SUMMARY

Significant advances in interventional techniques, particularly in vascular and neurovascular radiology, in the last decade led NCEPOD to explore the morbidity and mortality associated with such procedures. This report not only highlights the frequency with which these procedures are now being carried out, but also the safety of such techniques, recognising that the patients in question are frequently seriously ill, such that minor complications can have various serious outcomes. The increasing demand for interventional procedures of this type is as yet unmet by the number of consultant vascular radiologists and neurovascular radiologists who are available to satisfy that need.

These studies were also the first by NCEPOD to collect denominator data on the total number of procedures performed, as well as details of those patients who died, allowing the calculation of mortality rates.

Recommendations for Interventional Vascular Radiology

- *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.*
- *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.*
- *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.*
- *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.*
- *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.*

Recommendations for Interventional Neurovascular Radiology

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

Interventional Vascular Radiology

and

Interventional Neurovascular Radiology

A Report of the National Confidential Enquiry into Perioperative Deaths

SUMMARY OF THE REPORT PUBLISHED ON 21ST NOVEMBER 2000

NATIONAL CEPOD

Interventional Vascular Radiology

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. As these procedures can be done under local anaesthetic, usually with minimal upset to the patient, less fit patients, who would not be well enough to undergo a formal surgical operation, can be treated. 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 and analysis

Data were requested from all NHS hospitals undertaking these procedures in England, Scotland, Wales, Northern Ireland, Guernsey and Jersey. Participation was voluntary and 154 hospitals agreed to take part in the study. 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.

Procedures performed and deaths reported

Just over 21 000 procedures (21 112) were performed, giving a mean of 137 procedures per centre. A total of 476 reports of deaths within 30 days of the procedure were received.

The most common procedures were balloon angioplasty, of which nearly 12 000 were performed (primarily in the iliac, femoral and popliteal arteries) and stents, of which there were more than 1800 (1200 in the iliac artery); the mortality for these two procedures was 1%.

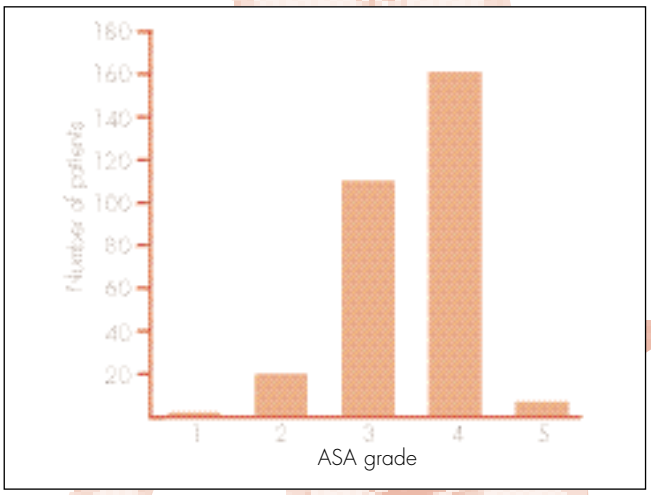
Intra-arterial thrombolysis was performed in nearly 1200 patients, primarily in lower limb vessels, with a mortality of 4%. Arterial embolisation was performed in over 1000 patients with a mortality of 2%. Endovascular stenting of abdominal aortic aneurysm was excluded from the study.

There were far fewer endovascular procedures for venous disease; of 247 angioplasties the majority were in the brachiocephalic or subclavian veins (mortality <1%) and 266 stents were performed for superior vena cava obstruction with a mortality rate of 6%. Ninety-seven venous thrombolysis procedures were performed; the mortality rate of 4% was identical to that for arterial thrombolysis.

Other procedures included the following: central venous access, of which more than 3000 were performed with a 30-day mortality of 1%; inferior vena cava filters, of which 500 were inserted for recurrent pulmonary emboli with a 3% mortality in this very seriously ill group of patients; transjugular intrahepatic portosystemic shunts (TIPS), of which 158 were performed with a mortality rate of 17% in a group of patients who are desperately ill with life threatening bleeding from oesophageal varices.

Patient profile

The majority of those patients who died were over 60 years of age with a preponderance of males. Ninety-two percent of patients who died were ASA grade 3 or higher and 88% had coexisting medical conditions.



The radiologist

There was very high consultant input by radiologists of appropriate specialisation and experience with the vast majority of procedures being performed to a high standard. There was evidence of supervised training of registrars, although it is not known whether this is adequate for the future number of consultants required. It is essential that vascular radiologists and surgeons work together as a team and interventional radiologists should have sufficient experience, facilities, equipment and personnel to perform the procedure safely and to deal with any complications that may arise. There needs to be a sufficient number of fully-staffed interventional radiology sessions for urgent patients to receive their treatment without delay.

Monitoring

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.

Postprocedural care

In almost one third of cases there was no recovery area for patients after the procedure; this facility should be available.

As in so many specialties there were examples where intensive or high dependency care beds were not available; these patients may be desperately ill and it is essential that these facilities are available when required.

Postmortem examinations

A total of 73 postmortem examinations were performed, of which 58 were coroner's postmortems. In only seven cases did a radiologist attend and in four instances another clinician. A copy of the postmortem report was received by the clinical team in only half the cases.

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.

Audit

In only 41% of cases was the patient's death discussed at a local audit or quality control meeting. It is as important for radiologists to assess and audit their results as it is for other clinical staff.

Other selected key points

- *Retroperitoneal haematoma* Cannulation of the femoral artery should always be below the inguinal ligament to avoid the danger of retroperitoneal haematoma. Radiologists, together with medical and nursing staff responsible for patients after the procedure, must be aware of the risks of this serious complication in order to prevent it occurring or, when necessary, to diagnosis and treat it early.
- *Lower limb revascularisation* 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.
- *Thrombolysis* Although a very useful procedure, there is a significant risk of bleeding locally and at a distance. 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 need close observation to detect complications and to monitor the response, so that thrombolysis is given for the shortest possible time to clear the vessel adequately. Whenever intra-arterial thrombolysis needs to continue after the patient leaves the radiology department they should be monitored on a high dependency unit or specialist vascular ward, where there are an adequate number of appropriately trained nurses.
- *Embolisation* This is particularly useful for persistent bleeding as well as for treatment of some tumours, and for AV malformations. If embolisation is to be used for severe persistent bleeding, radiologists should be called early 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.
- *SVC stents* Two hundred and sixty-six superior vena cava (SVC) stents were performed for advanced malignancy causing obstruction of the superior vena cava with venous engorgement of the upper half of the body; none of the 17 deaths reported were caused by the procedure but were due to the underlying disease.
- *Central venous access* Over 3000 procedures to gain central venous access were performed for haemodialysis, administration of chemotherapy for malignancy or for long-term intravenous feeding. Of the 36 patients who died, one had a pneumothorax, which was thought to have contributed to their death. In the remainder death was due to the underlying disease, indicating the safety of the 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. These patients are desperately ill and the fact that 83% of patients in this study survived the procedure is very creditable. These are technically difficult procedures and centres undertaking less than five cases per year are unlikely to achieve the required expertise, arguing for the referral of patients to specialised units with a greater experience.

Interventional Neurovascular Radiology

Over the past two decades or more, interventional neurovascular radiology has become an important and sophisticated specialty in its own right and has benefited from the same advances in technology as 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.

Data collection and analysis

Data were requested from all NHS hospitals undertaking these procedures in England, Scotland, Wales and Northern Ireland. Participation was voluntary and 27 hospitals agreed to take part in the study. 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.

Procedures performed and deaths reported

A total of 1616 procedures were performed and 41 reports of deaths within 30 days of the procedure were received. Thirty-six questionnaires were included in the final review of those patients who died.

The most common procedure performed was for the treatment of subarachnoid haemorrhage due to intracranial aneurysm, treated by embolisation using detachable coils; the mortality rate of 3% for this procedure is low considering the very serious nature of the disease.

Patient profile

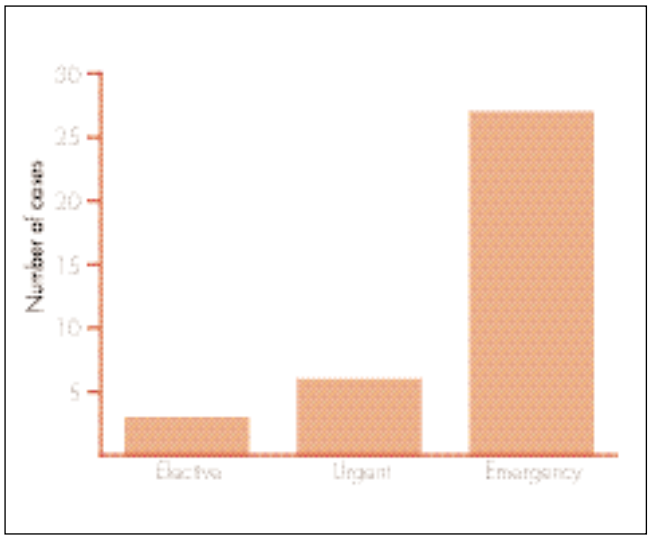
The majority of those who died were aged between 30 and 60 years with an equal sex distribution. This is in contrast to those undergoing interventional vascular radiology procedures, or surgical procedures in general, where older patients predominate.

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 World Federation of Neurological Surgeons (WFNS) modification of the GCS is a useful prognostic indicator, where grades 1 and 2 have a 5-10% mortality whereas grades 3, 4 and 5 have a mortality of 40-50% following treatment. Without treatment the overall mortality at six months is 50%.

The majority of patients who died did so within a week of the procedure indicating that death was as a direct result of the subarachnoid haemorrhage rather than due to unrelated coexisting medical problems.

Urgency of procedure

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. These procedures therefore need to be performed as a matter of urgency; only three of the 36 procedures where patients died were performed electively.



The neuroradiologist

Thirty-five of the 36 cases were performed by a consultant and one by a specialist registrar with a consultant in attendance. There has been an enormous increase in the workload of interventional neuroradiologists since the introduction of the Guglielmi detachable coil, whose use has risen from none prior to 1992 to over 800 in the period of the study. There has been very little corresponding increase in the number of neuroradiologists or support staff and there is a need for recognised training programmes in the specialty.

Anaesthesia and monitoring

Thirty-one of the 36 procedures were performed under general anaesthetic and three under sedation administered by an anaesthetist. The X-ray department is a more difficult environment than the operating theatre in which to give an anaesthetic and it is important that the anaesthetist is experienced and has a trained assistant. Of the two cases performed under local anaesthetic, in one the monitoring; was done by the neuroradiologist. This is unacceptable; 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.

Postprocedural care

It is essential that intensive and high dependency beds are available for the care of these patients in whom there is an ever-present danger of the development of serious complications.

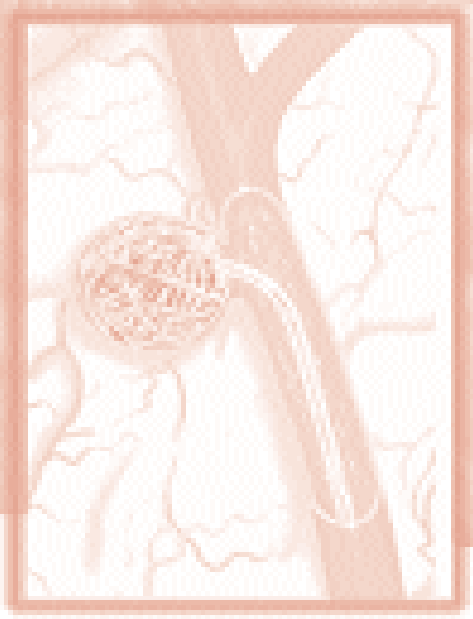
Many of the postprocedural complications were probably related to the initial pathology. There were, however, some instances of thromboembolic events; patients should normally be given systemic anticoagulation during these procedures and the dose should be monitored using the activated clotting time (ACT).

Postmortem examinations

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.

Audit

In 61% of cases the death was discussed at an audit meeting; it was felt that all should be considered.



WHAT IS NCEPOD?

The National Confidential Enquiry into Perioperative Deaths (NCEPOD) is a registered charity whose aim is to review clinical practice and identify potentially remediable factors in the practice of anaesthesia, surgery and other invasive medical procedures. The aim is to look at the quality of the delivery of care and not specifically the causation of death. The commentary and recommendations made in the annual Reports are based on peer review of the data, questionnaires and other records submitted to us. NCEPOD is not a research study based on differences against a control population and does not produce any kind of comparison between clinicians or hospitals.

NCEPOD is an independent body to which a corporate commitment has been made by the Royal Colleges, Faculties and Associations related to its activity. Each of these bodies nominates members of the Steering Group.

Since 1 April 1999, NCEPOD has come under the aegis of the National Institute for Clinical Excellence (NICE), who provide the majority of the organisation's funding. Financial support is also provided by the Welsh Office, Health and Social Services Executive (Northern Ireland), States of Guernsey Board of Health, States of Jersey, Department of Health and Social Security (Isle of Man) and many of the independent hospitals who also submit data to the Enquiry. This study received additional financial assistance from the Department of Health. The total annual cost of NCEPOD is approximately £500,000 (1999/2000).

NCEPOD routinely collects basic details on all deaths occurring in hospital within 30 days of a surgical procedure. This data is submitted to the Enquiry by a designated Local Reporter within each hospital. A surgical procedure is defined by NCEPOD as "any procedure carried out by a surgeon or gynaecologist, with or without an anaesthetist, involving local, regional or general anaesthesia or sedation". The Enquiry does not review maternal deaths, which come under the remit of the Confidential Enquiry into Maternal Deaths (CEMD).

Other NCEPOD Reports

In addition to this report, NCEPOD also published a report on Percutaneous Transluminal Coronary Angioplasty (PTCA) and its main annual report, entitled "Then and Now", in November 2000.

Obtaining the full Report

- This report is available for downloading from the NCEPOD website at www.ncepod.org.uk.
- Alternatively please send a sterling cheque for £10 (inc. P&P) payable to NCEPOD at the address below.

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