

ANNEX 1 (Qualification for kidney transplantation)

KIDNEY TRANSPLANT: INFORMATION FOR THE PATIENT

Drafted in accordance with the information of the Organisational and Coordination Centre for Transplantation "Poltransplant"

The aim of kidney transplant is to achieve a prolonged and significantly improved quality of life for the patient. In order to make the decision to take the risk of surgery an informed one, we want to provide you as much information as possible. It is important to become aware that any surgical procedure carries risks. This risk depends on a number of factors. Some of them can be predicted and determined quite accurately, some, unfortunately, are unpredictable. Knowing and weighing them will allow a rational and informed decision to be made consenting to transplantation. We present information on statistics, donor selection, procedure, prognosis, post-operative treatment and the risks of the surgery and possible post-operative complications.

In Poland, more than 2,000 patients are waiting for a kidney transplant, and around 1,000 of them receive it each year. All patients qualified for surgery are placed on the National Transplant Waiting List. This list is common to the whole of Poland. The criteria for transplantation and the order in which the procedure is performed depend on many medical factors and are strictly defined by the National Transplant Council and Poltransplant. (<http://www.poltransplant.org.pl/klo.html>). The most important prerequisites are the matching of the main blood groups A, B, AB, 0 (Rh factor compatibility is irrelevant), the urgency of the procedure (priority is given, for example, to patients who cannot undergo dialysis), the similarity of tissue antigens between the donor and the recipient, the absence in the recipient's blood of antibodies directed against the transplant cells, and the waiting time for the transplant. Some priority on the list is also given to children. Unfortunately, it can take several years before the right organ for a particular person is found. During this time (waiting for a kidney transplant), your serum will be sent to all tissue matching labs every 6 weeks so that when a potential kidney donor emerges, a cross-match can be performed and once a year your application to KLO will be updated by your attending physician. A patient for whom treatment with a kidney harvested from a living donor is anticipated is also placed on the National Transplant Waiting List. In this case, the donor and recipient are strictly defined. The recipient or their legal representative consents to a kidney transplant from a specific donor, and the donor gives separate consent for the kidney to be harvested and transplanted to a specific recipient.

Kidney transplantation is associated with the following benefits:

1. Further treatment with dialysis is not necessary.
2. In most cases, quality of life is improved.
3. The life expectancy for a patient with an active kidney transplant is usually longer than that of a patient of similar age remaining on dialysis treatment.
4. Successful kidney transplantation may result in resolution of anaemia and improved physical performance.
5. The secretion of other hormones, including sex hormones, returns. A woman can become pregnant and give birth to a healthy baby, and a man can father a child.

However, it is difficult to guarantee that all or even any of the above-mentioned elements will improve, because the outcome of transplantation, as we have already pointed out, is influenced by many factors, and the importance of some in a specific case is difficult to predict before transplantation. When an organ suitable for transplantation becomes available, you will be notified by telephone. When you receive this notification, you should go to your kidney centre as soon as possible, to be examined to rule out any current medical contraindications for transplantation (e.g. exclusion of a developing infection, exacerbation of cardiovascular or respiratory disease) and, if necessary, dialysis. You will then travel to the hospital (one of several in Poland) where the transplant procedure will be performed. At this point, your transplant team should already know the risks associated with the specific organ available for transplantation and is obliged to provide you with comprehensive information about the risks of transplantation and the risks associated with potentially waiting for the next available organ. You always have the right to refuse to give your consent for a procedure. In this case, or if the organ retrieved would prove unsuitable for transplantation, you will return home and your existing treatment will continue.

Kidney transplantation procedure

The procedure is performed under general anaesthesia; you will be informed of the details of the anaesthesia by the anaesthetist. The surgeon will make an incision in the lower abdomen, usually on the right or left side. The new kidney is sutured to the large blood vessels near the urinary bladder. In rare situations, a different choice of transplant site or additional procedures, such as removal of the own kidney, are required. Necessary decisions, having only your best interests in mind, may be changed or taken during the procedure. During the surgery,

a catheter will be inserted into your bladder and a tube will be inserted into the area around the transplanted kidney, which will be removed a few days after the procedure. Usually, the procedure lasts between 2 and 4 hours. After kidney transplantation, the patient takes daily immunosuppressants to prevent the rejection. This treatment is necessary throughout the life of the transplant. Photographic or video documentation can be made during the procedure. These records will not identify you personally and may only be used for teaching or research purposes.

Kidney recipient post-transplant treatment

The length of your hospital stay after the surgery will depend on your recovery rate, the occurrence of any complications and the function of the transplanted kidney. Typically, patients are hospitalized for 2–3 weeks. Some restrictions on physical activity will apply for a few weeks after surgery. Immediately after surgery, you will need to visit the transplant centre every 1–2 weeks, and a little less frequently after a few months, for follow-up, laboratory test and scans to assess the function of the transplanted kidney and the quality of treatment. Among these tests is a percutaneous transplant biopsy, performed routinely or when clinically indicated, to diagnose rejection, recurrence of the underlying disease or other complications. Throughout the life of the transplant, you will need to take immunosuppressants to maintain its function and prevent rejection. Under no circumstances should this treatment be withdrawn, interrupted, forgotten or arbitrarily adjusted! Immunosuppressants can cause a number of adverse reactions (e.g. weight gain, depression, neurological symptoms, hypertension, hair loss, gum overgrowth, etc.). Your doctor will provide you the details prior to transplantation, when the composition and immunosuppressive treatment regimen suitable for you will be determined, and whenever a change in treatment proves necessary thereafter. Some of the drugs can be very harmful to the foetus, so women with childbearing potential need to use effective contraception and possible pregnancy should be planned in advance and discussed with their doctor.

Risks

Before undergoing a kidney transplant, you should be aware of the risks involved. The risks listed below are generally known, but there are also, as already mentioned, risks that are difficult to foresee and cannot be listed.

1. In about 30% of patients, the transplanted kidney does not become functional immediately after surgery, but with a delay of several days or weeks. During this period, the patient continues to be dialysed, as was the case before the transplantation. It increases the length of the recipient's hospital stay and the risk of other complications.

2. During or after surgery due to bleeding from damaged vessels, the need for blood or blood products transfusion may arise and, in some cases, re-surgery to close the bleeding sites.
3. A small percentage of patients develop artery or vein thrombosis in the transplanted kidney (vessel occlusion). The occurrence of this complication requires another surgical procedure, in some cases resulting in transplant removal and return to dialysis.
4. Many patients experience impaired wound healing. Approximately 5% develop bleeding, infection, hernia, urinary leakage or urinary stricture requiring further surgery. Most patients experience pain in the surgical wound area, which decreases over a few days and then subsides. Some patients also experience temporary sensory disturbances in the wound area.
5. In a few percent of patients, leakage of liquid contents persists for several days (rarely longer) through the tube left in the wound, making it impossible to remove the tube and sometimes forcing surgical treatment. Sometimes, after the tube removal, reservoirs of fluid (lymph) appear in the transplant area compressing the kidney or threatening to develop infection and may need to be emptied by puncture, tube reinsertion or surgery.
6. In some patients, to increase the safety of the ureter-bladder anastomosis, the catheter is left in the urinary tract for about six weeks, after which it is removed under anaesthesia through the urethra.
7. All transplant recipients must continuously take medication to prevent transplant rejection (immunosuppressants). You will take these drugs for the rest of your transplant life. These drugs can sometimes cause serious and even life-threatening complications. The most important and most common complications are infections (including pneumonia and urinary tract infections in the early stages), certain types of cancer and damage to the nervous system. To avoid these complications, immunosuppression must be strictly controlled and drugs taken systematically as prescribed by your doctor. These drugs can also raise blood pressure, serum cholesterol, reduce bone density, cause or exacerbate diabetes, inhibit the production of blood cells in the bone marrow and cause unwanted cosmetic effects such as facial swelling, acne, excessive hair growth or hair loss, gum overgrowth.
8. More severe complications are rare and occur in less than 1 in 10 patients. These include, but are not limited to: a. blood clots in large veins, especially in the lower limbs b. transmission of disease from the organ donor with the transplant (infection, cancer, kidney disease) c. recurrence in the transplanted organ of the disease that led to the failure of the organ's own



kidneys d. failure of the transplant to function e. damage to nerves, blood vessels, gastrointestinal tract or reproductive organs during surgery f. heart attack g. stroke h. deep infection of the surgery site i. cancer j. death of the recipient

9. On average, a kidney transplanted from a deceased donor survives 7–10 years, and from a living donor about 15 years. In some patients, the underlying disease recurs or chronic rejection develops. Sometimes a second kidney transplant is required, although some patients will not be eligible for subsequent transplants.

10. Based on data collected in the Polish transplant registry on kidney transplant treatment, the risk of graft loss 3 years after the surgery is 17%

where the transplant is from a deceased person and 6% where the kidney is from a living donor. The risk of the recipient's death within three years after transplantation is 8% when the organ is from a deceased person and 1% when from a living donor. On average, a transplanted kidney survives for just over 10 years, but there are known survivals of more than 30 years.