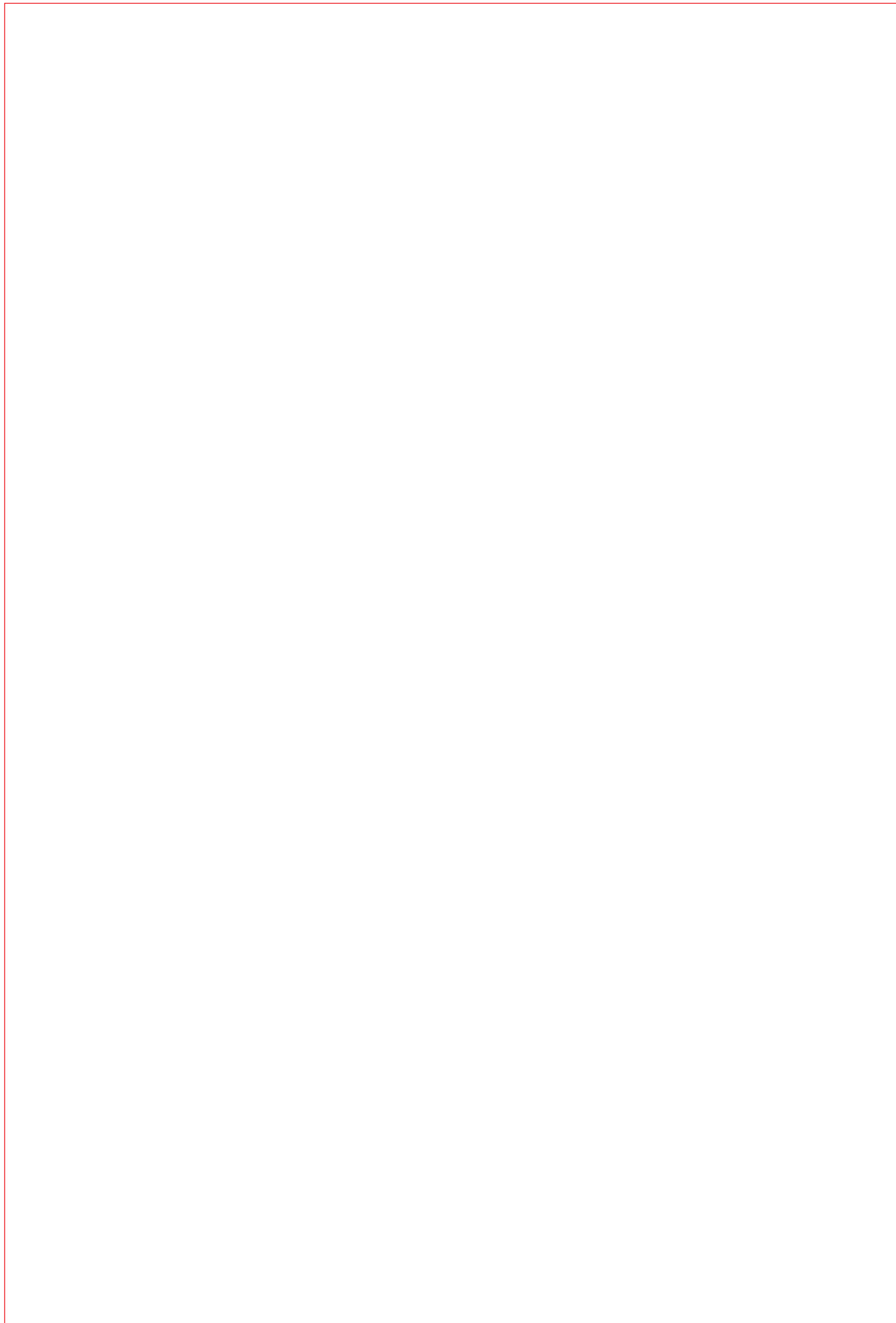


1 INTERVENTIONAL VASCULAR RADIOLOGY

RECOMMENDATIONS

- It is essential that vascular radiologists and surgeons work together as a team both in the decision as to what procedures to undertake and in the management of any complications (pages 13-14, 20, 22).
- The interventional radiologist needs to have sufficient experience, facilities and equipment to perform the procedure safely and to deal with any complications which may arise (pages 14-18, 20).
- Monitoring of pulse oximetry, blood pressure and ECG should be performed during all interventional radiology procedures; this should be done by someone other than the radiologist performing the procedure (page 17).
- Cannulation of the femoral artery should always be below the inguinal ligament to avoid the danger of retroperitoneal haematoma. Medical and nursing staff must be aware of the risks of this serious complication in order to act early when necessary (pages 19-20).
- Thrombolytic therapy should be used with caution, especially in the elderly (over 75 years) who are more prone to cerebral haemorrhage. Patients with thrombolysis continuing after they have left the radiology department should be nursed in a high dependency unit so that complications may be diagnosed and treated without delay (pages 21-22).



1. INTERVENTIONAL VASCULAR RADIOLOGY

INTRODUCTION

With the availability of new and smaller devices over the last 20 years, interventional vascular radiology has become increasingly important in the treatment of blood vessel related diseases. The interventional procedure is attractive to both doctors and patients because it is performed under local anaesthesia and the insertion of the device is done by direct needle puncture through the skin without surgical incision. It may be used to treat a wide variety of conditions, but the common theme is that a fine catheter is inserted into a blood vessel and, by the use of imaging (usually X-ray) and a guidewire, narrow areas in blood vessels may be stretched (balloon angioplasty) or held open (stent); used to deliver a drug to dissolve blood clot (thrombolysis); used to insert a central venous catheter to deliver chemotherapy or intravenous nutrition or for haemodialysis; used to occlude vessels with small particles to stop bleeding in inaccessible sites (embolisation); used to place a filter to allow blood through, but not to allow blood clot to pass (inferior vena cava filter); or used to make a new connection between the portal and systemic circulation in portal hypertension (TIPS).

As these procedures can be done under local anaesthetic, usually with minimal upset to the patient, less fit patients can be treated, who would not be well enough to undergo a formal surgical operation. Inevitably, therefore, some of these patients are going to die from their underlying disease following, for example, an angioplasty which in many of the patients is an incident in the course of their disease. However, because many of these patients are already very ill, otherwise minor complications may have very serious consequences.

DATA COLLECTION

Data were requested from all NHS hospitals undertaking these procedures in England, Scotland, Wales, Northern Ireland, Guernsey and Jersey. Participation was voluntary and some hospitals chose, for a variety of reasons, not to participate.

Information on the total number of patients undergoing interventional radiology procedures on a monthly basis, together with notification of any deaths occurring within 30 days of the procedure, were collected for the period 1 April 1998 - 31 March 1999.

GENERAL DATA ANALYSIS

Monthly returns of procedures performed

One hundred and sixty-two hospitals initially agreed to participate in the study, although this reduced to 154 who subsequently contributed monthly data. Each hospital was required to send in a monthly return of all patients undergoing interventional vascular radiological procedures in the hospital. A total of 1848 forms should therefore have been received. The return of monthly data is shown in Figure 1.1.

A regional breakdown of the number of monthly forms received is given in Table 1.1. The return rate of monthly forms was commendably high; the rate of 72% from Scotland was a little disappointing and may have been due to similar studies being conducted simultaneously in that country.

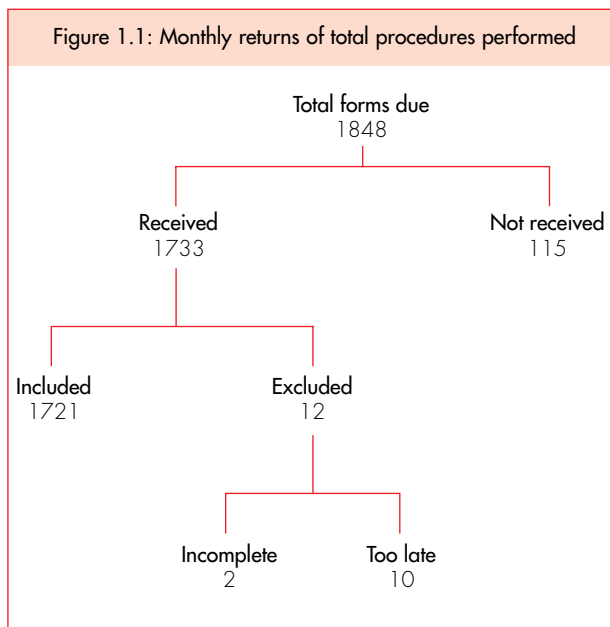


Table 1.1: Monthly returns by region

Region	Number of participating hospitals	Monthly forms received	Monthly forms expected	Return rate
Anglia & Oxford	12	144	144	100%
North Thames	12	132	144	92%
North West	21	243	252	96%
Northern & Yorkshire	19	213	228	93%
South & West	17	180	204	88%
South Thames	19	215	228	94%
Trent	15	165	180	92%
West Midlands	16	183	192	95%
Wales	10	120	120	100%
Northern Ireland	2	24	24	100%
Scotland	9	78	108	72%
Guernsey	1	12	12	100%
Jersey	1	12	12	100%
Total	154	1721	1848	94%

Reported procedures

This is the first study where NCEPOD has been able to collect data on the total number of procedures performed, as well as details of those patients who died. Just over 21 000 (21 112) of these procedures were reported by the 154 participating hospitals in the year from 1 April 1998 to 31 March 1999, giving a mean of 137 procedures per centre.

Reported deaths

Figure 1.2 shows that a total of 511 reports of deaths within 30 days of a procedure were received, reducing to 476 when 35 inappropriate reports were excluded (Table 1.2), giving a mortality rate of just over 2% (476/21 112; 2.3%).

A further 25 reports were received after the deadline of 31 August 1999 and 6 remained incomplete despite all efforts to identify missing information, leaving 445 cases for inclusion in the study.

A regional breakdown of the remaining 445 deaths is shown in Table 1.3.

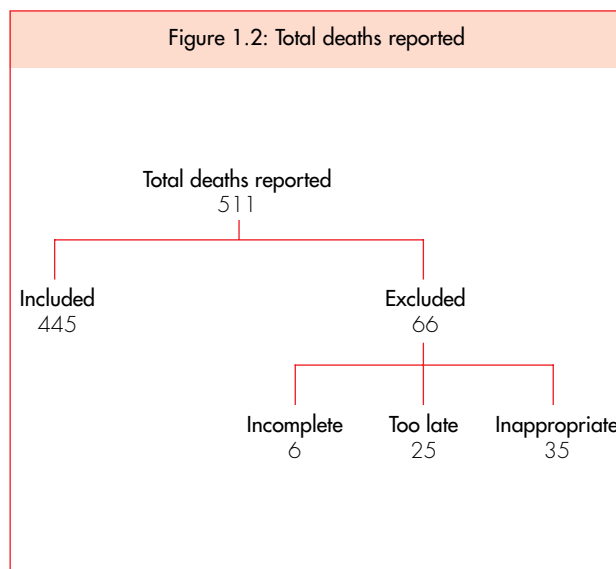


Table 1.2: Inappropriate reports received and excluded

Reason for exclusion	Number
More than 30 days (<i>day of procedure to day of death</i>)	19
Duplicate report	2
Procedure excluded by NCEPOD criteria	9
Procedure performed in non-participating independent hospital	4
Death outside study period	5
Total	35

Table 1.3: Deaths reported to NCEPOD by region

Region	Deaths reported
Anglia & Oxford	35
North Thames	68
North West	49
Northern & Yorkshire	67
South & West	68
South Thames	29
Trent	40
West Midlands	36
Wales	13
Northern Ireland	1
Scotland	39
Guernsey	0
Jersey	0
Total	445

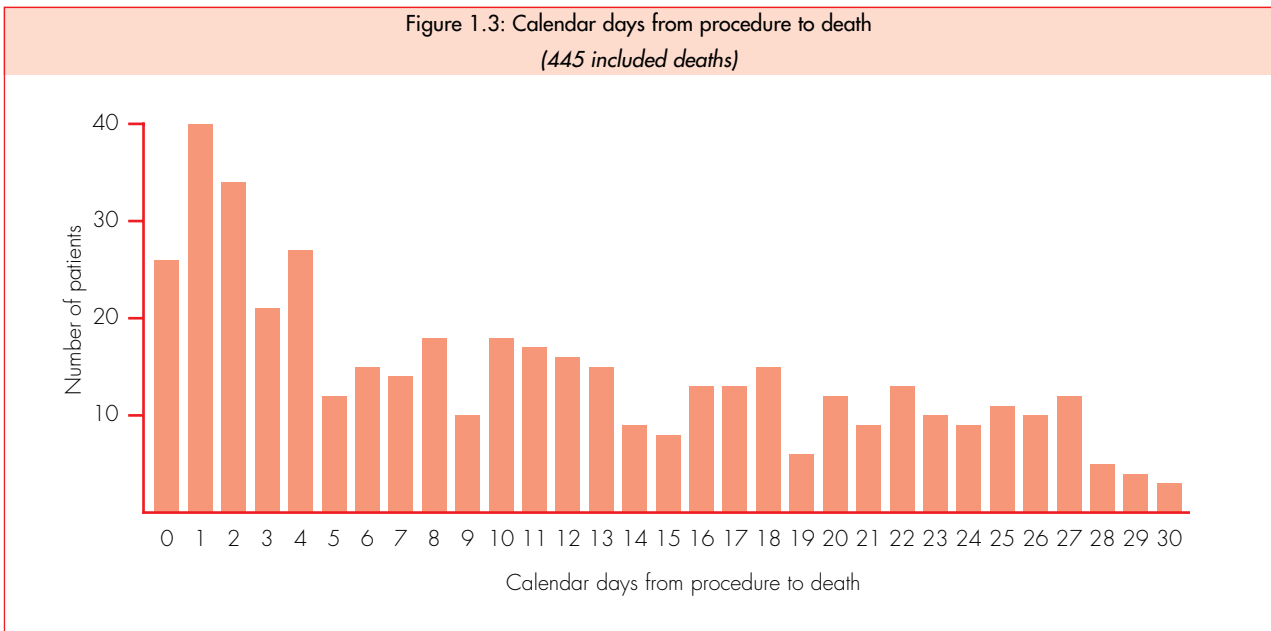
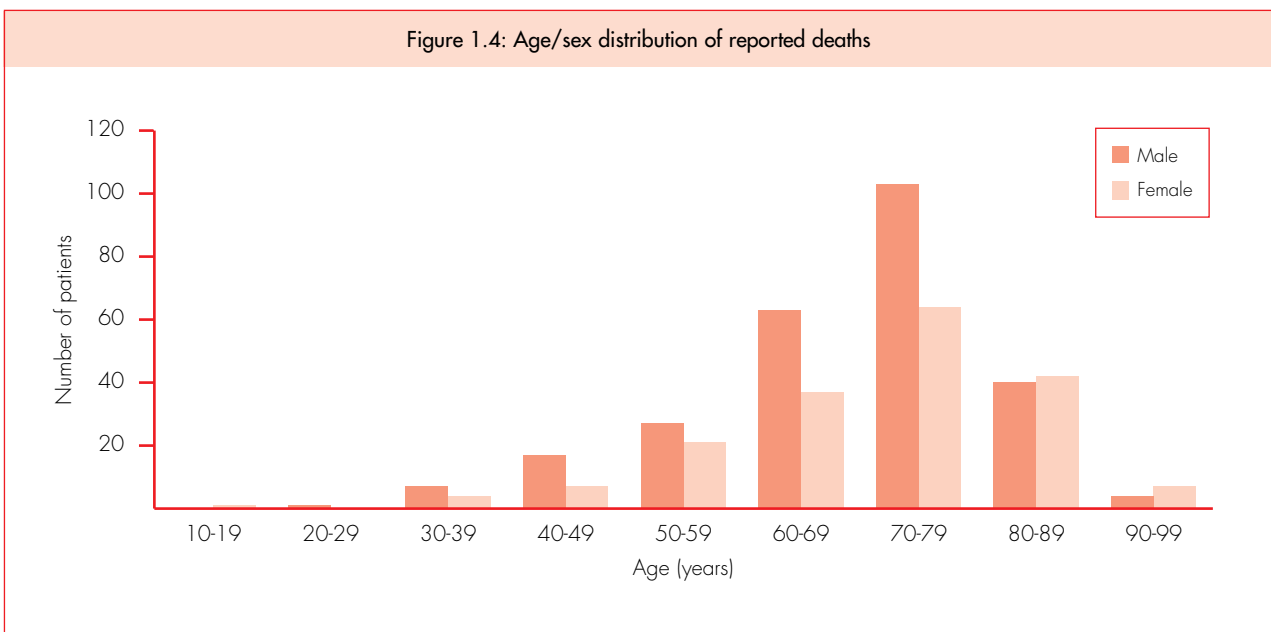


Figure 1.3 shows the distribution of the number of calendar days between procedure (day 0) and death. The fact that the number of days from procedure to death was so widely distributed suggests that most patients died for reasons unrelated to the procedure.

Figure 1.4 shows the distribution of age and sex.



Distribution, return and analysis of questionnaires

Questionnaires were sent to the consultant radiologist responsible for the care of each of the 445 patients included. Figure 1.5 shows the return and analysis rates of questionnaires sent.

Table 1.4: Reasons for exclusion of questionnaires from analysis

Reason for exclusion	Number
Questionnaire received too late	11
Questionnaire incomplete	2
Questionnaire completed for wrong procedure	1
Total	14

Figure 1.5: Distribution, return and analysis of questionnaires

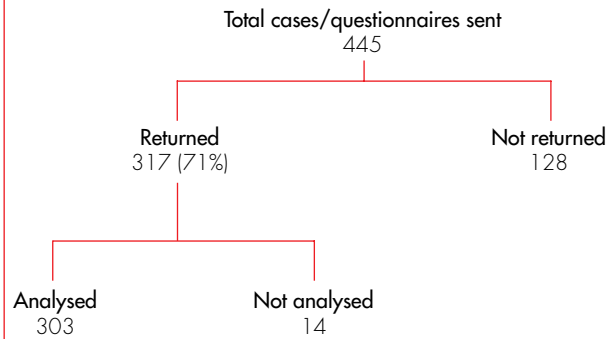
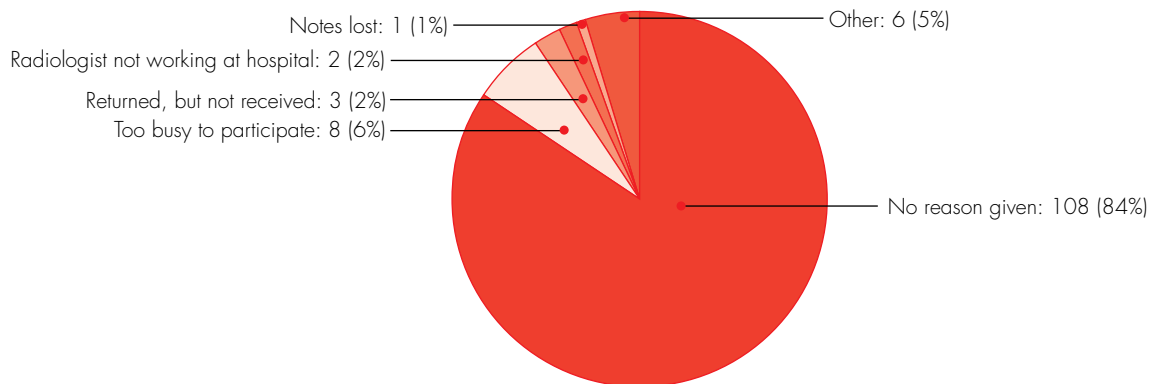


Figure 1.6: Reasons for non-return of questionnaires



In the majority of cases (84%) where no questionnaire was returned, no reason was offered for an inability to do so. In three cases the radiologist indicated that the questionnaire had been returned although it was not received in the NCEPOD offices.

Table 1.5: Regional distribution, return and analysis rates

Region	Questionnaires distributed	Questionnaires returned	Return rate	Questionnaires analysed
Anglia & Oxford	35	31	89%	30
North Thames	68	22	32%	20
North West	49	37	76%	37
Northern & Yorkshire	67	55	82%	55
South & West	68	55	81%	54
South Thames	29	15	52%	15
Trent	40	32	80%	29
West Midlands	36	29	81%	29
Wales	13	11	85%	11
Northern Ireland	1	1	100%	1
Scotland	39	29	74%	22
Total	445	317	71%	303

Table 1.5 shows the return rates by region and the majority of these were in excess of 80%; of note were the disappointingly low return rates of South Thames (52%) and, in particular, North Thames where only one third (32%) of questionnaires were returned.

Procedures

Tables 1.6, 1.7 and 1.8 summarise the total number of procedures performed, together with deaths, for arterial, venous and other interventions respectively.

Table 1.6: Endovascular interventions (arterial)

Intervention	Angioplasty		Stent		Thrombolysis		Atherectomy		Embolisation		Aneurysm exclusion	
	Total	Deaths	Total	Deaths	Total	Deaths	Total	Deaths	Total	Deaths	Total	Deaths
Carotid (includes internal & external)	18	-	57	1 (2%)	4	-	-	-	29	-	3	-
Brachiocephalic	13	-	8	-	10	-	-	-	4	-	-	-
Subclavian	103	-	50	-	23	2 (9%)	-	-	19	-	1	-
Other	27	1 (4%)	6	-	14	2 (14%)	-	-	298	4 (1%)	1	-
Gut	20	1 (5%)	18	1 (6%)	-	-	-	-	149	7 (5%)	2	-
Renal	408	5 (1%)	322	5 (2%)	6	-	-	-	214	3 (1%)	-	-
Aorta	71	-	73	-	6	-	-	-	2	-	3	-
Iliac	3619	31 (1%)	1208	8 (1%)	134	5 (4%)	13	-	31	-	8	-
Pelvic	70	1 (1%)	6	-	6	-	-	-	236	6 (3%)	2	-
Femoral	5680	47 (1%)	76	-	550	17 (3%)	11	-	33	1 (3%)	10	-
Popliteal	1101	15 (1%)	8	-	153	8 (5%)	-	-	3	-	1	-
Tibial	526	9 (2%)	1	-	41	-	-	-	20	-	1	-
Graft	219	-	6	-	227	17 (7%)	5	-	3	-	-	-
Pulmonary	-	-	1	-	11	1 (9%)	-	-	31	-	-	-
Total	11 875	110 (1%)	1840	15 (1%)	1185	52 (4%)	29	-	1072	21 (2%)	32	-

Table 1.7: Endovascular interventions (venous)

Intervention Site	Angioplasty		Stent		Thrombolysis		Embolisation	
	Total	Deaths	Total	Deaths	Total	Deaths	Total	Deaths
Brachiocephalic	47	-	26	-	16	-	-	-
Subclavian	63	-	32	-	26	1 (4%)	1	-
Superior vena cava	15	1 (7%)	266	17 (6%)	17	2 (12%)	1	-
Inferior vena cava	2	-	16	2 (13%)	3	-	-	-
Hepatic	9	-	25	-	-	-	11	-
Portal	43	-	13	-	1	-	13	-
Graft	48	-	3	-	15	-	-	-
Renal	3	-	3	-	1	-	4	-
Iliac	10	-	14	-	15	-	19	-
Infrainguinal	7	-	1	-	3	1 (33%)	15	-
Gonadal	-	-	-	-	-	-	491	-
Total	247	1 (<1%)	399	19 (5%)	97	4 (4%)	555	-

The two most common venous procedures were gonadal vein embolisation, which is performed for varicocele and has made operation for this condition a rarity, and superior vena cava (SVC) stent placement, performed to relieve swelling of the upper half of the body due to oedema caused by obstruction of the SVC, usually due to intrathoracic malignancy.

Table 1.8: Other interventions

Intervention	Total	Deaths
Central venous access (not temporary)	3052	36 (1%)
Foreign body	70	1 (1%)
Inferior vena cava filters	501	17 (3%)
Transjugular intrahepatic portosystemic shunt (TIPS)	158	27 (17%)
Total	3781	81 (2%)

In 35 cases death was considered to be related to the procedure and in 13 of these the advisors thought that the risk of complications related to the procedure was justified bearing in mind the very serious medical condition of the patient. Thus, technical problems where the procedure contributed to the death of the patient occurred in 22 cases (0.1%) or about one in 1000 cases. While this indicates a very high standard of care it still leaves some room for improvement. Details of these problems will be discussed in later sections of this report, together with recommendations for improvement. There were also a number of instances where it was felt that care could have been better, even though patients did not suffer as a result, and these too will be discussed.

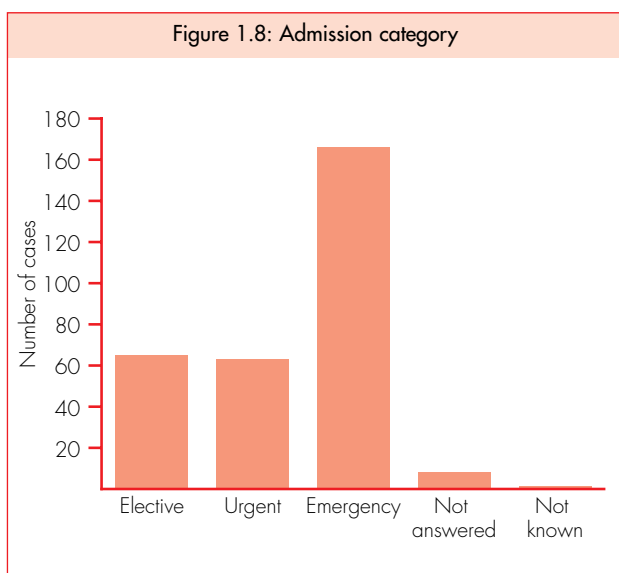
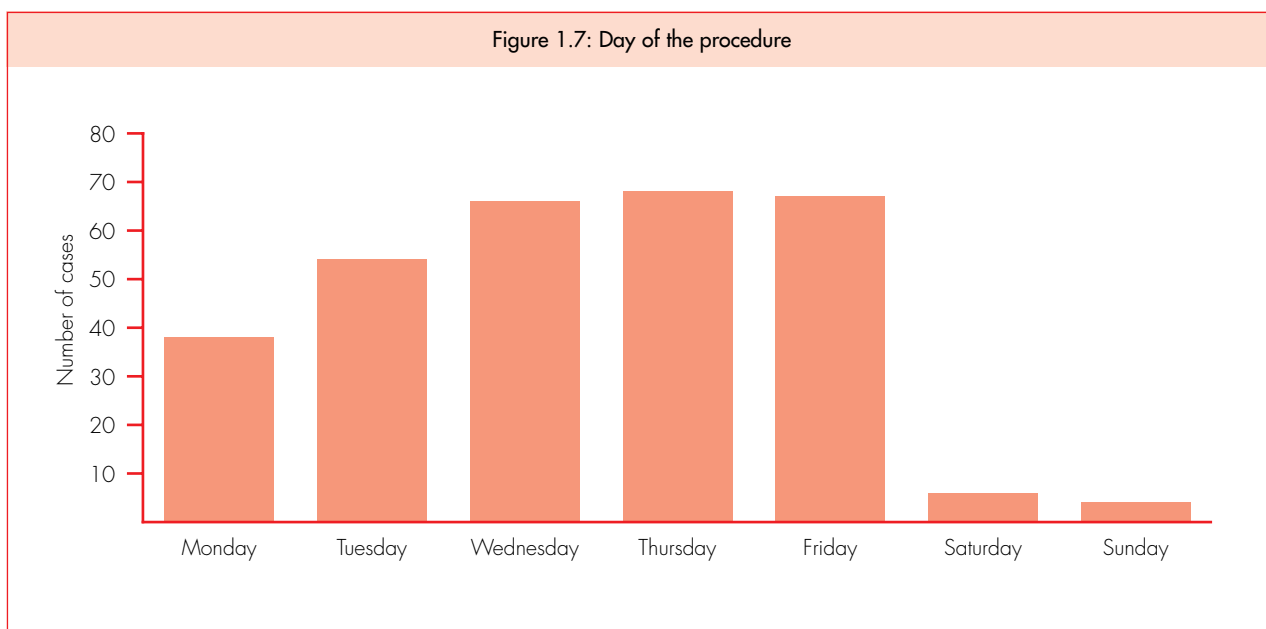
PATIENT PROFILE

The report hereafter deals only with those patients who died.

Key Point

- *Interventional vascular radiology procedures are generally safe with around 21 000 procedures performed in participating hospitals during the year and 476 deaths (2%). Many of these patients were extremely unwell and not fit enough for open surgery.*

Urgency of procedure

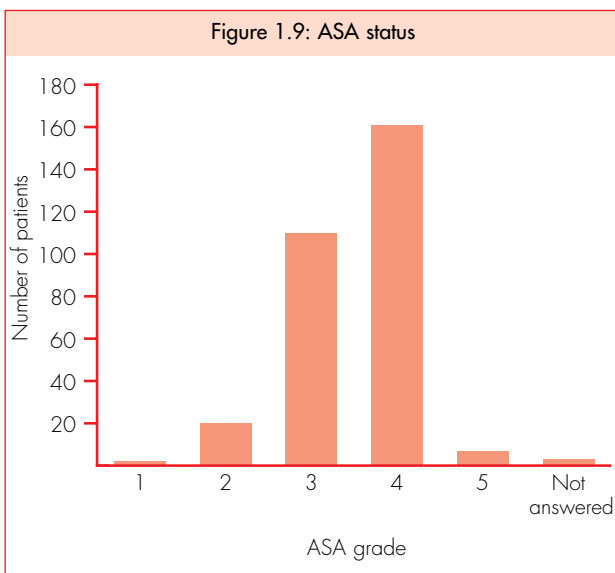


The majority of procedures appear to be done midweek, with less on a Monday and very few performed at a weekend. It is interesting to note, however, that although the majority of interventional vascular procedures were performed electively, of those who died a large number were done urgently (63/303; 21%) or as an emergency (166/303; 55%).

Fitness of the patient

This was assessed using the American Society of Anesthesiologists (ASA) Classification of Physical Status:

- ASA 1** a normal healthy patient.
- ASA 2** a patient with mild systemic disease.
- ASA 3** a patient with severe systemic disease that limits activity but is not incapacitating.
- ASA 4** a patient with incapacitating systemic disease that is a constant threat to life.
- ASA 5** a moribund patient not expected to survive for 24 hours with or without an operation.



The majority (278/303; 92%) of those patients who died following interventional vascular radiology had severe systemic disease (ASA grade 3 or higher). Many of these patients would not have been considered fit enough for open surgery.

Coexisting problems (other than the main diagnosis) existed in 268/303 (88%) of the patients and these are shown in Table 1.9. In only 29/297 (10%) cases where the question was answered did the patient have no coexisting medical problems.

Coexisting medical problem	Number
Cardiac	153
Respiratory	93
Vascular	81
Diabetes mellitus	76
Malignancy	62
Renal	57
Gastrointestinal	48
Sepsis	43
Neurological	38
Haematological	37
Nutritional	19
Alcohol-related problems	16
Musculoskeletal	15
Obesity	13
Psychiatric	10
Other endocrine	8
Genetic abnormality	1
Other	15

Table 1.9 gives further confirmation of the considerable extent to which patients who died following interventional radiology had a number of other coexisting medical problems.

Table 1.10: Anticipated risk of death related to the proposed procedure

Risk of death	Number
Not expected	163
Small but significant	76
Definite risk	50
Expected	7
Not answered	7
Total	303

There were seven patients who had vascular interventions even though they were expected to die (Table 1.10). Two were for the relief of very unpleasant symptoms:

CASE 1 • A 58-year-old patient with lung cancer in whom embolisation was performed to stop his distressing, severe recurrent haemoptysis.

CASE 2 • A 55-year-old patient with distressing swelling of the face and arms, together with breathlessness due to superior vena cava (SVC) obstruction caused by squamous carcinoma of the lung. She had previously had a successful stent which had then thrombosed and thrombolysis was given to try and clear the stent and relieve her unpleasant symptoms.

In a further two cases the intervention was a 'last ditch' attempt to save life:

CASE 3 • A 76-year-old patient who had persistent severe bleeding following a transurethral prostatectomy. Embolisation of the internal iliac artery was performed to try and stop bleeding. The radiologist thought that there would have been a better chance of the patient surviving had the urologist called for help earlier.

CASE 4 • An 89-year-old patient having revision of a recurrent fractured neck of femur developed very heavy bleeding which had proved impossible to control surgically, so embolisation of the profunda femoris was performed. This was technically successful but sadly by this time the patient had developed a coagulopathy.

There were a further two patients with persistent pulmonary emboli despite adequate anticoagulation:

CASE 5 • A 64-year-old patient with multiple pulmonary emboli had sudden deterioration due to a further pulmonary embolus confirmed on spiral CT. He had already survived a previous massive pulmonary embolism so it was thought worth trying a caval filter to prevent further emboli. This was believed to be his only hope, as he would not have survived a pulmonary embolectomy.

CASE 6 • A 51-year-old patient with multiple pulmonary emboli who, despite anticoagulation, was in respiratory distress. It was felt that there was a small chance of recovery if further pulmonary emboli could be prevented and an IVC filter was inserted.

Lastly, thrombolysis was tried in a relatively young man who was not fit enough to withstand an operation:

CASE 7 • A 45-year-old patient with acute on chronic aortoiliac occlusion. He was not considered fit enough to survive surgery because of severe ischaemic heart disease. Death was expected because of the severe extent of his ischaemia, and thrombolysis was thought to be the only hope of restoring the circulation and giving him a chance of survival. The fact that there was no ICU or HDU bed did not help in this patient's management and he subsequently died of pulmonary oedema due to congestive cardiac failure (see also page 18).

Each of these cases was reviewed by the vascular radiology advisors and was considered to be justifiable either in the relief of symptoms or because there was a very small chance of the patient surviving a procedure that would cause very little upset to them.

SPECIALTY AND EXPERIENCE OF THE MEDICAL TEAM

Specialty of the clinical team

Tables 1.11 and 1.12 show the specialty of the consultants under whose care the patients were at the time of their procedure.

Table 1.11: Specialty of consultant surgeon under whose care the patient was at the time of the procedure

Specialty	Number
General	2
General with interest in vascular surgery	97
General with interest in gastroenterology	18
General with interest in urology	1
General with interest in endocrinology	1
General with interest in breast surgery	1
General with interest in hepatobiliary surgery	1
General with interest in thoracic surgery	1
Vascular	46
Urology	3
Gynaecology	2
Orthopaedic	2
Transplantation	2
Cardiac/thoracic/cardiothoracic	1
Oral/maxillofacial	1
Oncology	1

Table 1.12: Specialty of consultant physician under whose care the patient was at the time of the procedure

Specialty	Number
General with interest in gastroenterology	16
General with interest in renal medicine	8
General with interest in thoracic medicine	6
General with interest in endocrinology	5
General with interest in cardiology	3
General with interest in rheumatology	2
General with interest in paediatrics	1
Gastroenterology	11
Renal medicine	9
Haematology	9
Thoracic medicine	8
Care of the elderly	8
Oncology	6
Endocrinology	3
Cardiology	2
Radiotherapy	1
Pulmonary oncology	1
Palliative care	1

Almost all patients were under the care of the appropriate specialist, such as vascular patients under the care of the vascular surgeons and the patients having TIPS under the care of gastroenterologists. However, there were a few exceptions:

CASE 8 • A 55-year-old patient who was referred by a nephrologist for dilatation of popliteal arterial stenosis. This occluded two days later and the patient was not seen by a vascular surgeon until too late and an amputation was subsequently performed.

CASE 9 • A 76-year-old patient who underwent bilateral external iliac angioplasty and had a retroperitoneal haemorrhage. He was nursed on the general surgical ward and seen only by a senior house officer following the procedure. Although the patient was deteriorating neither a radiologist nor vascular surgeon were called. The problem was not recognised until the patient had a cardiac arrest and a subsequent postmortem was performed (see also page 19).

CASE 10 • An 89-year-old patient suffered a retroperitoneal haematoma following femoral angioplasty performed in a hospital where there was no on-site vascular surgeon (see also page 19).

CASE 11 • An 81-year-old patient with claudication, but no rest pain, had an external iliac stent performed. She was considered to be a high risk because of coexisting medical problems. Because of this combination of factors it was the advisors' view that this was an ill-advised procedure.

Table 1.13: Grade of the most senior doctor who referred the patient

Grade	Number
Consultant	257
Staff grade	1
SpR Accredited/CCST	6
SpR 4	9
SpR 3	8
SpR 2	4
Visiting SpR	2
SHO 2	1
Other	2
Not known	1
Not answered	12
Total	303

It is reassuring to see that the vast majority (85%) of these patients were referred by a consultant. Of those that were not, the majority were referred by reasonably experienced registrars and in no cases were locums involved.

Radiologist's assessment prior to procedure

Grade	Number
Consultant	275
SpR Accredited/CCST	5
SpR 4	5
SpR 3	1
Other	2
None	13
Not answered	2
Total	303

The radiologist should not be seen as a technician who performs interventions when requested, but should assess the patient prior to, and after, the procedure and, where necessary, discuss with the referring clinicians. It was encouraging to see that 275/303 (91%) patients were assessed by a consultant radiologist, but disconcerting that there were 13 patients who were not reviewed by a radiologist prior to the procedure (Table 1.14).

Specialty and seniority of radiologist

Key Point

- *The interventional radiologist should have sufficient experience to perform the procedure safely and to deal with any complications that may arise.*

Specialty	Number
General radiologist with vascular interventional interest	187
Specialist vascular interventional radiologist	101
General radiologist	4
Other	7
Not answered	4
Total	303

In the majority (95%) of cases the most senior radiologist was one with an appropriate special interest in interventional radiology and in only four cases were they designated simply as a 'general radiologist'.

Grade	Number
Consultant	283
SpR Accredited/CCST	9
SpR 4	6
SpR 3	2
SpR 2	1
Not answered	2
Total	303

Question 1.1: If the most senior operator was not a consultant, was a more senior doctor immediately available?

Yes	12
No	4
Not answered	4
Total	20

The majority of procedures were performed by consultants (93%), with some being performed by registrars indicating that training is in progress (Table 1.16). We do not have the evidence as to whether or not this is sufficient for the future number of consultants required. In 12 of these cases a consultant was immediately available and, whilst this is generally good, in four cases there was no consultant available and this is a situation that should not occur. Some examples of problems which may arise are:

CASE 12 • A 69-year-old patient with lower limb ischaemia was undergoing an iliac angioplasty and insertion of stent. The radiologist had done only six similar procedures in the previous year. The external iliac artery ruptured during the procedure and attempts to control the bleeding with a balloon failed. There was a delay in getting the patient to theatre (see also page 20).

CASE 13 • A 57-year-old patient with alcoholic liver disease and oesophageal varices had a failed TIPS because of inability to puncture the portal vein in a small cirrhotic liver. The radiologist had done only two such cases in the previous three years (see also page 23).

CASE 14 • A 67-year-old patient had an attempted renal angioplasty which failed for technical reasons. The radiologist had done only two similar procedures in the last year.

FACILITIES, PERSONNEL AND MONITORING

Dedicated room

Key Point

- *Interventional vascular radiological procedures should be performed in a dedicated interventional room.*

Table 1.17: Location in which the procedure was performed

Location	Number
Dedicated interventional room	276
General fluoroscopy room	24
Other	2
Not answered	1
Total	303

In 276 cases the procedure was performed in a dedicated interventional room while in 24 a general fluoroscopy room was used. It is not satisfactory that 8% of procedures were carried out in a general fluoroscopy room; a dedicated interventional room should be available for all cases.

Equipment

Key Points

- *There should be adequate equipment to perform the procedure safely.*
- *It is the radiologist's responsibility to check the equipment prior to commencing the procedure.*
- *A designated member of the team should be responsible for 'stock-taking'.*

There were examples where lack of equipment resulted in less than ideal treatment being given:

CASE 15 • A 77-year-old patient with a tight renal artery stenosis had a renal angioplasty performed. It was thought that a stent should be used, but none was available.

CASE 16 • A 54-year-old patient with an occluded femorodistal graft had this cleared with thrombolysis. This unmasked a stenosis for which it was felt a 3 or 4 mm balloon would be ideal. However, there was none available and a 5 mm balloon had to be used. Although, in fact, this did not cause any problem it is not an ideal situation.

It is essential that all vascular radiology suites are equipped with the full range of stents, angioplasty balloon catheters and other equipment that may be required. There should be a checklist and a designated member of the team responsible for 'stock-taking'. The radiologist performing the procedure has the ultimate responsibility for ensuring that everything which may be needed is present before commencing each procedure.

Shortage of personnel

Key Point

- *There should be sufficient staff to perform the procedure safely.*

Question 1.2: Was there a shortage of personnel in this case?

Yes	4
No	285
Not answered	14
Total	303

Whilst it is encouraging that there was a shortage of personnel in so few cases it is nevertheless vital, if a high standard is to be maintained, to ensure sufficient staff in all cases. The interventional radiology nurse is an important member of the team.

If yes, which? (4 cases, answers may be multiple)

Consultant radiologist	1
Radiographer	1
Consultant anaesthetist	1
Nurses	2
Porter	1

Delays

Key Point

- *There needs to be a sufficient number of fully-staffed interventional radiology sessions for urgent patients to receive their treatment without delay.*

Question 1.3: Were there any delays (between admission and procedure) due to factors other than clinical?

Yes	11
No	285
Not answered	7
Total	303

Table 1.18: Reasons for non-clinical delay between admission and procedure (11 cases; answers may be multiple)

Reason	Number
Pressure of work	8
Poor communication	2
Shortage of beds	1
Insufficient cover at weekends	1
Vascular radiologist on leave	1
Patient refused	1

Anaesthesia

Question 1.4: Was the procedure performed solely under local anaesthetic or sedation administered by the operator?

Yes	254
No	47
Not answered	2
Total	303

In 254/303 (84%) cases the procedure was performed under local anaesthetic or sedation administered solely by the operator.

An anaesthetist was present for 43 of the procedures and in 30 administered general anaesthesia. In the remainder they were there to administer local anaesthesia and sedation.

Of the 43 anaesthetists, one was an SpR 1, 16 were SpR 3 or higher and twenty were consultants; the grade was not known in the remaining six cases. The X-ray department is a more difficult environment than the operating theatre in which to give an anaesthetic. It is, therefore, inappropriate for an inexperienced anaesthetist to be responsible for such cases.

Monitoring

Key Point

- *Monitoring of pulse oximetry, blood pressure and ECG should be performed during all interventional radiological procedures; this should be done by someone other than the radiologist performing the procedure.*

Table 1.19: Monitoring performed during or immediately after the procedure (303 cases; answers may be multiple)

Monitoring	Number
Pulse	271
Blood pressure	263
Pulse oximetry	239
ECG	108
Other	30
None	19
Not answered	6

Of concern is the fact that in 19 cases no monitoring was performed, as all patients having interventional procedures should be monitored. In addition, there was no monitoring of the pulse in 32 patients, of the blood pressure in 40 patients, of oxygen saturation in 64 patients and the ECG in 195 patients.

Table 1.20: Responsibility for monitoring the patient's general condition during the procedure (303 cases; answers may be multiple)

Person	Number
A nurse	211
The operator	97
An anaesthetist	42
Another doctor	17
A radiographer	16
Not answered	1

In 97 cases monitoring was undertaken by the person performing the interventional radiological procedure. In 60 of these monitoring was also being performed by another member of the team. However, in 37 cases the operator was the only person monitoring the patient, and this is a cause for concern. Interventional procedures are frequently technically demanding and it is not possible for the same person to carry these out and adequately monitor the patient. Radiographers are not trained to perform monitoring, and ideally this should be performed by a nurse or an operating department assistant. An oxygen supply should be

available and if any sedation in the form of benzodiazepines or opioid drugs is used then the specific antagonists should be available (flumazenil or naloxone respectively)¹. In all areas where invasive procedures are performed, there should be resuscitation equipment that is regularly checked and core staff trained and regularly updated in resuscitation.

Care following the procedure

Recovery

Question 1.5: Was there a recovery room/area available attached to the procedure suite?

Yes	210
No	88
Not answered	5
Total	303

It is unsatisfactory that in almost one third (29%) of cases there was no recovery area for patients after their interventional procedure. A recovery area should be available.

Intensive and high dependency care

Key Point

- *These patients may be desperately ill and it is essential that ICU/HDU beds are available when required.*

Forty patients were admitted to an intensive care unit (ICU) and 20 to a high dependency unit (HDU) immediately after their procedure, with a further 18 being admitted to ICU and six to HDU after a period on a routine ward. In the remainder admission to ICU/HDU was not felt necessary, except in three cases where the patient's condition did warrant admission to ICU or HDU, but there was no bed available within the hospital in which the procedure took place:

CASE 7 • A 45-year-old patient with acute on chronic aortoiliac occlusion (see also page 12).

CASE 17 • A 44-year-old patient with alcoholic liver disease, together with haematemesis and melaena due to oesophageal varices, was referred for a TIPS procedure. The patient had to be transferred back to the original hospital after the procedure, as there was no HDU bed available. It would have been more satisfactory to keep him at the same hospital.

CASE 18 • A 57-year-old patient with acute myeloid leukaemia had a Hickman line inserted for administration of chemotherapy. The procedure was uneventful. A week later he developed coagulase-negative septicaemia. A further week later he became seriously ill despite antibiotics. The Hickman line was removed. There was no ICU or HDU bed available so he was nursed on the general medical ward and died three days later.

COMPLICATIONS

Table 1.21: Unexpected procedural complications
(37 cases; answers may be multiple)

Complication	Number
Unable to cross the vascular lesion	6
Embolus/thrombosis of run-off vessels	6
Occlusion of artery during procedure	5
Bleeding/haematoma from groin	3
Rupture of iliac artery	3
Thrombosis of brachial artery when used to approach aortoiliac segment	2
Lack of correct-sized balloon	2
Unexpected cardiac arrest during procedure	2
Internal flap in superficial femoral artery	1
Stroke during carotid angioplasty	1
Patient's rest pain so severe he could not lie still	1
Groin puncture site very painful	1
Extravasation of blood from femoropopliteal segment	1
Myocardial infarction during procedure	1
Severe nose bleed during thrombolysis	1
Coagulopathy during embolisation for blood loss	1
Axillary vein thrombosis during SVC stent (cleared at lysis)	1
Tumour more extensive than realised prior to SVC stent	1
Pneumothorax during insertion of Hickman line	1

In 37 cases there were unanticipated procedural complications; in three of these there were two unexpected complications.

The list of complications in Table 1.21 is typical of those that arise during interventional procedures. The vast majority were unavoidable and dealt with appropriately. There were particular problems in a few cases which are discussed later.

Table 1.22: Postprocedural complications
(303 cases; answers may be multiple)

Complication	Number
Respiratory distress	46
Low cardiac output/other cardiac problems	45
Renal failure	44
Peripheral ischaemia	34
Haemorrhage/postoperative bleeding requiring transfusion or surgical endovascular intervention	31
Cardiac arrest	29
Hepatic failure	25
Generalised sepsis	22
Stroke or other neurological problems	15
Other organ failure	11
Persistent coma	9
Pulmonary embolus	8
Problem with analgesia	6
Nutritional problems	6
Pressure sores	3
Wound infection/dehiscence	1
Endocrine system failure	1
DVT	1
Urinary retention/catheter blockage	1
Other	29
Not answered	110
None	20

With the exception of haemorrhage and postoperative bleeding, which were more common in patients having thrombolysis, there was no obvious correlation between any particular procedures and subsequent complications.

Specific problems

Level of puncture

Key Point

- *Cannulation of the femoral artery should always be below the inguinal ligament to avoid the danger of retroperitoneal haematoma. Medical and nursing staff must be aware of the risks of this serious complication in order to act early when necessary.*

There were several cases where retroperitoneal bleeding occurred:

CASE 9 • A 76-year-old patient who underwent bilateral external iliac angioplasty and had a retroperitoneal haemorrhage (see also page 13).

CASE 10 • An 89-year-old patient had a high femoral puncture in order to perform a superficial femoral artery angioplasty. She developed a massive retroperitoneal haematoma. There was no on-site vascular surgeon on the day of the angioplasty (see also page 13).

CASE 19 • An 83-year-old patient with an acutely ischaemic left leg, due to a left external iliac thrombosis, had thrombolysis followed by balloon angioplasty. Four days later he died and at postmortem was found to have a retroperitoneal haematoma.

Great care must always be taken to keep the level of puncture below the inguinal ligament so that bleeding is recognised immediately. Above the inguinal ligament a very large amount of blood may be lost in the retroperitoneal space and may not be recognised until the patient is clinically in the advanced stages of shock. Elderly patients with heart disease make up quite a high proportion of patients having angioplasties and they do not tolerate blood loss well. If the radiologist or any other clinician is at all suspicious, an ultrasound or CT scan should be performed to confirm and

perhaps monitor the amount of bleeding. It is also essential to warn clinical staff looking after the patient and ensure they are aware of the possibility and dangers of retroperitoneal bleeding. The patient should be nursed on a specialist vascular ward where nurses and medical staff are fully aware of the risk of the possibility of development of retroperitoneal haematoma and its serious consequences. If bleeding does not stop the patient must be taken to theatre to suture the bleeding point before it is too late.

Lower limb revascularisation

Key Points

- *The interventional radiologist should have sufficient experience, facilities and equipment to perform the procedure safely and to deal with any complications that may arise.*
- *It should always be possible to control bleeding of a ruptured iliac artery either temporarily with a balloon catheter or permanently with a covered stent.*
- *A 'rupture box' containing all necessary equipment should be available in every interventional radiology department.*

If angioplasties and stents performed in the iliac, femoral and popliteal arteries are included then a total of 11 692 of these procedures were performed, of whom 101 patients died, giving a mortality of less than 1% (0.9%) (Table 1.6, page 8). Bearing in mind that a significant number of these patients are severe arteriopathies with critical ischaemia, on whom vascular surgeons are not keen to operate, then these results are generally very creditable. However, there was some cause for concern in three cases where the external iliac artery was ruptured during angioplasty.

CASE 12 • A 69-year-old patient had an iliac angioplasty and stent. The artery ruptured, the bleeding was controlled with a balloon, but because of ischaemia was let down again before the patient was taken to theatre! There was a delay of forty minutes in getting the patient to theatre (see also page 14).

CASE 20 • A 74-year-old patient had an external iliac angioplasty which ruptured the artery. No radiological measures were taken to try and control the bleeding. The patient was taken to theatre urgently for iliofemoral bypass.

CASE 21 • A 63-year-old patient having an iliac stent placed had a rupture of the iliac artery with the stent in situ. A covered stent would almost certainly have stopped the bleeding.

These cases illustrate the need for suitable experience and ability of the operator and the availability of equipment. It should be possible to control the bleeding of a ruptured iliac artery permanently with a covered stent and these are

commercially available. If this does not control the bleeding then a balloon should give temporary control until the patient can be taken to theatre, which obviously needs to be done as a matter of great urgency. It is recommended that every interventional radiology department should have a 'rupture box' containing all the necessary equipment, which can be opened at a moment's notice, to deal with this emergency.

The conclusion, therefore, is that angioplasty should not be performed unless the radiologist has the experience to recognise, and ability and equipment to deal with, complications. The immediate help of a vascular surgical team should be available when needed.

Thrombolysis

Key Points

- *There is a danger of cerebral haemorrhage with thrombolytic therapy particularly when used in the elderly (over 75 years) or if too large a dose is given.*
- *Patients having continued thrombolytic therapy after leaving the vascular radiology suite should be nursed on an HDU or specialist vascular ward where there are an adequate number of nurses to monitor them closely.*

Thrombolysis can be extremely useful in dissolving clot that has formed in the blood vessel or graft, but it must be remembered that at best it can merely restore the vessel to the state it was in prior to the thrombus forming. The underlying cause will still need to be treated, for example an arterial thrombosis secondary to a stenosis will need an angioplasty once the thrombus has been cleared. Similarly, in a peripheral arterial embolus, or a deep vein thrombosis, anticoagulation will be needed to prevent further thrombosis. There is a risk of bleeding both locally and at distance, which may include spontaneous retroperitoneal haemorrhage or, more seriously, cerebral haemorrhage. The incidence of minor haemorrhage is about 15%, major haemorrhage about 5%² and haemorrhagic stroke is 1%. Other studies have found the risk of stroke (both haemorrhagic and ischaemic) to be 2.3%³. The risks seem to be greater in patients over 75 years⁴. Although patients with simple emboli and normal peripheral arteries are a rarity, nevertheless where the clinical features strongly suggest an embolus then surgery may give better results, especially in the elderly⁵. The risk of bleeding increases with a larger dose and a longer period of administration. The question of dose has been discussed in detail⁵, but absolute recommendations on drugs and dosage are not possible on available data, although current practice has moved away from the use of streptokinase to rt-PA.

Some examples of problems with thrombolysis include:

CASE 22 • An 87-year-old patient was given thrombolysis for a thrombosed femoropopliteal graft and died due to cerebral haemorrhage.

CASE 23 • An 83-year-old patient having thrombolysis for a thrombosed iliac artery died of cerebral haemorrhage.

There were three other patients aged 84, 87 and 97 years who, although they did not suffer a cerebral haemorrhage, were considered by the advisors to be too old to have treatment by thrombolysis.

There were two further patients in whom it was felt the dose was inappropriate:

CASE 24 • A 77-year-old patient had an ischaemic left arm due to subclavian thrombosis. This was treated with streptokinase 20 000 units per hour and heparin 15 000 units per hour. This was continued for 18 hours when a check angiogram showed only partial thrombolysis. The patient subsequently died of angina and a stroke. No postmortem was performed and therefore it is unknown whether this was a haemorrhagic or thrombotic stroke, but either way the advisors considered that this was too large a dose of streptokinase.

CASE 25 • A 68-year-old patient had thrombolysis for an acute occlusion of the right superficial femoral artery due to an underlying popliteal aneurysm. He was given 50 mg of rt-PA in 5 mg aliquots over a two hour period. One hour later the patient was taken to theatre for a femorodistal bypass. As far as was possible to ascertain from the questionnaire the surgeon was not aware of how large a dose had been given. Certainly the advisors considered that this was too great a dose. The patient died 24 hours later and although postmortem did show some haemorrhage around both puncture sites death was due to peripheral vascular disease.

Although thrombolysis can be very effective, its use does carry significant risks particularly in patients over 75 years, and even more so over the age of 80. However, one needs to bear in mind that surgery for acute ischaemia in elderly patients is also hazardous with a mortality rate of about 30%⁶. Whatever choice of treatment is given it is essential that the patient is warned of the risks of both thrombolysis and surgery, and indeed of not undergoing either. Certainly the risks with thrombolysis are greater the higher the dose used and the longer it is given. Although it is not possible to give absolute guidelines, since there is insufficient data, the advisors considered that the normal dose of streptokinase for continuous infusion should not exceed 5000 units per hour, but that it is probably better to use rt-PA with the dose not normally exceeding 0.5-1.0 mg per hour, although it may be greater if the pulse spray infusion is used⁷.

Patients having thrombolysis need close observation for early detection of any complications and for monitoring the response, so that it is given for the shortest possible time, but also so that an adequate amount has been given to clear the vessel. Therefore they should go to an HDU or specialist vascular ward with an adequate number of nurses to monitor closely, and the easy facility for repeat angiograms as required. Case 7 (see pages 12 and

18) was an example where the advisors thought it would have been preferable to manage the patient on an HDU or ICU. The view of the advisors was that wherever there is ongoing thrombolysis the patient should be nursed on an HDU or a specialist vascular ward.

Embolisation

Key Points

- *If embolisation is to be used for severe persistent bleeding, radiologists should be called sooner rather than later in order to instigate treatment before a serious coagulopathy has developed.*
- *It must be remembered that embolisation to stop bleeding can occasionally cause ischaemic infarction.*

Table 1.6 (page 8) showed that embolisation was used via the internal iliac artery for uterine fibroids, for the treatment of bleeding pelvic fractures, for renal disease, most commonly to reduce the vascularity prior to removing a large tumour, and for gastrointestinal bleeding. Other sites of embolisation included the liver for treatment of secondaries, particularly for carcinoid tumour or AV malformations, and embolisation of the internal mammary artery for haemoptysis due to lung cancer.

When embolisation is used for persistent bleeding, early communication with the vascular radiologist is necessary if embolisation is going to have a chance to be effective before a serious coagulopathy has developed (see case 3 and case 4 on page 12).

Gastrointestinal bleeding can be particularly problematic both to diagnose where the bleeding is coming from and to treat adequately. Embolisation can be extremely useful, but the following illustrate the problems that can occur:

CASE 26 • A 78-year-old patient with severe colonic bleeding was treated with selective Sterispon embolisation which successfully stopped the bleeding. The radiologist wrote in the notes: 'There is a risk of colonic infarction following this procedure and the patient should be closely observed for signs of this.' Colonic infarction did indeed develop and the patient required a laparotomy to remove ischaemic bowel on the following day.

CASE 27 • A 74-year-old patient with persistent bleeding from a duodenal ulcer was treated with coil embolisation of the pancreaticoduodenal arteries. This controlled the bleeding, but 13 days later the duodenum perforated and it was thought that ischaemia had played a part in this.

CASE 28 • A 67-year-old patient had a Whipples operation which was complicated by a pancreatic leak, sepsis and a subsequent false aneurysm of the hepatic artery which bled. This was treated by coil embolisation controlling the bleeding. The patient died a few days later of multiple organ failure which was thought to be due to sepsis, although in fact postmortem examination showed hepatic necrosis.

CASE 29 • A 51-year-old patient had embolisation for bleeding uterine fibroids. The ischaemic uterus became infected and the patient subsequently died.

While embolisation is an extremely useful therapeutic measure⁸ it must be remembered that it can cut off the blood supply to the affected area sufficiently to cause ischaemic necrosis. It is important to be aware of this possibility and recognise and treat it early if it should occur.

SVC stent

Two hundred and sixty-six of these were performed and seventeen of the patients died (6%). These procedures are performed for advanced malignancy which has obstructed the superior vena cava causing venous engorgement of the upper half of the body. In all these cases it was thought that death was due to the underlying disease, and that SVC stenting is a useful therapeutic measure⁹.

Central venous access

Over 3000 of these were performed, for haemodialysis, the administration of chemotherapy for malignancy or for long-term intravenous feeding. Of the 36 patients who died, one had a pneumothorax, which was felt to have contributed to the patient's death. In all the remainder it was considered that death was due to the underlying disease. Thus, this is a very safe procedure in the hands of a radiologist.

Transjugular intrahepatic portosystemic shunt (TIPS)

Acute variceal bleeding which fails to respond to medical management remains the primary indication for TIPS and accounts for over 80% of cases performed. Most of these patients are desperately ill and operating on them is almost always more hazardous^{10,11}. Of the 158 cases performed, 27 patients died (17%). Bearing in mind the very serious nature of the disease these were felt to be acceptable results. It has, however, been suggested that centres undertaking less than five cases per year are unlikely to achieve the required expertise¹¹; this does argue for referral of patients to centres with a large experience of these procedures. Case 13 (see page 14) reinforces this point.

DVT prophylaxis

Question 1.6: Were any measures taken (before, during or after the procedure) to prevent venous thromboembolism?

Yes	115
No	169
Not answered	18
Not known	1
Total	303

Bearing in mind that most of these patients were middle-aged or elderly, with a significant number of other medical problems, and the majority of them generally unfit as judged by the ASA grade, according to the THRIFT¹² they should probably all have had some form of DVT prophylaxis, mainly subcutaneous heparin. However, the advisors were not unanimous on this, particularly bearing in mind that many diagnostic angiograms are performed as day cases.

POSTMORTEM EXAMINATIONS

Key Point

- *In one in eight of the postmortems performed the pathological finding was different from that expected by the clinical team. This surely must have educational benefit and is the reason why more postmortems should be performed.*

Ninety-six of the 303 deaths were reported to the coroner and of these 58 had a coroner's postmortem performed. Of the remaining 245 cases, only 15 patients had a hospital postmortem. Of the 73 postmortems performed, in only seven did a radiologist attend and in only four did another clinician do so. A copy of the postmortem report was only received by the team in 37/73 (51%) cases.

Question 1.7: Did the pathological information confirm the team's clinical impression?

Yes	56
No	8
None received	2
Not answered	6
Not known	1
Total	73

In eight out of the 64 cases on which this information was available, the pathological finding at postmortem was different from that which the clinical team was expecting. The details are as follows:

CASE 28 • A 67-year-old patient had embolisation to control bleeding from the hepatic artery. Postmortem showed unsuspected hepatic necrosis (see also page 22).

CASE 30 • A 60-year-old patient had embolisation for hepatic metastases. He was thought to have died as a result of this but postmortem showed death was due to an unsuspected haemorrhage into a cerebral metastasis.

CASE 31 • A 60-year-old patient was thought to have carcinoma of the colon and heart failure. At postmortem she was found to have ischaemic colitis and death was due to a pulmonary embolism caused by a DVT.

CASE 32 • A 69-year-old patient was admitted with a femoral vein thrombosis. She was treated with heparin which had to be stopped when she had a gastrointestinal bleed. An IVC filter was inserted. She was thought to have died from gastrointestinal bleeding but at postmortem no source could be found. There was a DVT of the left leg and an old pulmonary embolus, but death was caused by acute myocardial ischaemia due to coronary artery atheroma with plaque rupture.

CASE 33 • A 76-year-old patient had a stent for renal artery stenosis. Despite having heparin prophylaxis he was thought to have died from pulmonary embolism. Postmortem showed no evidence of an embolus, and death was due to congestive cardiac failure due to myocardial infarction.

CASE 34 • A 67-year-old patient had a stent and thrombolysis for SVC thrombosis secondary to enlarged mediastinal lymph nodes thought to be due to a bronchogenic carcinoma or possibly a lymphoma. Postmortem showed no evidence of either but death was due to metastases of intestinal origin.

CASE 35 • A 63-year-old patient had a stent for SVC obstruction due to mediastinal lymphadenopathy. He was given dexamethasone. Two days later he died of circulatory collapse. Postmortem showed death was due to peritonitis caused by a completely unsuspected perforated duodenal ulcer.

CASE 36 • An 87-year-old patient had a popliteal angioplasty for a critically ischaemic leg. Death was thought to be due to sepsis from the ischaemic limb, but postmortem showed it was caused by peritonitis due to a perforated duodenal ulcer.

These cases illustrate why postmortem examinations need to be performed more frequently.

AUDIT AND AVAILABILITY OF PATIENT RECORDS

Key Point

- *It is as important for radiologists to assess and audit their results as it is for other clinical staff.*

It is disappointing that in only 125/303 (41%) cases was the patient's death discussed at a local audit or quality control meeting. The figure should be very much higher. The need for radiologists to assess and audit their results is every bit as important as it is for other clinical staff.

It was also disappointing that in 82/303 (27%) cases there was difficulty in obtaining the patient's notes and in 64 cases (21%) either notes or images were unavailable. The most common problem was finding the death certificate (43 cases) and other problems included obtaining a postmortem report (14 cases), postprocedure notes (12 cases) and the images (10 cases). With the introduction of clinical governance it is to be hoped that the systems will be in place for all notes and other information to be readily available.

