

Issues related to non-heart-beating organ donation

RAJESH BARDALE

Department of Forensic Medicine, Government Medical College and Hospital, Nagpur, 440 003 INDIA email: bardalerv@yahoo.co.in

Abstract

Since the enactment of the Transplantation of Human Organs Act, 1994, the brain dead person remains the primary source of organs legally obtained for transplantation purposes in India. With the increasing demand of organs for transplantation purposes, non-heart-beating donors can help meet this need. However, the process of retrieving organs in non-heart-beating donors is more complex and raises ethical and legal as well as medical issues. This essay discusses some of these concerns.

Since the enactment of the Transplantation of Human Organs Act, 1994, the brain dead person remains the primary source of organs legally obtained for transplantation purposes in India. However, the demand for organs always been high and continues to grow, and potential donors are few, so the supply of organs remains limited. Therefore, alternative sources have been sought, including the retrieval of organs from individuals declared dead according to cardiopulmonary criteria, that is when cardiac function ceases. Such individuals are known as non-heart-beating donors (NHBD) (1).

The NHBD is defined as one who sustains cardio-respiratory arrest and whose organs are retrieved after irreversible cessation of cardiac and respiratory function (2). In contrast, a conventional heart-beating donor is one who sustains irreversible brain insult and whose death is based on neurological criteria. The concept of NHBD is not new. When organ transplant programmes first started, all organs were retrieved from patients immediately after cardiorespiratory arrest (3). However, with the recognition of brain death, the use of NHBD has decreased considerably.

The modified Maastricht classification of NHBD identified five categories of potential donors. A more practical classification may be “uncontrolled” or “controlled” NHBD depending on whether cardiopulmonary function ceases spontaneously or after medical therapy is withdrawn. Donors from categories 1, 2 and 5 have been classified as uncontrolled donors whereas those in categories 3 and 4 are described as controlled donors (3).

The modified Maastricht classification of non-heart beating donors	
Category	Type of potential donors
I	Dead on arrival
II	Unsuccessful resuscitation
III	Awaiting cardiac arrest
IV	Cardiac arrest in a brainstem dead donor
V	Unexpected cardiac arrest in a critically ill patient

It is proposed that NHBD could contribute to an increase in the number of solid organ and tissue donation for transplantation purposes. The solid organs that are suitable for transplantation purposes include the kidneys, liver, lungs and pancreas, and tissues such as corneas, bone marrow and pancreatic islet cells (1, 3-6). The results of transplantation of kidneys are encouraging (7, 8) and the recipients of NHBD kidneys have a five-year survival that is the same as those who received a conventional heart-beating donor kidney (2). It is estimated that the introduction of an NHBD programme would have the greatest impact on the cadaveric organ pool compared to cadaveric donations (9). However, the retrieval of organs for transplantation is more complex in NHBD due to time constraints, medical concerns about organ damage owing to “warm ischaemia” and the ethical and legal issues involved therein.

Ethical issues

The procedure of retrieval organs in NHBD raises ethical concerns and these issues deserve attention. In these donors, to minimise the organ damage due to warm ischaemia, some centres use postmortem *in situ* preservation. There are data showing that *in situ* preservation can lengthen the permissible period between the determination of death and organ retrieval from one hour up to six hours (1). Similarly postmortem interventions such as putting the dead on ventilation and cardiopulmonary bypass are done in an attempt to preserve the organs. At times, these procedures are done without the knowledge and consent of family members. The intention of these procedures is to prevent warm ischaemia and organ damage but they raise ethical concerns. Conducting an invasive procedure without the consent of the patient or relatives or, alternatively, failing to act in the patient’s best interest, amounts to assault. It might be argued that it is unclear whether interference with a corpse without legitimate authority would be considered a crime, there being no property in a body. However, the act can be construed as indignity if done with intention (section 297 of the Indian Penal Code, IPC). Similarly the deceased’s relative may file a claim for mental trauma, particularly if the interference has been witnessed (10).

The use of controlled donors allows organ retrieval to be planned, warm ischaemic time to be minimised and the usage of organs for transplant optimised (3). But ascertaining death is important. Questions are often raised regarding the certification of death. The NHBD protocol rests upon the “dead-donor rule”: patients must be dead – according to a specified definition – before organ retrieval, and death must be neither caused nor hastened by retrieval (11). To

declare a person dead by cardiopulmonary criteria, it must be established that circulation and respiration have ceased and their function will not resume. However, these functions may reverse spontaneously (auto resuscitation) if they were due to a disturbance of the cardiac rhythm, or they may be reversed by interventional resuscitation (10). Menikoff (12) has criticised the definition of death in NHBD programmes, noting that the cessation of cardiopulmonary activity is not irreversibly lost as long as there is a possibility of its being restored by resuscitation. Supporters of NHBD argue that if a specified duration of absent cardiac activity is not associated with spontaneous "auto resuscitation", then the absence of activity can be considered irreversible (1). The Maastricht workshop considered that 10 minutes without perfusion of the brain was necessary before any intervention geared towards organ retrieval. The Institute of Medicine recommends a five-minute observation period. The Pittsburgh protocol sanctions surgical retrieval of organs at two minutes after asystole (10). Despite the premise of certainty in determining irreversible death, it is worrisome that centres cannot agree to adopt a common standard (1).

Second, concerns are raised about the methods used to decrease warm ischaemic time. NHBD protocols commonly use heparin to prevent intravascular clotting and pentolamine to maintain vascular perfusion. These agents are given when the patients are alive. Neither of these medications can be considered for use for the benefit of the patient. As such, would their use not seem to violate the ethical responsibility to the still alive patient?

The practice of cannulation of the patient, prior to withdrawal of care, for the purpose of preservative perfusion is also not acceptable. It could be argued that interventions of this nature would require an escalation of analgesic and sedative or anaesthetic agents with the potential for destabilisation of the cardiovascular system, thereby precipitating, or priming for, a more rapid death. The process too could not be contained within the principles of "double-effect". That principle holds that an action that produces a good effect and a bad effect might be permissible if the good effect is intended and the bad effect is merely foreseen but unintended. Cannulation might have been permissible for giving medicines; here it is done to preserve the organs by injecting a preservative perfusion. It does not benefit the patient, so any foreseen and harmful effect not ethically permissible.

Another question is related to the withdrawal of active treatment. In the United Kingdom, the decision to withdraw treatment is made in accordance with the guidelines of the Intensive Care Society, the British Medical Association and the General Medical Council. In the Indian context, explicit withdrawal of active treatment is a relatively new phenomenon. No national guidelines are available and there is a lack of education in bioethics and a paucity of case law in India (13) on this subject. While applying these programmes in India, uniform national guidelines are needed. Moreover, it is important that withdrawal of active treatment should be according

to a protocol and should not differ when organ donation is being considered. While taking such decisions, the benefit of the patient should be paramount. There must be an absolute prohibition on active euthanasia. Similarly, if the withdrawal of active treatment is being considered for harvesting organs, it should be mandatory that the transplant team is not involved in any decision to withdraw treatment. This ensures that the interest of the dying patient remains paramount. The decision to withdraw treatment should be communicated to the family by the clinician and should be documented in the clinical notes.

Medicolegal issues

In India, the Transplantation of Human Organs Act, 1994, provides for the regulation removal, storage and transplantation of human organs for therapeutic purposes, and for the prevention of commercial dealings in human organs. It gives legal sanction to cadaveric organ donation. According to this Act, a deceased person means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place (14). According to section 3(3) of the Act, in the absence of a living will, the person in lawful possession of the body may make the decision to donate the organs. The medical team should use only those organs for which consent has been given, and the remaining tissues and organs should be treated with respect (15).

Medicolegal cases are a valuable source for organ retrieval for transplantation purposes. However, section 4(1) of the Act restricts the retrieval of organs. According to this section,

...removal of organs [is] not to be authorized, if the person required to grant such facilities, or empowered to give such authority, has reason to believe that an inquest may be required to be held in relation to such body in pursuance of the provisions of any law for the time being in force.

Therefore, without proper authority, the removal of organs before or at autopsy may attract action amounting to causing indignity to a human corpse under section 297 of the IPC against the doctors involved in the organ retrieval, or the autopsy surgeon. After the death of a person, in medicolegal cases, the body is handed over to the police for further formalities and investigation. The police take possession of the dead body. When a body is in police custody, no intervention of any kind can be done on the dead body without obtaining proper written consent, permission, or a no objection certificate from the police. Any intervention without permission may amount to destruction of evidence or "disappearance of evidence" as mentioned under sections 201 and 202 of the IPC.

It is also stated in section 6 of the Act that in cases where the body has to be sent for medico-legal autopsy, a person deemed competent under this Act may authorise the removal of certain organs from the body if he or she has reason to believe that such organs would not be required for the purpose for which the autopsy was being conducted, provided that he is satisfied that the deceased person has not expressed an objection to

any of his organs being used for therapeutic purposes after death. The competent authority under this Act is not clearly defined. The authority seems to have been vested in the autopsy surgeon who is in lawful possession of the dead body for postmortem examination (16).

The All India Institute of Medical Sciences, New Delhi, has framed guidelines to carry out the retrieval of organs in medicolegal cases without violating any of the procedures prescribed under the law. The advantage of these guidelines is that the procedure does not hamper the functioning of the investigating officer, the autopsy surgeon or the courts of law (16). However, these guidelines are formed for organ retrieval in brain-stem death cases. Similar, uniform guidelines are needed for an NHBD programme. The presence of such guidelines will help retrieve organs from medicolegal cases after observing legal procedures and without violating existing laws.

Conclusion

In conclusion, it can be stated that non-heart-beating donors can to some extent help meet the increasing demand for organs for transplantation purposes. In order to implement such a programme in India, a comprehensive discussion should be had to address the ethical, medical and legal issues involved therein and arrive at a clear policy. An NHBD programme should be implemented on a need basis and not on a demand and supply basis; in the medical field, especially when organs are being retrieved, the programme should be implemented for the benefit of the patient according to need and priority.

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Are we ready for non-heart-beating organ donation in India?

SANJAY NAGRAL

Department of Surgical Gastroenterology, Jaslok Hospital and Research Centre, GD Deshmukh Marg, Mumbai 400 026 INDIA email: sanjay.nagrals@gmail.com

With the success of organ transplantation as an effective modality of treating end stage disease of various organs, increasing numbers of organ transplants are being performed all over the world. However, this procedure requires a "donor" pool of either "living" or "cadaveric" donors. Since this pool is limited, the gap between "demand" and supply is widening. In the context of organ donation "cadaveric" donation has largely meant "brain dead" or "heart beating" donors. In the last four decades, the concept of "brain death" – a state in which the brain is irreversibly damaged but the heart is beating – has been legalised and accepted in many countries of the world. However, in spite of the legal sanction as well as sustained campaigning, the number of such donors is limited.

In an effort to increase the donor pool, other strategies are now being implemented. The first area involved improving the consent rate for brain dead donors. This includes "donor cards" which citizens sign and keep during their lifetimes; "required request" where it is mandatory for a doctor to ask the relatives of a brain dead patient about organ donation, and, in some countries, "presumed consent" which grants authority to doctors to remove organs from brain dead individuals whenever usable organs are available, in the absence of objection from the deceased in his or her lifetime, or the family members. The ethical and social dimensions of presumed consent have recently been discussed in the pages of this journal (1, 2).