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Kidney transplantation in Romania: two transplant centers experience

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Abstract

Purpose Kidney graft survival rates improved from decade to decade, but data about factors that affect patient and graft survival remain challenging and even controversial.

Methods We analyzed retrospectively data from kidney transplanted patients followed in two Romanian transplant centers (Iasi and Bucharest)—new programmes specifically developed after 1989 to cover transplantation requirements for two-thirds of Romania. We used a composite survival outcome defined as 50% reduction in estimated glomerular filtration rate (eGFR), return to dialysis or death. Survival analysis was performed using uni- and multivariable Cox regression with baseline and time-updated covariates.

Results From the entire cohort of 365 patients, 243 had the outcome of interest. In the univariable Cox survival analysis, age, hemoglobin, eGFR, cholesterol, AST and transplant center were associated with the outcome. The multivariable Cox analysis reveals that only cholesterol (HR 0.97, 95% CI 0.94–0.99 per 10 mg/dL increase) and transplant center (HR 3.64, 95% CI 2.67–4.97) remain associated. For the time-updated Cox survival analysis we found that eGFR (HR 0.91, 95% CI 0.87–0.96 per 10 ml/min/1.73 m^2 increase) and cholesterol are associated with the outcome in the univariable analysis and only eGFR and transplant center in the multivariable Cox survival analysis.

Conclusions Our study reports data from two distinct transplant centers from a developing country. Our results are similar to the current literature data, but also reveal that the approach of a center to the transplantation management is an independent factor associated with graft survival.

Keywords Kidney transplantation · Graft survival · Patient survival · Living donor · Cadaveric donor · Estimated glomerular filtration rate

Introduction

End-stage renal disease (ESRD) prevalence and transplantation rates are continuously rising in the last decade [1]. Even though improvements in the dialysis care were made, renal transplantation remains the treatment of choice for ESRD due to its lower mortality rate, higher quality of life and cost-effectiveness [2, 3].

In a single center experience, Matas et al. compared outcomes of transplant recipients from living donors in the 1960s to those transplanted in the 1990s, showing a 8-year graft survival rate increase from 50 to 80% [4]. A retrospective analysis of 427 adult kidney transplantations performed from 1990 to 2010 from a tertiary care center in Turkey reports 5-year graft survival rates of 78.3 and 74.8% for living versus cadaveric donors [5].

These results are not similar with other single center experience reports [6, 7] or large databases graft survival data. Using the 2004–2008 and 2004–2009 cohorts from 23 United Kingdom (UK) adult transplant centers, the 17th and 18th UK Renal Registry Annual Report shows a 5-year graft survival rate of 89% for deceased donor recipients and 91% for living-related donor recipients [8, 9]. The 2014 European Renal Association–European Dialysis and Transplant

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Association (ERA-EDTA) Registry Annual Report reveals 87.0 versus 81.6% 5-year-adjusted graft survival for living donor versus deceased donor [10]. Published data thus show that graft survival rates improved from decade to decade, and this applies also for older and multisensitized patients.

However, data regarding the factors that might affect patient and graft survival remain challenging and even controversial, particularly when single center experience is compared to large databases. The impressive improvement is mainly explained by modifications of immunosuppressive regimens, but other factors like HLA-matching, time on dialysis, recipient and donor age seem also to have important contribution [11–13].

The aim of this study is to report the experience in renal transplantation management of two transplant centers from a European developing country of the former Central-Eastern European communist region.

Methods

Patients

We retrospectively analyzed data from patients that received a kidney transplant and were followed in two Romanian transplant centers (Iasi and Bucharest)—new programs specifically developed after 1989 to cover transplantation requirements for two-thirds of Romania. We included all transplanted patients in Iasi Transplant Center from 2000 to 2015 and patients transplanted in Bucharest Transplant Center in 2008 and 2009. Data collected from the patient files included: age, gender, type of donor, primary kidney disease, comorbidities (diabetes, viral hepatitis), type of induction and maintenance immunosuppression, and estimated glomerular filtration rate (eGFR), hemoglobin, cholesterol, proteinuria and AST values at baseline and during follow-up. We used the CKD-EPI formula for eGFR assessment [14].

Table 1 Baseline demographic and clinical characteristics of the study population

	All ($N = 365$)	Group 1 ($N = 122$)	Group 2 ($N = 243$)	p
Age (years)	34.9 ± 12.0	33.2 ± 10.9	35.9 ± 12.5	**0.04**
Male, *n* (%)	219 (60.0)	76 (62.3)	143 (58.9)	0.53
Diabetes, *n* (%)	14 (3.8)	2 (1.6)	12 (4.9)	0.12
HCV, *n* (%)	37 (10.1)	14 (11.5)	23 (9.5)	0.55
HBV, *n* (%)	13 (3.6)	4 (3.3)	9 (3.7)	0.84
Hemoglobin (g/dl)	11.1 ± 1.6	11.6 ± 1.5	10.9 ± 1.5	**< 0.001**
eGFR, ml/min/1.73 m^2	63.4 ± 22.9	65.1 ± 22.8	62.5 ± 22.9	0.49
Proteinuria, *n* (%)	31 (8.5)	13 (10.7)	18 (7.4)	0.29
Cholesterol (mg/dL)	219.2 ± 45.3	232.1 ± 50.6	212.8 ± 41.1	**< 0.001**
Triglycerides (mg/dL)	219.7 ± 92.9	221.8 ± 104.2	218.7 ± 87.1	0.56
Glycemia (mg/dL)	90.5 ± 18.0	92.8 ± 25.3	89.4 ± 12.9	0.16
AST, U/L	41.9 (24.0–47.8)	30.0 (18.0–46.0)	43.8 (31.0–47.9)	**< 0.001**
Cadaveric donor, *n* (%)	243 (66.6)	80 (65.6)	163 (67.8)	0.77
Primary renal disease, *n* (%)				
Diabetic	6 (1.6)	0 (0.0)	6 (2.47)	**0.01**
Glomerulonephritis	180 (49.3)	69 (56.6)	111 (45.7)	
Secondary GN/vasculitis	15 (4.1)	10 (8.2)	5 (2.1)	
Interstitial nephritis/Pyelonephritis	38 (10.4)	10 (8.2)	28 (11.5)	
Hypertension/large-vessel disease	5 (1.4)	0 (0.0)	5 (2.1)	
Hereditary	35 (9.6)	9 (7.4)	26 (10.7)	
Miscellaneous	86 (23.6)	24 (19.7)	62 (25.5)	
CsA use, *n* (%)	184 (50.4)	69 (56.6)	115 (47.3)	0.09
Transplant center, *n* (%)				
Iasi	160 (43.8)	99 (81.2)	61 (25.1)	**< 0.001**
Bucharest	205 (56.2)	23 (18.9)	182 (74.9)	

Bold values indicate $p < 0.05$

Data are expressed as mean ± SD, median with IQR, or percent frequency, as appropriate

Group 1: patients who did not have the composite outcome; Group 2: patients who had the composite outcome

Table 2 Univariate and multivariate Cox analysis using baseline values

	HR	95% CI
Univariable analysis		
Age (per 10 years increase)	1.11	1.00–1.23
Hemoglobin (g/dl)	0.86	0.79–0.94
eGFR (per 10 ml/min/1.73 m^2 increase)	0.78	0.62–0.97
Cholesterol (per 10 mg/dL increase)	0.96	0.94–0.99
Log AST (per 1 SD increase)	1.14	1.01–1.28
Transplant center (1—Iasi; 2—Bucharest)	3.81	2.81–5.17
Multivariable analysis		
Age (per 10 years increase)	1.09	0.98–1.23
Hemoglobin (g/dl)	0.92	0.84–1.01
eGFR (per 10 ml/min/1.73 m^2 increase)	0.99	0.94–1.06
Cholesterol (per 10 mg/dL increase)	**0.97**	**0.94–0.99**
Log AST (per 1 SD increase)	1.11	0.97–1.27
Transplant center (1—Iasi; 2—Bucharest)	**3.64**	**2.67–4.97**

Bold values indicate variables associated with the outcome of interest

Table 3 Univariate and multivariate Cox analysis using time-varying variables

	HR	95% CI
Univariate analysis		
eGFR (per 10 ml/min/1.73 m^2 increase)	0.91	0.87–0.96
Cholesterol (per 10 mg/dL increase)	0.97	0.95–0.99
Immunosuppression (1—CsA; 2—Tac)	1.24	1.01–1.52
Transplant center (1—Iasi; 2—Bucharest)	3.86	2.96–5.03
Donor type (1—Alive; 2—Cadaveric)	1.54	1.31–1.81
Multivariable analysis		
eGFR (per 10 ml/min/1.73 m^2 increase)	**0.92**	**0.88–0.96**
Cholesterol (per 10 mg/dL increase)	0.98	0.96–1.01
Immunosuppression (1—CsA; 2—Tac)	0.85	0.69–1.03
Transplant center (1—Iasi; 2—Bucharest)	**4.01**	**3.06–5.26**
Donor type (1—Alive; 2—Cadaveric)	1.15	0.95–1.39

Bold values indicate variables associated with the outcome of interest

Table 4 Glomerular filtration rate, hemoglobin and proteinuria change during the follow-up—a comparison between cyclosporine and tacrolimus

	Length of follow-up						p*	$p^{\dagger}$
	Baseline	1 year	2 years	3 years	4 years	5 years		
eGFR, ml/min/1.73 m^2								
CsA	64.3 (61.2–67.3)	61.8 (58.6–65.0)	62.2 (58.9–65.4)	61.4 (58.2–64.6)	60.7 (57.4–64.0)	58.9 (55.6–62.3)	0.77	< 0.001
Tac	62.7 (59.7–65.8)	65.9 (62.7–69.0)	65.6 (62.3–68.9)	66.5 (63.2–69.9)	63.8 (60.2–67.3)	69.1 (65.4–72.7)		
$p^{\ddagger}$	0.49	0.08	0.15	0.03	0.23	< 0.001		
Hemoglobin (g/dL)								
CsA	11.2 (10.7–11.7)	12.8 (12.2–13.4)	13.1 (12.5–13.7)	13.7 (13.1–14.3)	12.9 (12.4–13.6)	13.0 (12.4–13.6)	< 0.001	0.41
Tac	11.1 (10.6–11.6)	13.5 (12.9–14.0)	13.2 (12.6–13.7)	13.3 (12.7–13.9)	13.5 (12.9–14.2)	13.3 (12.6–13.9)		
$p^{\ddagger}$	0.77	0.14	0.92	0.31	0.21	0.51		
Log proteinuria (g/day)								
CsA	0.13 (0.07–0.19)	0.07 (0.01–0.13)	0.12 (0.07–0.18)	0.13 (0.08–0.19)	0.16 (0.09–0.21)	0.15 (0.09–0.21)	0.003	0.90
Tac	0.13 (0.08–0.19)	0.06 (0.01–0.11)	0.13 (0.07–0.18)	0.16 (0.09–0.21)	0.15 (0.09–0.21)	0.12 (0.05–0.18)		
$p^{\ddagger}$	0.99	0.79	0.96	0.55	0.80	0.42		

Data are presented as mean (95% CI) at baseline, and least-squares mean (95% CI) at follow-up intervals. Analysis was conducted using a mixed model for repeated measures. Analyses are adjusted for baseline values, gender, donor type, transplant center, age and diabetes

* p value for time effect—trend over time in both arms

† p value for treatment x time interaction—evaluates if changes in one arm are different from the changes in the other arm

‡ p value for comparison between arms at each moment

Outcome

We used a composite outcome defined as 50% reduction in estimated glomerular filtration rate, return to dialysis or death.

Statistical analysis

Baseline data are expressed as mean ± standard deviation (SD), median with inter-quartile range (IQR) or as percent frequency, as appropriate. Between-groups comparisons were assessed for nominal variables with the Chi-square test, and by independent-samples *t* test or Mann–Whitney test for the rest of the variables. Logarithmic conversion was performed for non-normally distributed variables.

We used the Cox regression (with baseline values, but also for the time-varying variables) to estimate the association between different variables and the composite outcome. Initially, we tested all the variables available in our database in the univariable Cox analysis; secondly, we included in the multivariable Cox analysis only those variables that had a significant association with the outcome in the univariable analysis (with a $p < 0.05$). Data are presented in the form of hazard ratios (HR) and 95% confidence intervals (CI).

We also tested using time repeated analysis if there was a difference during the follow-up in regard with the eGFR, hemoglobin and proteinuria levels between cyclosporine versus tacrolimus users and between Iasi and Bucharest transplant centers. Time repeated measurements were analyzed using linear mixed models including cyclosporine versus tacrolimus or Iasi versus Bucharest center, time and the cyclosporine versus tacrolimus or Iasi versus Bucharest center by time interaction term. Group inferences, effect estimates and 95% CIs were taken from these models. Due to the increased number of missing values, for the Cox analyses and mixed models, we fixed the follow-up at a maximum of 5 years.

All analyses were performed using Stata SE software, version 12 (Stata Statistical Software: Release 12. College Station, TX: StataCorp LP.). A two-tailed $p < 0.05$ was considered to be significant.

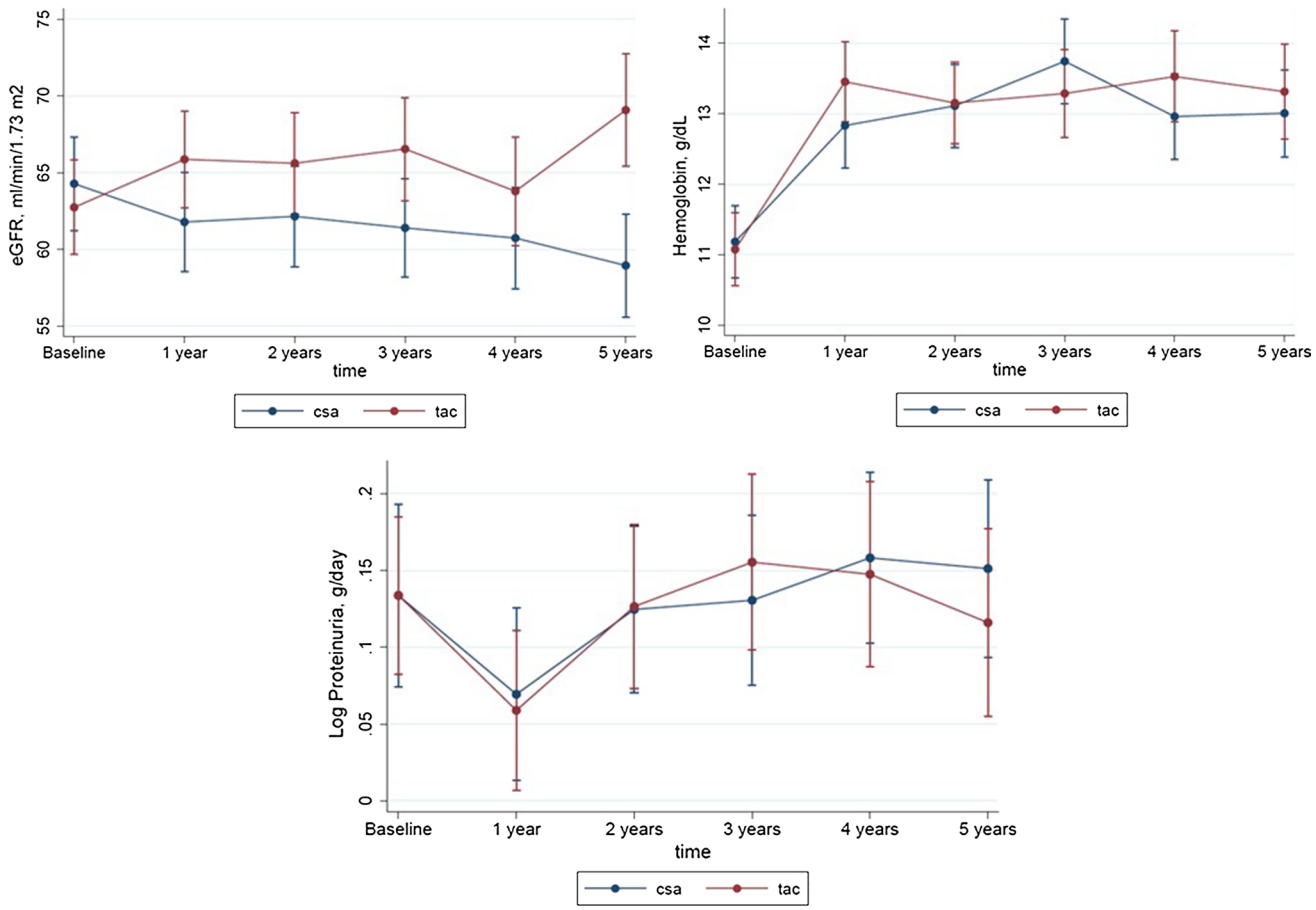

Fig. 1 Glomerular filtration rate, hemoglobin and proteinuria change during the follow-up—a comparison between cyclosporine and tacrolimus

Results

Baseline characteristics

The final cohort included 365 patients. The mean age at transplantation was 34.9 ± 12.0 years; 219 patients (60%) were male, 14 (3.8%) had diabetes, and 184 (50.4%) used cyclosporine as the calcineurin inhibitor in the immunosuppressive regimen. The majority of the patients were transplanted from a cadaveric donor (66.6%). Other demographic, clinical and biological characteristics evaluated in our study are given in Table 1.

During the entire follow-up (mean 8.96, median 8.47 years) there were 13 (3.6%) deaths in the entire cohort. The mean survival time was 20.94 (95% CI 20.34–21.54) years when we considered all centers, 17.92 (95% CI 17.38–18.47) years for the Iasi center and 20.79 (95% CI 19.88–21.69) years for the Bucharest center. Furthermore, there were 30 patients that had to return to dialysis, with a mean and median follow of 8.85 and 8.45 years, respectively. The average time to return to dialysis was 19.79 (95% CI 18.91–20.67) years when we considered all centers, 17.01 (95% CI 16.21–17.81) years for the Iasi center and 19.95 (95% CI 18.91–20.99) years for the Bucharest center.

Survival analysis of the renal function

A total of 243 patients had the outcome of interest (more than 50% reduction in eGFR, return to dialysis or death). These patients were older, had lower hemoglobin values, higher AST levels and were more frequently transplanted in other center then Iasi (Table 1).

In the univariable Cox survival analysis, using only baseline values of the variables in the analysis, age, hemoglobin, eGFR, cholesterol, AST and transplant center were associated with the outcome (Table 2). Including all these variables into a multivariable Cox analysis, only cholesterol (HR 0.97, 95% CI 0.94–0.99 per 10 mg/dL increase) and transplant center (HR 3.64, 95% CI 2.67–4.97) remained associated with the outcome of interest (Table 2). We also performed a Cox survival analysis accounting for changes in hemoglobin, eGFR, cholesterol, AST, triglycerides and glycemia levels during the follow-up (time-updated Cox survival analysis). From these time-varying variables, only eGFR (HR 0.91, 95% CI 0.87–0.96 per 10 ml/min/1.73 m^2 increase) and cholesterol (HR 0.97, 95% CI 0.95–0.99 per 10 mg/dL increase) were associated with the outcome in the univariable analysis (Table 3). The type of immunosuppression (cyclosporine vs. tacrolimus), transplant center and donor type were also associated with the outcome. In the multivariable Cox survival analysis,

Table 5 Glomerular filtration rate, hemoglobin and proteinuria change during the follow-up—a comparison between Iasi and Bucharest transplant centers

	Length of follow-up						p*	$p^{\dagger}$
	Baseline	1 year	2 years	3 years	4 years	5 years		
eGFR, ml/min/1.73 m^2								
Iasi	64.3 (61.1–67.6)	65.3 (61.9–68.6)	66.7 (63.3–70.1)	68.5 (64.9–72.1)	66.1 (62.3–69.8)	64.1 (60.1–67.9)	0.83	0.03
Bucharest	62.9 (60.0–65.7)	62.7 (59.7–65.8)	61.6 (58.5–64.7)	60.6 (57.6–63.6)	59.5 (56.3–62.6)	63.0 (59.8–66.2)		
$p^{\ddagger}$	0.61	0.37	0.05	0.01	0.02	0.75		
Hemoglobin (g/dL)								
Iasi	11.3 (10.7–11.8)	13.4 (12.8–13.9)	12.9 (12.3–13.5)	13.2 (12.5–13.8)	12.9 (12.2–13.7)	12.7 (11.9–13.5)	< 0.001	0.24
Bucharest	11.0 (10.5–11.5)	12.9 (12.4–13.5)	13.3 (12.8–13.9)	13.8 (13.2–14.3)	13.4 (12.8–13.9)	13.4 (12.8–13.9)		
$p^{\ddagger}$	0.46	0.30	0.34	0.16	0.33	0.29		
Log proteinuria (g/day)								
Iasi	0.17 (0.11–0.22)	0.06 (0.01–0.12)	0.10 (0.05–0.16)	0.12 (0.06–0.19)	0.17 (0.11–0.24)	0.19 (0.12–0.26)	0.002	0.02
Bucharest	0.09 (0.05–0.15)	0.07 (0.01–0.12)	0.15 (0.09–0.19)	0.16 (0.10–0.21)	0.14 (0.09–0.19)	0.09 (0.05–0.15)		
$p^{\ddagger}$	0.08	0.91	0.24	0.45	0.40	0.04		

Data are presented as mean (95% CI) at baseline, and least-squares mean (95% CI) at follow-up intervals. Analysis was conducted using a mixed model for repeated measures. Analyses are adjusted for gender, immunosuppression (CsA or Tac), age and diabetes

* p value for time effect—trend over time in both arms

† p value for treatment x time interaction—evaluates if changes in one arm are different from the changes in the other arm

‡ p value for comparison between arms at each moment

only eGFR and transplant center maintained a significant association with the outcome (Table 3).

Hemoglobin, proteinuria and eGFR levels change during the follow-up

We also wanted to evaluate the progression of eGFR, hemoglobin and proteinuria values during the follow-up of the various subgroups of patients: cyclosporine versus tacrolimus and those patients transplanted in the Iasi versus those transplanted in the Bucharest center.

During the follow-up, we did not observe a significant change in eGFR levels, but we did observe a significant increase in hemoglobin and proteinuria levels. There were no differences between the cyclosporine and tacrolimus groups in regard with hemoglobin and proteinuria change. However, there was a significant trend for better eGFR in the tacrolimus group (Table 4 and Fig. 1).

When we compared the two transplant centers, there was a significant interaction between transplant center and time, with higher eGFR, but also proteinuria levels observed in the patients from the Iasi center during the follow-up (Table 5 and Fig. 2).

Discussion

We performed an observational retrospective cohort study, which included 365 kidney transplant recipients, followed in two large Renal Transplant Units in Romania: Iasi and Bucharest. We used a composite outcome consisting of 50% reduction in eGFR, return to dialysis or death. The patients who reached the outcome (243–66.5%) were older, had lower hemoglobin values, higher AST levels and were more frequently transplanted in other center then Iasi (74.9%), and most of them were from cadaveric donors (67.8%).

In our analysis, patients who had the outcome of interest were older. However, data from the literature regarding the relationship between recipient age and graft survival are quite discrepant. Analyzing 42.193 patients from the

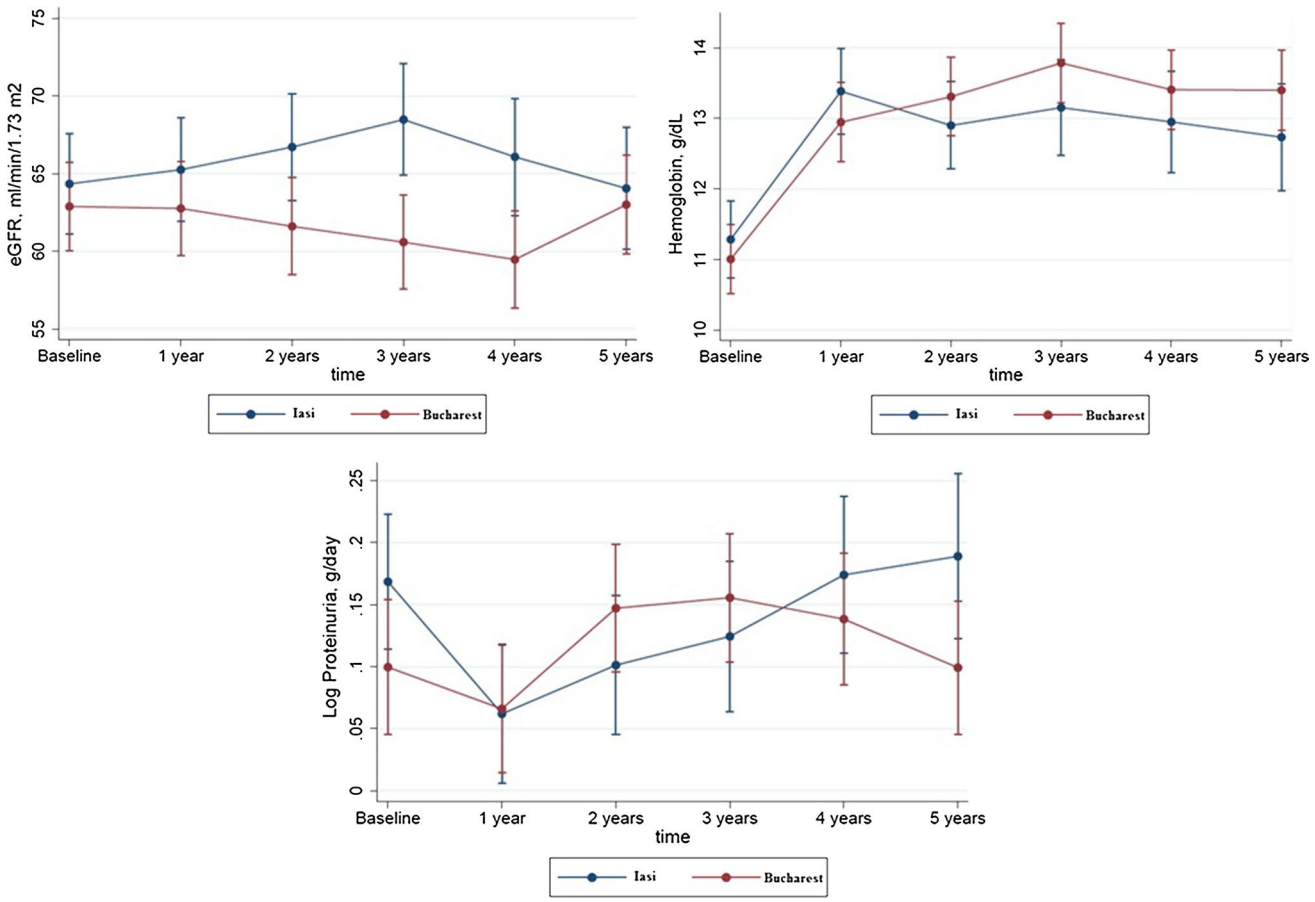

Fig. 2 Glomerular filtration rate, hemoglobin and proteinuria change during the follow-up—a comparison between Iasi and Bucharest transplant centers

US Renal Data System, Meier-Kriesche et al. [15] showed that in Caucasians the increased recipient age (65 and older) is an independent risk factor for the development of chronic renal allograft failure. On the other hand, in a 627 kidney transplant recipients cohort, the 5-year graft survival was not influenced by age [16]. In our case, age was associated with the outcome only in the univariate analysis probably, due to the young cohort since in Romania recipients > 65 years are still an exception.

Several recent studies outline an association between anemia, graft failure and mortality [17–19]. Although these data together with evidence that ESA usage in targeting higher hemoglobin levels could improve graft survival [20] we did not find an association between hemoglobin levels and our composite end point. A possible explanation, besides the rather small size of our cohort, could be that hemoglobin levels were close to 11 g/dl in both groups.

Multivariable Cox analysis revealed only the cholesterol and the transplant center as independent associated factors with our end point. Our findings are relatively similar to published data regarding cholesterol levels. In a retrospective single center study, Booth et al. show that pretransplant total cholesterol levels > 5.5 mmol/L are associated with higher patient survival, but no difference could be found in graft survival [21]. Also, recent studies outline early statin use as independent predictor of long-term graft survival [22, 23]. Using time-varying variables only eGFR and transplant center were associated with the outcome.

Graft survival and predictive factors differences are seen also in large databases when comparing two different regions. Gondos et al. [24] found higher cumulative survival estimates in Europe when comparing 23.530 transplant patients from the European Collaborative Transplant Study database to a 32.258 UNOS population. Similar data are found when comparing a Spanish cohort to US kidney transplant recipients regarding death with functioning graft [25].

Conclusions

Our study reports data from two distinct transplant centers from a developing country. Our results are similar to the current literature data, but also reveal that the approach of a center to the transplantation management is an independent factor associated with graft survival.

Compliance with ethical standards

Human and animal rights statement All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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