

Predictors of Survival and Clinical Outcomes in Hemodialysis Patients: A 9-Year Multicenter Cohort Study

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Introduction. Cardiovascular and non-cardiovascular mortality rates among hemodialysis patients continue to be high despite advances in dialysis therapy.

Materials and Methods. This prospective cohort study enrolled 185 adult patients with end-stage kidney disease (ESKD) on maintenance hemodialysis (HD) from three hemodialysis facilities (Shariati hospital, Shohadaye Hafte-Tir hospital and Sevome-Sha'ban hospital) in September 2012. Causes of death and HD exit were tracked over a follow-up period of 103 months (8.5 years). The Cox proportional hazards model was employed to predict mortality after adjusting for case-mix and laboratory data variables.

Results. The mean age of the patients was 57 ± 15.2 years, with a mean dialysis vintage of 39 ± 45 months. The cohort comprised 52.5% males and 48% diabetic patients. In the univariate analysis, mortality rate was higher among women (81% vs. 63%), diabetics (89% vs. 55%), and those with higher body mass index, older age, and lower serum creatinine, albumin, and intact PTH levels. A total of 132 patients (71%) died, with a mortality rate of 19 per 100 patient-years. The leading causes of death were cardiovascular diseases (47%) and infections (32.5%). Kidney transplantation was performed in 25 patients (14%), including 7 women and 18 men. The median survival was 4.1 years (95% CI: 3.3-5.0). The survival rates at one, two, three, five, and nine years were 83%, 64%, 56%, 39%, and 19%, respectively.

Conclusion. Older age, poor nutritional biomarkers, diabetes mellitus, and catheter vascular access are the primary factors contributing to poor long-term prognosis in hemodialysis patients.

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INTRODUCTION

Although uremia-related deaths can be effectively prevented with maintenance dialysis, survival rates among individuals with end-stage kidney disease (ESKD) persist extremely low. Patients undergoing hemodialysis (HD) are at much higher risk of mortality than individuals who are not on HD, and this risk is even greater when compared to those

with cancer, diabetes mellitus, or cardiovascular disease. Nonetheless, there has been a noted improvement in mortality rates among ESKD patients over time.¹

Cardiovascular disease accounts for about half of all mortality among dialysis patients. While cardiovascular-related deaths have declined in the general population, this trend has not

been significant among dialysis patients.² This discrepancy can be partly explained by the individual characteristics, advanced age, substantial burden of other comorbidity such as diabetes, hypertension, pre-existing cardiac problems.³ Infections represent the second most common cause of death, frequently related to vascular access complications as well as other infectious sources.^{3,4} It is estimated that dialysis withdrawal accounts for approximately 15–25% of patient mortality.^{4,5}

The primary objective of this study was to determine the rate and predictors of mortality among hemodialysis patients across three facilities, throughout a prospective follow-up period of 103 months.

MATERIALS AND METHODS

In this prospective cohort study, 185 adult patients with end-stage kidney disease (ESKD) on maintenance hemodialysis were enrolled during September 2012 from three hemodialysis facilities (Shariati hospital, Shohadaye Hafte-Tir hospital, Sevome-Sha'ban hospital) in Tehran and followed for 103 months, until March 2021 to determine the causes of death and HD withdrawal. Enrolled patients were adults (≥ 18 years) on outpatient HD for more than three months. Comprehensive demographic, clinical, and laboratory data were collected using a detailed data collection form. The recorded information included age, gender, causes of ESKD, weight, height, body mass index (BMI), characteristics of HD treatment, single-pool Kt/V, and laboratory results (both pre- and post-dialysis serum blood urea nitrogen [BUN], creatinine, potassium, calcium, phosphorus, iPTH, albumin, ferritin and hemoglobin.). Additional data on access-related queries, history of kidney transplantation, history of cardiovascular and ischemic heart diseases was also collected. For every participant, at least three previous laboratory measurements were documented, and their mean values were applied in the analysis.

Data were retrieved from organizational forms and medical records by trained medical students in collaboration with dialysis unit staff. Recorded outcomes during follow-up included the cause and date of hemodialysis discontinuation, whether due to recovery of kidney function or transfer to peritoneal dialysis, kidney transplantation, or death. The study was approved by relevant review

boards and ethics committees.

Informed written consent was obtained from all patients. The ethical number was IR.TUMS.MEDICINE.REC.1400.1123.

Demographic characteristics and laboratory data were summarized using percentages of the total, means \pm standard deviations, or medians with interquartile ranges, as appropriate. The mean values from the last two to three laboratory tests for each patient were used in the analyses. Categorical variables were compared using Chi-square or Fisher's exact tests, while continuous variables were compared using t-tests or Mann-Whitney U tests, as applicable. Cox proportional hazard models were utilized to determine the hazard ratio (HR) associated with death, adjusting for relevant covariates. The follow-up period for each participant was from the start of dialysis until the event (death) or censoring (recovery, transplantation, peritoneal dialysis, or last visit), whichever occurred first. Survival time was measured as the time from start of dialysis until death from any cause or last date of follow-up alive.

Unadjusted and progressively adjusted multivariable models were employed to investigate the relationships between case-mix variables (age and sex), bone mineral data (phosphorus and intact PTH), nutritional biomarkers (serum albumin, creatinine, hemoglobin, and body mass index), diabetes mellitus, and vascular access. A P-value of less than .05 was considered statistically significant.

RESULTS

Total patients

The mean age of the patients was 57 ± 15.2 years (Table 1), and 97 patients (52.5%) were male. Diabetes mellitus was the leading cause of ESKD, affecting 48% of patients. Other causes included glomerular diseases (17.5%), urological issues (8.5%), autosomal dominant polycystic kidney disease (3.5%), and hereditary conditions (2%). Additionally, high blood pressure and unidentified causes contributed to 20.5% of the cases. A total of 73% had an AV-fistula, 8% had an AV-graft, and 19% had a catheter inserted.

Sex pattern

Women constituted 47.5% of the patients (88 patients) (Table 2), and their mortality rate was significantly higher than men (81% vs. 63%,

Table 1. Survival rate and comparison of demographic, clinical, and laboratory data for all patients, survived and died hemodialysis patients

Characteristics	Total patients (N = 185)	Survived (N = 53)	Died (N = 132)	P
Sex (%) (female)	88 (47.5%)	17 of 53 (32%)	71 of 132 (54%)	.009
Age (year)	57 ± 15.2	46.0 ± 15.0	62.0 ± 13.0	< .001
Body mass index (kg/m ²)	24.2 ± 4.6	23.1 ± 4.1	24.7 ± 4.8	.026
Hemodialysis vintage (month)	39 ± 45	43 ± 53	37 ± 41	NS
Serum albumin (g/dL)	3.84 ± 0.34	3.95 ± 0.31	3.80 ± 0.34	.008
Serum hemoglobin (g/dL)	10.8 ± 1.7	10.4 ± 1.7	11.0 ± 1.7	.07
Serum creatinine (mg/dL)	8.1 ± 2.4	9.2 ± 3.0	7.6 ± 2.1	.001
Pre-dialysis BUN (mg/dL)	57.3 ± 13.1	58.8 ± 13.5	56.8 ± 13.0	NS
Single-pool Kt/V	1.30 ± 0.17	1.30 ± 0.16	1.29 ± 0.17	NS
Serum potassium (meq/L)	5.2 ± 0.6	5.2 ± 0.7	5.3 ± 0.5	NS
Serum calcium (mg/dL)	8.8 ± 0.8	8.8 ± 0.9	8.9 ± 0.8	NS
Serum phosphorus (mg/dL)	5.6 ± 1.4	5.8 ± 1.5	5.5 ± 1.3	.14
Serum iPTH (pg/mL)	364 ± 314	458 ± 325	325 ± 302	.001
Serum ferritin (ng/mL)	479 ± 256	468 ± 283	483 ± 246	NS
Diabetes (yes)%	89 (48%)	10 of 53 (19%)	79 of 132 (60%)	< .001
Hemodialysis vascular access				
AV-Fistula	135 (73%)	43 (81%)	92 (70%)	NS
AV-Graft	15 (8%)	3 (6%)	12 (9%)	
Catheter	35 (19%)	7 (13%)	28 (21%)	

Table 2. Comparison of different variables in 185 hemodialysis patients in different sex

Characteristics	Female (n = 88)	Male (n = 97)	P
Age (year)	60.5 ± 15.1	54.7 ± 14.9	.01
Body mass index (kg/m ²)	24.9 ± 5.2	23.7 ± 3.9	.062
Hemodialysis vintage (month)	40 ± 50	36 ± 41	NS
Serum albumin (g/dL)	3.78 ± 0.33	3.91 ± 0.34	.012
Serum hemoglobin (g/dL)	10.8 ± 1.7	10.8 ± 1.8	NS
Serum creatinine (mg/dL)	7.3 ± 1.6	8.7 ± 2.9	< .001
Single-pool Kt/V	1.33 ± 0.17	1.27 ± 0.16	.014
Serum potassium (meq/L)	5.3 ± 0.6	5.1 ± 0.6	.066
Serum calcium (mg/dL)	9.1 ± 0.8	8.7 ± 0.8	.005
Serum phosphorus (mg/dL)	5.6 ± 1.4	5.5 ± 1.3	NS
Serum iPTH (pg/mL)	321 ± 283	403 ± 335	.038
Serum ferritin (ng/mL)	510 ± 264	451 ± 248	.171
Cuffed-catheter (yes)	15 (17.5%)	16 (17%)	NS
Diabetes (yes)	43 (49%)	46 (47.5%)	NS
Kidney transplantation (yes)	7 (8%)	18 (18.5%)	.05
Death (yes)	71 (81%)	61 (63%)	.009

$P = .009$). The mean survival time for men was 55 months (95% CI: 47–63), whereas for women, it was 46 months (95% CI: 38–54). The relative risk of death for females compared to males was 1.28 (95% CI: 1.07–1.54). Female patients were older (60.5 ± 15.1 vs. 54.7 ± 14.9 years, $P = .01$) and had lower serum albumin (3.78 ± 0.33 vs. 3.91 ± 0.34 g/dL, $P = .012$) and serum creatinine levels (7.3 ± 1.6 vs. 8.7 ± 2.9 mg/dL, $P < .001$) than male patients. Additionally, women had significantly higher serum

calcium levels and lower serum intact PTH levels ($P = .005$ and $P = .038$, respectively). There was no significant difference in the prevalence of diabetes mellitus between the sexes. However, compared to male patients, the proportion of female patients who received kidney transplants was significantly lower. (8% vs. 18.5%, $P = .05$).

Diabetic patients

Out of 185 patients, 89 (48%) had diabetes

mellitus. In the univariate analysis (Table 3), diabetic patients were significantly older than non-diabetic patients (62.5 ± 10.3 vs. 52.8 ± 17.5 years), had a shorter duration of dialysis (26 ± 28 vs. 49 ± 55 months), and a higher BMI (25.6 ± 4.9 vs. 23.1 ± 4.1). Diabetic patients also exhibited lower serum creatinine levels (7.5 ± 2.1 vs. 8.5 ± 2.6 mg/dL), single-pool Kt/V (1.27 ± 0.16 vs. 1.32 ± 0.17), and intact PTH levels (278 ± 187 vs. 445 ± 382 pg/mL). Kidney transplantation was performed in 5.6% of diabetic patients compared to 21% of non-diabetic patients ($P = .003$). Mortality was significantly higher among diabetic patients (89% vs. 55%; $P < .001$). The mean survival time for diabetic patients was 41 months (95% CI: 35-47) compared to 61 months (95% CI: 53-69) for non-diabetic patients. The relative risk of death for diabetic patients compared to non-diabetic patients was 1.60 (95% CI: 1.32-1.95).

Patient outcome

By the end of the 8.5-year follow-up period, 12.5% of patients (23 patients) remained on dialysis, 71% (132 patients) had passed away, 14% (25 patients) had undergone kidney transplantation, 2% (4 patients) had shifted to peritoneal dialysis, and 1 patient had achieved renal function recovery.

During the follow-up duration of 672 patient-years, there were a total of 132 deaths (71%), yielding a mortality rate of 19 per 100 patient-years. The primary causes of death included cardiovascular

disorders (47%), infections (32.5%), complications from fractures (6%), low BMI (4%), and malignancies (1.5%); other causes accounted for 9% of mortality. Cardiovascular mortality indirectly influenced the mortality of at least an additional 37% of the individuals. One death was attributed to COVID-19. It is notable that COVID-19 was first reported in Iran in March 2020, and our study continued until April 2021 for the latest follow-up.

Non-survivors were significantly more likely to have diabetes mellitus (60% vs. 19%, $P < .001$) and were more likely female (54% vs. 32%, $P = .009$). They were also older (62.0 ± 13.0 vs. 46.0 ± 15.0 years, $P < .001$) and had lower levels of serum albumin (3.80 ± 0.34 g/dL vs. 3.95 ± 0.31 g/dL, $P = .008$), serum creatinine (7.6 ± 2.1 mg/dL vs. 9.2 ± 3.0 mg/dL, $P = .001$), and intact parathyroid hormone (intact PTH) (325 ± 302 pg/mL vs. 458 ± 325 pg/mL, $P = .001$) (Table 1).

The mean and median time of survival rate were 4.3 years (95% CI: 3.8-4.8) and 4.1 years (95% CI: 3.3-5.0), respectively. The one-year survival rate was 83% (95% CI: 80%-86%), the two-year survival rate was 64% (95% CI: 60%-68%), the three-year survival rate was 56% (95% CI: 52%-60%), the five-year survival rate was 39% (95% CI: 35%-43%), the seven-year survival rate was 24% (95% CI: 20%-28%), and the nine-year survival rate was 19% (95% CI: 16%-22%).

In univariate analysis, age, diabetes mellitus, serum albumin, type of access (double-lumen

Table 3. Comparison of different variables in 185 hemodialysis patients based on diabetes status

Characteristics	Diabetics (n = 89)	Non-diabetics (n = 96)	P
Sex (female)	43 of 89 (48%)	45 of 96 (47%)	NS
Age (year)	62.5 ± 10.3	52.8 ± 17.5	$< .001$
Body mass index (kg/m ²)	25.6 ± 4.9	23.1 ± 4.1	$< .001$
Hemodialysis vintage (month)	26 ± 28	49 ± 55	.008
Serum albumin (g/dL)	3.81 ± 0.33	3.88 ± 0.35	.19
Serum hemoglobin (g/dL)	10.9 ± 1.6	10.7 ± 1.8	NS
Serum creatinine (mg/dL)	7.5 ± 2.1	8.5 ± 2.6	.004
Pre-dialysis BUN (mg/dL)	57.3 ± 13.1	57.4 ± 13.3	NS
Single-pool Kt/V	1.27 ± 0.16	1.32 ± 0.17	.01
Serum potassium (meq/L)	5.3 ± 0.5	5.2 ± 0.6	NS
Serum calcium (mg/dL)	8.8 ± 0.7	8.9 ± 0.9	NS
Serum phosphorus (mg/dL)	5.4 ± 1.4	5.7 ± 1.3	.16
Serum iPTH (pg/mL)	278 ± 187	445 ± 382	.025
Serum ferritin (ng/mL)	428 ± 226	526 ± 274	.011
Cuffed-catheter (yes)	14 (16%)	17 (18%)	NS
Kidney transplantation (yes)	5 (5.6%)	20 (21%)	.003
Death (yes)	79 (89%)	53 (55%)	$< .001$

cuffed catheter vs arteriovenous fistula), female sex, BMI, hemoglobin, serum creatinine, and intact parathyroid hormone (i PTH) levels significantly affected mortality.

Cox proportional hazards regression analysis was utilized to identify predictors of mortality. In the incremental multivariable model analysis, age (HR: 1.019; 95% CI: 1.003-1.036, $P = .023$), diabetes

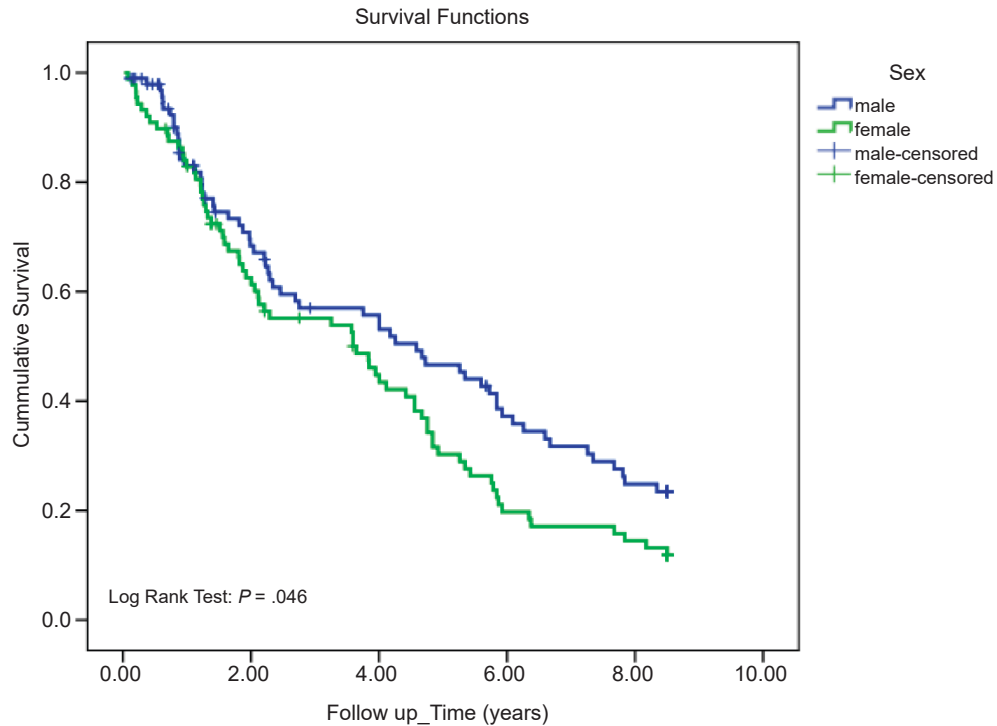


Figure 1. Kaplan-Meier survival in women versus men.

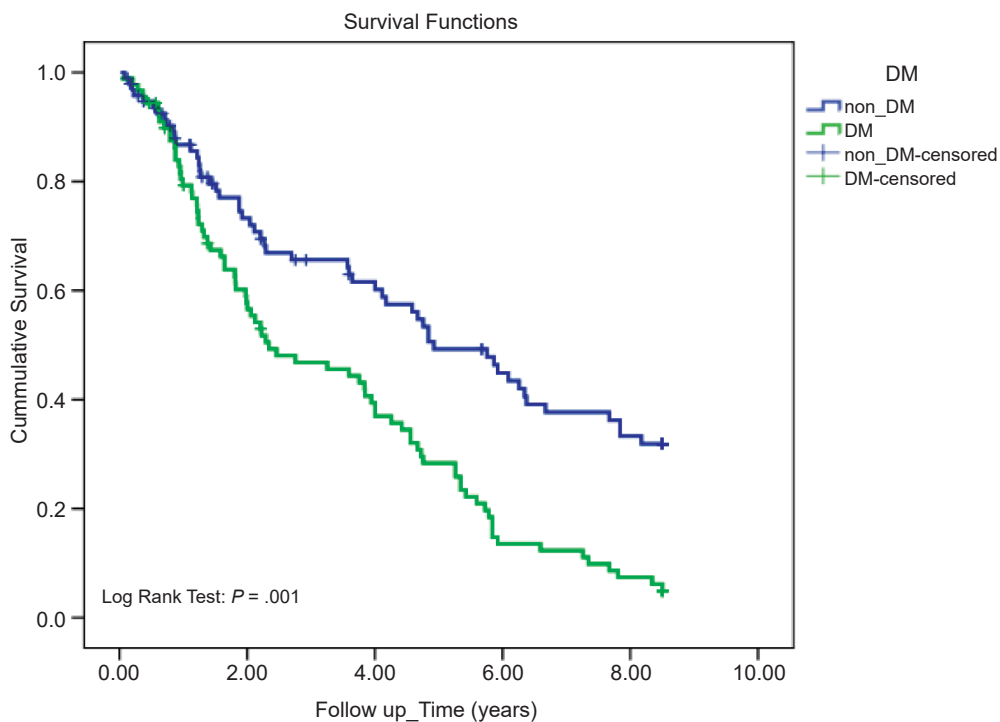


Figure 2. Kaplan-Meier survival in diabetic versus non-diabetic patients.

mellitus (HR: 2.22; 95% CI: 1.45-3.39, $P < .001$), serum albumin level (HR: 0.379; 95% CI: 0.195-0.735, $P = .004$), and double-lumen cuffed catheter access (HR: 1.73; 95% CI: 1.07-2.79, $P = .026$) were independent predictors of mortality. There was a trend towards higher mortality in women (HR: 1.35; 95% CI: 0.95-1.96, $P = .095$). Kaplan-Meier survival curves based on sex and diabetes mellitus are depicted in Figures 1 and 2, respectively.

DISCUSSION

Despite advancements in the management of dialysis patients, ensuring patient survival continues to be a major concern. Nevertheless, recent declines in mortality rates indicate beneficial effects of improvements in dialysis therapy. This study aims to provide comprehensive evaluation of long-term hemodialysis outcomes within our patient population.

In the present study, the mortality rate was 19 per 100 patient-years. Mortality rates among dialysis patients vary significantly across different countries. This discrepancy may arise from differences in underlying comorbidities such as diabetes mellitus and cardiovascular diseases, as well as age, types of vascular access, and psychosocial factors, which are important prognostic indicators.⁵

In our research, the survival rates at one, two, three, five, seven, and nine years were 83%, 64%, 56%, 39%, 24%, and 19%, respectively. The leading causes of death were cardiovascular disorders (47%) and infections (32.5%). Complications due to fractures, cachexia, and malignancies accounted for 6%, 4%, and 1.5% of mortality, respectively. These results are in concordance with data reported in regional and international studies. A single-center Iranian study, reported survival rates of 88%, 56%, and 16% at 1, 4, and 10 years of follow-up, respectively.⁶ Similarly, a 10-year follow-up study in Japan found a mortality rate of 49.5% in hemodialysis patients, due to cardiovascular disorders (36.1%), infectious diseases (25.8%), and malignant neoplasms (13.5%).⁷ Additionally, a single-center study in India reported a mortality rate of 19.8% over two-years.⁸ Another multicenter Iranian study, with a 28-month follow-up period, showed a mortality rate of 30%, representing 17 deaths per 100 patient-years.⁹

In the current investigation, diabetes mellitus emerged as the predominant cause of end-stage

kidney disease (48%). Mortality rates were significantly higher among diabetic patients compared to non-diabetic individuals (89% versus 55%; $P < .001$), with diabetes was identified as an independent predictor of mortality (HR: 2.22). The mortality rate remains highest among hemodialysis (HD) patients with diabetes mellitus. The diminished survival primarily correlates with a higher prevalence of cardiovascular disorders in this patient group.¹⁰⁻¹² The 2022 USRDS report described that around 60% of dialysis patients had diabetes.¹³ The five-year survival rate for patients on hemodialysis varies depending on the underlying kidney disease and it is lowest in patients with diabetic nephropathy. Five-year survival rate for patients with diabetic nephropathy, reported to be as low as 20%.^{2,14}

In this study, the mean age of the patients was 57 ± 15.2 years, with advanced age identified as an independent predictor of mortality (HR: 1.019). It was shown that survival rate decreases as age increases, for instance, patients younger than 45 years have the best survival outcomes.^{2,14-16} Survival rates among patients on hemodialysis have been significantly lower in the United States compared to Europe and Japan.¹⁵⁻¹⁹ Comorbid conditions, including diabetes mellitus, cardiovascular diseases, and psychiatric disorders, are more prevalent in the United States, resulting in reduced survival rates among dialysis patients.^{17,19}

This study revealed that serum albumin is an independent predictor of mortality (HR: 0.379). Nutritional status is an important determinant of medical risk and mortality, especially among those with undernourished and hypoalbuminemia.²⁰ Studies have consistently demonstrated that individuals with malnutrition and low body mass index (BMI), are associated with increased mortality.²¹⁻²³ These patients frequently present with hypoalbuminemia and lower-than-expected blood urea nitrogen (BUN) and creatinine levels relative to their dialysis intensity. A plasma albumin concentration below 4 g/dL is the laboratory finding most strongly correlated with an elevated risk of mortality. There is a dose-dependent increase in risk; when the plasma albumin concentration is in the range of 3.5 to 3.9 g/dL and the risk substantially escalates when albumin levels fall in the range of 3.0 to 3.4 g/dL.²¹ This underscores the importance of addressing malnutrition and

monitoring plasma albumin levels in dialysis patients to improve their overall well-being and reduce the risk of mortality. Hypoalbuminemia in dialysis patients attributed to malnutrition, can also be a marker of chronic inflammation. Therefore, untreated underlying inflammatory process may contribute to the decreased survival among chronic hemodialysis patients with hypoalbuminemia.^{24,25}

In our research, women constituted 47.5% of the patient population, and their mortality rate significantly higher than men (81% vs. 63%, $P = .009$) according to univariate analysis. The relative risk of death for females compared to males was 1.28 (95% CI: 1.07-1.54). However, in multivariate adjusted analysis, the mortality difference between females and males diminished, as females were generally older and had lower serum albumin levels, despite a trend for elevated mortality among women. Our results differ from the prevailing trend observed in most studies, which suggest equal or higher mortality rates in men.^{26,27}

We demonstrated that type of vascular access is as an independent predictor of mortality (HR: 1.73). Consistent evidence indicates that hemodialysis catheters are associated with higher complication rates and lower survival outcomes compared to arteriovenous fistula (AVF).^{28,29} In a study by Soleymanian *et al.*, catheter-related infections either isolated or compounded by underlying cardiovascular disease accounted for 2% and 10.5% of all mortality cases, respectively.³⁰ Moreover, catheter infections alone were responsible for approximately 10% of hospital admissions. Survival advantage of AVFs is largely attributed to their lower risk of infection and thrombosis. Other advantages of AVF include greater longevity, improved blood flow, and reduced healthcare costs.²⁹⁻³¹

In this study, the distribution of vascular access type of AV fistula, AV graft, and catheter was 73%, 8%, and 19%, respectively. According to the guidelines set by the United States Kidney Disease Outcomes Quality Initiative (K/DOQI), chronic hemodialysis access catheters should be limited to less than 10 percent of prevalent patients without contraindications for permanent AV access. Additionally, AV fistulas should be utilized in over 65 percent of prevalent patients.³¹

While we did not observe any independent effect of mineral alteration on mortality in our

study, numerous reports have underscored an elevated risk of both all-cause and cardiovascular mortality in patients with mineral metabolism disorders.³²⁻³⁴ The association with decreased survival is primarily related to elevated phosphate levels. The relationship between mineral metabolism parameters and mortality can be complex and multifactorial. Danese *et al.* recently published a study demonstrating that the presence of at least two out of three bone markers outside the target range can pinpoint patients at an elevated risk for adverse clinical outcomes.³⁵ In a recent study, Streja *et al.*, demonstrated that maintaining balance in serum phosphorus and iPTH levels improves outcomes in patients undergoing HD.³⁶ A multicenter study in Iran found a significant association between increased serum levels of intact PTH (≥ 600 pg/mL), phosphorus (≥ 6 mg/dL), and calcium (≥ 10 mg/dL) and mortality.³⁷

Notably, consistent with findings from previous studies,^{38,39} we observed no adjusted survival benefit associated with higher hemoglobin levels or increased Kt/V. A retrospective study of hemodialysis patients demonstrated that each 1 g/dL increase in hemoglobin variability was associated with a 33% increase in mortality.⁴⁰ Several observational studies support the hypothesis that more intensive dialysis improves survival. One of them is a national sample survey in the United States, reported a 7% reduction in mortality for every 0.1-unit increase in Kt/V.⁴¹ Although no statistically significant benefit was observed a Kt/V above 1.3, there was a trend toward greater benefit with higher dialysis levels.

Fracture-related complications accounted for 6% of the mortality in our cohort. Patients with ESKD are at an increased risk of bone fractures, and hospitalizations due to fractures are associated with a relatively high one-year mortality rate.⁴²⁻⁴⁴ For example, dialysis patients who experience hip fracture have approximately twice the risk of death compared to those without such fractures.⁴⁴

CONCLUSION

In conclusion, optimizing of modifiable clinical targets such as serum albumin concentration, mineral metabolism, dialysis adequacy, hemoglobin levels and preferential use of arteriovenous fistulas as vascular access can enhance survival outcomes and overall quality of life in dialysis

patients. Furthermore, effective management of cardiovascular disease, diabetes mellitus, and infections remains essential and improve survival and outcome in dialysis patients.

Strengths and limitations of the study

Our study had several limitations, including its observational design and lack of assessment for residual kidney function. Another limitation is the absence of time-dependent analyses for certain variables, as some variables may change over the course of follow-up. However, we partially addressed this by using the average of at least two or three laboratory measurements at study entry. Additionally, the potential influence of unmeasured confounding factors can not be excluded.

Ethical consideration

The study was approved by relevant review boards and ethics committees in Tehran University of Medical Sciences. Informed written consent was obtained from all patients. The ethical number was IR.TUMS.MEDICINE.REC.1400.1123.

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