The donor crisis in heart transplantation

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Orthotopic heart transplantation is an effective treatment for patients in end-stage heart failure. Two outstanding problems prevent its wider employment: these are the lack of donor hearts and our inability to preserve the heart safely for 24 hours. The purpose of this article is to discuss the issues surrounding donor organ shortage as it impacts on heart transplantation.

By the end of 2002 in the UK the number of people on the donor organ register reached 10 million. The results of heart transplantation have shown steady improvement over the last 20 years, with current figures for one- and five-year survival of 85% and 70% respectively.[1] Why is there such an imbalance between supply and demand? Why is the situation getting worse?

The shortage of donor hearts

The guidelines for accepting donor hearts have recently been re-examined as part of a UK Transplant audit of 'unused' thoracic organs to try to ensure that no potentially viable hearts are discarded. All donors are considered up to the age of 60–65 years and should be matched to within 10% of height. There are obvious contraindications such as positive serology for hepatitis or HIV, and myocardial infarction. The ECG exclusion criteria have been narrowed to formal criteria for left ventricular hypertrophy, recurrent ventricular tachycardia and evidence of previous transmural myocardial infarction. It is common under the conditions of death due to brain stem injury to see widespread ST segment changes. At first glance the requirement for inotropes to the donor might signify a damaged heart, but invariably their presence is required in the neurosurgical intensive care unit (ICU) to counterbalance a low central venous pressure. A pulmonary artery (PA) catheter may be inserted and this is recorded. Proposed changes, referred to later, will make it easier to initiate treatment of donor organs at the donor hospital.

Over the last 10 years the aetiology of brain stem death in the ICU has changed. There has been a steady fall in the number of traumatic brain deaths but a rise in the incidence of intracranial haemorrhage (UK Transplant figures). The decline in the number of road traffic accidents in the UK is a very pleasing result of strong drink-drive legislation, seat belts and more effective motorcycle helmets. Firearm injuries remain infrequent, unlike the situation in the US. Many of the patients who die of intracranial bleeds are hypertensive and have significant atherosclerosis. As a consequence they frequently are found to have significant left ventricular hypertrophy and coronary artery disease, which makes them unsuitable for heart donation. Interestingly, during this period the number of lung donors has remained constant.

In the wake of recent medical scandals, particularly the Alder Hey retention of organs problem, there have been increased bureaucratic safeguards concerning organ donation and a perceived reluctance among some doctors to become involved in donor issues. Nevertheless, thanks to a very positive attitude amongst the transplant community, one year following the publication of the Alder Hey report there was no fall in the number of donor organs.

Current legislation

The Human Tissue Act 1961 describes the circumstances in which organs may be removed after death in the UK. A 'designated person' may authorise removal of organs once enquiries have been made to ensure that there is no reason to believe that: the deceased had objected, the spouse/partner or *any* relative objects (my italics) or that there are any religious objections. Organs or tissues may only be removed with the specific authorisation of the coroner, or the procurator fiscal in Scotland. During the last 40 years confusion has arisen, and remains, concerning two phrases in the Act – 'lawful ownership of the body' and 'such reasonable enquiry as may be practicable'. The standard practice which has evolved is to seek the consent of the relatives, even though the Act only requires that the person lawfully in charge of the body has inquired whether there is any objection from the relatives.

This is a difficult task, carried out in an emotionally charged atmosphere by highly trained transplant coordinators. In the wake of a well publicised case concerning live related kidney donation brought to the General Medical Council (GMC), another piece of legislation arrived on the statute book, the Human Organ Transplant Act 1989. This Act prohibits the sale of human organs and stipulates that living organ donors must be genetically related to the recipient. It established a new authority, the Unrelated Live Transplant Regulatory Authority (ULTRA), which can, under restricted circumstances, give approval to unrelated donation. Although this is primarily aimed at kidney donation it is also directly relevant to live lung lobe donation and to the use of homograft aortic or mitral valves.

Over the last few years there have been a number of attempts to change this confusing law. A private member's bill was introduced in the House of Commons in April 2000 but the order for the second reading elapsed and there is currently no legislation in the pipeline.

The British Medical Association (BMA) has recently proposed major changes, some of which are controversial and will need to be thoroughly debated before they are implemented (*Organ Donation in the 21st Century. Time for a consolidated approach*). The BMA has joined 17 other organisations to form the Transplant Partnership. The proposals fall under three headings: new legislation, a new organ donation programme, and changes to the practice of organ donation. Under the umbrella of new legislation they aim to provide a clear and unambiguous framework within which organ donation may take place. It is proposed to give legal authorisation to the use of invasive procedures such as a PA catheter or transoesophageal echocardiography to protect organs and, in the case of lungs and kidneys, to facilitate greater use of donors whose hearts are not beating. New guidelines for determining death by brain stem tests and the introduction of 'presumed consent' are included in their recommendations.[2]

Presumed consent

The idea of 'presumed consent' has been on the discussion table for more than 20 years[3] and is enshrined in law in a number of European countries including Austria, Belgium and Spain. There are 'hard' and 'soft' versions of this principle – the latter is being proposed for the UK. Under such a system, complete with safeguards, it is assumed that individuals wish to donate organs after their death unless they have registered an objection to donation during their lifetime. Doctors would have the discretion not to proceed if the potential donor's wishes were not known or if it were clear that the donation would cause major distress to a first-degree relative or long-term partner. Those in favour of this system argue that individual citizens are encouraged to make their own decisions, that the relatives are relieved of a heavy emotional burden and that the whole process of donation would be less fraught and more routine. The opposing argument is that the principles of personal autonomy and altruism are lost,[4] and that this could lead to adverse publicity and hostility from the media. In some countries such as Austria where the 'hard' version of this principle has been law for some years there has not been a significant rise in organ donation. In Belgium the scheme has been more successful, however.[5]

Spain is the country where organ donation has been most successful and where the numbers have increased year on year for the last 10 years.[6] Although they have the 'presumed consent' principle in law, permission is always sought from relatives of the potential organ donor. There are other factors which probably contribute to Spain's success: they have a system of donor-coordinators, who are doctors in community hospitals throughout the country, and their drink-drive laws are less strict than those in the UK.

The Department of Health in the UK has recently introduced 35 donor-coordinators into large district general hospitals around the country. These individuals are mostly nurses with a significant experience in ICU. For the first time, donor rates will be monitored as health authority performance indicators. Further proposals from the Royal College of Surgeons are to set up consultant-led multi-organ retrieval teams and to provide improved support and reimbursement for donor hospitals.

The pressure for change comes from different sources. Surveys carried out by the British Kidney Patients Association and the Department of Health favour presumed consent.[7] The donor card system, which has been in existence for about 30 years, is an ineffective public relations exercise. In 1999, an opinion poll carried out by the Department of Health reported that 50% of the public wanted to keep the 'opt in' policy, 24% said it was time to change and 26% had no preference. Finally, the experience of other European countries, especially Spain, has been taken on board.[8]

Required request

A policy of required request or required referral is operated in the US. Required referral is defined thus: "it shall be illegal, as well as irresponsible and immoral, to disconnect a ventilator from an individual who is declared dead following brain stem testing without first making proper enquiry as to the possibility of that individual's tissues and organs being used for the purposes of transplantation". The policy means that opportunities for donation are less likely to be overlooked. Many individuals may be denied their right to donate if their relatives are not approached. The next of kin also have a moral and legal right to know that they can donate organs and tissue if they or the family so wish.

Although the introduction of this scheme saw an initial increase in the availability of organs, over time the numbers have declined.

Mandated request

Because donor cards have been less effective than was initially hoped, should they be considered in the same way as an advanced directive? Donor cards are only of benefit if they are available when needed, or if relatives know of their existence and inform the doctors or transplant coordinators. The mandated option would require all adults to express their written preference or objection to organ donation and could be linked to regular reminders such as a driving licence renewal or income tax return. The success of this strategy would still be dependent on a public that is informed and educated regarding the purpose and importance of organ donation.

Waiting lists

A further issue affecting heart transplant activity is the transplant waiting list. Transplant surgeons and physicians are keen to ensure that patients are placed on the list only if they have a realistic chance of receiving a transplant. This is a difficult balancing act, for if the list is too long one invites the criticism of dishonesty and raising false hopes for the patient, but if it is too short then good donor organs may be turned away. A satisfactory transplant waiting list needs to contain a range of patients of different body sizes and blood groups.

A recent report from Germany has stirred up a great deal of controversy.[9] Deng and colleagues conducted a prospective observational study of 889 patients listed for a first heart transplant in 1997. They concluded that, apart from patients with the highest risk of dying on the waiting list, there was no survival advantage. As Treasure and Murday observed,[10] the overall impression given was that there was little to be gained from heart transplantation. This is at odds with the strongly held beliefs of those involved, both doctors and patients. The German study concentrated on survival at one year, which for transplanted patients was 71% (95% confidence intervals [CI] 68% to 74%). Better figures were reported by the Registry of the International Society for Heart and Lung Transplantation (78%) and by UK transplant units (79%: 95% CI 77% to 82%), which are audited by the Clinical Effectiveness Unit of the Royal College of Surgeons of England.[11] A comparison at one year is heavily biased against the operated group, who face their highest risk at operation and in the following weeks. In recent clinical trials of heart failure the annual death rate ranged from about 10% to 20% and was more or less constant over the two to three years of the trials.

If there is real doubt about where maximum benefits can be gained, the best way to resolve this is by a clinical trial. The features of patients who receive transplants in the UK include a peak oxygen consumption of less than 14 ml/Kg/minute, who are at high risk according to the Heart Failure Survival Score. They have usually received full medical treatment, including neurohormonal blockade, for at least three months. Before being placed on the transplant list a structured evaluation has occurred. In some countries these conditions do not always obtain. In the face of intense public scrutiny, particularly by private insurance companies, of one-year transplant results there is an inevitable temptation to transplant lower-risk patients in order to bolster the results.

Conclusion

In the area of heart failure, public debate and research funding have been focused on new trends such as xenotransplantation and tissue engineering. Neither approach is expected to have an important role during this decade. We should not neglect organ transplantation, though it is dependent on a scarce resource. Legislation can be effective in the long term, but improving rates of organ donation has more to do with changing attitudes and behaviour.

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