The Introduction of a Non–Heart-Beating Donation Program and the Medical Ethics Committee

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THE GAP between the number of available kidneys for donation and the number of patients awaiting renal transplantation is growing over the years. The introduction of a non–heart-beating kidney donation (NHBD) program can help to reduce this gap.[1] However, a NHBD program is not easily introduced in the hospital. A very detailed and strict protocol has to be written, the possible participants should be informed, and approval of the institutional Medical Ethics Committee (MEC) has to be obtained. In our experience, a NHBD program proposal caused considerable confusion and misunderstanding among the members of the MEC, mainly concerning the definitions of cardiac and brain death. The dialogue and the discussions that we had with the MEC were clarifying and worthwhile for all who were involved in the introduction of our NHBD program and eventually led to a protocol that was broadly accepted in our institution.

PROTOCOL AND METHODS

The criteria for NHBD are:

1. Cardiac and circulatory arrest does not last longer than 45 minutes. Periods of resuscitation are included in this 45 minutes.
2. The patient is between 15 and 60 years of age.
3. The patient does not belong to a high risk group for acquired immune deficiency syndrome (AIDS), hepatitis B, or hepatitis C infection, and screening tests for these infections are negative.
4. The patient has no primary kidney disease, uncontrollable hypertension, or insulin-dependent diabetes mellitus. There are no signs of intravascular coagulation with anuria and no signs of malignancy other than a primary (nonmetastatic) cerebral tumor.
5. There are no signs of sepsis or serious infection.
6. Patients who died after assisted suicide or euthanasia are also excluded from the protocol.
7. There should always be the possibility to take blood samples for virology screening.

These strict criteria limit the group of potential donors. The most suitable patients for NHBD are those who are admitted to the emergency room with fatal wounds after a (traffic) accident or with cardiac arrest caused by myocardial infarction. Some patients dying in the intensive and cardiac care units may also fulfil the criteria of the protocol.

When the NHBD criteria have been checked, the family is approached with the request for kidney donation. In the Netherlands, the donor card is a legal document that would justify organ donation even without the approval of the relatives. However, whenever the deceased has a donor card, and his relatives do not agree with organ donation, the donation procedure is cancelled. In cases of NHBD, this means in practice that a donor card legitimates the immediate introduction of a catheter for in situ perfusion. The surgical procurement of the kidneys will, however, never take place without the approval of the relatives. When no donor card is present and the relatives cannot be reached in time, the NHBD procedure cannot be started.

After resuscitation attempts have been stopped, a 10-minute waiting period is observed before the catheters are inserted. The kidneys are rapidly cooled by in situ perfusion by a double balloon triple lumen (DBTL) catheter. The DBTL catheter is inserted through the femoral artery into the aorta. The kidneys are cooled by using histidine tryptophan ketoglutarate (HTK) preservation fluid. The detailed method has been described before.[1] Usually the surgical procedure for procurement of the kidneys is started within the following hour.

DIALOGUE ON ETHICS

The proposal for a protocol for NHBD was submitted to the MEC of our hospital. In the dialogue that followed, discussions focused on: How should death be defined in a NHB donor? Is there no conflict of interest between the different teams involved in the NHBD procedure? Considering the urgent nature of NHBD procedures, is there enough time to pay attention to and take care of the relatives?

How Should Death be Defined in a NHB Donor?

The final criterium for the death of a human being is brain death. Through the years the definitions of brain death as used in the field of transplantation have become widely accepted. For these reasons, the MEC initially thought that the diagnosis of death of a patient who is a potential organ donor always has to be made using the current methods of the examination for brain death. However, when cardiac arrest has occurred, and the medical team has decided that further treatment is meaningless, the diagnosis of death becomes quite simple. Complementary investigations are

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not necessary, because after a circulatory arrest of 10 minutes, it is certain that the patient is brain dead.

When in a NHBD protocol cardiac massage and ventilation are started immediately after the cardiac arrest and are subsequently continued for reasons of preservation of the kidneys, this could maintain adequate cerebral perfusion, thus preventing the occurrence of brain death. Therefore, a 10-minute waiting period has to be observed after attempts to resuscitate the patient have been given up, before cardiac massage can be resumed.

Is There no Conflict of Interest Between the Different Teams Involved in the NHBD Procedure?

In cases of NHBD there are often more medical teams involved. The physicians who treated the patient until his death, physicians who will approach the relatives with the request for donation, and doctors who take care of the in situ cooling and the procurement procedure. When it is the cardiologist who has treated the patient and who has tried to save his life, he will be the one who will bring the bad news to the family. He may ask the family for organ donation, and after the permission of the relatives has been obtained, he will inform the surgeon on call, who will start the NHBD procedure. However, when a patient is brought to the emergency ward after a traffic accident, it will often be the surgical team that will give first aid to the patient. When they have not succeeded in saving the patient's life, they have to bring this message to the relatives and at the same time they will ask for NHB donation, if it concerns a suitable donor. If the relatives agree, these doctors will also begin the NHBD procedure. This particular situation caused concern to the MEC.

The Dutch Health Council stated in its advice concerning brain death and organ donation that in case of the slightest doubt, a physician must consult another. Because of the delicate situation of brain death and organ donation, everyone involved will often choose the safe side of decision making, even if all circumstances are clear. In cases of NHBD, the MEC wanted to be sure that there was a strict separation between the treating physicians and the transplantation team. In practice, this cannot always be arranged, and more importantly, it is not an absolute requirement. The Dutch Health Council stated in 1975 that in case of organ donation, one has to aim at a separation of the teams involved in the treatment of the patient and in the donation procedure. When this separation cannot be guaranteed, one has to ensure a separation of responsibilities.

When NHBD is considered a possibility in a patient who died due to a traffic accident, the surgeons involved have to realize that they are responsible for all decisions taken during the procedure. In the objective evaluation after each NHBD procedure, this principle should be kept in mind. Equally important is the subjective element of trust. Also, one should realize that negative publicity as a consequence of careless behaviour of the individuals involved makes continuation of a well-running NHBD program impossible.

Considering the Urgent Nature in NHBD Procedures, is There Enough Attention and Care for the Relatives?

In a NHBD procedure there are two specific moments that the nursing and medical staff have to pay extra attention to. The first is when the family is asked for organ donation, usually at the same time when they receive the message that their beloved has passed away. The second one is the moment when they pay their final respects. Requesting organ donation is a delicate subject for all people involved. Merely asking for organ donation is not enough, and insufficient communication and empathy at that time can result in a feeling of great dissatisfaction for both the relatives and the hospital staff. All aspects of death and of the donation procedure must be part of the information supplied and must accompany the request for donation. Given in the right way, correct information makes the decision making easier for the relatives. A prerequisite is that the hospital staff is well informed so that they can better deal with the situation and can give adequate care and attention to the family. Personal feelings and thoughts are always reflected in a conversation with relatives. Doctors, as well as nurses, have to be aware of this. Therefore, they have to be well trained for this difficult situation. Again, when they have the skills to approach the family in the right way, it is easier for all parties involved. Relatives who are satisfied about their experience in the hospital and the donation process can have an important positive influence on their social environment. On the other hand, insufficient care can have a negative effect on the availability of donor organs in the future. In NHBD procedures time limits play an important role. Despite this urgency, there must always be enough time for relatives to pay their final respects. It is these delicate moments that have to be organized with great care, and no minor detail may disturb the intimate moments. An atmosphere must be created in which the relatives feel free to express their feelings, so that at least this particular moment will not disturb the process of grieving.

NON–HEART-BEATING DONATION IN PRACTICE

When a doctor or a medical team declares a patient dead and his relatives agree with organ donation, cardiac massage and ventilation are started to maintain sufficient renal blood perfusion in several NHBD protocols. For the reasons explained above, we observe a 10-minute waiting period to be certain that brain death has occurred. During this waiting period, the family can be approached with the request for organ donation. Because there is no scientific evidence that significant perfusion is achieved during cardiac massage, we eventually decided to drop it completely from the protocol. This also obviates the psychological burden of having to carry out cardiac massage and artificial ventilation on a dead body.

Because of the possible conflict of interest between the different medical teams involved, we agreed to evaluate every NHBD procedure both orally and in writing. Proper

evaluations can clarify the position of every person involved and analyze the problems faced during the NHBD procedures. By this means, the evaluations will enrich and further refine the NHBD protocol in our institute.

To help doctors and nurses to deal with the request for organ donation Eurotransplant, in cooperation with the University of Maastricht, developed an awareness program: the European Donor Hospital Education Programme. This 1-day course is an interactive skills-awareness workshop. The participants acquire a better understanding of the grief reactions of families and learn through communication skills how to approach the relatives with the request for organ donation. Because the participants concentrate for a whole day on the subject of organ donation, they feel less frightened and more confident in the future, when they have to ask a deeply grieving family for donation.

The moment the relatives pay their final respects has to take place in a quiet room and in a quiet atmosphere. Despite the time limitations of a NHBD procedure, relatives must get sufficient time to do this in their own way. A suitable moment to do so is after the in situ perfusion has been started and before the operation starts. A NHBD coordinator organizes the different processes in the procedure, with regard to both the technical and the psychological aspects. The NHBD coordinator also collects the information necessary for the evaluation of the NHBD procedures.

The atmosphere in which a NHBD procedure takes place in the emergency room and the operating theatre is an emotional one, not only for the relatives who have just lost a beloved member of their family, but also for the doctors and nurses involved. Perhaps because of this emotional situation, a feeling of unity is created in which all have their own thoughts and feelings. It is of the greatest importance that attention is paid to these emotions.

REFERENCES

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