

Cardiac surgery: the medicolegal issues

Mr J R L Hamilton

Abstract

This article provides the lawyer and other uninitiated readers with an introduction to the principles and practice of cardiac surgery. Medicolegal problems relating to consent, professional competence, supervision of trainees and peri-operative care are outlined. Liability issues in three cardiac operations – valve surgery, aortic surgery and coronary artery bypass grafts – are discussed.

History and background

The year 1953 was a significant landmark for patients with heart disease – it was then that John Gibbon performed the first successful ‘open heart’ procedure in the world using cardiopulmonary bypass (the heart/lung machine). It was rightly hailed as a breakthrough – the downside was that only one of his first four patients survived. Things have changed dramatically in the intervening half century – expected survival for the operation he performed (closure of an atrial septal defect (hole in the heart) is now 100%.

Cardiac surgery is part of the legally defined specialty of cardiothoracic surgery – essentially anything within the chest. Training covers surgery for the heart and great vessels (including the aorta), lungs, oesophagus and mediastinum. Some surgeons focus solely on cardiac surgery, some on thoracic surgery (lungs, oesophagus and mediastinum) while some have a mixed cardiothoracic practice. Cardiac surgery is performed for both congenital (meaning ‘born with’) heart disease and acquired heart disease – this article will focus on cardiac surgery for acquired heart disease in adults.

Perfusion/cardiopulmonary bypass

Surgery is referred to as ‘open’ heart surgery if cardiopulmonary bypass is used and ‘closed’ if it is not. Cardiopulmonary bypass is a machine which does the work of the heart and lungs, thus allowing the surgeon to stop the heart and carry out the intended procedure. It essentially consists of an artificial lung and a pump. However, the technology is complex and the bypass circuit is managed by a perfusionist; they have their own professional body: The Society of Clinical Perfusion Scientists of Great Britain and Ireland.¹

There are a number of potential medicolegal issues with regard to perfusion.

Preparation of the circuit

The perfusionist has to prime the circuit with a ‘cocktail’ of fluid. Errors in priming have led to serious injury or death of the patient. As the circuit will be connected directly to the patient’s arterial system, it is important that all air is evacuated from the circuit before starting the circulation.

Any bubbles of gas or particulate matter could cause injury to any of the patient’s organs.

Intra-operative perfusion

The perfusionist has to adjust the flow of gas into the artificial lung to maintain the normal levels of oxygen and carbon dioxide in the patient. They also have to ensure that there is sufficient volume in the ‘reservoir’ of the circuit – if the volume falls to low, air could be pumped into the patient’s circulation causing stroke or other serious injury.

Temperature

The temperature of the patient will be adjusted (using the heat exchanger in the circuit) depending on the surgeon’s operative strategy. It is important that the patient is neither cooled nor re-warmed too quickly – injury, particularly to the brain, can occur.

The team

While the cardiac surgeon is the leader of the team, good teamwork is the key to the successful outcome of the patient – an error by any member can have serious consequences. The team includes the referring cardiologist who is responsible for carrying out the appropriate investigations and making an accurate diagnosis (and from the medicolegal point of view, the one to give reports on condition and prognosis as they are responsible for follow-up). The medical and nursing staff in the ward are responsible for preparing the patient for theatre. In theatre, the team consists of the consultant surgeon plus one or two assistants (depending on the operation). The anaesthetist is a key member of the team. Cardiothoracic anaesthesia is a subspecialty and the anaesthetists have their own professional body: the Association of Cardiothoracic Anaesthetists.² These anaesthetists will have an assistant (either an anaesthetic trainee or a trained anaesthetic nurse/Operating Department assistant). There is a perfusionist and a ‘scrub’ nurse plus a ‘floor/runner’ nurse. The average cardiac operation lasts about four hours and so extra staff are needed as back up.

Medicolegal issues occasionally arise with regard to delegation of all or part of the procedure to more junior members of the team. This most often involves surgical trainees – in the past, ‘would be’ cardiac surgeons trained first in general surgery and then undertook a six-year programme of training in cardiothoracic surgery. This was essentially an apprenticeship (no formal assessments) with

Mr J R L Hamilton FRCS Eng FRCS Ed (C-Th), Consultant Cardiac Surgeon, Freeman Hospital, Newcastle Upon Tyne, NE7 7DN, UK
E-mail: leslie.hamilton@nuth.nhs.uk

increasing delegation as training progressed. From 1 August 2007, the Royal Colleges' Intercollegiate Training Committee has set out a clearly defined competence-based curriculum.³ In future, therefore, trainees will not undertake any part of the procedure without supervision unless they have been signed off as competent.

Another issue is that of a consultant undertaking a new procedure – although many of the operations in cardiac surgery are standard, there have been a number of recent major developments and consultants have had to learn new procedures. Defining competence at consultant level is a more difficult issue but each Trust has a standard protocol under Clinical Governance for the introduction of new operations.

General issues

A number of issues are common to all cardiac operations.

Consent

Both the Department of Health⁴ and the General Medical Council⁵ have produced clear guidelines on consent for surgery – it is a process and not a 'one-off' signing of a consent form. It should be undertaken by someone who is capable of carrying out the procedure. In best practice the process should begin with a discussion with the consultant surgeon responsible, in advance of admission for surgery. It should include an explanation of the condition and the natural history of the disease process (without surgery). The details of the proposed operation should be explained and an indication of the expected benefits and outcome given (cardiac surgery has an extensive international evidence base for surgery).

- *Alternative treatments:* In the current era it is important that the patient is given information on the alternative treatments – dramatic technological advances have enabled cardiologists to undertake both dilatation of narrow valves (balloon valvuloplasty) and direct dilatation and stenting of narrowed coronary arteries (percutaneous coronary intervention, PCI). However, this raises an important medicolegal aspect of practice – as the referring cardiologist may also be the person who carries out the percutaneous intervention, it is very important that the cardiologist discusses surgery as a possible option (the evidence base for surgery is much stronger than for cardiological interventions as it is a relatively new speciality). Failure to do so would invalidate the consent process.
- *Risks:* One of the most difficult and controversial areas of consent process is that of the risks of the procedure – not only of mortality but probably more importantly of complications. Determining how much detail to offer/give to an individual patient is a challenge. Recognizing that this area generates a significant number of complaints (many of which reach the Ombudsman) and medicolegal cases, UK cardiac surgeons have worked with the Ombudsman to produce 'Consent in Cardiac Surgery – a Good Practice Guide'.⁶ Formal risk stratification is possible for patients undergoing cardiac surgery – the one most commonly used is EuroSCORE.⁷ However, a fundamental problem is that statistics refer to large groups/populations of patients, not individuals. The mortality rate for a 'straightforward' patient undergoing coronary bypass surgery is 2% – this does mean that two patients out of every 100 will die unexpectedly postoperatively.

- *Stroke:* The risk of surgery encompasses not only the mortality but also morbidity – the most feared is that of a stroke. Overall, 3% of patients will suffer a stroke in the peri-operative period but some patients have clearly defined risk factors for an increased risk. One of the points of debate is whether all patients should be formally screened for risks factors for a stroke – in some patients interventions are available which may reduce the risk of stroke. The American Heart Association has defined guidelines for investigations and many (but not all) units in the UK use these guidelines.⁸ Failure to adhere to these guidelines would not necessarily demonstrate a breach of duty of care.

Cardiopulmonary bypass

The role of the perfusionist has been noted above.

- *Postoperative bleeding:* Patients have to be fully anti-coagulated (the blood thinned so it does not clot in the bypass machine) during surgery – this process has to be reversed at the end. Sometimes it is difficult and bleeding is a well recognized postoperative problem.
- *Myocardial protection:* While the heart is stopped during the procedure, it does not have a blood supply. It is therefore important that the surgeon uses an appropriate strategy to limit damage to the heart – a not uncommon point in 'Particulars of Claim' is that of 'inadequate myocardial protection'. This is a difficult question as there is no set standard of practice.
- *Brain damage:* Another area which generates claims is that of brain injury following surgery – it is multifactorial in aetiology. The risk of stroke has already been mentioned. Another problem is that, during open heart surgery, the heart is full of air. This air must be removed from the heart at the end of the procedure or air bubbles could travel to the brain causing damage. Inadequate 'de-airing' is another source of claims.

Intensive care

All patients have a period of 'intensive care' following cardiac surgery. Each patient has an individual nurse who has particular skills in caring for patients in this area. The intensive care nurse has significant delegated management authority – it is not surprising that because of the complexity of the area, claims often originate in intensive care.

- *Medical cover:* There is no set pattern in the UK of providing medical cover for intensive care – traditionally this was undertaken by the consultant surgeon assisted by their team, with much of the care delegated to an experienced surgical trainee. The consultant anaesthetist was usually involved with particular regard to management of the respiratory system. Out-of-hours care is a particular thorny issue – the European Working Time Directive now limits the working hours of trainees and this has put significant strain on the traditional pattern of trainees providing resident experienced surgical and anaesthetic cover.
- *Chest re-opening:* Patients are not uncommonly quite unstable and on occasions (particularly in response to sudden bleeding) the patient has to have their chest opened in intensive care. It is a standard of care that all units will have facilities to enable this to happen as soon as possible but the time involved and the personnel responsible are a matter of intense debate at present.

- *Intra-aortic balloon pump*: Often the patient's circulation requires more support than can be provided by drugs. One option is to insert a 'balloon pump' into the descending aorta (main body artery) through the femoral (leg) artery. As many of the patients with heart disease also have disease in their peripheral arteries, ischaemia of the leg is not uncommonly associated with an intra-aortic balloon pump and can lead to amputation. This may generate a medicolegal claim but does not necessarily indicate a breach of duty of care.
- *Infection*: Media interest in hospital-acquired infection in general, and MRSA (methacillin resistant *Staphylococcus aureus*) in particular, has raised patients' awareness of this problem. Unfortunately the media have not been good at explaining the origin of MRSA – all of us have staphylococci growing normally on our skin. Partly as a consequence of bacterial genetic mutation and partly as a consequence of use of antibiotics in the community, 30% of the population have MRSA on their skin and bring it into hospital with them. Most hospitals now operate a screening system. All patients after cardiac surgery are vulnerable to infection – partly because their immune system is functioning less well after major surgery (and cardiopulmonary bypass) and partly because they have invasive intra-arterial and intravenous lines used for monitoring (these lines act as a source of entry for skin bacteria). For this reason, all patients receive prophylactic antibiotics prior to bypass – it is important that these antibiotics have circulated around the body and are in the tissues before the operation starts or they are ineffective. There is no set standard regimen for antibiotic prophylaxis.

Incision: median sternotomy

The standard incision used to approach the heart is the median sternotomy – the sternum (breastbone) is split down the middle using a mechanical saw. In most cases it heals afterwards uneventfully but when it doesn't it causes major problems, often leading to a claim. Underlying structures can be damaged during the sawing process. The innominate vein lies immediately under the top of the sternum – damage to it during sawing is a rare but well recognized complication and there is no fail-safe way of preventing it. It is usually repaired without consequence but this has been the subject of a claim. Some patients come back for re-operation; part of the healing process after the first part of the operation is the scar tissue which forms around the heart. This may cause adherence between the heart and the back of the sternum – the heart can be damaged directly at sternal re-entry. For this reason, many surgeons would use the femoral (leg) artery to connect the patient to the heart/lung machine. However, femoral bypass carries its own specific complications and has generated medicolegal claims.

Acquired adult heart surgery – specific operations

Coronary artery bypass grafts (CABG)

In ischaemic heart disease the blood supply to the heart muscle is restricted by blockages inside the coronary arteries. The surgeon uses a conduit to bypass the narrow area in the coronary artery. For the main artery on the front of the

heart a 'spare' artery (the left internal mammary artery [LIMA]) from behind the breastbone is used – this is a standard of care. Although a matter of debate, the standard method for the other arteries is to use segments of vein from the lower leg – these have side branches which have to be clipped or tied.

- Sudden bleeding postoperatively is a recognized complication but can lead to a claim if there is an adverse outcome. A recent (unsuccessful) case⁹ was based on *res ipsa loquitur* – if the side branch bled, it hadn't been secured adequately.
- Recurrent angina: some grafts fail immediately or in the early period after surgery – sometimes related to the quality of the conduit or the target vessel but sometimes for technical reasons. Graft failure is not necessarily a breach of duty.

Valve surgery

Although the heart has four valves, it is the two on the left which usually need surgical attention. The left ventricle is the main pumping chamber of the heart and its function is to pump blood around the body. As a pump it has an inlet valve (mitral) and an outlet valve (aortic). Medicolegal issues can arise in relation to:

- consent – the patient needs to be well-informed to be able to choose an appropriate prosthesis;
- damage to surrounding structures during implantation – the commonest problem relates to the electrical wiring system of the heart. If it is damaged, a pacemaker will be needed. The back of the heart can tear or disrupt during a mitral valve replacement. Neither are necessarily indications of poor surgical technique;
- valve dysfunction – technical problems are seen on occasion and ideally an echocardiogram would be performed in the operating theatre. It is good practice to perform an echocardiogram before discharge;
- infection (known as endocarditis) – a dreaded complication which can appear early, and so presumably due to infection in theatre (all patients should receive prophylactic antibiotics), or late – the issue of prophylactic antibiotics for dental treatment is currently provoking much controversy.

Aortic surgery

The aorta is the main body artery – it arises from the heart and passes up to the neck before turning to pass through the chest into the abdomen. Cardiac surgeons deal with the part in the chest. The aorta is prone to dilatation (aneurysm) or dissection (a process in which the inner lining tears and allows blood into the middle layers of the aorta). Both these processes can lead to rupture and sudden death. Surgery is sometimes undertaken prophylactically or as an emergency. Failure to refer for surgery could be a breach of duty. Aortic surgery carries significant risks (especially in the emergency situation) of brain damage and spinal cord ischaemia leading to paralysis.

Professional organization and scrutiny of performance

The Society for Cardiothoracic Surgery for Great Britain and Ireland is the professional organization for cardiac surgeons¹⁰ – individual surgeons have their own web page

within the international collaboration CTS Net.¹¹ The Society holds a list of surgeons who undertake medicolegal work and can be contacted by e-mail.¹² However, it is important to note that this list is held by the Society to facilitate contact between solicitors and surgeons and inclusion on this list does not in any way imply any endorsement by the Society.

Cardiac surgeons have led the way in collecting data on their performance – the Society began collecting (albeit very crude) data in 1977. Believing it was important to provide information to patients, the Society has collaborated with the Healthcare Commission, the press and patient groups in the development of a public database.¹³ A recent review of the unit in Oxford by the Healthcare Commission¹⁴ commented: ‘there is no other specialty that has collected as much data, in as much detail as cardiac surgery. The diligence of this group of surgeons has resulted in a high level of scrutiny of their performance in a way that is not currently possible for any other surgical specialty.’

Cardiac surgeons have demonstrated their desire to provide the highest quality care. However, the number of people involved, the complex nature of the work, the

technology used and the variability of patients in their individual risk for cardiac surgery mean that mortality and morbidity can never be eliminated. Medicolegal claims will continue to be an inescapable aspect of practice.

References and notes

- 1 www.scps.org.uk
- 2 www.acta.org.uk
- 3 www.iscp.ac.uk
- 4 <http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Consent/Consentgeneralinformation/index.htm>
- 5 <http://www.gmc-uk.org/guidance/archive/library/consent.asp>
- 6 http://www.ombudsman.org.uk/improving_services/best_practice/cardiac05/patients.html
- 7 www.euroscore.org
- 8 <http://www.americanheart.org/downloadable/heart/112977349318CABG%202005pocket.pdf>
- 9 See *Clinical Risk* 2007; 13: 82–3
- 10 www.scts.org
- 11 www.ctsnet.org
- 12 sctsadmin@scts.org
- 13 www.heartsurgery.healthcarecommission.org.uk
- 14 http://www.healthcarecommission.org.uk/newsandevents/pressreleases.cfm/cit_id/5331/FAArea1/customWidgets.content_view_1/usecache/false