

Percutaneous Transluminal Coronary Angioplasty

A Report of the National Confidential Enquiry into Perioperative Deaths

SUMMARY OF THE REPORT PUBLISHED ON 21ST NOVEMBER 2000

Percutaneous transluminal coronary angioplasty (PTCA) has developed over the last twenty years and NCEPOD was delighted to have this opportunity to work, for the first time, with cardiologists. The study was also one of the first conducted by NCEPOD where it was possible 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.

The basic principle is to introduce a guidewire and catheter via a needle in a peripheral artery, most commonly the femoral, and steer them round, under X-ray guidance, to the coronary arteries. A variety of devices may be used, most commonly a balloon catheter, often in association with a metal stent. Until relatively recently PTCA was used for patients with a single coronary stenosis who were in a stable condition. However, because of technical advances and increasing expertise, multiple coronary lesions, including occlusions, are now routinely treated with generally very good results, and many patients undergo PTCA in the emergency situation.

Recommendations

- ◆ Interventional cardiology centres should have a sufficient number of appropriately experienced clinicians and other staff to run an emergency PTCA service.
- ◆ It is essential that there is an efficient system for transferring patients from the district general hospital to the interventional centre; ambulance services should be able to respond rapidly to calls for urgent transfer of patients requiring PTCA in the setting of acute myocardial infarction.
- ◆ There is a need for consistency in the definition of cardiogenic shock, in order to give an accurate prognosis and compare outcomes of treatment.
- ◆ All catheter laboratory staff should have regular resuscitation training.
- ◆ Intra-aortic balloon pumps should be available for appropriate patients; staff should be familiar with their use.
- ◆ Catheter laboratories should have a designated person responsible for checking that all necessary equipment is both present and functional.
- ◆ All catheter laboratories should have appropriately equipped recovery areas.
- ◆ Monitoring with pulse oximetry should be available for all cases and performed whenever sedation or opiates are used or oxygen therapy is required; this should be performed by an appropriately trained nurse or technician.
- ◆ Glycoprotein IIb/IIIa receptor blockers should be used more widely for patients undergoing high risk PTCA. Heparin doses should be adjusted accordingly, and monitored using activated clotting time (ACT) or equivalent, in order to minimise the risk of bleeding.
- ◆ Clinicians should be informed of the date and time that postmortem examinations are being performed and should do their best to attend; a copy of the postmortem report should always be sent to the appropriate clinician.
- ◆ Regular audit meetings should be held in all interventional cardiology centres.
- ◆ For the practice of angioplasty and the assessment of its risk to be improved, and for patient consent to be better informed, comprehensive systems for recording patient and procedural data need to be in place. Data should be regularly audited and submitted to allow comparison with national averages.
- ◆ Hospitals should provide access to case records for audit purposes.

DATA COLLECTION AND ANALYSIS

Data was requested from all NHS hospitals undertaking PTCA procedures in England, Scotland, Wales and Northern Ireland, together with relevant hospitals in the independent sector. Participation was voluntary and 41 hospitals agreed to take part in the study. Information on the total number of patients undergoing PTCA on a monthly basis, together with notification of any deaths occurring within 30 days of the procedure, were collected for the period 1 September 1998 - 31 August 1999.

PROCEDURES PERFORMED AND DEATHS REPORTED

A total of 21 222 procedures were performed, giving a mean of 518 procedures per centre. The overall mortality of 0.87% seen in this study is almost identical to that previously reported by the British Cardiovascular Intervention Society (BCIS).

The majority of coronary angioplasties are performed as elective procedures in patients with stable angina. However, of the 121 patients who died (and for whom a questionnaire was received) 82% had the procedure performed as an emergency; only ten deaths were reported following elective procedures, indicating the safety of PTCA when performed on a planned basis. In addition, 97 of those who died were admitted with acute coronary syndromes (unstable angina or acute myocardial infarction) of whom 40 were reported to be in cardiogenic shock. The majority of these patients had other coexisting medical conditions in addition to their coronary artery disease. The majority also had disease in more than one coronary artery and a high proportion had moderate or severe left ventricular dysfunction.

Nearly half the patients who died were referred from another hospital. Some instances of delay in interhospital transfer were cited, although no patient in this study was recorded as having deteriorated during the journey. It is essential that there is a smooth and efficient system for transferring patients from the district general hospital to the interventional cardiology centre; ambulance services need to be aware of the need for urgent transfer of patients in the context of myocardial infarction. Although ambulance services have protocols for response times after emergency calls from outside hospital, there are no legal obligations for rapid transfer from one hospital to another; this matter should be addressed.

EXPERIENCE AND AVAILABILITY OF THE OPERATOR

There was very high consultant involvement in both the decision to undertake and in the performance of the PTCA procedures. Operators were fully trained and considered to be suitably experienced to perform the procedures in almost all cases. Ninety-five percent of cardiologists complied with the BCIS recommendations on the number of procedures that should be performed each year. It is recommended that interventional cardiology centres should have a sufficient number of appropriately experienced clinicians and other staff to run an emergency PTCA service.

ANAESTHESIA AND RESUSCITATION

Ninety percent of procedures were performed under local anaesthetic; it is, however, essential that facilities for managing the airway and all other anaesthetic equipment are available and regularly checked by a designated person. If a general anaesthetic is given, a trained assistant should be available to help the anaesthetist.

Ninety-four percent of catheter laboratory staff receive regular resuscitation training; whilst this is commendable, such training should be carried out in all centres.

MONITORING

Monitoring with pulse oximetry should be available for all cases and performed whenever sedation or opiates are used or oxygen therapy is required.

An appropriately trained nurse or technician should be responsible for monitoring, rather than the cardiologist performing the procedure.

POSTPROCEDURAL CARE

A designated and fully equipped recovery area was available in 81% of cases; this facility should be available for all patients.

The majority of patients were transferred to some form of higher dependency area after leaving the catheter laboratory.

Other selected key points

- ◆ **Cardiogenic shock** Forty patients (33%) in this study were reported to be in cardiogenic shock. There was a poor correlation between the estimated risk of death and the stated presence of cardiogenic shock, a condition with a universally poor outcome. It was considered after review of the data that there was not always clear evidence of the presence of cardiogenic shock and there is a need for a better understanding of its clinical definition. A clear and universally accepted clinical definition would allow an accurate prognosis in order to obtain reliable informed consent.
- ◆ **Elective stenting** Intracoronary stents were inserted in almost half the cases. Recent trials have shown a lower restenosis rate after stenting compared with angioplasty alone and the National Institute for Clinical Excellence (NICE) has favoured their use in the majority of angioplasty procedures.
- ◆ **Intra-aortic balloon pumps (IABPs)** IABPs would appear to be under-used considering the fairly high proportion of patients reported to be in cardiogenic shock. Staff caring for patients after PTCA procedures should be familiar with the use of the IABP; these should be functional, and reserve machines should be available.
- ◆ **Anticoagulants** The majority of patients received heparin, but glycoprotein IIb/IIIa receptor blockers were thought to be under-used. It was recommended that they be used more widely in high risk patients; heparin doses should be adjusted accordingly and monitored using activated clotting time or equivalent, to minimise the risk of bleeding.
- ◆ **Coronary artery bypass grafts (CABG)** All centres performing PTCA in this study had access to emergency cardiac surgery and in 93% this was on the same site. Ten patients were referred for CABG, although surgery was actually performed in only eight. Four were transferred directly from the catheter laboratory, two underwent surgery within 24 hours and a further two during the same admission. One patient suffered a delay due to lack of theatre availability and another had been previously assessed as unsuitable for elective CABG.
- ◆ **Cardiopulmonary resuscitation (CPR)** CPR was attempted in half the patients who died and was considered by those involved to have been performed satisfactorily in all cases. In 12 cases where CPR was not attempted, the decision had been recorded prior to the procedure; all these patients were in cardiogenic shock at the time of cardiac arrest. The decision whether or not CPR should be performed was made in a responsible way by experienced cardiologists.

POSTMORTEM EXAMINATIONS

A total of 38 postmortem examinations were performed, of which 31 were coroner's postmortems. Only 37% of cardiologists were informed of the date and time of the postmortem examination; clinicians should receive this information and make every effort to attend.

A copy of the postmortem report should always be sent to the appropriate clinician.

In almost one in four of the postmortem examinations performed the pathological findings differed from the clinical impression, emphasising why it is important that they be performed.

AUDIT MEETINGS AND AVAILABILITY OF CASE NOTES

In 92% of cases the interventional centres held regular audit meetings; whilst this is commendable, those not holding such meetings should do so.

In 27% of cases a delay of more than a week was experienced when trying to obtain the medical records and in 12% the notes were incomplete; this is not satisfactory and it is hoped that clinical governance will improve the situation.

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 Interventional Vascular and Neurovascular Radiology and its main annual report, entitled "Then and Now", in November 2000.

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Bodies nominating members of the Steering Group

- Association of Anaesthetists of Great Britain & Ireland
- Association of Surgeons of Great Britain & Ireland
- Faculty of Dental Surgery of the Royal College of Surgeons of England
- Faculty of Public Health Medicine of the Royal Colleges of Physicians of the UK
- Royal College of Anaesthetists
- Royal College of Obstetricians and Gynaecologists
- Royal College of Ophthalmologists
- Royal College of Pathologists
- Royal College of Physicians of London
- Royal College of Radiologists
- Royal College of Surgeons of England

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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