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Research Article

A Fast Decline of Residual Renal Function in the First Year is a Predictor for Early Withdrawal from Peritoneal Dialysis in Non-Diabetic Patients

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Key Words
Residual renal function • Survival • Peritoneal Kt/V urea • Peritoneal dialysis

Abstract
Background/Aims: Little is known about the relationship between residual renal function (RRF) decline in early period and survival in non-diabetic peritoneal dialysis (PD) patients. ***Methods:*** A total of 567 non-diabetic patients who began PD from January 1, 2005 to June 30, 2013 was investigated. The rate of RRF decline was determined by the "slope of the trend equation" of serial RRFs. A composite end-point of all-cause mortality and conversion to hemodialysis (HD) was used, survival status was censored on June 30, 2016. ***Results:*** The median of "the slope of RRF decline equation" was 0.308 (0.001-2.111) ml/min/1.73 m2/month. In the median follow-up period of 43 months (range 12 to 120 months), 65 (11.5%) patients died, 90 (15.9%) patients converted to HD and 171 (30.2%) patients received kidney transplantation. Multivariate linear regression showed male, high baseline RRF, high baseline peritoneal Kt/V urea, low serum albumin and low uric acid were independently associated with the rate of RRF decline in the first year of PD. Multivariate Cox models revealed that RRF decline in the first year remained a predictor for composite end-point (HR, 2.74, 95% CI, 1.53 to 4.90, P=0.001). The patients were divided into high RRF decline group (>0.308ml/min/1.73m2/month) and low RRF decline group (≤0.308 ml/min/1.73m2/month). In the first three years of PD, the rate of end-point events was higher in high RRF decline group (23.2%) than that in low RRF decline group (11.0%) (P<0.001). There were 189 patients in low RRF decline group and 171 patients in high RRF decline group maintaining PD for more than 3 years, in a median follow-up of 54 months (range 37 to 120 months), the survival rate was 30.9% in high RRF decline group and 46.4% in low RRF decline group (P=0.883). In high

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RRF decline group, there were 92 patients reaching composited end-point and 112 patients maintaining PD; multivariate Cox model showed high peritoneal Kt/V urea after 1 year of PD and high albumin level were protective factors (HR, 0.29, 95% CI, 0.13 to 0.61, P= 0.001; HR, 0.94, 95% CI, 0.90-0.99, P=0.022, respectively), while fast RRF decline remained risk factor for composite end-point (HR, 3.28, 95% CI,1.48-7.31, P=0.004). ***Conclusion:*** A faster RRF decline in the first year was a predictor for all-cause mortality and conversion to HD in non-diabetic PD patients, mainly in the first three year. For patients with faster RRF decline, increasing PD dose was effective to improve survival.

Introduction

Preservation of residual renal function (RRF) is strongly associated with better survival in both peritoneal dialysis (PD) and hemodialysis (HD) [1, 2]. Evidences from many studies suggest that preservation of RRF is better in PD than HD [3-5]. However, the rate of RRF decline varies among PD patients. Moist LM et al. found that among new PD patients, factors including female, non-white race, diabetes mellitus or congestive heart failure, using angiotensin-converting enzyme inhibitor (ACEI) or calcium channel inhibitor might be related with faster RRF loss [3]. Szeto CC et al. reported that patients with proteinuria, high baseline RRF, or using diuretics would have faster RRF decline [6].

The factors influencing RRF are conflicting among studies [3, 6-8]. It was reported that peritonitis was a risk factor for RRF decline in PD patients [9-11], whereas some other studies did not prove this phenomenon [12, 13]. Kim JK et al. found that excessive weight gain during the first year was correlated with RRF loss [14], however some other findings did not support this observation [15, 16].

Diabetes was proved to be associated with RRF loss [3, 6, 7]. However, little is known about whether RRF decline during the early period has more significant effects on patients' survival or technical survival in non-diabetic PD patients. In this study, we did a longitudinal cohort observation of incident non-diabetic PD patients in our center to determine which factors could predict RRF decline in the first year and quantitatively investigate the impact of RRF decline on non-diabetic patients' survival and technical survival.

Materials and Methods

Study population

All incident non-diabetic patients who began PD therapy at the First Affiliated Hospital of Zhejiang University in China from January 1, 2005 to June 30, 2013 were investigated. The exclusion criteria included patients with diabetes, anuria (24-hour urine volume less than 100 mL) at PD start, age below 18 years at PD start, conversion from HD to PD or from renal allograft failure to PD, recovery of renal function after PD and incomplete data for study. This study was performed in accordance with the Declaration of Helsinki and was approved by the Clinical Research Ethics Committee of the FirstAffiliated Hospital of Zhejiang University. All participants provided written informed consents.

Data collection

Clinical data were collected from our regularly updated electronic records and reviews of the patients' medical and nursing notes. Demographic and clinical data, including gender, age, body mass index (BMI), cause of end stage renal disease (ESRD), mean arterial blood pressure (MAP) and comorbidities (angina, myocardial infarction, cerebrovascular disease, chronic pulmonary disease, diabetes, peripheral vascular disease and malignancy) were collected during the follow-up period. The Charlson comorbidity index (CCI) was calculated according to presence of each comorbidity [17]. The collected biochemical data included very low-density lipoprotein cholesterol (VLDL-C), triglycerides, total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), hemoglobin, serum albumin, uric acid,

phosphates, calcium, alkaline phosphatase (ALP), potassium, C-reactive protein and parathyroid hormone during the follow-up period. Use of angiotensin-converting enzyme inhibitor (ACEI)/ angiotensin receptor blocker (ARB) and diuretics, and episodes of peritonitis in the first year of PD period were also collected during the follow-up period.

The primary outcome was a composite end-point including all-cause mortality and conversion to HD. Survival status was censored on June 30, 2016, for the patients who were still on PD therapy at our center. In survival analysis, the censored events included kidney transplantation and loss to follow-up.

Assessment of RRF and dialysis indices

In the pre-dialysis period, the glomerular filtration rate (GFR) was estimated by the Modification of Diet in Renal Disease (MDRD) equation [18]. In the PD period, RRF was calculated as the mean of urea and creatinine clearance and adjusted for 1.73 m2 of body surface area from a 24-hour urine collection [19, 20]. We measured RRF generally at 3- to 6-month intervals in the first year of PD period. RRF was no longer assessed when a patient became anuric. The outcome measure in the study was the rate of RRF decline, determined by the "slope of the trend equation" of serial RRFs, which were checked over time for each patient.

Slope of the trend equation：

$$\hat{b} = \frac{\sum_{i=1}^{n}(x_i - \bar{x})(y_i - \bar{y})}{\sum_{i=1}^{n}(x_i - \bar{x})^2} = \frac{\sum_{i=1}^{n} x_i y_i - n\bar{x}\bar{y}}{\sum_{i=1}^{n} x_i^2 - n\bar{x}^2}$$

Adequacy of dialysis was determined by renal and peritoneal urea clearance index (Kt/V urea) calculated based on 24-hour dialysate collection using PD Adequacy software (Baxter Healthcare). In the subgroup analysis, the outcome measure was the peritoneal Kt/V urea, determined by the average of peritoneal Kt/V urea at all visits after a year of PD period. A standard peritoneal equilibration test was performed to determine the peritoneal transport characteristics.

Statistical analysis

Continuous variables are presented as means and standard deviations or medians with the range depending on the distribution, and categorical variables are presented as frequencies with percentages. Differences between groups were examined with one-way analysis of variance, Mann-Whitney U tests, or chi-square tests as appropriate. A multivariate linear regression model was used to identify the determinants of RRF decline in Year 1 of PD period.

Survival was analyzed using Kaplan-Meier method, and the groups were compared using a log-rank test. The Cox proportional hazards regression model was used to assess the relationship between RRF decline and composite end-point after adjusting for several groups of covariates. Covariates with *P*-value <0.1 in univariate models or for importance of concern were selected for multivariate Cox regression models. The results are expressed as hazard ratio (HR) and 95% confidence interval (95% CI). All statistical analysis was performed using SPSS version 22.0 (SPSS Inc.). A $P<0.05$ was considered statistically significant.

Results

Patient characteristics

A total of 973 non-diabetic patients received PD at our center during the study period; 406 patients were excluded, and the remaining 567 patients were included in the final analysis (Fig. 1). Their mean age was 49±14years, 57% of the patients were male, and the median of "the slope of RRF decline equation" was 0.308 (0.001-2.111) ml/min/1.73m2/month. The baseline (defined as within 1 week before initiation of PD therapy) characteristics of the patients are summarized in Table 1.

Factors correlating with the rate of RRF decline in year 1 of PD period

After incorporating the covariates with P-value <0.1 in univariate models into a multivariate linear regression model (Table 2), the results showed that male, high baseline RRF, high baseline peritoneal Kt/V urea, low serum albumin and low uric acid were independently correlated with a fast RRF decline in the first year of PD.

The effects of RRF decline on composite end-point

The median follow-up period was 43 months (range from 12 to 120 months). During the study period, 65 (11.5%) patients died, 90 (15.9%) patients were converted to HD and 171 (30.2%) patients received kidney transplantation.

Table 3 shows the risks of composite end-point (all-cause mortality and conversion to HD) associated with RRF decline. RRF decline in the first year remained a significant predictor of composite end-point of all-cause mortality and conversion to HD in both the univariate and the fully adjusted multivariable Cox regression models. The fully adjusted hazard ratios (HRs) for composite end-point associated with 1 ml/min/1.73m2/month deterioration of RRF decline in the first year was 2.74 (95% CI, 1.53 to 4.90, *P* =0.001).

The patients were divided into the following two groups based on the median RRF decline: low (≤0.308 ml/min/1.73m2/month) and high (>0.308ml/min/1.73m2/month). The Kaplan-Meier estimates of the patients with different RRF decline in relation to the composite end-point are

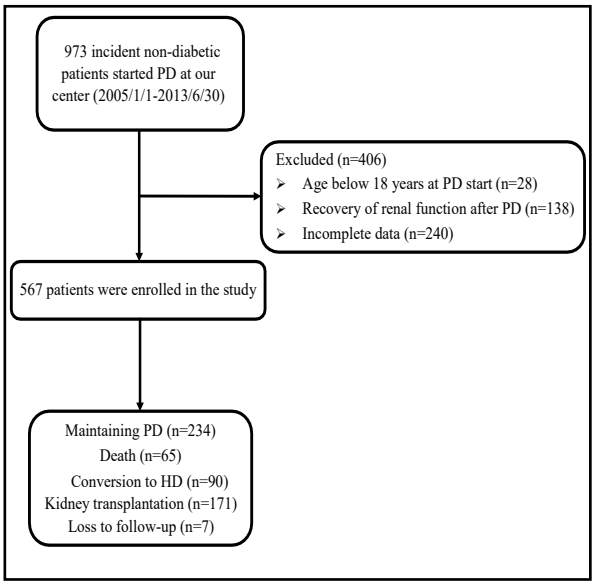

Fig. 1. Flow chart of the participants in the study cohort. PD, peritoneal dialysis. HD, hemodialysis.

Table 1. Demographics and biochemical characteristics. Note: Baseline was defined as within 1 week before initiation of PD therapy. Abbreviations: VLDL-C, very low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein; RRF, residual renal function; BMI, body mass index; Kt/V urea, urea clearance index

Characteristics	Value
Slopes of RRF decline in the first year (ml/min/1.73 m^2/month)	0.308 (0.001-2.111)
Age (years)	49 ± 14
Male (%)	57
Primary chronic Glomerulonephritis (%)	75.3
BMI (kg/m^2)	20.81 (13.8-30.2)
Mean arterial pressure (mmHg)	109 (60-180)
Charlson comorbidity score	2 (2-32)
Peritonitis episodes in the first year	0 (0-5)
Baseline biochemistry	
Hemoglobin (g/L)	82 (42-156)
Albumin (g/L)	37.44 ± 5.37
Uric acid (μmol/L)	516.49 ± 130.90
Calcium (mmol/L)	2.11 (1.26-3.51)
Phosphate (mmol/L)	1.76 (0.40-3.90)
Triglycerides (mmol/L)	1.37 (0.23-12.51)
Total cholesterol (mmol/L)	4.09 (1.77-14.13)
HDL-C(mmol/L)	1.04 (0.34-2.63)
LDL-C (mmol/L)	2.22 (0.69-8.77)
VLDL-C (mmol/L)	0.75 (0.11-3.89)
Alkaline phosphatase (U/L)	66 (17-528)
Potassium (mmol/L)	4.55 ± 0.72
Parathyroid hormone (pg/mL)	303.50 (3-2500)
C-reactive protein (mg/L)	2.80 (0-162)
Fasting blood-glucose (mmol/L)	4.57 (3.13-18.99)
Baseline RRF (ml/min/1.73 m^2)	6.35 (1.46-16.15)
Baseline peritoneal KT/V urea	1.17 ± 0.42

Table 2. Linear regression analysis of rate of RRF decline in Year 1 of PD period. Abbreviations: VLDL-C, very low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein; RRF, residual renal function; BMI, body mass index; PD, peritoneal dialysis; Kt/V urea, urea clearance index

Factor	Univariate linear regression		Multiple linear regression	
	Adjusted regression coefficient	P value	Adjusted regression coefficient	P value
Age	0.024	0.570		
Gender (female versus male)	-0.145	0.001	-0.118	0.001
BMI	-0.055	0.192		
Primary causes	0.044	0.303		
Charlson comorbidity score	0.066	0.118		
Peritonitis episodes in the first year	0.017	0.683		
Mean arterial pressure	-0.074	0.080	-0.056	0.099
Hemoglobin	0.097	0.022	0.007	0.850
Uric acid	-0.183	<0.001	-0.151	<0.001
Albumin	-0.178	<0.001	-0.126	<0.001
Calcium	0.093	0.027	0.021	0.554
Phosphate	-0.211	<0.001	0.045	0.264
Triglycerides	0.003	0.936		
Total cholesterol	0.000	0.999		
HDL-C	-0.037	0.386		
LDL-C	0.008	0.849		
VLDL-C	0.013	0.754		
Alkaline phosphatase	0.059	0.161		
Potassium	0.003	0.938		
Parathyroid hormone	-0.062	0.140		
C-reactive protein	0.005	0.937		
Fasting blood-glucose	-0.033	0.435		
Baseline RRF	0.499	<0.001	0.619	<0.001
Baseline peritoneal Kt/V urea	0.105	0.013	0.348	<0.001

illustrated in Fig. 2. During first three years of PD period, the rate of end-point events was higher in high RRF decline group (23.2%) than in low RRF decline group (11.0%) (log-rank test P<0.001). There were 189 patients in low RRF decline group and 171 patients in high RRF decline group maintaining PD for more than 3 years, in a median follow up time of 54 months (range from 37 to 120 months), no significant difference of survival was observed between these two groups after maintaining PD for more than three years (30.9% in high RRF decline group vs 46.4% in low RRF decline group, log-rank test P=0.883).

Table 3. Risks of composite end-point with RRF decline. Note: Composite end-point included all-cause mortality and transfer to hemodialysis. Abbreviations: CI, confidence interval; HR, hazard ratio; RRF, residual renal function. Model 1: Unadjusted, Model 2: Adjusted for age, gender, Model 3: Adjusted for the model 2 covariates and primary causes, Charlson comorbidity score, peritonitis episodes in the first year, Model 4: Adjusted for the model 3 covariates plus serum albumin, phosphate, parathyroid hormone, alkaline phosphatase and baseline RRF

Model	HR (95% CI)	P Value
Model 1	3.02 (1.91-4.78)	<0.001
Model 2	2.91 (1.84-4.62)	<0.001
Model 3	2.77 (1.75-4.39)	<0.001
Model 4	2.74 (1.53-4.90)	=0.001

The effects of therapies in high decline group after 1 year of PD period on composite end-point

In high RRF decline group, there were 92 patients reaching composited end-point and 112 patients maintaining PD at the end of follow up. Table 4 shows the comparation of characteristics at 1 year of PD period between patients reaching composite end-point and patients maintaining PD. Patients maintaining PD had younger age, lower peritonitis episodes in the first year, higher serum albumin level and higher peritoneal Kt/V urea after 1 year than patients reaching composite end-point (P<0.05). Patients maintaining PD also had an increased tendency to use ACEI/ARB though it did not reach statistic difference.

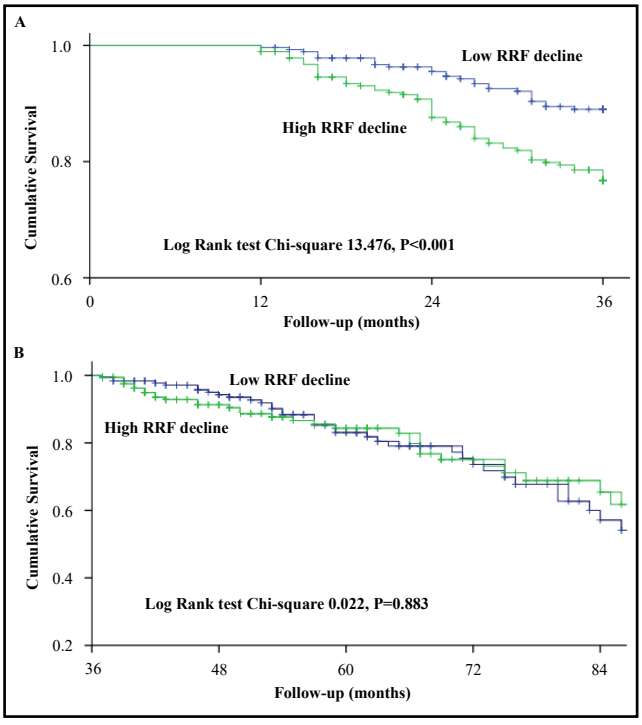

Fig. 2. The Kaplan-Meier estimates of the patients stratified by median of RRF decline in relation to the composite end-points. Composite end-points included all-cause mortality and conversion to hemodialysis. A. the cumulative survival for both groups of patients in first three years of peritoneal dialysis; B. the cumulative survival for both groups of patients maintaining peritoneal dialysis for more than 3 years.

After incorporating the covariates with P-value<0.1 in Table 4 into a multivariate Cox regression model (Table 5), we showed that in high RRF decline group, high peritoneal Kt/V urea after 1 year of PD period and high albumin level were the protective factors (HR, 0.29, 95% CI, 0.13 to 0.61, P = 0.001; HR, 0.94, 95% CI, 0.90-0.99, P=0.022, respectively), while fast RRF decline remained the risk factor for composite end-point (HR, 3.28, 95% CI,1.48-7.31, P=0.004) .

Discussion

In this observational study, we found that a fast RRF decline in the first year of PD period was an independent predictor for high risks of all-cause mortality and conversion to HD in non-diabetic PD patients, mainly during the first 3 years of PD period. However, for patients maintaining PD for more than 3 years, RRF decline no longer correlated with the composite end-point (all-cause mortality and conversion to HD). High peritoneal Kt/V urea after 1 year of PD period could be the protective factor for patients with fast RRF decline.

It's important to preserve RRF, even in dialysis patients [21]. The evidences from many studies strongly indicated an association between preservation of RRF and improved patients' survival [1, 2, 22-24]. However, there were many arguments with respect to the factors influencing RRF decline among PD patients. In this study, we found male, high baseline RRF, high baseline peritoneal Kt/V urea, low serum albumin and low uric acid were independently correlated with a fast RRF decline in the first year of PD. An interesting result is that higher serum uric acid level was correlated with lower RRF decline in the first year during PD period. To our knowledge, only a few studies have examined the relationship between serum uric acid level and RRF in PD patients [25, 26].

Table 4. Comparation of characteristics at 1 year of PD period of patients reaching composite end-point versus patients maintaining PD in high RRF decline group. Note: Composite end-point included all-cause mortality and transfer to hemodialysis. Abbreviations: RRF, residual renal function; PD, peritoneal dialysis; Kt/V urea, urea clearance index

Factor	Patients reaching composite end-point (92)	Patients maintaining PD (112)	P value
The average of peritoneal KT/V urea 1 year later	1.38 ± 0.38	1.55 ± 0.31	0.001
Medicine			
ACEI/ARB (%)	70.3	81.3	0.069
Diuretics (%)	78.0	83.0	0.368
Age (years)	57 ± 15	50 ± 12	0.001
Male (%)	66.3	60.7	0.411
BMI (kg/m^2)	21.47 ± 3.08	21.33 ± 2.65	0.728
Mean arterial pressure (mmHg)	104 (50-135)	102 (63-136)	0.215
Charlson comorbidity score	2 (2-4)	2 (2-32)	0.218
Peritonitis episodes in the first year	0 (0-3)	0 (0-3)	0.003
Biochemistry			
Hemoglobin (g/L)	103 ± 17	103 ± 17	0.850
Albumin (g/L)	39.2 (25.3-50.6)	40.8 (28.7-48.3)	0.003
Uric acid (μmol/L)	417.5 (197-592)	404 (192-748)	0.347
Calcium (mmol/L)	2.30 (1.62-3.05)	2.32 (1.81-2.75)	0.617
Phosphate (mmol/L)	1.54 (0.49-3.31)	1.45 (0.71-3.68)	0.332
Triglycerides (mmol/L)	1.65 (0.53-16.62)	1.54 (0.52-11.12)	0.427
Total cholesterol (mmol/L)	4.99 (2.36-13.37)	4.97 (2.76-10.15)	0.487
HDL-C(mmol/L)	1.17 (0.52-2.50)	1.14 (0.71-3.14)	0.613
LDL-C (mmol/L)	2.77 (0.34-5.48)	2.57 (0.80-5.77)	0.695
VLDL-C (mmol/L)	0.94 (0.13-8.17)	0.88 (0.10-4.07)	0.984
Alkaline phosphatase (U/L)	63.5 (18-361)	71 (30-300)	0.078
Potassium (mmol/L)	4.26 (2.67-6.59)	4.12 (3.12-6.32)	0.367
C-reactive protein (mg/L)	3.08 (0-254)	2.85 (0-66.5)	0.275
Fasting blood-glucose (mmol/L)	5.11 (3.59-9.99)	5.15 (3.81-11.96)	0.963
RRF (ml/min/1.73 m^2)	1.60 (0-7.17)	1.31 (0-8.02)	0.355
peritoneal KT/V urea	1.29 ± 0.48	1.38 ± 0.39	0.167
Slopes of RRF decline in the first year (ml/min/1.73 m^2/month)	0.55 (0.31-2.11)	0.45 (0.31-1.93)	0.063

Table 5. Multivariate Cox regression of the risk factors for composite end-point in high RRF decline group. Note: Composite end-point included all-cause mortality and transfer to hemodialysis. Abbreviations: CI, confidence interval; HR, hazard ratio; RRF, residual renal function; Kt/V urea, urea clearance index

Factor	HR (95% CI)	P value
Average peritoneal KT/V urea 1 year later	0.29 (0.13-0.61)	0.001
Peritonitis episodes in the first year	1.35 (0.94-1.94)	0.110
Slopes of RRF decline in the first year	3.28 (1.48-7.31)	0.004
ACEI/ARB	0.68 (0.40-1.16)	0.157
Age	1.01 (0.99-1.02)	0.379
Albumin	0.94 (0.90-0.99)	0.022
Alkaline phosphatase	1.00 (0.99-1.00)	0.220

In this study, we demonstrated that the faster RRF decline in the first year of PD period was associated with higher risks of all-cause mortality and conversion to HD in PD patients even after adjusting for several potential confounders (e.g., demographic characteristics, the Charlson comorbidity score, and laboratory parameters) during the first 3 years of PD period. Similar to our results, Maiorca et al. reported a 50% reduction in mortality in PD patients with RRF [27]. Rocco et al. also reported that for each 10L/week/1.73m2 increase in renal Creatinine clearance, there was a 40% reduced risk for death [28]. A post-analysis of the CANUSA study, which was a multicenter prospective cohort study of 680 incident PD patients in Canada and USA, reported that for each increment of RRF of 5 L/week/1.73m2 there was a 12% reduction in the risk for death and that for each 250ml increase in urine volume there was a 36% reduction of risk for death [1]. Different from those studies, we chose two main clinic outcomes including all-cause mortality and conversion to HD as a composite end-point to present the survival status including patients' survival and technical survival in PD. With

the PD time extending, we found 3 years later, RRF decline no longer affected the composite end-point. Besides, we found that using the "slope of the trend equation" of serial RRFs to observe the dynamic process of RRF decline was more in line with the law of RRF decline. Since high RRF is correlated with reduced inflammatory markers, better solutes clearance, improved nutrition and even improved quality of patients' life [29-33], it may suggest that the preservation of RRF in the early PD period is valuable to improve patients' survival.

In the subgroup analysis, we found the high peritoneal Kt/V urea after 1 year of PD period could be the protective factor for patients with fast RRF decline in the first year of PD period. Similar to our result, in a published study including 1, 677 incident PD patients in America, the PD patients with higher laboratory values for albumin and weekly Kt/V had lower mortality but no less conversion from PD to HD therapy in the first year of PD period [34]. Fried L et al. also found Kt/V calculated using actual body weight less than 1.7 in anuric PD patients was associated with increased mortality and more hospitalization [35]. However, a study including 183 PD patients showed the presence and severity of peritoneal calcification were associated with high peritoneal Kt/V [36]. Therefore, it may suggest increasing the PD dose for therapy in fast RRF decline group. Whether high peritoneal Kt/V really benefits would also need to be verified in further prospective studies.

This study has several limitations. First, it was a single-center retrospectivestudy, which only revealed associations but no causation due to its observational nature. Second, only non-diabetic PD patients were included in our study; therefore, it may not be applied to the other dialysis populations. Third, due to the lack of follow-up data, we did not investigate the influence of changes in factors during the observation period on the RRF decline.

Conclusion

In conclusion, our study revealed that a faster RRF decline in the first year was a predictor for all-cause mortality and conversion to HD in non-diabetic PD patients, mainly in the first three year. For patients with faster RRF decline, increasing PD dose was effective to improve survival.

Acknowledgements

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Disclosure Statement

The authors declare that no conflicts of interest exist.

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