2 INTERVENTIONAL NEUROVASCULAR RADIOLOGY

RECOMMENDATIONS

- The number of neuroradiologists and support staff needs to increase to ensure a satisfactory on-call rota, including weekends (page 36).
- There is a need for recognised training programmes in neuroradiology to meet the demand for more consultants (page 36).
- Monitoring of the patient should be performed in all cases, and should be the responsibility of someone other than the neuroradiologist performing the procedure (page 38).
- It is important that there are sufficient facilities for a prompt emergency service, and ICU/HDU beds for subsequent care (pages 36, 39).





2. Interventional neurovascular radiology

INTRODUCTION

Key Points

- In all cases the procedures were performed by appropriately experienced specialists and there was a high standard of care.
- By far the most common condition was subarachnoid haemorrhage due to intracranial aneurysm, treated by detachable coils.
- Use of these techniques has developed from almost none in 1992, to over 800 patients a year, with very little increase in staff or facilities.
- The majority of patients are otherwise medically fit with good long-term outlook after successful treatment.
- Patients who survive an initial subarachnoid haemorrhage have an increasing risk of a further bleed as each day passes; treatment is therefore a matter of urgency.

This is an important study, being the first time an audit of deaths has been carried out for this specialty.

Over the past two decades or more, interventional neurovascular radiology has become an important and sophisticated specialty in its own right. It has benefited from the same advances in technology as coronary angioplasty and peripheral vascular interventional radiology. The specialty has developed with the close cooperation of neurosurgeons and neurologists and requires the full neuroscience support team, including other disciplines. In particular, access to high dependency and intensive care units is needed every bit as much as these facilities are required after neurosurgery.

The most common problem is the prevention of further bleeding from subarachnoid haemorrhage (SAH) in patients with intracranial aneurysms. Arteriovenous malformations (AVMs) of the brain are a less common cause of cerebral haemorrhage. These conditions are treated by embolisation which may be by the use of detachable coils for aneurysms, or the tissue adhesive N butyl cyanoacrylate (Histoacryl or NBCA), or newer liquid embolic agents which are just becoming available, for AVMs. The liquid agents such as cyanoacrylates have the advantage that they permeate into very small vessels and reach far distally, thus enabling occlusion of the nidus of the malformation on a permanent basis. A number of ingenious devices have been invented which enable, for example, the coils to stay attached until they are in precisely the correct position and then released. The most notable is the Guglielmi detachable platinum microcoil (GDC) which is

soldered at the end of an insulated stainless-steel guidewire and is detached by passing a current through it which causes electrolysis of the exposed detachment zone^{13,14}.

The method of embolisation that is used depends on the precise detail of the vasculature to be embolised and the amount of risk there is to the surrounding normal tissue. Embolisation may also be used for cerebral tumours.

Vasospasm of the cerebral vessels occurs in about 20% of patients following aneurysmal haemorrhage. Treatment for this may take the form of either super-selective injection of papaverine or of angioplasty to the cerebral vessel in spasm, or a combination of both.

Cerebrovascular occlusive disease may be treated by angioplasty, or angioplasty and stent, and thrombotic disease may be treated by thrombolysis.

When thrombolysis is used for cerebral vascular thrombosis, it runs all the same risks as it does elsewhere of causing haemorrhage both locally where it is applied and at a distance. It is particularly likely to cause a problem if used for thromboembolic complications following treatment for SAH due to intracranial aneurysm and should be used with great caution, particularly under these circumstances.



DATA COLLECTION

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

Information on the total number of patients undergoing interventional neurovascular 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

27 hospitals agreed to participate in the study. Each hospital was required to send in a monthly return of all patients undergoing interventional neurovascular radiological procedures in the hospital. A total of 324 forms should therefore have been received. The return rate of monthly data is shown in Figure 2.1.

A regional breakdown of the number of monthly forms received is given in Table 2.1. The return rate of monthly forms was excellent; only North Thames (75%) and North West (89%) failed to achieve complete returns.

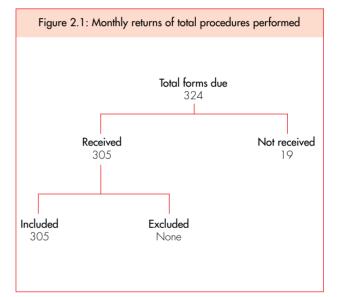


Table 2.1: Monthly returns by region				
Region	Number of participating hospitals	Monthly forms received	Monthly forms expected	Return rate
Anglia & Oxford	2	24	24	100%
North Thames	6	54	72	75%
North West	3	32	36	89%
Northern & Yorkshire	4	48	48	100%
South & West	2	24	24	100%
South Thames	3	36	36	100%
Trent	2	24	24	100%
West Midlands	1	12	12	100%
Wales	1	12	12	100%
Northern Ireland	1	12	12	100%
Scotland	2	24	24	100%

Neurovascular Radiolog

Reported deaths

Figure 2.2 shows that a total of 41 reports of deaths within 30 days of a procedure were received. Of these, two were excluded from further analysis: one was received after the deadline of 31 August 1999 and one remained incomplete despite all efforts to identify missing information.

A regional breakdown of the 39 included deaths is shown in Table 2.2.

The differences in numbers of deaths reported by each region reflects the total number of procedures undertaken, together with the completeness of the data submitted.

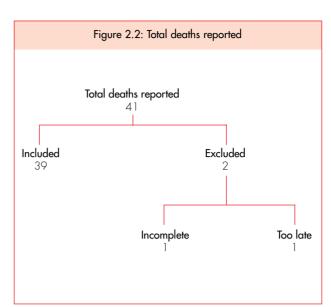


Table 2.2: Deaths reported to NCEPO	D by region
Region	Deaths reported
Anglia & Oxford	8
North Thames	0
North West	6
Northern & Yorkshire	7
South & West	2
South Thames	4
Trent	4
West Midlands	1
Wales	1
Northern Ireland	2
Scotland	4
Total	39



Distribution of deaths

Key Points

- The majority of patients who died did so within a week of the procedure as a direct result of subarachnoid haemorrhage.
- The peak age groups were between 30 and 60 years with equal sex distribution.

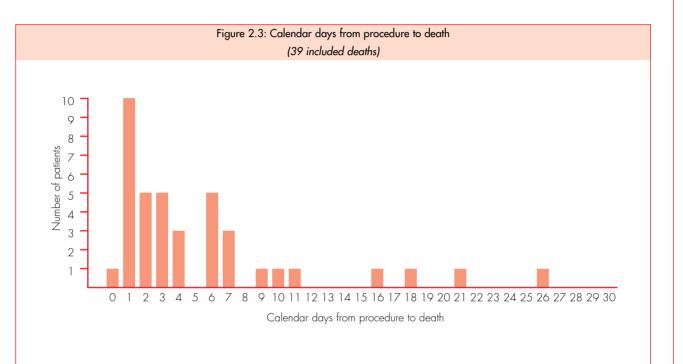
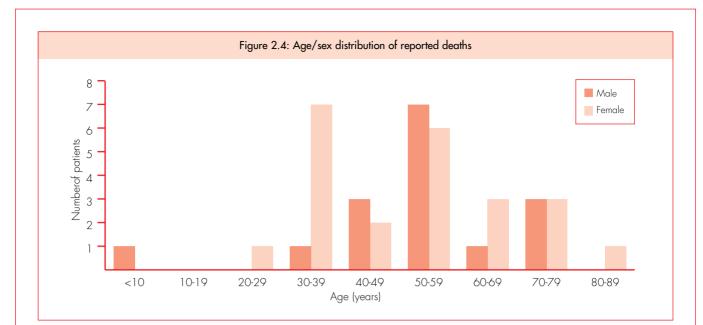


Figure 2.3 shows the distribution of the number of calendar days between procedure (day 0) and death. It is interesting to note that the majority of deaths occurred in the first few days following neurovascular procedures and there are very few deaths after more than a week. This is in contrast to Figure 1.3 on page 6 showing the distribution of deaths following interventional vascular radiological procedures where there is a wider spread over the month following the procedure. This is presumably because neurovascular patients die as a result of their intracranial haemorrhage, whereas the interventional vascular patients die as a result of their coexisting medical conditions.

It is interesting to note from Figure 2.4 how much younger these patients are on average than those having interventional vascular radiology (see Figure 1.4 on page 6). The vascular patients also have an obvious preponderance of males whereas there is no such difference in the neurovascular patients.

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Distribution, return and analysis of questionnaires

Questionnaires were sent to the consultant radiologist responsible for the care of each of the 39 patients included. Figure 2.5 shows the return and analysis rates of questionnaires sent.

The return rate of 92% was excellent; in two cases the radiologist indicated that he/she was too busy to complete the questionnaire and the third gave no reason for failing to return the form. It was not necessary to exclude any questionnaires from subsequent analysis.

Table 2.3 shows the returns by region and the majority achieved a 100% return rate; indeed the overall return rate of 92% was due to a nil return rate from South & West and West Midlands.

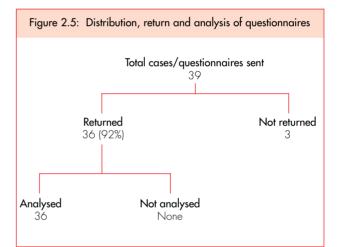


Table 2.3: Regional distribution and return rates			
Region	Questionnaires distributed	Questionnaires returned	Return rate
Anglia & Oxford	8	8	100%
North Thames	0	0	-
North West	6	6	100%
Northern & Yorkshire	7	7	100%
South & West	2	0	-
South Thames	4	4	100%
Trent	4	4	100%
West Midlands	1	0	-
Wales	1	1	100%
Northern Ireland	2	2	100%
Scotland	4	4	100%
Total	39	36	92%



Procedures

Key Points

- By far the most common condition was subarachnoid haemorrhage due to intracranial aneurysm treated by detachable coils.
- A mortality rate of approximately 3% for detachable coil treatment is low considering the very serious nature of the disease.

	Table 2.4 Neurov	rascular interventions			
Condition	Procedure		Total performed	De	aths
Aneurysm	Endosaccular occlusion	GDC	802	25	(3%)
		Other coils	7		-
	Parent vessel occlusion		75	5	(7%)
	Spasm	Papaverine	24		-
		Angioplasty	0		-
		Papaverine + angioplasty	1		-
	Thrombolysis		7		-
Arteriovenous malformation (AVM)	Brain	Pial AVM	293		-
		Dural AVM	40		-
		CC fistula	30	1	(3%)
		Vein of Galen malformation	21		-
		Other	12		-
	Craniofacial		23		-
	Spine	Dural	28		-
		Other	16		-
Tumour	Brain		84		-
	Head & neck		42		-
	Spine		20		-
Cerebrovascular disease	Occlusive disease	Angioplasty + stent	32	2	(6%)
	Thrombotic disease	Arterial thrombolysis	10	2	(20%)
		Venous thrombolysis	3	1	(33%)
Other			46		-
Total			1616	36	(2%)

Table 2.4 shows that by far the greatest number of procedures performed, and subsequent deaths, were for occlusion of aneurysms. It should be noted that AVMs usually require several treatments over a period of months, therefore exaggerating their numbers, whereas aneurysms are usually only treated once. The overall mortality rate is low for a serious disease where the clinical grade of the patient is a major factor in the outcome.



PATIENT PROFILE

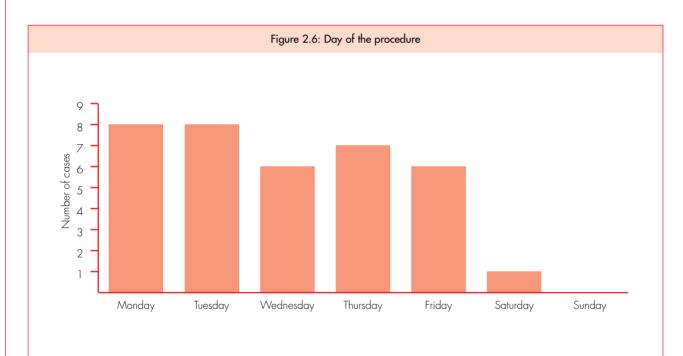
The report hereafter deals only with those patients who died.

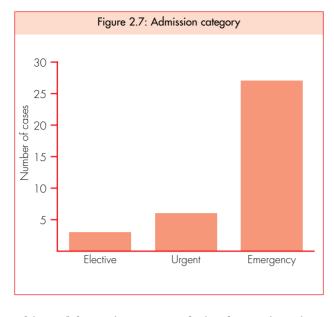
Urgency of procedure

Key Points

- Patients who survive a subarachnoid haemorrhage have a 4% risk of a further bleed in the first 24 hours and a 1% risk per day thereafter.
- The majority of patients were treated as emergency or urgent cases.
- Detachable coils were introduced to the UK in 1992 and their use has risen from none to over 800 patients treated in a year.

Following a subarachnoid haemorrhage the likelihood of a further bleed is 4% in the first 24 hours and thereafter 1% per day¹⁵. It is, therefore, very important that patients are treated urgently.





Thirty of the patients were admitted as an inpatient from another acute hospital or directly from the A&E department, and the majority were admitted to a neurosurgery ward, ICU or HDU under the care of a neurosurgeon. In no patient was there thought to be a deterioration in their condition during transfer, but in two patients there was a delay in referral or admission, though details are lacking. In a further two patients there were delays between admission and procedure, due to factors other than clinical ones:

CASE 1 • A 59-year-old patient with a subarachnoid haemorrhage was delayed three days for GDC embolisation of her aneurysm due to the heavy workload caused by other patients. The patient died from rupture of the aneurysm during the procedure. This is a recognised complication of this procedure and not related to the delay.

CASE 2 • A 56-year-old patient with a subarachnoid haemorrhage was delayed due to a shortage of anaesthetic and nursing staff at the weekend. Death was due to rebleed because of incomplete coil occlusion, and therefore not caused by the delay.

Fitness of the patient

Key Points

- Comorbidities are relatively low when compared with vascular radiology or general surgical patients and probably represent those in the general population of equivalent age.
- The prognosis depends on the neurological grading based on the Glasgow Coma Scale (GCS) rather than the ASA grade.

The majority of neurovascular patients were generally fairly fit when compared with, for example, the large number of comorbidities found in the interventional vascular radiology group (see Table 1.9, page 11) or many general surgical patients¹⁶.

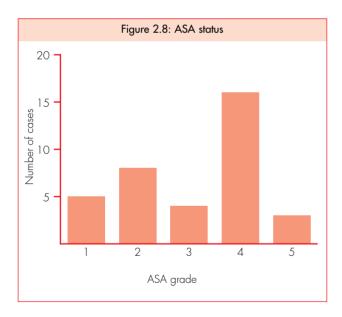
There has been an enormous increase in the workload of interventional neuroradiologists over the last ten years, mainly due to the introduction of the Guglielmi detachable coil (GDC). Their use has risen from none prior to 1992, when they were first marketed in the UK, to over 800 in the last year, and yet there has been very little increase in the number of neuroradiologists or support staff. Most of this work is urgent or emergency and there is some evidence from this study that this is having an adverse effect on the service provided, particularly in relation to weekend work. The advisors considered that this is a very real problem and considerably greater than the evidence in this report would suggest. A possible short-term solution would be sharing emergency cover, particularly at weekends, with neighbouring units. In many places this is not possible for geographical reasons. The only satisfactory long-term solution is for a steady and progressive increase in staff, which will take time due training implications to for neuroradiologists and support staff. There is a need for recognised training programmes in neuroradiology to be set up in order to meet the consultant expansion which is needed.

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Coexisting problems (other than the main diagnosis) existed in 14/36 (39%) patients and these are shown in Table 2.5.

Table 2.5: Coexisting medical problems (14 cases; answers may be multiple)	
Coexisting medical problem	Number
Respiratory	8
Cardiac	4
Vascular	4
Musculoskeletal	2
Psychiatric	2
Sepsis	2
Alcohol-related problems	1
Diabetes mellitus	1
Malignancy	1
Neurological	1
Renal	1

Figure 2.8 shows the ASA status of the patients; details of assessment of ASA status are given on page 11.



Thirteen patients (36%) were graded 1 or 2 and most of those in ASA grades 4 and 5 were so graded because of a poor level of consciousness rather than because of cardiovascular or respiratory problems. Although assessed routinely by anaesthetists the ASA grade is not normally used by neuroradiologists, who are far more concerned with the level of consciousness as measured by the Glasgow Coma Scale (GCS). Table 2.6 shows the World Federation of Neurological Surgeons (WFNS) grading scale that is used following SAH; it is based on the Glasgow Coma Scale.

Table 2.6: Modified Glasgow Coma Scale (GCS)			
GCS	WFNS grade	Number	
GCS 15	Grade 1	14	
GCS 14-13	Grade 2	9	
GCS 14-13+motor deficit	Grade 3	3	
GCS 12-7	Grade 4	4	
GCS 6-3	Grade 5	6	
Total		36	

This classification is a useful prognostic indicator as the first two have a good prognosis, with a procedure related mortality of 5-10%, whereas the lower three have a poor prognosis with a mortality of 40-50% following treatment. Without treatment the overall mortality at six months is $50\%^{17}$.

The outlook for patients undergoing neuroradiological intervention depends on their GCS rather than their previous medical condition. Prior to their SAH most of the patients are as fit and well as the general population, and following successful treatment return to a near-normal life expectancy. This makes it particularly important that the facilities for their treatment are as good as it is possible to be.





FACILITIES, PERSONNEL AND MONITORING

Key Point

• All procedures were performed by appropriately experienced specialists in a dedicated interventional room.

Seniority and specialty of the radiologist

Thirty-five out of the 36 cases were performed by a consultant and one by a specialist registrar with a CCST, with a consultant present.

Table 2.7: Specialty of the most senior radiologist present	
Specialty	Number
Specialist neuroradiologist	33
Specialist interventional vascular radiologist	1
Neurosurgeon with training in radiology	1
Not stated	1
Total	36

Table 2.7 shows that in all cases there was an appropriately experienced specialist present.

Dedicated room

All cases were performed in a dedicated interventional room.

Monitoring

All patients had monitoring of their pulse, blood pressure and pulse oximetry; 34 had ECG monitoring. Thirty-one patients had a general anaesthetic, three received local anaesthetic with sedation and two had local anaesthetic alone. administered by the radiologist. In all 34 cases where an anaesthetist was present they monitored the patient. Of the two cases performed under local anaesthetic, in one the monitoring was done by a nurse and in the other by the neuroradiologist performing the procedure. The latter is unacceptable as monitoring should be performed by a member of the team who is not preoccupied with what may be the very demanding technicalities of the procedure.

Anaesthesia

Thirty-one out of the 36 procedures were performed under general anaesthetic and three under sedation administered by an anaesthetist. In 27 of these 34 cases, the anaesthetist was a consultant and in a further four the anaesthetist was an accredited specialist registrar. In two cases the anaesthetist was an SpR 4 and in one an SpR 3. Thus in all cases the anaesthetist was appropriately experienced.

Question 2.1: Was there non-medical help with anaesthesia?

Yes	
No	
Not answered	
Total	

If yes, who (30 cases; answers may be multiple)

Radiographer	1
Trained anaesthetic nurse	
Trained operating department assistant	
Operating department orderly	7
Other	

In five cases the anaesthetist did not have a trained assistant; one should be available for all patients having a general anaesthetic. This is particularly important in the X-ray department being a more difficult environment than the operating theatre and distant from other immediate anaesthetic assistance.

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Care following the procedure

Intensive and high dependency care

Key Point

• It is essential that ICU/HDU beds are available for neurovascular radiological patients, in whom there is an ever-present danger of the development of serious complications.

Twenty-one patients were admitted to an intensive care unit (ICU) and nine to a high dependency unit (HDU) immediately after their procedure, with a further four being admitted to ICU after a period on the ward. One patient, a child of 18 months, was transferred to another hospital which had a paediatric intensive care unit, and a further case was managed on a neurosurgical ward:

CASE 3 • A 71-year-old patient had a subarachnoid haemorrhage treated by GDCs and developed severe vasospasm. There was no ICU or HDU bed available and he had to be transferred back to the neurosurgical ward.

Vasospasm is a very serious condition which may require a combination of hypervolaemia, hypertension and haemodilution (Triple H therapy). Only on an HDU can this be done adequately or, if the patient needs ventilation, an ICU bed is required.

It is essential that ICU/HDU beds are available for the postprocedure care of these patients in whom there is an ever-present danger of serious complications occurring and, therefore, a need for specialist intensive care.

COMPLICATIONS

Table 2.8: Postprocedural complications (36 cases; answers may be multiple)	
Complication	Number
Cerebral oedema	10
Haemorrhage from aneurysm	8
Thromboembolic event (CNS)	8
Persistent coma	6
Respiratory distress	5
Haemorrhage from other causes	3
Migration of coils or other embolic agents	3
Hydrocephalus	2
Low cardiac output/other cardiac problems	2
Other organ failure	2
Generalised sepsis	1
Other	8
Not answered	2
None	1

Many of the complications shown in Table 2.8 are, or may be, related to the initial pathology, e.g. hydrocephalus, cerebral oedema or persistent coma. The main problems were CNS thromboembolic events and haemorrhage from an aneurysm, both of which may result in brain oedema and persistent coma, the other two common complications listed. Systemic heparin is normally given to prevent these CNS thromboembolic events, and in 32 patients this was monitored using the Activated Clotting Time (ACT), while in two heparin was given with no monitoring. In addition, three had aspirin, one had another antiplatelet agent and only two had no treatment aimed at preventing thromboembolic problems. Several patients were given thrombolysis following a thromboembolic complication and then subsequently had a further fatal rebleed.

The advisors' view was that patients should normally be given systemic anticoagulation (heparin) during these procedures, and that the dose should be monitored using the ACT. Patients who have bled from an intracranial aneurysm should not normally be given thrombolysis, even if they do develop CNS thromboembolic complications, because of the risk of a further bleed although, at present, there is insufficient data to rule out this mode of treatment completely. It was also thought by the advisors that specific antiplatelet therapy should be given, although there is no systematic data to support either this or the monitoring with ACT.

Of those complications described as 'other', six were patients who developed cerebral vasospasm. This was due to the initial disease, rather than a complication of the procedure itself.



POSTMORTEM EXAMINATIONS

Key Point

• Two out of seven postmortem examinations did not confirm the clinical team's impression; it is for this reason that more postmortem examinations are recommended.

Twenty-eight of the 36 deaths were reported to the coroner and of these three had a coroner's postmortem performed. Of the remaining 33 cases, only six patients had a hospital postmortem. Of the nine postmortems performed, a radiologist attended in seven cases. The team received a copy of the postmortem report in six of the nine cases.

Question 2.2: Did the pathological information confirm the team's clinical impression?

Yes	5
No	2
Not answered	
Total	9

Table 2.9: Specialty of the pathologist who performed the postmortem examination	
Specialty	Number
General histopathologist	4
Neuropathologist	3
Home Office histopathologist	1
Not answered	1
Total	9

The postmortem rate was low, though slightly higher than for surgical specialties previously cited by NCEPOD¹⁸. The attendance of radiologists was commendable. It is interesting that in two out of seven cases the postmortem did not confirm the team's clinical impression:

CASE 4 • A 36-year-old patient had a GDC to a large berry aneurysm of the internal carotid artery. She developed a cerebral thrombosis from which she died. The neuroradiologist thought the coil had impinged on the lumen of the internal carotid artery, but the postmortem showed it was in perfect position.

CASE 5 • A 57-year-old patient had an uncomplicated embolisation of an anterior communicating aneurysm which had bled. He was allowed home a week later but was readmitted after two days with confusion and agitation. It was thought that the coil had prolapsed back into the parent vessel although a CT scan showed no focal ischaemia. He deteriorated and died and postmortem showed death was caused by acute pulmonary oedema due to coronary artery disease.

These cases illustrate the reason why postmortems are recommended.

Specialist neuropathologists are few in number and it is not surprising that they only performed a third of the postmortems; ideally they should be doing the majority.

AUDIT AND QUALITY

Audit

In 22/36 (61%) cases the death was discussed at an audit meeting; it was felt that all should be considered, highlighting those to be discussed in detail.

Quality of questionnaires

A case summary was written in 34/36 (94%) questionnaires returned. In 33 the general standard of filling in the forms was good; a further two were felt to be fair and one mediocre. None were considered to be really poor.

Standard of care

In 34/36 (94%) cases the standard of care was felt to be adequate and appropriate. In two cases there was cause for concern. One was a patient who had endovascular coiling for a subarachnoid haemorrhage, developed postprocedure vasospasm and whose general condition was deteriorating; there was no ICU or HDU bed and this lack was felt to contribute to the death of the patient.

The other was an overweight patient having embolisation of an aneurysm who developed a serious groin haematoma. There was a delay in recognising this and during the subsequent surgical repair of the femoral artery the patient suffered hypovolaemia which caused an exaggeration of the cerebral state. The use of newer arterial closure devices to secure haemostasis after femoral puncture should be considered in patients at a high risk of serious groin haematoma¹⁹. It is obviously important that the staff caring for these patients are aware of the risk of groin haematoma and should be observing carefully for it so that appropriate timely treatment can be given.

40 ENATIONAL EPOD