



Development of a System of Care for the Living Kidney Donor

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ABSTRACT

Kidney transplantation from a living donor is a method of choice in the treatment of end-stage renal disease. The programme of care for a living kidney donor should cover the assessment of health status and quality of life and an analysis of the data collected on the basis of the same criteria. The conclusions drawn should be used in the assessment of the risk associated with the kidney harvesting procedure, assessment of the health status of the living donor and an improvement of the results of kidney transplantation from a living donor.

CONTENT

he disproportion between the number of recipients and donors of organs for transplantation is one of the most important challenges of contemporary transplantation medicine. The pool of organs for transplantation may be increased in the procedures of their harvesting from living donors. Kidney transplantation from a living donor is a method of choice in the treatment of end-stage renal disease. The best results of treatment of end-stage renal disease are obtained in the predialysis period. In Poland, only 5% of renal transplantations in the general pools are kidneys harvested from a living donor (in contrast to approximately 50% in Scandinavia). An essential issue is to develop a system which would ensure, through the process of screening tests and care for the living kidney donor, the safety of the conducted procedure and a long-term follow-up of donor's health after the kidney removal surgery.

Kidney transplantation from a living donor is an operation that brings benefits to the recipient. On the other hand, it is associated with the risk borne by the donor. This risk is related both to the surgery itself as well as to the consequences of living with only one kidney. Harvesting the kidney for transplantation from a living donor is a complex surgical procedure which does not improve the donor's health. The prospective donor must meet strict health and psychological criteria to be found eligible for the surgery. In scientific literature there are many examples proving that the procedure of kidney transplantation from a living donor is safe for the donor in the early and late period after the donation. (1, 2) Along with the growing number of transplantations performed, loosening of medical (3, 4) (age, obesity, arterial hypertension well controlled by monotherapy) and psychosocial (5) (unrelated donors) criteria for donors is being observed, which is associated with an increase of prospective eligible donors for living kidney donation. Most of the observations concerning the health status of living kidney donors presented in the literature apply to patients originating from one transplant centre. In many cases, the data are incomplete, the studies are conducted retrospectively, and the research methodology varies. The system of providing medical care for the living kidney donor should also be rooted in the legislation in force in the territory of a given country.

The most important piece of legislation regulating the transplantation issued in the territory of the European Union is the Directive of the European Parliament and of the Council 2010/53/EU of 7 July 2010. In Poland, the legal regulations related to transplantation are contained in the Transplantation Act of 1 July 2005, concerning the procurement, storage and transplantation of cells, tissues and organs. The issues related to living donations are regulated by Chapter 3 of this Act, titled: "Procurement of cells, tissues or organs from living donors". The principles of harvesting, storing and transplanting cells, tissues and organs are defined in that Chapter. The Act defines inter alia the legal framework of transplanting organs from a living donor. The health requirements that must be met by a donor of cells, tissues and organs are stated in the Regulation of the Minister of Health of 25 April 2006. (6) Moreover, it includes a list of diagnostic examinations and tests and contraindications to donation. The Regulation also defines the type and scope of tests of living organ donors performed within the framework of their health monitoring.

There are a number of contraindications to donations. Those listed in Table 1 were established at a conference on the procurement and transplantation of organs from living donors that was held in Amsterdam in 2004. These contraindications are used in Poland. In such countries as Canada or the United Kingdom, donor exclusion criteria developed by local institutions are used. (7, 8) Moreover, European and American organizations have developed the respective guidelines. (9, 10)

The basic screening tests are performed at the regular medical centre of the kidney recipient. The

remaining diagnostic and laboratory tests and examinations as well as the necessary consultations are performed at the transplant Centre. The required examinations and tests are listed in Table 2. (11)

If a disease is diagnosed in the prospective donor in the screening process, such a person is found temporarily or finally ineligible for surgery. The prospective donor is referred to further diagnostics and treatment. (13) It should be emphasized that the screening process and the medical examinations make it possible to detect and diagnose early the disorders of which the prospective donor is unaware, which increases the chance for curative treatment. It is the direct benefit that the prospective donor may obtain. Despite loosening of the criteria, less than a half of potential living donors meet the donation requirements. (9, 14) At the Centre employing the author, this percentage is similar, and the analysis of the screening process was conducted by Dr Gozdowska et al. (13) The study applied to the screening process of 124 potential donors for 111 kidney recipients in 2007 - 2011. As shown by the results, non-eligibility causes were:

- medical reasons (39.7%),
- cadaveric renal transplantation (25%),
- immune factors (23.5%),
- consent withdrawal by the donor (4.6%),
- psychological and social factors (4.4%).

Romagnolli et al. (15) described similar causes of non-eligibility. The main causes were medical factors increasing the cardiovascular risk.

Harvesting a kidney from a living donor is possible only when the donor has been fully informed of the possible complications, the risk of surgery is small and the transplantation has a high chance for success. The donor's must be fully informed and consent must be voluntary. (8) The donor may withdraw the consent until the surgery itself.

The donor who donated regenerating cells and tissues more than once and the organ donor have the right to the title of the "Distinguished Graft Donor". (16) This title is assigned at a request of the Polish Transplant Coordinating Centre Poltransplant and gives the right, for example, to jump the queue in pharmacies and health establishments.

There are no clear global or European guidelines which would state precisely the scope of tests performed in the course of the control and on the length of time for which the care for the donor is to be provided. Under the Transplantation Act (16), in Poland transplant centres are responsible for the care for the living kidney donor. The care must be provided for up to 10 years after transplantation. (16) The Regulation of the Minister of Health (14) includes the information what examinations and tests are to be performed at the follow-up visit of a living kidneys donor at the transplant centre. In line with this Regulation, the follow-up visits are held at 1, 6 and 12 months after surgery and annually for 10 years. At the centre employing the author, the visits are held additionally at 3 months, and then annually, without a time limit. Follow-up examinations and tests are performed in the course of one- or two-day hospitalisation. At the hospital, donors undergo physical examinations, imaging examinations and biochemical blood and urine tests. In justified cases, the diagnostics is expanded (e.g. by pressure Holter). Moreover, the health status is also assessed in the psychological aspect. In the model developed in the Chair and Department of General and Transplant Surgery of the Medical University of Warsaw, a psychologist plays an integral role in the care for the kidney donor and recipient. The care is provided in cooperation with a team of psychologists led by Dr Mateusz Zatorski from the University of Social Sciences and Humanities in Warsaw.

Since 2008, American transplant centres must provide medical care for the kidney donor for 2 years, and the test results are to be transferred to the UNOS register.17 Follow-up visits should take place at 3, 6, 12 and 24 months after hospital discharge, but it is not clearly stated whether the follow-up examinations and tests are to be performed at the transplant centre or in the family physician's office. (18) In response to a question posed in a survey to persons responsible for conducting programmes of care for the living donor at the majority of transplant centres in the USA, 31% of the respondents considered that care for the donor should last for 5 years or more, 30% considered 2 years to be enough, for 32% it was one year, and 8% considered up to 6 months to be a sufficient period. (17) In Australia, there is no programme of care for the living donor and it only depends on the living donor whether and how they will follow up on their health status. Medical monitoring is conducted by the family physician. (19)

In the study of Mandelbrot et al., (18) the authors state that in a large number of American transplant centres the only examinations and tests are blood pressure measurement, serum creatinine test, general and biochemical urin analysis and a physical examination of the patient. Health status assessment in the psychological aspect is performed in the minority of cases. In less than half of the cases, a psychological assessment of the health status is performed. As shown by a study conducted by Waterman et al., (17) in the case of assessment of the health status of a living donor it is necessary to monitor a larger number of parameters than monitored so far.

It arises from the data presented by UNOS that 30% of living donors in the USA are not covered by medical care and there is no information in registers about their actual health status. (20) At certain transplant centres, living renal donors are not covered by the system of care at all. (17)

In Poland, the data collected at follow-up visits, con-

cerning the health status of donors, are to be entered into the Register of the Living Donor operating since 1 January 2007. This register covers liver and kidney donors. Transplant centres are responsible for updating the data in the register. The purpose of keeping the register is health monitoring and creating a safe system of care for donors. In 2013, the Register of Living Donors was supplemented by donors of earlier years, i.e. starting from 1967. The extent of updating the data in the Register of Living Donors is still unsatisfactory. Follow-up examination at 5 years after the operation are entered into the register on average only in 11%. In view of the small number of data, the register does not perform its function of a tool for the monitoring and assessment of health status of a living donor. (21)

An important aspect of building a correctly operating healthcare system is the method of its financing. This issue applies to numerous countries, including Poland, and the existing financing methods are based mainly on public sources or on private insurers. Professor Wojciech Rowiński considered the donated kidney to be an input made by living donors into the healthcare system in the area of transplantation. According to Prof. Rowiński, it is the State which is responsible for developing a healthcare system in the form of outpatient care as well as compensation for lost earnings. In many cases, insufficient funds are the reason for the lack of medical care for the living kidney donor. Moreover, increasing migration of the society is important in the aspect of developing a system of care for the living donor. The aim should be to develop such mechanisms which will make it possible to provide care for a living donor not only at the centre where transplantation was performed but also at the nearest place of permanent residence of the donor.

On the basis of surveys, Waterman et al. (17) specified the causes of improper operation of the long-term system of care for the living donor in the United States. The main factor of the inappropriately functioning programme of care for the living donor is the donors' unwillingness to participate in the programme. More than half of the respondents indicated financial reasons – the lack of possibility to finance the procedures performed within the framework of the care for the donor at transplant centres and the lack of compensation for the costs borne by the donors related to examinations and tests and to getting to the follow-up visit.

So far, more than 250 kidneys have been transplanted from a living donor in the Chair and Department of General and Transplant Surgery. The coordinator for the living donor plays an important role in the "local" healthcare system functioning in the Department. The coordinator's task is to integrate the care for the donor, to organise follow-up visits of patients and to keep the Register of the Living Donor. The programme of care for a living kidney donor should cover the assessment of health status and quality of life and an analysis of the data collected on the basis of the same criteria. The conclusions drawn should be used to assess the risk associated with the kidney harvesting procedure, to assess the health status of the living donor and to improve the results of kidney transplantation from a living donor.

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TAB. 1. CONTRAINDICATIONS TO DONATION

Absolute contraindications

- mental disease precluding an informed decision
- ineffectively treated psychiatric disease
- addiction (alcohol, cigarettes, illicit drugs)
- renal disease symptoms (elevated creatinine level, decreased GFR, proteinuria, unexplained haematuria and pyuria)
- significant anatomical anomalies of kidneys
- recurrent nephrolithiasis or bilateral presence of kidney stones
- systemic vascular diseasesdiabetes mellitus
- poorly controlled arterial hypertension
- past myocardial infarction or coronary heart disease in the course of treatment
- moderate to severe lung disease
- presence of cancer (except in situ cancer of the skin, uterine cervix and colon)
- diagnosis of malignancy in the past (lungs, breasts, urinary tract, melanoma, gastrointestinal tract, haematopoietic system)
- family history of clear cell renal carcinoma
- infections

Relative contraindications

- age below 18 years and above 60 years
- obesity, particularly when BMI > 30 35
- moderately well controlled arterial hypertension
- previous single episode of nephrolithiasis
 minor abnormalities of the urinary tract
- young donor with more than one first-degree relative with diabetes
- mellitus or renal diseases in family history
 history of gestational diabetes
- mistory of gestational di tobacco smoking
- IODACCO SITIOKING
- Jehovah's Witness

TAB. 2. EXAMINATIONS AND TESTS PERFORMED IN A POTENTIAL LIVING KIDNEY DONOR

List of examinations and tests

- blood typing
- peripheral blood count
 blood biochemistry
- coagulation panel
- CRP
- urinalysis 2 x
- urine culture 2 x
- 24-h proteinuria
 microalbuminuria
- thyroid hormones, in justified cases
- virological panel: HCV, HBV, CMV, EBV, HIV, syphilis test
- HBV vaccination
- 3 blood pressure measurements ABPM*
- chest X-ray
- ECG
- cardiac ECHO
- exercise test if there are ECG and ECHO abnormalities or when age > 50 years
- urography, abdominal ultrasound
- dental consultation, pantomogram
- gynaecological consultation and examination, Papanicolaou test, pregnancy test (if justified), mammography
- urological consultation, PSA in men aged > 40 years
- psychological consultation

* According to the guidelines of the Amsterdam forum, ABPM is recommended, especially in prospective donors aged >50 years. (12)

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