# EARLY OUTCOMES OF KIDNEY TRANSPLANTATION IN RECIPIENTS WITH TYPE 1 DIABETES MELLITUS AND END-STAGE KIDNEY DISEASE RESULTING FROM DIABETIC NEPHROPATHY

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**Objective:** to analyze early outcomes of kidney transplantation (KT) in patients with type 1 diabetes mellitus (T1D) and stage 5 chronic kidney disease resulting from diabetic nephropathy. Materials and methods. The study group included 145 T1D patients who underwent KT at the kidney and pancreas transplant department of Sklifosovsky Research Institute for Emergency Medicine between January 1, 2007 and December 31, 2023. Among them were 57 men (39.3%) and 88 women (60.7%), the median age was 41.5 [35–47] years. The median age at disease onset was 14.6 [9-17] years. Organ donors consisted of 100 (69%) men, 40 (27.6%) women, and there was no information on the sex of 5 donors (3.4%). Donor median age was 46 [35.5–53] years. Results. Ninety-nine recipients (68.3%) had primary renal allograft function (PRAF), whereas 46 recipients (31.7%) had delayed function. The median time for azotemia to normalize was 6 [3; 6] days in PRAF patients and 20.5 [14; 27] days in those with delayed function. Overall, there were 9.7% (n = 14) surgical complications, 12.4% (n =18) acute rejection crisis, and 9.7% (n = 14) infectious complications. Median serum creatinine and urea levels at discharge were 123 [99–164] umol/L and 10 [7.4–14] mmol/L, respectively; median fasting blood glucose levels before transplantation and at discharge were 9.8 [7.8; 12] mmol/L and 8.1 [6.5; 10] mmol/L, respectively. A total of 125 patients (86.2%) were discharged with adequately functioning kidney graft, while 13 patients (9%) were discharged with graft dysfunction that did not require renal replacement therapy; one patient (0.7%) was transferred to the outpatient stage of treatment to continue dialysis therapy; however, renal allograft function was restored within 2 months post-transplant. Conclusion. Although T1D patients remain the most severe category of dialysis patients, our findings suggest that KT is an effective treatment option for them with high graft and recipient survival rates.

Keywords: kidney transplantation, diabetic nephropathy, chronic kidney disease, type 1 diabetes mellitus.

# INTRODUCTION

Diabetes mellitus (DM) is a heterogeneous group of metabolic disorders characterized by chronic hyperglycemia resulting from impaired insulin secretion, insulin action, or both. It is classified as a chronic disease with significant socioeconomic impact due to early disability and high mortality rates. According to the International Diabetes Federation, the global prevalence of DM among individuals aged 20–79 is estimated at 537 million [1]. The growth rate of DM cases is concerning, far exceeding earlier predictions, with the number of affected individuals expected to nearly double by 2045, reaching 783 million [1, 2].

In the Russian Federation, the National Diabetes Registry reports that as of January 1, 2023, over 4.9 million people were registered with diabetes, accounting for 3.3% of the population. Among them, more than 277,000 individuals were diagnosed with type 1 diabetes (T1D), representing 5.6% of the diabetic population. Over a 13-year period (2010–2022), the prevalence of T1D increased from 146 to 191 cases per 100,000 population [3]. A one-time cross-sectional analysis of diabetic complications in T1D on January 1, 2023, revealed the following frequency of microvascular complications: diabetic neuropathy (41.3%), diabetic nephropathy (DN)/ chronic kidney disease (CKD) (22.8%), and diabetic retinopathy (DR) (28.9%) [4].

Individuals with diabetes represent the fastest-growing group among those receiving renal replacement therapy (RRT). In 1985, when the first edition of Diabetes in America was published, 20,961 people with diabetes were receiving RRT, comprising 29% of all

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new chronic kidney disease (CKD) cases. By 2012, this number had surged to 239,837, accounting for 44% of all new CKD cases [5]. The prevalence of diabetes-related CKD varies globally, with the condition representing 10-15% of CKD cases in Europe, but rising to 45% in the United States [6, 7].

Patients with diabetic CKD on dialysis face lower survival rates compared to those with non-diabetic CKD. Although dialysis techniques have improved survival, diabetic dialysis patients often have a median survival of less than three years. Cardiovascular disease (58%) and infections (13%) were the leading causes of death among diabetic dialysis patients between 1995 and 2009. In contrast, diabetic patients who undergo kidney transplantation (KT) tend to have significantly better longterm survival outcomes compared to those on RRT [8].

The 5-year survival rate for KT recipients with T1D is significantly lower compared to recipients with nondiabetic CKD, primarily due to the higher incidence of mortality related to cardiovascular complications [9, 10]. Despite advancements in RRT, diabetic CKD remains a major risk factor for poor posttransplant outcomes and continues to be an independent predictor of posttransplant mortality [11].

Reports suggest that simultaneous pancreas-kidney transplants (SPKTs) are associated with better survival rates for patients with diabetic nephropathy than other transplant options. SPKTs reduce mortality by decreasing the incidence of cardiovascular complications and secondary diabetic complications [12, 13]. However, this approach is linked to a higher incidence and severity of complications during the first year after surgery compared to isolated KT. These complications include prolonged hospitalization, higher re-hospitalization rates within the first 30 days post-surgery, more severe infectious complications, and increased perioperative mortality [14–16].

Meanwhile, in the long term, SPKTs offer improved patient survival, especially for recipients with a longfunctioning pancreas graft. For example, the 10-year survival for SPKT recipients is 50% higher than for those undergoing a KT alone [15, 16]. Unfortunately, organ shortages mean that not all T1D recipients can receive SPKTs. Consequently, KT remains the most viable treatment for diabetic CKD, offering improved quality of life and lower mortality rates in this patient population [8, 17].

**Objective:** to analyze early KT outcomes in patients with T1D and stage 5 CKD resulting from DN.

# MATERIALS AND METHODS

## **Recipient characteristics**

The study group comprised 145 recipients with T1D who underwent KT between January 1, 2007, and December 31, 2023, at the Kidney and Pancreas Transplant

Department of Sklifosovsky Research Institute for Emergency Medicine in Moscow. Among these recipients, 57 (39.3%) were men, and 88 (60.7%) were women. The median age was 41.5 years [range: 35–47], with a median body mass index (BMI) of 22.3 kg/m<sup>2</sup> [range: 19.8–25]. The median age at disease onset was 14.6 years [range: 9–17].

Of the recipients, 17 (11.7%) underwent pre-dialysis KT, while 128 (88.3%) had received RRT prior to transplantation. Of those on RRT, 86 patients (67.2%) were on long-term hemodialysis (HD), and 42 (32.8%) were on peritoneal dialysis (PD). The duration of RRT ranged from a few months to 15 years, with a median duration of 2 years [range: 1–4]. Among the recipients, 17 (13.3%) had been on RRT for less than one year, 86 (67.2%) had been on RRT for 1–5 years, 22 (17.2%) had been on RRT for some than 5 years, and 3 (2.3%) had been on RRT for over 10 years.

The majority of patients (93.1%) underwent primary KT, while only 6 (2.8%) underwent repeat KT. Before transplantation, 67 recipients (46.2%) had preserved residual urine output of more than one liter per day. In addition to DN, recipients had other secondary diabetic complications of varying severity, including diabetic polyneuropathy.

Pre-transplant macroangiopathy, particularly coronary heart disease, was present in 31 recipients (21.4%). Of these, 7 (22.6%) had a history of myocardial infarction, and 9 (29%) underwent coronary artery stenting as part of the KT preparation process. Nine (6.2%) patients had a history of stroke before transplantation. Nineteen patients (13.1%) had a history of trophic ulcers on the lower limbs, with 14 (73.7%) requiring amputations of one or more toes. Ninety recipients (62%) had chronic urinary tract infections, which required treatment for urosepsis and/or antibacterial therapy.

## **Donor characteristics**

The organ donor pool included 100 males (69%) and 40 females (27.6%); gender information was unavailable for 5 donors (3.4%). The median donor age was 46 years [range: 35.5–53]. Brain death was confirmed in 143 donors. The primary causes were stroke in 99 donors (68.3%) and traumatic brain injury in 41 donors (28.3%). Cause of death could not be determined in 3 donors (2.1%). Two recipients (1.3%) received kidneys from living-related donors.

At the time of organ procurement, median serum creatinine and urea levels in donors were 95.3  $\mu$ mol/L [range: 72–112] and 6.3 mmol/L [range: 4–7.59], respectively. Microbiological examination of the transplant grafts revealed the presence of microbial flora in 9 donors (6.2%).

## Surgical features of kidney transplantation

KT was performed using a standardized surgical approach. Access to the retroperitoneal space was estab-

lished, followed by mobilization of the external iliac vessels. The kidney allograft (KAG) was revascularized by creating arterial and venous anastomoses between the graft and the recipient's external iliac vessels. Urinary drainage was achieved through ureteroneocystostomy, connecting the donor ureter to the recipient's bladder. Median cold ischemia time of KAG was 13.5 hours [range: 11–16].

## Immunosuppressive therapy

All patients received baseline triple-drug immunosuppressive therapy (IST), with or without induction. Induction IST using mono- or polyclonal antibodies was administered to 124 recipients (85.5%). Among them, 97 patients received monoclonal antibodies: basiliximab in 88 cases (60.7%) and daclizumab in 9 cases (6.2%). Polyclonal antibody therapy was given to 27 patients, comprising horse-derived antithymocyte globulin in 7 cases (4.8%) and rabbit-derived antithymocyte globulin in 20 cases (13.8%). In the remaining 21 patients (14.5%), methylprednisolone alone was used for induction.

Maintenance IST consisted of a triple-drug regimen including a calcineurin inhibitor, an antimetabolite or proliferative signal inhibitor, and corticosteroids. Tacrolimus was prescribed to 108 recipients (74.5%), while cyclosporine was used in 37 cases (25.5%). As the second drug, mycophenolic acid derivatives were used in 143 patients (98.6%), while everolimus was used in 2 patients (1.4%). Methylprednisolone was included in the regimen of 144 patients (99.3%); only one patient (0.7%) received a steroid-free maintenance IST regimen.

**Study design:** observational longitudinal retrospective, cohort, single-center study.

**Inclusion criteria:** technically successful KT in patients with T1D and stage 5 CKD resulting from DN.

**Non-inclusion criteria:** technically unsuccessful KT; SPKTs.

## Graft function assessment criteria

Primary initial graft function was defined as the absence of a need for RRT during the first 7 days posttransplant. Delayed initial graft function was defined as

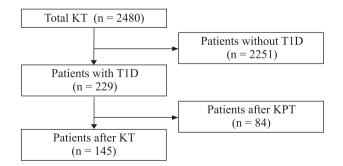


Fig. 1. Patient recruitment scheme for the study

the requirement for at least one session of extracorporeal detoxification within the first postoperative week. Death-uncensored graft loss was defined as return to RRT, death with a functioning graft, or repeat pre-dialysis KT. Death-censored graft loss excluded deaths with a functioning graft from the definition of graft loss.

# Statistical data processing

Statistical analysis was conducted using Statistica for Windows v. 10.0 (StatSoft Inc., USA) and StatTech v. 2.8.8 (StatTech LLC, Russia). The Shapiro–Wilk test was used to assess the normality of data distribution. Quantitative data were expressed as median (Me) and interquartile range [Q1–Q3]. Qualitative data were compared using Pearson's Chi-square test; for binary variables, Fisher's exact two-tailed test was applied. The Mann–Whitney U test was used for comparisons between two independent groups of non-parametric data. Overall survival and functional graft survival were estimated using the Kaplan–Meier method. A p-value of <0.05 was considered statistically significant in single comparisons.

# RESULTS

# Initial graft function

Primary initial KAG function was observed in 99 recipients (68.3%), while delayed graft function occurred in 46 recipients (31.7%). In patients with primary initial graft function, median time to azotemia normalization was 6 [3–6] days. In cases of delayed function, median time extended to 20.5 [14–27] days. Median number of hemodialysis sessions required during the recovery phase of graft function was 6.5 [4–9].

# Frequency of surgical complications

Early postoperative complications related to urinary tract reconstruction were noted in 7 recipients (4.8%): in six recipients, ureteroneocystostomy failure was attributed to necrosis of the distal ureter. These cases required reoperation with excision of the necrotic ureteral segment and repeat ureteroneocystostomy (Clavien–Dindo grade IIIb). In one case, ureteroneocystostomy failure resulted from an infectious process due to transplantation of a primarily infected KAG. This led to suppuration of the surgical wound and abscess formation in the graft bed, classified as Clavien–Dindo grade IVa. Renal transplantectomy was performed to preserve the patient's life.

Lymphocele formation in the KAG bed was observed in 6 recipients (4.1%) during the early postoperative period. In 5 cases, the condition required only dynamic observation and was classified as Clavien–Dindo grade I. One patient required surgical intervention, corresponding to Clavien–Dindo grade IIIb. Ureteral stricture developed in one recipient (0.7%), leading to hydronephrotic transformation of the KAG. This complication necessitated initial nephrostomy placement, followed by surgical excision of the strictured ureteral segment and repeat ureteroneocystostomy (Clavien–Dindo grade IIIb).

#### Frequency of acute rejection crisis

The overall incidence of acute rejection was 12.4% (n = 18). All cases presented with unexplained decrease in diuresis, elevated azotemia, and graft enlargement with ultrasound evidence of edema. In 9 patients, acute rejection episodes were successfully managed with methylprednisolone pulse therapy alone (3 injections totaling 1–1.25 g). Three patients received combined therapy consisting of methylprednisolone pulse therapy and infusions of polyclonal antithymocyte antibodies. In 6 patients, triple-modality therapy was administered, including methylprednisolone pulse therapy, polyclonal antithymocyte antibody infusions, and plasmapheresis sessions.

In total, 17 patients (94.4%) demonstrated favorable clinical and laboratory responses to anti-rejection therapy, with normalization of diuresis and azotemia, and restoration of graft function confirmed by instrumental assessments. In one patient (5.6%), therapy proved ineffective; the graft was deemed nonviable and required transplantectomy.

#### Frequency of infectious complications

The overall incidence of infectious complications was 9.7% (n = 14). Among these, 8 recipients developed graft pyelonephritis in the early postoperative period. Management involved administration of broad-spectrum antibacterial therapy, tailored according to microbiological findings from urine cultures, which identified *Klebsiella pneumoniae* and *Enterobacter spp.* as the predominant pathogens.

Four recipients experienced postoperative wound infections, necessitating surgical revision and sanitation of the graft bed, followed by secondary wound healing.

Two patients developed cytomegalovirus (CMV) pneumonia during the early postoperative phase. Both were successfully treated with ganciclovir-based antiviral therapy, demonstrating favorable clinical responses.

Hospitalization period for recipients ranged from 7 to 83 days, with a median duration of 23 [17–30] days.

Laboratory parameters at discharge: Median creatinine and urea levels at discharge were 123 [99–164]  $\mu$ mol/L and 10 [7.4–14] mmol/L, respectively. Pretransplant fasting blood glucose levels ranged from 3.5 to 22 mmol/L, with a median of 9.8 [7.8–12] mmol/L. During the first three days post-transplant, blood glucose levels varied between 3.3 and 30 mmol/L, with a median of 15 [12–17] mmol/L. At discharge, glucose levels ranged from 3.9 to 19.5 mmol/L, with a median of 8.1 [6.5–10] mmol/L.

Pre-transplant daily insulin dose ranged from 0.3 to 1.49 U/kg, with a median of 0.7 [0.55–0.9] U/kg. In the

early postoperative period (first three days), insulin requirements increased to 0.45–2.37 U/kg, with a median of 0.99 [0.8–1.25] U/kg. By discharge, doses ranged from 0.35 to 1.7 U/kg, with a median of 0.88 [0.7–1.1] U/kg.

Pre-transplant glycated hemoglobin levels ranged from 4.4% to 13.4%, with a median of 7.7 [6.9–8.6]%. Post-transplant values ranged from 5.5% to 11.3%, with a median of 7.3 [6.7–8.3]%.

In-hospital and 90-day death-uncensored renal graft and recipient survival: In-hospital recipient survival was 100% (n = 145), and graft survival was 95.85% (n = 139). A total of 125 patients (86.2%) were discharged with a functioning graft and serum creatinine levels below 200  $\mu$ mol/L. An additional 13 patients (8.97%) had functioning grafts with creatinine levels above 200  $\mu$ mol/L, but did not require RRT. One patient (0.69%) was discharged for continuation of RRT in the outpatient setting; graft function was subsequently restored within 2 months post-transplantation.

Morphologically verified primary non-function was observed in 4 patients (2.76%). These patients were discharged for continued outpatient RRT and were re-listed for repeat KT.

Two recipients (1.38%) underwent in-hospital transplantectomy. In one case, persistent graft dysfunction due to an uncontrollable acute rejection crisis led to the graft being deemed nonviable and subsequently removed. In the second case, although the graft was initially functioning, a primary graft infection led to postoperative wound suppuration and abscess formation in the graft bed. To preserve the patient's life, a transplantectomy was performed, IST was discontinued, and targeted antibiotic therapy was initiated based on microbiological sensitivity testing.

The 90-day patient survival rate (post-discharge) was 97.2%. Death-uncensored graft survival was 93%, while death-censored graft survival reached 97.2%.

Among the 139 recipients (95.86%) discharged with functioning grafts, 3 patients developed elevated azotemia in the early post-discharge period. Two of these cases were attributed to immunological complications. In the first patient, graft biopsy revealed borderline changes and signs of calcineurin inhibitor toxicity. The treatment strategy involved pulse glucocorticoid therapy and a reduction in tacrolimus dosage, resulting in clinical improvement and normalization of azotemia. The second patient's biopsy indicated early antibody-mediated rejection and acute tubular necrosis. In addition, CT angiography revealed graft artery stenosis. The patient underwent arterial stenting, combined with pulse glucocorticoid therapy, which led to normalization of graft function. The third patient was diagnosed with ureteroneocystostomy stenosis. Placement of an internal ureteral stent successfully resolved the obstruction, contributing to normalization of renal graft function.

Graft loss occurred in 4 recipients (2.9%). In 3 cases, immunological complications were the cause of graft failure, with diagnoses confirmed post-discharge at another hospital. In the first case, graft rejection led to the development of destructive-necrotic foci, as confirmed morphologically, necessitating transplantectomy. The second patient experienced acute vascular rejection (Banff grade 3), with necrotic foci, requiring transplantectomy. In the third case, acute vascular-cellular rejection (Banff grade 2b–3) did not respond to anti-crisis therapy, and there were no indications for transplantectomy. In the fourth case, transplantectomy was performed due to abscessed graft pyelonephritis. All four patients resumed long-term hemodialysis (HD) following graft loss.

One patient died with an adequately functioning graft due to a septic lesion against the background of fungal

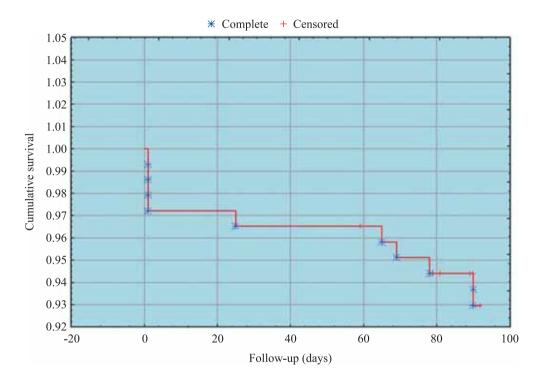


Fig. 2. Kidney graft survival rate in the early postoperative period

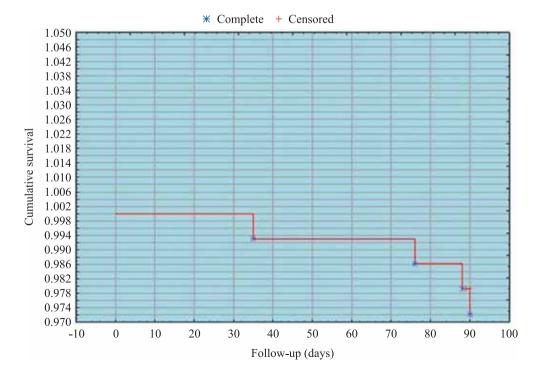


Fig. 3. Survival of recipients with T1D in the early postoperative period

pneumonia. Among those discharged with primary nonfunction (n = 4, 2.76%), all continued to receive RRT. Of these, 1 had the allograft removed in the early posttransplant period due to abscessed graft pyelonephritis, while 2 patients died from cardiovascular complications.

Two patients were discharged without functioning grafts (n = 2, 1.38%). Of these, one later underwent repeated KT in the long-term period, while the other died in the early post-transplant period due to cardiovascular complications.

#### DISCUSSION

Diabetes remains a socially significant disease due to the continually rising incidence rates, which remain concerning. Secondary diabetic complications lead to high disability and mortality, significantly reducing the quality of life for these patients. Non-transplant treatment options for stage 5 CKD resulting from DN have limited effectiveness, making KT the preferred treatment. KT has been shown to substantially improve both the duration and quality of life for these patients [18].

Patients with diabetic CKD that has progressed to stage 5 CKD represent the fastest-growing group among those needing renal RRT. Registry data from various countries show that DM is consistently ranked as the second or third most common disease among patients on the kidney transplant waiting lists.

The frequency of post-KT surgical complications in T1D patients varies widely, with reports ranging from 1% to 30% [19–21]. In our study, the overall rate of surgical complications was 9.7%. Notably, 35.7% of complications (n = 5) were classified as Clavien–Dindo grade I, requiring no surgical intervention. The remaining 57.1% of complications were grade IIIb, necessitating surgical intervention under general фтуыеруыщф. Only one complication was of grade IVa, which led to graft loss.

The overall frequency of immunological complications of KT ranges from 4.8% to 19% according to existing medical literature [21, 22]. In our study, 12.4% of patients experienced immunological complications. The diagnostic protocols, immunological monitoring, and anti-crisis therapy used in our center were highly effective. Only one patient experienced graft loss due to immunological causes.

According to several studies, the overall incidence of infectious complications in the early postoperative period after KT is estimated at 2%–25% [19, 21, 23], or 9.7% according to data from our center. The selected protocols for prophylactic antibiotic treatment and management of infectious complications were effective in preserving graft function. Only one patient required transplantectomy due to transplantation of a primarily infected kidney graft to preserve the patient's life.

A total of 138 patients (95.2%) were discharged with a functioning kidney graft. One patient, who was

discharged to continue RRT, had their graft function restored 2 months after KT. The incidence of primary non-function was 2.8% (n = 4). Two patients (1.4%) had their allografts removed during the hospital stay due to immunological and infectious complications.

In-hospital survival rates for kidney transplants in our study were 95.9%, with a 90-day death-uncensored graft survival of 93% and 90-day recipient survival of 97.2%. In comparison, other transplant centers report 98–99% survival rates [24, 25]. However, such publications are rare, as most studies focus on 1-year and longer posttransplant outcomes. The difference in survival rates may be attributed to factors such as initial condition of recipients, concomitant conditions, and the more stringent selection criteria used by other centers for placing patients on the kidney transplant waiting list.

## CONCLUSION

The fatalities recorded in our study highlight the high mortality associated with cardiovascular complications in patients who experience renal graft loss and must return to RRT dialysis. It is clear that patients with T1D and stage 5 CKD present as one of the most complex patient groups. They require more extensive pre-transplant evaluations when being placed on the waiting list, careful preparation for transplantation, and closer management during the early and late postoperative periods.

The authors declare no conflict of interest.

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