Observational Study

The telltale heart : Issues related with non-heart-beating organ donation

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After enactment of the Transplantation of Human Organs Act 1994, brain dead person remains the primary source of organs obtained for transplantation purpose in India. With increasing demand of organs for transplantation purpose, the non-heart-beating donors can fulfill the need up to some extent. However, the process of retrieving organs in non-heart-beating donors (NHBD) is more complex and raises ethical, medical and legal issues. For implementing these programs in India, a comprehensive discussion should be made for formation of comprehending policy.

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After enactment of the Transplantation of Human Organs Act 1994, brain dead person remains the primary source of organs obtained for transplantation purpose in India. However, the growing demand for organs always remains high and the potential donors are few, thus the supply of organs remains limited. In consequences, alternative sources have been sought, including the retrieval from individuals declared dead by cardiopulmonary criteria ie, when cardiac function ceases, known as a group – non-heart-beating donors (NHBD)[1].

A non-heart-beating-donor (NHBD) is defined as one who first sustains cardiorespiratory arrest; 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 death is based on neurological criteria. The concept of NHBD is not new. Nevertheless, when transplantation started, all organs were retrieved from patients immediately after cardiorespiratory arrest[3]. However, with recognition of brain death, the use of NHBD decreases considerably.

The modified Maastricht classification of NHBD identified five categories of potential donors (Table 1). 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or "Controlled" NHBD depending on whether cardiopulmonary function ceases spontaneously or after medical therapy is withdrawn.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 category 1, 2, & 5 have been classified as uncontrolled donors whereas category 3 & 4 as controlled donors.

It is proposed that NHBD could contribute to an increase in the number of solid organs and tissue donation for transplantation purpose. Solid organs suitable for transplantation purpose include kidneys, liver, lungs and pancreas and tissues such as cornea, bone marrow and pancreatic islet cells[1,3-6]. The results of transplantation of kidneys are encouraging[7,8] and the recipients of NHBD kidney have a 5-year survival that is same as those who received a conventional heart-beating donor kidney[2]. It is estimated that the introduction of NHBD program would have the greatest opportunity to increase the cadaveric organ pool[9]. However, retrieval of organs for transplantation is more complex in NHBD due to time restraint, concern of organ damage owing to "warm ischemia" and the ethical, legal and medical issues involved therein.

Table 1 — *The modified Maastricht classification of non-heart beating donors (3)*

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

Ethical Issues :

The procedure of retrieval organs in NHBD raises ethical concerns and these issues deserves attention. In these donors, to minimize the organ damage due to warm ischemia, some centers use postmortem in situ preservation. There are data showing that in situ preservation can lengthen the period from one hour up to six hours between the determination of death and organ retrieval[1]. Similarly postmortem intervention 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

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without knowledge of family members or without their consent. The intention behind these procedures is to prevent the warm ischemia and organ damage but these measures raises ethical concern. Conducting invasive procedure without consent or alternatively failing to act in the patient's best interest is key points and technically speaking doing invasive procedure without consent amounts to assault. Some claims that it is unclear whether interference with a corpse without legitimate authority would be considered a crime at law, there being no property in a body. However, the act can be construed as indignity, if done with intention (Sec 297 of Indian penal Code). Similarly the possibility also exists if the deceased's relative may claim for psychiatric injury, particularly if the interference has been witnessed[10].

The controlled donors allow organ retrieval to be planned, warm ischemic time to be minimized and organs outcomes optimized[3] yet, ascertaining death is important. Questions are often raised regarding the certification of death. The NHBD protocol rest upon the "dead-donor rule": patients must be dead before organ retrieval and death must be neither caused nor hastened by retrieval[11]. To declare dead by cardiopulmonary criteria, it has to be established that the circulation and respiration have ceased and their function will not resume. However, the function may reverse spontaneously (auto resuscitation) if due to a disturbance of cardiac rhythm or may be reversed by interventional resuscitation[10]. Menikoff[12] has criticized the definition of death in NHBD program noting that cessation of cardiopulmonary activity is not irreversibly lost as long as it could be 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 centers cannot agree to adopt a common standard[1].

Secondly concerns are raised against the methods used to decrease warm ischemic 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 to use for the benefit of patient. As such, would it not seem to violate an 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 anesthetic agents with the potential for destabilization 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".

Another question is related with withdrawal of active treatment. In UK, the decision for withdrawal of treatment is made in accordance with guidelines from Intensive Care Society, British Medical Association and the General Medical Council. Considering this in Indian context, it is relatively new phenomenon. No national guidelines are available and there is lack of education in bio-ethics and paucity of case law in India[13]. While applying these programs in India, uniform national guidelines are needed. Moreover, it is important that withdrawal of active treatment should be according to protocol and should not differ when organ donation is being considered. While taking such decision, the benefit of patients 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 transplant team should not be involved in any decision to withdraw treatment. This ensures that the interest of the dying patient remains vital. The decision 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 purpose and for the prevention of commercial dealings in human organs. It gives legal sanction to cadaveric organ donation. According to this Act, deceased person means a person in whom permanent disappearances 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]. As per section 33 of the Act, in absence of living will, the person in lawful possession of the body may make the decision to donate the organs. The medical teams should use only organs for which consent has been given and remaining tissues and organs should be treated with respect[15].

Medicolegal cases are valuable source for organ retrieval for transplantation purpose. However, section 4(1) of the Act, restricts the retrieval of organs. The section states that “removal of organs 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, removal of organs before or at autopsy may attract action amount to causing indignity to human corpse under section 297 of IPC against doctors involved in organ retrieval or autopsy surgeon. After death of a person, in medicolegal cases, the body is handed over to police for further formalities and investigation. The police take the possession of the dead body. During the possession of body in custody of police, no intervention of any kind can be done on the dead body without obtaining proper written consent/permission/no objection certificate from the police. Any intervention without permission may amounts to destruction of evidences or disappearance of evidences as mentioned under section 201 and 202 of IPC.

It is also stated in section 6 of the Act that in case where the body has to be sent for medico-legal autopsy a person deemed competent under this Act may authorize the removal of certain organs from the body if he has reason to believe that such organs would not be required for the purpose for which an autopsy was being conducted, provided that he is satisfied that the deceased person has not expressed his objection to any of his organs being used for therapeutic purpose after his 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 (AIIMS), New Delhi has framed guidelines to carry out retrieval of organs in medicolegal cases without violating any procedure prescribed under the law. The advantage of these guidelines is that the procedure does not hamper the functioning of the investigating officer, autopsy surgeon and the courts of law[16]. However, these guidelines are formed for organ retrieval in brain-stem death cases. Similar, uniform guidelines are needed for NHBD program. Presence of such guidelines will help to retrieve organs from medicolegal cases after observing legal procedure without violating existing laws and Acts.

Conclusion :

In conclusion, it can be added that with increasing demand of organs for transplantation purpose, the non-heart-beating donors can fulfill the need up to some extent. For implementing these programs in India, a comprehensive discussion should be made to address the ethical, medical and legal issues involved thereon and need a comprehending policy. The NHBD program should be executed on need basis and not on demand and supply basis.

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