“Brain Death” and dead donor rule
Discussion and proposals on the thesis of Truog

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The introduction in 1968 by the “ad hoc” Harvard committee of the concept of “Brain Death” gave birth to the worldwide diffusion of organ transplantation. Recently “Total Brain Failure” has been proposed as preferred term, instead of “Brain Death”, by the President’s Council on Bioethics. The concepts of “brain death” and of “dead donor rule” remain the ethical and moral support of organ transplantation. However both criteria has been questioned, either separately or all together, by many authors and particularly by Dr. Robert D. Truog.

KEY WORDS: Brain Death, Dead donor rule, Extended Criteria Donor (ECD), Informed consent, Reciprocity, Transplantation

Moving from a clinical case of apparently “reversible” brain death, Dr. Truog came to the personal conclusion that “brain death” is a “legal fiction” which is still so “useful” that it will be very difficult to be replaced. Truog, as other authors, neither believes that “brain death” as total loss of encephalic function is the “death” of an individual or the permanent loss of an organism as a “whole”, nor that brain death is a “horizon event” in the process of dying. Truog, as other authors, would accept for the diagnosis of “brain death” the permanent, that is irreversible, loss of any conscience, but doing so we should consider “dead” also the patients in Permanent Vegetative Status, who still breath spontaneously. Recently “Total Brain Failure” has been proposed as preferred term, instead of “Brain Death”, by the President’s Council on Bioethics, subsequently disbanded in June 2009 by President Barack Obama. As a consequence, this term has never been adopted in clinical practice. According to Truog, this clinical condition would relate to death as the concept of “legal blindness” (according to the local laws) is related to effective blindness. Truog’s proposal probably would met the opposition of some religious communities (not accepting at all the concept of “brain death”), and their members, as it presently happens for Muslims in Singapore, should be allowed to opting out organ donation by signing a “card”, or enrolling a special register.
The abolition of the “dead donor” rule, that is the fact that the donor has to be dead and it is not possible to harvest life-sustaining organs from a living donor, would not be accepted by the Roman Catholic Church.

As addressed by Benedict XVI to participants in the international congress “A Gift for Life. Considerations on Organ Donation” on November 7, 2008, sponsored by the Pontifical Academy for Life, the International Federation of Catholic Medical Associations, and the Italian National Transplant Center: “In any case, it is useful to remember that the various vital organs can only be extracted “ex cadavere” [from a dead body], which possesses its own dignity and should be respected. Over recent years science has made further progress in ascertaining the death of a patient. It is good, then, that the achieved results receive the consensus of the entire scientific community in favor of looking for solutions that give everyone certainty. In an environment such as this, the minimum suspicion of arbitrariness is not allowed, and where total certainty has not been reached, the principle of caution should prevail. For this it is useful to increment interdisciplinary research and study in such a way that the public is presented with the most transparent truth on the anthropologic, social, ethical and legal implications of a transplant.

In these cases respect for the life of the donor should be assumed as the primary criterion, in such a way that the extraction of the organs only take place after having ascertained the patient’s true death (cf. Compendium of the Catechism of the Catholic Church, No. 476)

In Italy the declaration of brain death is ruled by Legge 29 dicembre 1993, n.578 (“Norme per l’accertamento e la certificazione di morte”): death is the irreversible stop of all brain functions, either as a consequence of cardiac arrest for no less than 20 minutes (as proven by electrocardiogram-ECG) or by a lesion that has completely damaged the brain.

In this latter case three physicians (an anesthesiologist, a neurologist/neurosurgeon with experience in electroencephalogram – EEG, and an expert in forensic medicine), appointed by the Direzione Sanitaria (Medical Direction) of a Public Hospital and absolutely not related to the potential organ recipient or the organ procurement team, have to confirm the contemporary presence of:
- unconsciousness
- absence of reflexes of the encephalic trunk
- absence of spontaneous breath
- electric silence of cerebral activity

Art. 4 of Decreto Ministeriale 11 aprile 2008, n. 136 (bringing up-to-date D.M. 22 agosto 2994 n.582) regulates this period of observation, mandatory for all patients before disconnection from ventilator, whose duration must not be inferior to 6 hours for adults and children. If the patient is suitable to become an organ donor, the coordinating physician verify in the Sistema Informativo Trapianti (SIT) if the patient expressed his willingness to donate, or if the patient has a donor card or other document stating that he/she wants to be an organ donor.

These “brain death” criteria had already been accepted in 1985 by Pontificia Accademia delle Scienze.

As previously stated, the “brain death” criteria seem too “restrictive” to some transplant professionals and bioethicists, who would like to overcome the “dead donor rule” to increase organ transplants.

G. Boniolo, H.R. Doyle, B. Fantini, J. Harris, I.R. Marino, T. Powell, M.C. Tallacchini, R.D. Truong and S.J. Youngner stated, in the conclusions of the International Workshop of Bioethics “Brain Death and Organ Donation: Ethical and Scientific Issues”, organized in Viareggio (Italy), on September 24, 2009: “we are still learning about brain death (clinically, legally, socially) and how it evolves in relation to differences due to culture, religion, etc.” and recommended: “…..Keep open discussion with the public…..Reconsider the rigid definitions (“irreversible”, “entire functions”, “entire brain”), as they are impossible to put into clinical practice today’. However, many other transplant professionals believe that organ donation should be increased without overcoming the “dead donor rule”, coercion to donation, economical incentives or organ commercialism but by introducing into the laws of each country the principle of “reciprocity”, that is the prioritization in the transplant waiting list of patients who had previously subscribed “donor cards”, as already happened in Israel 6-11.

Concerning the new Israeli law, as written in Lancet in 2010, “I also disagree with the fact that, at least for the first year of the new plan, everyone who has signed a donor card, including listed transplant candidates, will be given prioritization rights after only a 1-year waiting period”. It has to be appreciated that the final law prolonged the waiting period to 3 years, although should not have granted prioritization rights also to those who “have given their consent for actual organ donation of their designed next-of-kin…..” because “relatives should not violate the decisions made by the deceased about the fate of the body, including organ donation”.

In conclusion, Italy has always had, since 1968, very good laws defining “brain death”, that have allowed the diffusion of transplant activity with optimal clinical results, and without any problem or mistake in the diagnosis of brain death. Therefore there is no apparent need to change the current law, or to abolish the “dead donor rule”, as proposed by Truong.

Riassunto

L’introduzione nel 1968 da parte del Comitato “ad hoc” di Harvard del concetto di “Morte Cerebrale” ha permesso la diffusione del trapianto di organo.
Il concetto di “Morte Cerebrale” e quello conseguente di “dead donor rule”, rimangono alla base dei trapianti di organo, anche se entrambi sono stati oggetto di critiche da parte di alcuni autori, tra i quali il Dr. Robert D. Truog.

References
