Legal Aspects of Organ Transplantation in Italy

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ABSTRACT

Informed consent is of paramount importance in any field of surgery, both from the ethical and the legal points of view. Concerning organ transplantation, potential recipients are fully informed before entering the waiting list. However, according to Italian law, they have to sign another informed consent form before entering the operating room. In our opinion, not only should recipients be informed of the quality of the donor and of the particular organ(s) they are going to receive, but also before entering the waiting list they should accept or refuse the future possibility of receiving an organ from a so-called marginal or extended criteria donor (ECD) and/or a non–heart-beating donor (NHBD).

KIDNEY TRANSPLANTATION from a living donor, accomplished for the first time in 1954 by Murray, who confirmed the possibility of successfully performing this kind of procedure with long-term recipient survival, is now considered a good clinical solution, complementary to cadaveric donor (CD) kidney transplantation, to increase the donor pool. In fact, in the last decade the number of transplantations has remained steady notwithstanding the exponential increase among patients entering the waiting list.

Since the origin of kidney transplantation, the use of living related donors (LRD) has been accepted worldwide. With the increasing availability of dialysis, many centers subsequently discouraged transplantation from living donors; however, the introduction of cyclosporine with a significant improvement in the results of CD kidney transplantation together with the dramatic growth in the number of patients on the waiting list, due to inadequate supply of cadaveric kidneys, prompted us to expand the acceptable criteria for living donors. The validity of this kind of procedure is based upon many ethical and clinical considerations, including the results which in most reports are better than those with CD kidney transplantation, the free willingness of the donor, and the limited health risks for the donor. Both conventional and laparoscopic living donor nephrectomy are safe procedures, with worldwide overall mortality of 0.03%.[1] However, at least 4 kidney donors developed end-stage renal failure and underwent kidney transplantation.[2]

The use of living unrelated donors (LURD) in kidney transplantation is more debated: emotionally related donors such as spouses and acquired relatives are usually preferred. In any case, the consent always has to be completely unconditional: some forms of psychological pressure are difficult to recognize in a family setting, while economic dealings may be concealed even by the donor with the bending risk of commercialism.

According to published data,[3] as well as our personal experience,[4–6] presently there could be no clinical (only ethical) objections to LURD kidney transplantation. Many donors report increased self-esteem as a consequence of having helped to restore the health and improve the quality of life of a significant one. Some people in fact argue that the theoretical risk for the donor, which as previously discussed is extremely low, does not compensate for the evident socioeconomic advantages and increased quality of life of the recipient, who avoids a long waiting time and is usually able to return to social activity and work earlier. In selected cases, such as younger recipients, kidney transplantation can be performed in a pre-uremic phase, avoiding the psychological and physical stresses of dialysis, which in pediatric cases is not well tolerated and cannot prevent retarded growth. The consent must be free and without any form of coercion, which may be subtle and difficult to detect, as some forms of psychological conditioning are difficult to recognize in a family setting, while economic dealings may be purposely concealed even by the donor. According to the Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor,[7] organized

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0041-1345/08/$–see front matter
doi:10.1016/j.transproceed.2008.05.004

on April 1–4, 2004 by the Ethics Committee of the Transplantation Society, "Minors less than 18 years of age should not be used as living kidney donors." In agreement with these guidelines, commercialism must be effectively prevented, possibly by using only spouses or relatives-in-law as LURDs. One must be reminded that results of commercial kidney transplants are discouraging, providing a further issue against transplantation from paid donors, as a consequence of poor donor screening with consequent transmission of HIV and other infective agents, as well as inappropriate medical and surgical management of recipients, who present an unacceptable morbidity rate and, often after having been discharged too early, seek medical attention in their native countries. "Rewarded gifting" or other financial incentives to compensate for the inconvenience and loss of income related to the donation are not advisable, at least in our opinion. All over the world most public or private insurance companies are considering living kidney donation to be a safe procedure without long-term harm or impairment and therefore do not increase the premium for these donors, while recipient insurance of course should cover the donor's hospital fees. Due to obvious ethical reasons, transplant physicians and surgeons cannot take part in kidney donation from prisoners, even when such a procedure has been proposed to death-row inmates as an alternative to execution.

To increase the possibility of LURD kidney transplantation between blood group incompatible pairs, Rapaport proposed in 1986 a national network to exchange kidneys harvested from living donors with a blood group not compatible with their emotionally related recipients. This suggestion was proposed again in 1997 by Ross as a local program and by Park et al.[8] This so-called crossover procedure allows living kidney transplantation also in cases of couples with direct positive cross-matches and, if applied on a larger scale, could also allow HLA matching, which is probably useful in this kind of transplant. However, only 5% of couples could benefit from "crossover", which theoretically could have negative psychological and ethical effects, such as decreased willingness to donate to a stranger or greater risk of donor coercion and organ commercialism.

Informed consent is of paramount importance in any field of surgery, both from the ethical and the legal points of view. The consent must be free and without any form of coercion, which could be subtle and difficult to detect, as some forms of psychological conditioning are difficult to recognize. Concerning organ transplantation, potential recipients are fully informed before entering the waiting list. However, according to Italian law, they have to sign another informed consent form before entering the operating room. At this time the patients are deeply emotionally involved and may not be able to express a fully informed consent, particularly if they have to accept or refuse an organ from an extended criteria donor (ECD).

Not only should the recipients be informed of the quality of the donor and of the particular organ(s) they are going to receive, but also before entering the waiting list they should accept or refuse the future possibility of receiving an organ from a so-called marginal[9] or ECD[10] and/or a non–heart-beating donor (NHBD).[11] Some transplant centers[12] in Italy also enroll the appropriate recipients, of course after a fully informed consent, into different waiting lists for organs from "normal" or ECDs. Presently, NHBD is still in an early phase in Italy, but this procedure could increase, as has already happened in Spain, the Netherlands, the United States, and Japan.[13]

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