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The modifiable non-immunological prognostic factors for medium-term kidney transplant outcomes

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ABSTRACT

Introduction: Current management of patients after kidney transplantation focuses on medium- and long-term graft survival. The lack of new immunomodulatory agents available for routine use in immunosuppressive therapy has led to slow progress in reducing late allograft loss rates. This has drawn attention to non-immunological factors that influence the maintenance of transplanted kidney function.

Materials and methods: This retrospective study reviewed the characteristics of 191 kidney transplant recipients and 191 deceased donors from a single center. The analysis evaluated the influence of donor-related factors (age, cause of death, last plasma creatinine concentration, and duration of intensive care unit stay) and recipient-related factors (gender, age, time from initiation of dialysis, cause of chronic kidney disease, number of prior kidney transplantations, and cold ischaemia time – CIT) on graft function and survival. Outcomes were assessed by the incidence of primary non-function, delayed graft function, plasma creatinine concentration on day 30 and at 6, 12, 24, 36, and 60 months post-transplant, early (within the first year) or late recipient death, and early graft explantation.

Results: Significant donor-dependent risk factors included older donor age and cerebrovascular accident as the cause of death. Recipient-dependent risk factors included older recipient age, male gender, and a higher number of prior kidney transplantations. According to the Cox proportional hazards model, each additional hour of CIT increased the risk of graft loss by 7%, and each additional year on haemodialysis increased the risk by 12%.

Conclusions: Cold ischaemia time and duration of dialysis treatment are significant modifiable non-immunological factors influencing medium-term kidney transplant outcomes. Efforts to reduce these factors may improve transplantation results.

Keywords: kidney transplantation; transplant outcomes; chronic kidney disease; haemodialysis; cold ischaemia time.

INTRODUCTION

Analysis of the effects of kidney transplantation has demonstrated significant improvements in outcomes since the 1980s, when revolutionary therapies with azathioprine and cyclosporine were introduced. Advances in short-term renal allograft survival have outpaced improvements in long-term outcomes. The addition of mycophenolate mofetil and tacrolimus to therapeutic regimens in the 1990s further extended these gains, with a strong emphasis on the prevention of acute rejection (AR). Currently, AR rates are approx. 10%, and 1-year graft survival exceeds 90%. Since 2000, few opportunities for further enhancement of short-term outcomes have been identified, while long-term results have remained relatively stable, with only a slight, gradual decline in graft failure rates. A major factor contributing to this plateau is the limited availability of new immunomodulatory agents for routine use in immunosuppressive therapies.

Long-term kidney graft survival is multifactorial, depending on chronic rejection, recurrence of primary kidney disease, post-transplant infectious and metabolic complications, patient adherence, and the quality of medical care. However, potentially modifiable non-immunological factors, including donor and recipient characteristics, the duration of pre-transplant dialysis, and cold ischemia time (CIT), have been recognized as influencing early graft survival and function [1].

Chronic kidney disease (CKD) affects 8–10% of the population in Western countries. In Poland, approx. 4 million individuals are affected by CKD, and about 30,000 patients (115 per million inhabitants) undergo regular dialysis treatment. More than half of these patients are over 65 years of age. The kidney transplant waiting list in Poland includes 20.5 patients per million inhabitants, compared to 84.1/million in the United Kingdom, 115/million in Italy, and 105/million in Eurotransplant countries. Both potential kidney graft recipients and donors are now considerably older than 10–15 years ago, and the prevalence of comorbidities has increased [2]. Patients with CKD are often subjected to prolonged periods of hemodialysis, frequently awaiting second or third transplantations, and are often highly immunized, all of which significantly impact graft outcomes [3].

The aim of this study was to evaluate the influence of a set of non-immunological, recipient- and donor-related factors on 3-year kidney graft function and survival.

MATERIALS AND METHODS

In this retrospective study, we reviewed the medical data of 191 kidney transplant recipients and 191 deceased donors from a single center. The analyzed recipient characteristics included: gender, age, time since initiation of dialysis, causes CKD, number of kidney transplantations, CIT, human leukocyte antigen (HLA) mismatches, panel reactive antibodies (PRA) actual and maximal, the incidence of primary non-function (PNF) of the kidney graft and delayed graft function (DGF), plasma creatinine concentration on the 30th day, and at the 6th, 12th, 24th, 36th, and 60th month after transplantation (only 32 recipients were observed for 60 months; the mean observation time was 33.41 ±18.66 months), incidents of early (within the first year after transplantation) or late (after the first year) death, and early explantation of the kidney graft within the first year (Tab. 1).

The donor-related variables included age, cause of death (cerebrovascular accident – CVA, trauma, or other), last plasma creatinine concentration, and duration of treatment in the intensive care unit (ICU) – Table 2.

The influence of the above factors on kidney graft function and survival in medium-term follow-up was assessed.

The study was approved by the Bioethical Committee of the Pomeranian Medical University in Szczecin, Poland.

Statistical analysis

The results are presented as the arithmetic mean ±standard deviation (SD), median, and lower (Q1) and upper (Q3) quartiles. The Shapiro–Wilk test showed that the distribution of the quantitative variables was not normal. Therefore, non-parametric tests were used – the Wilcoxon signed-rank test for paired variables and the Mann–Whitney U-test for unpaired variables. Spearman's rank correlation coefficient (R_s) was used to measure correlations between quantitative variables. Qualitative variables were compared using the chi-square test. Associations between potential predictors and dichotomous clinical endpoints (early death, early graft loss and explantation, DGF, PNF, and a composite endpoint combining DGF, PNF, and early kidney graft loss) were expressed as odds ratios (OR) with 95% confidence intervals (95% CI). Associations between potential predictors and graft survival time were analyzed using univariate and multivariate Cox proportional hazards models and presented as hazard ratios (HR) with 95% CI. Statistical significance was assumed at $p < 0.05$.

TABLE 1. Characteristics of kidney graft recipients (n total = 191)

Variables		Mean ±SD	Median (Q1, Q3)
Age (years)		47.86 ±13.90	49 (37, 59)
Time since first haemodialysis (months)		26.29 ±34.50	12 (4, 36)
HLA mismatches		2.89 ±1.17	3 (2, 4)
PRA actual		5.68 ±16.04	0 (0, 0)
PRA maximal		10.49 ±21.40	0 (0, 10)
CIT (h)		19.10 ±7.67	19 (13, 24)
Variables		**n**	**%**
Gender M/F		129/62	67.5/32.5
Causes of CKD	glomerulonephritis	93	48.9
	ADPKD	28	14.7
	diabetes mellitus	12	6.3
	pyelonephritis	28	14.7
	unknown	29	15.3
PNF		17	8.9
DGF		81	42.4
Number of kidney Tx >1		49	25.7
Graftectomy <1 year		17	8.9
Recipient death <1 year		11	5.8
Kidney graft survival		169	88.5
Recipient survival		176	92.1

SD – standard deviation; Q1 – lower quartile; Q3 – upper quartile; HLA – human leukocyte antigen; PRA – panel reactive antibodies; CIT – cold ischaemia time; M/F – male/female; CKD – chronic kidney disease; ADPKD – autosomal dominant polycystic kidney disease; PNF – primary non-function; DGF – delayed graft function; Tx – transplantation

RESULTS

The mean recipient age was 47 ±13 years and did not differ significantly from that of donors, who were aged 46 ±14 years ($p = 0.53$, Wilcoxon test). Older recipient age was associated with early death (OR 1.076; 95% CI: 1.014–1.142; $p = 0.014$), but no associations were found with early graft loss, PNF, DGF, or creatinine concentrations after transplantation (Tab. 3). Donor age correlated positively with recipient creatinine concentrations on the 30th day, and at the 6th, 12th, 24th, 36th, and 60th months after transplantation (Tab. 4).

TABLE 2. Characteristics of kidney graft donors (n total = 191)

Variables		Mean ±SD	Median (Q1, Q3)
Age (years)		46.80 ±14.50	52 (35, 58)
Time of ICU treatment (days)		5.34 ±3.29	4 (3, 7)
Creatinine concentration (mg/dL)		1.21 ±0.60	1.1 (0.9 ±1.4)
Variables		**n**	**%**
Gender M/F		191/0	100/0
Causes of death	CVA	78	40.8
	trauma	93	48.7
	other	20	10.5

SD – standard deviation; Q1 – lower quartile; Q3 – upper quartile; ICU – intensive care unit; M/F – male/female; CVA – cerebral vascular accident

TABLE 3. Model of univariate and multivariate logistic regression. Analysis of non-immunological prognostic factors of medium-term kidney transplant outcomes

Variables	Univariate OR (95% CI)	Multivariate OR (95% CI)
Recipient's death during the first year		
Cardiovascular cause of donor death	4.190 (1.066–16.475)	4.973 (1.166–21.211)[1]
Recipient age (years)	1.076 (1.015–1.141)	1.081 (1.013–1.154)[1]
Graphtectomy during first year		
CIT (min)	1.001 (1.000–1.002)	–
Duration of haemodialysis therapy (months)	1.012 (1.001–1.022)	–
Number of kidney transplantations >1	2.883 (1.038–8.006)	–
DGF		
Donor age (years)	1.042 (1.019–1.065)	1.037 (1.013–1.062)[2]
Cardiovascular cause of donor death	2.022 (1.119–3.656)	1.794 (0.933–3.447)[2]
Recipient male gender	2.876 (1.483–5.578)	3.261 (1.579–6.738)[2]
PNF/ kidney graft loss		
CIT (min)	1.0013 (1.0002–1.0024)	1.0017 (1.0004–1.0031)
Duration of haemodialysis therapy (months)	1.013 (1.003–1.023)	1.013 (1.002–1.026)
Number of kidney transplantations >1	2.883 (1.039–8.006)	2.141 (0.668–6.861)
PNF/DGF/ kidney graft loss		
Donor age (years)	1.051 (1.028–1.075)	1.043 (1.018–1.069)[2]
CIT (min)	1.0007 (1.0000–1.0014)	1.0005 (0.9997–1.0012)[2]
Recipient male gender	2.296 (1.225–4.267)	2.474 (1.194–5.127)[2]

[1] adjusted for donor age; [2] adjusted for panel reactive antibodies maximal
OR (95% CI) – odds ratio (95% confidence interval); CIT – cold ischaemia time; DGF – delayed graft function; PNF – primary non-function

The mean duration of donors' ICU treatment was 5.34 ±3.28 days, with trauma being the main cause of brain death and a mean creatinine concentration of 1.2 ±0.59 mg/dL. Donor death due to CVA was associated with a higher risk of DGF (OR 2.022; 95% CI: 1.118–3.656; p = 0.019) and early recipient death (OR 4.19; 95% CI: 1.07–16.5; p = 0.039) – Table 3.

Delayed graft function was associated with older donor age (OR 1.042; 95% CI: 1.019–1.065; p = 0.0003) and male gender of the recipients (OR 2.876; 95% CI: 1.483–5.578; p = 0.0017). In 25% of the observed population, it was the second or third kidney transplantation, a factor associated with the risk of early graft loss and explantation (OR 2.883; 95% CI: 1.038–8.006; p = 0.041).

Cold ischemia time was 19.1 ±7.7 h and was associated with a composite endpoint combining PNF, DGF, and early kidney graft loss (OR 1.0007; 95% CI: 1.0000–1.0014; p = 0.047) as well as early graftectomy (OR 1.0012; 95% CI: 1.0001–1.0023; p = 0.037).

The mean duration of hemodialysis treatment was 26.3 ±34.5 months; longer hemodialysis time was associated with a higher risk of early kidney loss with explantation (OR 1.012; 95% CI: 1.001–1.022; p = 0.027) and of PNF (OR 1.013; 95% CI: 1.003–1.024; p = 0.012).

In the univariate Cox regression model, longer hemodialysis treatment duration was associated with shorter graft survival (HR 1.009 per month; 95% CI: 1.002–1.017; p = 0.017). In the multivariate Cox analysis, adjusted for recipient age and gender, longer hemodialysis duration (months) and CIT (hours) were independent factors associated with shorter graft survival (HR 1.010; 95% CI: 1.001–1.018; p = 0.021, and HR 1.072; 95% CI: 1.007–1.142; p = 0.030, respectively) – Table 3.

DISCUSSION

The acceptance of the kidney for transplantation depends on donor and recipient characteristics and transplant-related factors. In the present study, important donor features significantly associated with kidney transplant outcomes were age and death from cardiovascular causes. The growing population on the waiting list and the decreasing number of potential donors have prompted organ donation from donors with extended criteria (ECD), defined as those aged 60 years or older, or 50–59 years old with at least 2 of the following conditions: history of hypertension, terminal serum creatinine level >1.5 mg/dL, or cerebrovascular cause of death. Approximately 25% of donors in Western Europe can be classified as ECD. The relative risk of ECD graft loss varied 1.7–2.69, but the ECD group was heterogeneous owing to different combinations of criteria. Kidneys from younger donors with comorbidities may also have a relatively high risk of failure. To predict the outcome in a particular clinical situation, the kidney donor risk index (KDRI) proposed by Watson et al. can be used [1]. The simplified scale includes: donor age (60+ relative to 40–59), history of

hypertension, increased body weight, longer ICU hospitalization, and use of adrenaline. A special feature is hypertension associated with a possible cardiovascular cause of death in the donor. Literature shows that it is connected with medium- and long-term kidney graft outcomes rather than early post-transplant. Other analyzed factors, such as donation after circulatory death, history of cardiothoracic disease, diabetes history, hepatitis C, and terminal creatinine, were not significant [1].

In our study, older donor age and CVA as the cause of death were associated with an increased risk of combined endpoints consisting of PNF, DGF, or early kidney graft loss. Donor serum terminal creatinine levels and time of ICU hospitalization showed no significant correlations. In the study by Watson et al., the time of ICU treatment influenced only the early post-transplant period [1]. When assessing terminal donor serum creatinine, it is important to distinguish stable impaired renal function from potentially reversible acute kidney injury (AKI); therefore, additional information about potential donors is needed. The acceptable value of donor creatinine is below 1.5 mg/dL. Donor AKI increases the risk of DGF; however, other clinical outcomes are not disturbed [2]. The dominant donor factor influencing kidney transplant medium-term outcomes remains age, as it determines the progressive decrease in glomerular filtration rate (eGFR) [4]. Donor age in the present study was also positively correlated with recipients' serum creatinine levels in all measurements from the 30th day to the 60th month.

The Eurotransplant Seniors Program (ESP) from 1999 allocated kidneys from donors aged 65 years or older to similar recipients. Five-year patient survival in the ESP group was 60%, compared to 74% in the any-to-old group [4]. Extended criteria donors have a higher incidence of DGF and infectious complications than standard criteria donors (SCD) [5]. Despite the worse outcomes compared to SCD, transplantation from ECD donors still provides more benefits than prolonged dialysis time and is a feasible approach to address organ shortage [6]. Transplanting ECD kidneys to younger recipients should be avoided due to less functional reserve and increased vasculopathy [7]. The simplified KDRI scale can be used independently from recipient assessment to obtain fully informed consent [8].

Prolonged CIT was associated with DGF, PNF, and early kidney graft loss. It causes acute tubular necrosis, which is recoverable damage, but may influence long-term graft function. The use of cold-machine perfusion is associated with a lower incidence of DGF, although not with improved graft survival [9]. Opelz and Döhler stated that a CIT of <18 h is not connected with graft survival [10]. Salahudeen et al. found that the relative risk of graft loss presented a monotonic increase with each 10-hour increment, but it was statistically significant only when comparing CIT >30 h and <10 h [11]. The US Renal Data System found a progressive worsening of outcomes associated with each 6-hour increase in CIT [9]. Summers et al. showed that kidneys from circulatory-death donors are particularly susceptible to cold ischemic injury [5].

In our study group, a longer CIT was an independent factor for shorter graft survival. According to the Cox proportional hazards model, an additional hour of CIT increased the risk of kidney loss by 7%. It was also associated with an increased risk of combined endpoints including PNF, DGF, and early kidney graft loss. However, the quality of the organ plays a decisive role, and an extended CIT may be an additional factor determining the subsequent function and survival of the graft.

The increasing incidence of CKD during the course of diabetes and hypertension contributes to the aging of the dialysis patient population and those qualified for kidney transplantation. Recipients over 65 years old account for about 20–30% in Western Europe and have increased from 10–15% over the last decade [12]. These patients, due to comorbidities, are at a higher risk of perioperative complications, which also depend on donor quality [6]. In the present study, older recipient age was a risk factor for early death (during the first year) and for the combined endpoint consisting of PNF, DGF, and early graft loss. Among dialysis patients, there are those awaiting a second or third kidney transplantation. According to our study, this group was at greater risk of PNF and early graft loss. The reasons for this are not only immunological factors but also surgical problems and comorbidities. However, the management of CKD and dialysis care has improved, leading to better survival on dialysis. Patients are subjected to individual assessments by the attending physician regarding the benefits of possible transplantation. Nevertheless, there are no strict guidelines for this assessment. Research has shown that early mortality after transplantation in elderly patients is higher, which also confirmed our observations, but for all

TABLE 4. Recipients' creatinine concentrations on the 30th day and 6th, 12th, 24h, 36th, 60th month after transplantation and their Spearman's rank correlation coefficients (R_s) with donors' age

Creatinine (mg/dL)	n	Mean ±SD	Median (Q1, Q3)	R_s ($p < 0.05$)
30th day	173	1.64 ±0.94	1.45 (1.08, 2.00)	0.312
6th month	167	1.47 ±0.54	1.36 (1.04, 1.77)	0.369
12th month	161	1.48 ±0.6	1.35 (1.07, 1.70)	0.355
24th month	130	1.56 ±1.01	1.34 (1.05, 1.78)	0.417
36th month	80	1.37 ±0.5	1.29 (1, 1.65)	0.331
60th month	32	1.35 ±0.51	1.23 (1, 1.57)	0.452

SD – standard deviation; Q1 – lower quartile; Q3 – upper quartile

risk groups, transplantation was associated with a long-term survival advantage [13]. Even those who were transplanted with an ECD kidney had a lower mortality risk than patients on the waiting list (overall about 41%).

A prolonged time spent on dialysis treatment may accumulate comorbidities and complications and lead to poorer conditions, especially coronary artery disease and cerebrovascular disease [14]. In our study group, an additional year on dialysis increased the risk of kidney loss by 12%. Coffman et al. assessed the influence of dialysis duration and modality on the outcomes of simultaneous pancreas-kidney transplantation. The preemptive and short dialysis group (<2 years of hemodialysis) had a lower incidence of DGF and relaparotomy. Patient survival in the long dialysis group (>4 years of hemodialysis) was 50% compared to 69.5% in the other groups combined [15]. Dong et al. reported that long-term dialysis treatment (>2 years) was an independent predictor of patient death and kidney graft failure [16]. However, both studies showed no significant associations between dialysis duration and pancreatic graft survival.

The literature shows that dialysis modality may affect outcomes after kidney transplantation [13]. Prior peritoneal dialysis increases the risk of death by 1.5-fold compared to patients on maintenance hemodialysis, especially those with a dialysis vintage of over 3 years. This may be due to lower hemoglobin and albumin levels compared to hemodialyzed patients [17]. All patients in the present study underwent hemodialysis treatment.

Additionally, recipient gender was a risk factor for the combined endpoint of DGF, PNF, and early graft loss. Male patients had a 2.3-fold higher OR than female patients. The explanation may be more comorbidities, a higher prevalence of second and third transplantations, and older age [18].

Other non-immunological factors that were not discussed in our study but can also be considered when assessing medium-term outcomes include: surgical complications, medical events (cardiovascular, infections), calcineurin inhibitor toxicity, viral nephropathies, urologic and vascular complications, recurrent diseases, effects of weight gain after transplantation, and pre- and post-transplant hydration status [19, 20].

Non-immunological factors affecting medium-term kidney transplant outcomes can be divided into 2 main groups – donor-dependent and recipient-dependent. Significant donor-dependent risk factors were: older age and CVA as the cause of death, while recipient-dependent risk factors were older age, male gender, higher number of kidney transplantations, longer CIT, and longer duration of dialysis treatment. The latter 2 are modifiable. Reducing the duration of CIT and the time spent on dialysis are crucial interventions available to each center to improve transplantation procedures.

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