, relevant recommendations on surgery as a whole have been made in The Royal College of Surgeons of England report on the 'Provision of emergency surgical services'[133] and the Senate of Surgery of Great Britain and Ireland report on 'Consultant surgical practice and training in the UK'.[134] These reports have been used, in addition to the evidence already described, to make recommendations on the provision of secondary care services for the management of peripheral vascular disease.

These reports recommend that the minimum catchment population required to provide a specialist vascular service is between 450 000 and 600 000. This is based primarily on the necessity to provide 24-hour emergency cover by full-time specialist vascular surgeons in an on-call rota of 1 in 3 or 1 in 4, with 1 in 3 being the minimum considered acceptable in present surgical practice. Since around one third of admissions to a vascular unit require major emergency or urgent surgery,[56,63] the provision of a high-quality emergency service is extremely important.

Audits in the UK,[135] Ireland[63] and Sweden[136] have shown that a population of 100 000 generates approximately 70–80 arterial operations per annum (excluding major amputations) plus a large number of venous procedures. These figures are higher than the national data for England (Tables 9 and 10) probably due to under-reporting.[62] A surgeon would normally be able to perform an average of two major elective arterial reconstructions per week, a similar number of emergency operations and several lesser procedures. From these figures, it has been estimated that a minimum population of 150 000 is required to generate an appropriate workload for one consultant surgeon practising full-time vascular surgery.[56,57,63] For a 1-in-4 rota to operate, a catchment population of at least 600 000 is required. A 1-in-3 rota would require a population of about 500 000.

The minimum staffing requirements for a major vascular unit serving a population of 500 000 are described in Box 1. The number of beds, theatre sessions, support services and other facilities are described in Box 2.

Box 1: Major vascular unit: staffing

Consultant vascular surgeons
Three fte (full-time equivalent) surgeons devoting all of their time to vascular work are required. This enables a 1-in-3 specialist rota to operate. It also assumes that these surgeons, in addition to performing surgery for peripheral arterial disease and aneurysms, including amputations, carry out complicated venous surgery, carotid surgery and renal dialysis access. A larger consultant complement is required if they have other responsibilities, such as teaching. Also, any trend towards a consultant-led service with consultants providing more direct patient care, particularly in emergency work, would require an increase in the number of consultants.

Specialist registrars and senior house officers in vascular surgery
Two of these middle grade staff are required to provide adequate support in the unit. In addition, two junior house officers are required, while accepting that cross-cover for out-of-hours work is required from house officers working in other units.

Interventional radiologists
The scope and volume of vascular interventional radiology is increasing greatly, both in the provision of diagnostic services and endovascular treatments. The Royal College of Radiologists has stated that specialised emergency procedures should be performed only by those who routinely undertake such procedures as part of their normal working day.[137] Thus at least three specialist radiologists need to be available to provide an on-call rota. The extent to which these radiologists work full time or part time on vascular cases depends on current practice in a unit, but the work is likely to increase with the technological advances in transluminal approaches.

Vascular physicians
Although there is not currently a recognised specialty of vascular medicine/angiology in the UK, the importance of the contribution of vascular physicians to the management of patients with peripheral arterial disease is being recognised increasingly. Despite the fact that the majority of patients referred to vascular outpatient clinics do not have surgery and that most outpatients and inpatients have cardiovascular problems requiring medical management, very few units at present have a dedicated vascular physician. The recent reports on vascular services[56,57,63] are unanimous in recommending that physicians with a special interest in vascular disease be integral members of the vascular team with recommendations ranging from 0.5 to 1.5 fte. This depends very much on the extent to which the vascular physicians have responsibility for the initial assessment of outpatient referrals.

Anaesthetists
For complex vascular cases, consultant anaesthetists with a specialist expertise are required to ensure optimal results, not only for elective operations but especially for emergency operations, including ruptured aneurysms. The number of anaesthetists required is about 1.5–2.0 fte, although it is likely that this will comprise 3–4 half-time in order that they can provide a dedicated on-call service for emergencies.

Nurses/professions allied to medicine
Consideration should be given to having a greater nursing complement than in a general surgical unit to take into account the high proportion of dependent elderly patients and amputees. Specialist support is also required from physiotherapists, occupational therapists, pharmacists and chiropodists with special expertise in the management of vascular patients, particularly the rehabilitation of amputees.

Vascular technologists
A major vascular unit will have a dedicated vascular laboratory for the purpose of performing appropriate diagnostic tests. This needs to be staffed by one FTE vascular technologist/nurse who has had special training in the conduct of the diagnostic tests.

These recommendations on staffing complement depend very much on local circumstances, for example, on the provision of outreach clinics, the staffing of intensive care and high dependency beds, and the presence of other specialties in a hospital. What is important, however, is that a major vascular unit has an integrated vascular team comprising all of the above professions working jointly in the care of vascular patients.

Box 2: Major vascular unit: facilities

Surgical beds
The number of acute surgical beds required in the vascular unit is about 30 and varies depending on whether amputations are carried out in the vascular or orthopaedic unit. If the early rehabilitation of amputees takes place in the vascular unit, a further 10 beds are required. These figures, recommended by specialist working groups,[57,63] are based on requirements specified currently by major vascular units.

Intensive therapy unit (ITU)/high dependency unit (HDU)
An ITU with specialist nursing care, clinical monitoring and facilities for ventilation are essential and must be available on the same site as the vascular unit. An HDU is also desirable as this may relieve demand on the more costly ITU. It has been estimated that a total of 1.5–5 intensive care/high dependency beds are required,[57,59] but this depends on the definition of 'high dependency' and on surgical and anaesthetic practice.

Operating theatre
Given a consultant's overall workload, which includes operating, outpatient sessions, pre- and postoperative inpatient care, and emergency work, about four elective operating sessions per week per consultant is appropriate. Additional theatre time for emergency work is required. Also it should be recognised that many vascular operations are complex and time-consuming with the possibility of sessions frequently running over time. In the theatre, there has to be provision for on-table angiography, invasive monitoring and microvascular repair.

Radiology
A dedicated angiography room with high-quality image intensification, digital subtraction angiography and C-arm function is required. Also the ability to carry out ultrasound scanning including colour flow and spectral Doppler is essential. In addition, spiral CT is desirable. MRA is currently available in only a few centres in the UK, but this may well become standard equipment for a major vascular unit in the future. It has been estimated that the capital cost of providing the appropriate radiological equipment, including that in the operating theatre, would be about £2.5 million with recurrent running costs of about £150 000.[56]

Vascular laboratory
In the vascular unit, a well-equipped vascular laboratory for performing diagnostic tests and postoperative surveillance of patients is essential. The equipment should include a treadmill, colour flow Duplex ultrasound and equipment for assessing microvascular circulation.

Day-care facilities
Day-care beds are becoming required increasingly for vascular diagnosis and treatment, particularly for angiography and percutaneous transluminal angioplasty.

Limb fitting and rehabilitation
This service should be provided in association with the vascular unit and should be sited within the geographical area of the vascular unit. Close proximity enhances the team approach to rehabilitation and makes it easier for limb fitting and rehabilitation to begin soon after amputation. The rehabilitation service also has to provide longer-term follow-up for patients, including those who live at some distance from the vascular unit.

Access to other specialties
In a small proportion of vascular patients, renal dialysis is required. Ideally, this is provided on the same site as the vascular unit, but in almost all cases patients can be transferred if necessary. Furthermore, for surgery and angioplasty of the renal artery, a close relationship with renal medicine and the provision of renal support is important. For many specialties it is desirable, although not essential, that they are on the same site as the vascular surgery unit in order to aid combined management of some patients. For patients with peripheral arterial disease and aortic aneurysm these specialties include cardiology, diabetic medicine, haematology and renal medicine.

Secondary care: organisation of vascular services

The provision of secondary care vascular services in the UK is currently not organised around major vascular units in all areas. There has been debate in recent years on whether vascular services should be centralised in specialist centres at regional or supra-district level or provided locally within districts as part of a general surgery service. Health service trials have not been carried out. However, some evidence on differing clinical outcomes can be obtained from: (i) observational studies or audits comparing outcomes in specialist and general surgical units; (ii) studies on outcome in relation to volume of activity; and (iii) the extent to which emergency transfer of patients from local to specialist centres is hazardous.

(i) In one of the first major audits of surgical practice in the UK, conducted in Edinburgh, the results of arterial surgery were found to be better in units in which surgeons specialised in vascular surgery than in units where vascular surgery formed a small proportion of the work.[138] This led to the concentration of services into one specialist vascular unit. Subsequent studies investigating outcomes before and after formation of the unit showed an improvement in survival of patients with a ruptured aneurysm from 42% to 68%.[139] For patients with acute limb ischaemia, the overall limb salvage rate improved, although no change was observed in mortality.[140] The authors of these reports thought it unlikely that other factors, such as change in surgical techniques, could fully explain the improved outcomes.

Comparisons between specialist and generalist centres in other parts of the UK have found similar differences to those found in Edinburgh. In the Northern Region, the mortality rate for elective aneurysm repair was 3.9% in teaching hospitals and 12.0% in district general hospitals, although there was no difference in mortality of emergency repair between the two categories of hospital.[141] In Glasgow, the overall case fatality for aneurysm repair was 7.9% in the specialist centre with full-time vascular surgeons and 19.7% in the other non-specialist hospitals.[142] The case fatalities for emergency repairs of ruptured aneurysm were 40.5% and 58.8%, respectively. Although some differences in casemix might explain the differences in outcome between specialist and generalist centres, there is some evidence to support the commonly held belief that specialist centres produce better outcomes than generalist units. Indeed the National Confidential Enquiry into Peri-operative Deaths has commented on the large number of deaths in vascular patients occurring under the care of non-specialists in vascular surgery.[143] Research in other countries has also produced similar findings and conclusions.[63]

(ii) One possible explanation for improved outcomes in specialist compared to generalist units is that the volume of work in generalist units may be too low to permit the maintenance of expertise or provision of specialist facilities. An extensive literature review of the evidence relating volume of activity and clinical outcome was published by the NHS Centre for Reviews and Dissemination in 1996.[144] Overall, the studies generally reported that outcomes were worse with decreasing levels of activity and that this relationship was most apparent at low levels of activity. There may also have been a minimum threshold effect above which outcome was not affected significantly by volume. However, many of the studies did not adequately adjust for casemix differences, emergency elective ratios and degree of specialisation, and did not distinguish between volumes per hospital and per clinician. When these are taken into account, the evidence suggests that overall 'there is no general relationship between volume and quality'.[144]

In some specialties, however, increased volume has been related to improved outcomes, and this includes peripheral vascular surgery. In this specialty, four better-quality studies[145–148] were identified in the review[144] in which age, severity of disease, comorbidities and other factors were adjusted. These studies investigated repair of abdominal aortic aneurysms and one also examined lower limb amputations, which were predominantly vascular.[145] No studies of adequate quality were found for reconstructive surgery or angioplasty. The conclusions of each of the better-quality studies[145–148] were summarised in the review as follows.[144]

- Standardised mortality ratio (SMR) for in-hospital mortality was 30% higher in hospitals treating < 14 aneurysm patients per annum, but no relationship was found between mortality and volume per surgeon.[145]
- Mortality for low-volume hospitals (< six aneurysm repairs per annum) was 12% compared with 5% for high-volume hospitals (> 38 repairs per annum). The mortality for low-volume surgeons (< six repairs per annum) was 9% compared with 4% for high volume surgeons (> 26 repairs per annum).[146]
- In-hospital mortality for aneurysm repair was inversely correlated with hospital volume but no correlation was found with number of repairs performed by surgeons.[147]
- A 2% increased risk of death occurred in hospitals performing < 21 aneurysm repairs per annum compared with those performing > 21. The risk difference was greater for ruptured aneurysms and was related to surgeon volume.[148]
- For lower-limb amputations, the SMR was 16% higher in hospitals with below the average annual volume of 10.5 amputations per annum.[145]

Although these studies[145–148] were conducted in the USA, the results may be relevant to practice in the UK. Some consistency of effect was found, at least for hospital volume and mortality related to aneurysm repair, and the results imply that volume is a consideration in relation to the organisation of services. However, the evidence is not sufficiently comprehensive or robust to indicate the minimum volume required to ensure the best outcomes.

(iii) Centralisation of vascular services into specialist units inevitably requires that emergency patients may need to travel greater distances to be admitted and that some transfer of emergency patients from generalist to specialist units may be required. These situations would arise principally for patients with ruptured abdominal aneurysms and, in a population of 250 000, would, in theory, affect fewer than 20 patients per annum (*see* Table 8). Currently, around 60% of patients with ruptured aneurysms do not reach hospital alive. A requirement for urgent surgery is obvious but the extent to which transportation and its duration affects survival is not clear. Most of the studies have investigated only patients who actually reached the specialist centre. The numbers were small in most studies and confounding factors were not always accounted for. In one study in the UK, for example, post-operative mortality was around 50% for patients transported < 5 miles and 40% for patients transported > 5 miles.[149] The patients travelling longer distances might have been less severely ill. In studies in Norway and the USA, transportation time had no independent effect on hospital mortality.[150,151] Although the duration between rupture and operation is likely to have an effect on survival, the maximal time undoubtedly varies greatly depending on many patient factors, such as duration of hypotension and co-existing cardiac disease,[152] so that it is not possible to identify a critical time for the purposes of organising vascular services.

Major specialist units versus district general service

The arguments for and against centralisation were summarised in one of the recent reports on vascular services.[57]

The case for centralisation

1. Audit has shown that specialist vascular units achieve better outcomes for patients.
2. Centralisation of services achieves economies in this 'high-tech', high-cost specialty.
3. Satisfactory training is possible only in units with a high throughput of patients with vascular disease.

4 Research is facilitated by centralisation of clinical cases, medical personnel and technical resources.
5 Centralisation permits appropriate specialist staff cover in a specialty with a particularly high emergency on-call component.
6 Centralisation enables collaboration with a wide range of other specialties, including access to special laboratory facilities and a blood bank.
7 Centralisation, with the need for transfer of emergency patients, does not prejudice survival.

The case against centralisation

1 Some general surgeons currently performing vascular operations may be excluded from such work.
2 Patients and their relatives would have to travel longer distances in order to consult vascular surgeons.
3 Fewer hospitals would have a vascular surgeon so that 'on-the-spot' diagnoses and treatment might suffer.
4 There would be no experience of vascular surgery for middle-grade surgical staff except in the centralised units.

In each of the reports published recently on the future of vascular and surgical services,[56,57,63] emphatic recommendations have been made on the desirability of centralisation and that implementation of such a service should be a high priority in the UK. This service should be centred around major vascular units as specified above.

However, each of the reports differed slightly on how services should be provided for substantial populations that fall short of the minimum catchment population of 500 000 for a major unit. Such populations might be urban and comprise about 250 000 people. One recommendation was that intermediate vascular units be formed.[57,63] These would not have the same high specification as a major unit but would provide a specialist on-call rota of surgeons with a special interest in vascular disease and would have many of the basic facilities of a major unit. However, such a recommendation was made partly in recognition of the current distribution and provision of services in the UK and recognised that an intermediate unit could not provide an ideal service to the populations in those areas.

Integrated regional/supra-district vascular service

A more attractive model has been suggested for providing a vascular service in which urban populations of insufficient size can have access to a major vascular unit. This model of an integrated regional or supra-district vascular service would have a centralised major vascular unit but would also provide certain services in local district general hospitals with smaller catchment populations.[56] Complex vascular work would be carried out in the major vascular unit. The outreach service in the local hospital would include the provision of outpatient clinics, some diagnostic facilities including Duplex scanning, pre-operative assessment, day surgery, post-acute care and rehabilitation. Also, vascular advice would be provided to other specialties in the hospital.

Such an arrangement would require split working by some staff but would allow good patient access to local outpatient and other facilities while allowing optimum provision of high-quality services for emergency and major elective surgery. The occasional transfer of emergency patients would not be problematic given the good transport links in most parts of the UK. This model has also been referred to as a 'hub and spoke' arrangement, with the major vascular unit sitting at the hub of the service.[63]

An alternative model has been proposed for certain areas of the country in which there are currently several small vascular units or individual surgeons providing a service in areas that are contiguous. This model does not envisage establishment of a major vascular unit but rather that smaller units provide cross-cover for each other, and that surgeons work together in a 'virtual' unit. This, however, is unsatisfactory because it leads to a fragmented service preventing the concentration of clinical activity. It inhibits the development of a 'comprehensive team approach with all the advantages of economies of scale, patient care, training and professional satisfaction'.[63]

Remote vascular units

There are, within the UK, a few small, geographically isolated hospitals, which do not easily fit into a conventional integrated vascular service and which serve a diffuse and sparse population. Transfer to major vascular units for such patients might involve unacceptable delay and might not be easily carried out. Under these circumstances, the local hospital would need to provide a more substantial range of vascular services, including emergency surgery and straightforward elective procedures. In such a hospital, there should be a minimum of one surgeon with a special interest in vascular surgery as well as other general surgeons on the on-call rota with some training and experience in vascular surgery. The number of beds required per head of population would be only slightly less than that specified for a major vascular unit. A radiologist with a special interest in vascular work would also be required, but it would have to be accepted that the care of patients by other specialists and professions would be provided by generalists rather than those with a special interest in vascular disease. Although such a remote unit would operate independently, close clinical and professional links would need to be established with a major vascular unit and arrangements made for the occasional transfer of particularly complex cases.

There are economic and resource implications of establishing integrated regional/supra-district vascular services in the UK. In terms of workload, beds and staffing, much of the rationalisation would require redeployment of existing resources within a region. Some capital expenditure might be required at the site of the major vascular unit unless some of the less severely ill patients currently managed at that site could be managed at the local 'spoke' hospital. Also, additional operating facilities might well be required at the site of the major vascular unit. On the other hand, centralisation might create savings in the provision of equipment and facilities by not having a requirement for 'duplicate' facilities in the local hospitals. The provision of vascular experts in the various specialties and professions associated with a major unit might be accommodated by slowly changing the responsibilities of staff within the institution rather than having to take on additional manpower. Overall, the economic implications will depend very much on local circumstances, but creation of an integrated vascular service will inevitably require additional resources.

Screening programmes

Screening for peripheral arterial disease and asymptomatic abdominal aortic aneurysms are currently not taking place in the UK and, until screening has been approved by the Department of Health, models of care cannot be recommended. If programmes are to be established, it would make sense for these to be part of an integrated vascular service with involvement of both the primary and secondary care sectors.

8 Outcome measures

Outcome measures

In assessing the quality of a peripheral vascular disease service, the 'outcome' measures should include structure, process and outcome criteria. The facilities provided and the procedures undertaken, as well as the end results of care, are important indicators of quality.

Primary care

Process criteria

In primary care, the key element of process that needs to be assessed is the risk factor management of patients with intermittent claudication. Such process criteria would include:

- smoking history taken in all patients
- serum cholesterol measured
- blood pressure measured
- antiplatelet therapy prescribed.

If necessary, the following treatment is given:

- smoking cessation advice
- nicotine replacement therapy
- lipid-lowering diet and/or therapy
- antihypertensives.

Outcome criteria

These would essentially comprise 'healthy' levels of the risk factors:

- smoking abstinence
- serum cholesterol < 5.2 mmol/l
- systolic pressure < 160 mmHg; diastolic pressure < 90 mmHg.

In assessing the clinical management of intermittent claudication, the most important outcome criteria measurable in the primary care setting are:

- walking distance (measured using the Walking Impairment Questionnaire,[153] which has been shown to be reasonably valid[154])
- quality of life (measured using standard generic questionnaire, such as the EuroQol or SF-36[155]).

There are no absolute desirable levels of the above two criteria but the effects of treatment should be to improve or maintain baseline levels. Therefore *change* in these criteria can be monitored. Other outcome measures, such as treadmill walking distance, are not feasible to assess in the primary care setting and the ABPI is insufficiently sensitive to detect change in disease status in the early stages.

Secondary care

Structure criteria

At secondary care level, criteria on structure are very important for ensuring that adequate facilities are in place. These criteria relate closely to the minimum specification of a major vascular unit as described in Section 7 above.

- 24-hour emergency cover is provided by full-time vascular surgeons.
- Minimum number of full-time consultant vascular surgeons is three.
- Number of full-time or part-time vascular interventional radiologists is equivalent to number of vascular surgeons.
- A physician with expertise in vascular medicine is a member of the vascular team.
- Anaesthetists have special expertise in the management of vascular cases.
- Number of vascular beds is 30 to serve population of 500 000.
- Intensive therapy unit is available on site.
- Specified radiological equipment is available in theatre and in the radiology department.
- Vascular diagnostic laboratory is part of the unit.
- Limb-fitting service is provided in association with the unit.

Process criteria

An assessment of the overall efficiency and appropriateness of care can be obtained by examining indicators of process. These are not necessarily valid indicators of actual quality, but may be screening criteria that are pointers to potential problems when targets are not achieved.

- Waiting time from referral to outpatient appointment is < 13 weeks.
- Waiting time on list for elective surgery is < 13 weeks.
- Angioplasty is performed as a day case.
- Length of stay for elective aneurysm repair is < 12 days.
- Ratio of arterial reconstruction to amputation is > 2:1 (a crude measure of a unit's practice to reconstruct instead of amputate).
- Amputations performed by non-vascular surgeon to occur after assessment for limb salvage by vascular specialist.

The above waiting-time criteria are derived from the Patient's Charter[156] and lengths of stay and surgical ratios from published norms (Tables 9 and 10).

Outcome criteria

The criteria that are the most important measures of the success of secondary care are those following the major treatments of reconstructive surgery, amputation and angioplasty for peripheral arterial disease, and elective and emergency repair of abdominal aortic aneurysms.

- Mortality, usually quoted within 30 days of surgery, for:
  - major arterial reconstruction
  - major amputation
  - emergency aneurysm repair
  - elective aneurysm repair.
- Limb survival at 4 years:
  - post-arterial reconstruction
  - post-angioplasty.

- Mobile post-major amputation.

These criteria cover some principal outcome measures but criteria covering other procedures and other outcomes can be set.

Audit methods

At primary care level, the most appropriate method of audit is by internal, or occasionally external, peer review of the management of individual patients with intermittent claudication. Routine GP and prescription records, despite some doubts on accuracy, are the most appropriate source of data because prospective collection of data when patients are being managed would undoubtedly influence practice.

At the present time none of the above criteria concerning secondary care has been set nationally, therefore it is important that such criteria are agreed locally, probably at regional level. Furthermore, an important principle of audit is that criteria are agreed before data on current practice are analysed. The data can be collected from routine hospital statistics, if available. If such data are not available, special ad hoc surveys may be required, mostly of hospital records. Rarely, special ad hoc surveys of patients may be required.

Targets

As national targets for the above criteria concerning vascular services have not been established, targets must be set locally. These will undoubtedly be based on perceived optimum levels and be influenced by current levels of practice. Targets are normally expressed as a percentage in relation to the criteria, e.g. the national waiting time standard for any condition states that 90% of patients waiting for an outpatient appointment can expect to be seen within 13 weeks and that all should be seen in 26 weeks.[156] For inpatient admissions, 100% should take place within 18 months of referral.[156]

In secondary care, the structural criteria above are essentially the minimum requirement, and therefore the target should be 100%. Targets for the process criteria are partly dependent on local circumstances and therefore it is more difficult to be prescriptive. Targets for the outcome criteria can be set in accordance with the results from research studies, as described in Section 6.

- 30-day mortality:
  - major arterial reconstruction < 5%
  - major amputation < 15%
  - emergency aneurysm repair < 50%
  - elective aneurysm repair < 6%.
- Limb survival at 4 years:
  - post-arterial reconstruction > 80%
  - post-angioplasty > 85%.
- Mobile post-major amputation (survivors):
  - > 40% (above knee)
  - > 80% (below knee).

For such criteria, terms such as patency and mobility must be defined precisely. Also, it should be recognised that case mix and other factors have a profound effect on these outcome indicators so that a unit not operating at an appropriate target level may still be providing high-quality care.

9 Information and research requirements

Further information

Current data systems can provide much information for successful audit and monitoring of vascular services, for example on waiting times and length of stay. However, the accuracy of some clinical discharge information has been shown to be lacking, with considerable under-reporting,[62] so that priority should be given more to improving the accuracy of current systems than collecting additional data. In Scotland, hospital discharges are now linked to mortality data, and this has proved useful in developing hospital outcome indicators. Nationally in the UK, availability of statistics on 30-day mortality figures following the major vascular operations might prove useful if adjustments could be made for case mix and comorbidities.

Further research

The chapter has highlighted many gaps in knowledge about the occurrence of peripheral vascular disease and its management. Further research in many areas would prove useful but the following should be given high priority.

- More information is required on the burden of peripheral vascular disease in the community. The impact of intermittent claudication on the quality of life and on patient and societal costs is required.
- Trends in peripheral arterial disease and aortic aneurysms need to be specified and more accurate predictors made of future incidence and prevalence, particularly as it is likely that an ageing population and increased survival from coronary heart disease will lead to an increased burden of disease and demand for services.
- In primary care, research is required on the management of intermittent claudication, particularly how to achieve smoking cessation in long-term older smokers. Also, cost-effectiveness studies are required of different approaches to increasing exercise in claudicants, including the value of different exercise programmes.
- Also, in claudicants, more specific trials are required on the management of risk factors. For example, the effects of combinations of antiplatelets such as aspirin and clopidogrel compared with aspirin alone need to be evaluated. Also, more information would be useful on the impact of good glycaemic control in peripheral arterial disease patients with diabetes.
- The interface between primary and secondary care needs to be studied, investigating differing thresholds for referral of claudicants, and the most appropriate strategies for long-term management of risk factors, including shared care.
- For patients referred to hospital, one-stop clinics need to be evaluated to determine which patients can be managed in this way, and the relative costs and effectiveness of this approach compared with routine outpatient referral.
- The initial management of claudicants referred to hospital also has to be evaluated to determine the optimum investigative strategies, the value of diagnostic technologies such as Duplex screening and the criteria for differing approaches to management, for example conservative therapy, angioplasty and reconstructive surgery.
- More research is required on angioplasty. In mild to moderate claudicant patients, a large trial to compare the cost-effectiveness of angioplasty versus conservative therapy is required, allowing for comparisons of lesions at different sites in the arterial tree. Further studies on the technological

advances in angioplasty, including adjuvant stenting, are warranted. Also the long-term effects of angioplasty on surgical rates in individuals and the community are of interest.

- The prognosis of claudication and the identification of factors that affect prognosis and treatment outcomes require further research with the eventual aim of being able to better predict the course of disease for an individual and to better target treatment.
- For patients with more severe peripheral arterial disease, more research is needed to better define the indications for arterial reconstruction versus amputation. Prognosis is very poor for such patients and the cost-effectiveness of different approaches needs to be specified, with more attention paid to quality of survival.
- In the treatment of aortic aneurysms, the upper size limit for conservative treatment is not well specified. Also, for aneurysm surgery, as well as for other elective procedures, there appears to be considerable differences between centres in lengths of stay and resource use, indicating a requirement for cost-efficiency studies.
- In terms of organisation of a vascular service, research on the impact of integrated regional networks would be helpful. A specific question, for example, might address the hazards of transferring emergency patients into regional centres.
- With the advent of clinical governance, research might be conducted on the sensitivity and appropriateness of performance indicators. More refined studies in the UK (rather than the USA) on the volume effect on quality and identifying a possible minimal threshold effect would be useful.
- Further research is required in prevention. The mortality from aortic aneurysm is high and surgery is the only effective treatment. Medical treatments to prevent growth and rupture will emerge only if there is greater understanding of the aetiology and natural history of aneurysms.

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