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Different mortality predictor pattern in hemodialysis and peritoneal dialysis diabetic patients in 4-year prospective observation

Odmienne czynniki zagrożenia śmiertelnością u chorych na cukrzycę leczonych hemodializą i dializą otrzewnową w 4-letniej prospektywnej obserwacji

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Summary

Introduction: The aim was to identify factors carrying an ominous prognosis in a cohort of diabetic patients (pts) on a hemodialysis (HD) and peritoneal dialysis (PD) program.

Materials and methods: We analyzed survival rates of 61 diabetic dialysis pts (35 HD/26 PD). The participants were matched in baseline characteristics, standard indicators of dialysis care and laboratory parameters. The studied group was prospectively observed up to 4 years.

Results: 21 pts (34.4%) survived the whole observation period. The annual mortality rate was 23.2%, with no difference between HD and PD. Irrespective of dialysis modality, the only factor associated with mortality in the Cox proportional hazard model was serum albumin lowering. Referring to dialysis modality, the HD survivors were characterized by lower IL-6 level, higher albumin concentration, and increased serum cholesterol values with higher cholesterol left in multivariate analysis; under PD therapy the only factor significantly associated with mortality was older age. In contrast to HD treatment, elevated cholesterol was a universal finding in PD patients, significantly above levels in HD, with a slight tendency to lower values in PD survivors.

Conclusions:
1. A difference in mortality predictor pattern appeared in diabetic patients treated by PD and HD.
2. In the PD group more advanced age had a decisive negative impact on survival whereas in the HD group the outlook was dependent on factors related to nutrition and inflammation.
3. Elevated cholesterol level was associated with survival benefit in HD patients, being a common abnormality in the PD group, without positive prognostic significance.

Keywords: diabetic patients • hemodialysis • peritoneal dialysis • survival

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Abbreviations: **BMI** – body mass index, **BP** – blood pressure, **CRP** – C-reactive protein, **Hb** – hemoglobin, **HD** – hemodialysis, **IL-6** – interleukin 6, **Kt/V** – adequacy of dialysis, **NT-proBNP** – N-terminal pro-B-type natriuretic peptide, **PD** – peritoneal dialysis, **pro-ANP** – serum pro-atrial natriuretic peptide.

Introduction

The number of patients requiring renal replacement therapy is growing continuously.

According to the last report from the ERA-EDTA Registry, the annual incidence of patients starting dialysis in the year 2008 was 122 per million population (pmp), with a significantly increasing proportion of elderly patients, mean age 64, and accompanied by a pronounced rise in the proportion of patients with diabetes, up to one third. These two tendencies, ageing and marked increase of type 2 diabetic patients, are responsible for ominous prognosis in dialysis programs. The five-year survival in patients with type 2 diabetes on dialysis was around 30% compared to 46% in non-diabetics [13]. Therefore, the aim of the current study was to identify factors exhibiting a marked impact on survival in a high risk cohort of 61 prevalent dialysis patients with diabetes mellitus. The included patients were prospectively observed for 4 years. An additional goal was to reveal possible differences in the efficacy of hemodialysis (HD) and peritoneal dialysis (PD) treatment, because both dialysis modalities were nearly equally distributed.

Materials and Methods

Study population

The study group was created from 61 prevalent diabetic dialysis patients who had been on a chronic HD or PD program. The patients were recruited from three dialysis centers in south-west Poland (Wroclaw, Zabrze, Walbrzych).

The selected patients carried pronounced cardiovascular risk – all patients with diabetes above the age of 40 with advanced Monckeberg type intravascular calcifications in the forearm arteries (confirmed by X-ray); 26 patients (42.62%) were above the age of 70.

The group was formed in 2006 and prospectively observed during the subsequent 4 years.

The patients included in the study were free of active infection, symptomatic coronary disease, overt heart failure, history of malignancy, and diseases requiring immunosuppressive treatment. Clinical data of patients were extracted from the hospital records.

Study measurements

The impact of the following factors on survival was tested: baseline characteristics (age, gender), residual diuresis, duration of dialysis, all standard indicators of dialysis care (blood pressure, Hb, body mass index (BMI), adequacy of dialysis – Kt/V) and the following laboratory parameters: serum pro-atrial natriuretic peptide (pro-ANP), serum N-terminal pro-B-type natriuretic peptide (NT-proBNP), serum C-reactive protein (CRP), interleukin 6 (IL-6), serum albumin and cholesterol.

All HD patients were dialyzed using a native arteriovenous fistula fulfilling a single-pool Kt/V ≥ 1.3. All PD patients were treated by continuous ambulatory peritoneal dialysis (CAPD) achieving weekly Kt/V > 1.7. Kt/V was calculated from three consecutive measurements at monthly intervals.

Laboratory methods

Routine laboratory tests (Hb [g/dl], CRP [mg/l], serum albumin [g/dl], and cholesterol [mmol/l]) were measured in the Central Hospital Laboratory as part of the standard care.

In addition, serum pro-ANP (amino terminal 1-98 ANP fragment) and serum NT-proBNP were assessed by ELISA (BIOMEDICA, Vienna, Austria); interleukin-6 (IL-6) was measured by ELISA (R&D Systems, Minneapolis, USA).

The blood samples were taken in HD patients before the midweek dialysis session, and in PD patients during a control visit at the outpatient clinic during morning hours before the first fluid exchange. Blood pressure measurements were performed three times with a standard sphygmomanometer, and the mean value from the last two readings was used for calculations.

Statistical analysis

The statistical analysis was performed with Statistica 9.1 software.

The statistical test to compare means of qualitative variables in two groups was the nonparametric Mann-Whitney U test. Survival analysis was conducted using the multivariate Cox proportional hazard model to investigate the influence of qualitative variables on risk of death. Backward stepwise removal of non-significant variables was used in multivariate Cox regression, which could result in a univariate regression model.

Statistical significance was recognized with a *p*-value less than 0.05. For quantitative variables, results are given as mean±SD.

Results

We analyzed data of 61 diabetic patients on dialysis (24 F; 37 M – all Caucasian), median age 68, who had been on maintenance dialysis at least 2 months (median period 17 months), with preserved median residual diuresis 500 ml/24 h.

Demographic, clinical and laboratory parameters of the investigated participants at the study entry are presented in Table 1. In the investigated cohort 14 patients had type 1 diabetes and 47 type 2; the proportion was 7/28 in the HD group, and 7/19 in the PD group. The data are shown separately for the HD (35) and PD (26) groups. There were two significant differences between the groups at the start of the study: significantly lower albumin level (p=0.024) and significantly higher cholesterol concentration (p<0.0001). In the search for the possible cause of these distinctions the records from dialysis initiation were checked. The albumin concentration was at dialysis onset essentially similar in both groups (3.54±0.32 g/dl in PD versus 3.56±0.41 g/dl in HD), whereas cholesterol values were significantly higher in PD patients (5.56±0.85 mmol/l versus 4.77±1.20 mmol/l – in HD; p=0.003).

Twenty-one patients from the initial cohort of 61 (34.4%) survived the whole 48-month observation period: 12 HD patients (34.3%) and 9 PD patients (34.6%).

Table 1. Clinical characteristics of study groups

Characteristics	PD n=26 pts [min-median-max]	HD n=35 pts [min-median-max]	All n=61 pts [min-median-max]	Mann-Whitney U – test p-value
Age [years]	64.38±11.05 [44-63-81]	67.97±10.35 [42-69-84]	66.44±10.72 [42-68-84]	0.184
Gender [M/F]	12/14 [46.2%/53.9%]	12/23 [34.3%/65.7%]	24/37 [39.3%/60.7%]	
BMI [kg/m^2]	26.94±3.83 [21.7-26.4-36.9]	25.59±4.32 [16.9-25.6-37.8]	26.17±4.14 [16.9-26.0-37.8]	0.240
Duration of dialysis [months]	24.31±20.63 [2-16.5-80]	21.91±18.14 [2-17-84]	22.93±19.11 [2-17-84]	0.971
Systolic BP [mmHg]	133.50±18.71 [103-130-182]	132.86±17.12 [90-130-170]	133.13±17.66 [90-130-182]	0.838
Diastolic BP [mmHg]	82.23±8.06 [65-80-102]	79.29±10.30 [50-80-95]	80.54±9.45 [50-80-102]	0.332
Residual diuresis [ml/24 h]	577.69±570.03 [0-550-2000]	567.14±450.81 [0-500-1500]	571.64±500.58 [0-500-2000]	0.793
Hb [g/dl]	11.37±1.10 [8.5-11.5-14.1]	11.15±1.30 [8.8-11.1-13.7]	11.24±1.21 [8.5-11.3-14.1]	0.453
CRP [mg/l]	13.66±19.40 [0.6-5-72.3]	12.83±17.78 [0.6-5.5-77.6]	13.18±18.33 [0.6-5.5-77.6]	0.850
IL-6 [pg/ml]	8.39±8.05 [1.8-4.6-30.1]	9.82±9.51 [1.6-5.9-40.5]	9.21±8.88 [1.6-5.2-40.5]	0.565
Serum albumin [g/dl]	3.34±0.51 [2.4-3.4-4]	3.71±0.58 [2.6-3.8-4.9]	3.55±0.58 [2.4-3.5-4.9]	0.024*
Cholesterol [mmol/l]	5.67±1.19 [3.9-5.6-9.0]	4.62±1.14 [2.5-4.4-8.2]	5.07±1.26 [2.5-5.0-9.0]	0.000*
Pro-ANP [nmol/l] 1-98	22.71±12.64 [5.5-27.4-40.8]	25.46±12.70 [4.6-26.0-58.9]	24.29±12.65 [4.6-26.0-58.9]	0.507
NT-proBNP [nmol/l] 1-76	0.27±0.23 [0.0-0.2-0.7]	0.27±0.31 [0.0-0.2-1.6]	0.27±0.27 [0.0-0.2-1.6]	0.600

* P<0.05 statistically significant; borderline** 0.05<P<0.1.

Table 2. Clinical characteristics of deceased and surviving patients treated by HD

Characteristics	Deceased pts n=23	Surviving pts n=12	Mann-Whitney U – test p-value
Age [years]	67.00±11.30	69.83±8.38	0.578
BMI [kg/m2]	24.78±4.49	27.14±3.66	0.089**
Duration of dialysis [months]	21.52±18.61	22.67±17.98	0.986
Systolic BP [mmHg]	131.96±17.24	134.58±17.51	0.574
Diastolic BP [mmHg]	78.91±10.44	80.00±10.44	0.794
Residual diuresis [ml/24 h]	578.26±488.70	545.83±386.98	0.958
Hb [g/dl]	11.06±1.36	11.33±1.20	0.566
CRP [mg/l]	16.20±20.90	6.39±5.83	0.144
IL-6 [pg/ml]	11.93±10.53	5.78±5.54	0.044*
Serum albumin [g/dl]	3.57±0.60	3.98±0.45	0.034*
Cholesterol [mmol/l]	4.19±0.80	5.44±1.26	0.004*
Pro-ANP [nmol/l] 1-98	27.18±12.75	22.17±12.47	0.404
NT-proBNP [nmol/l] 1-76	0.29±0.36	0.22±0.19	0.664

* P<0.05 statistically significant; ** 0.05<P<0.1.

Table 2 contains the clinical characteristics of the deceased and surviving patients treated by HD. The survivors were characterized by a lower IL-6 level (p=0.04), higher albumin concentration (p=0.03), and increased cholesterol (p=0.004).

The information on the deceased and surviving PD patients is shown in Table 3. The only factor significantly affecting survival was more advanced age in deceased patients (p=0.05).

Table 3. Clinical characteristics of deceased and surviving patients treated by PD

Characteristics	Deceased pts n=17	Surviving pts n=9	Mann-Whitney U – test p-value
Age [years]	67.65±10.15	58.22±10.50	0.052*
BMI [kg/m2]	27.26±3.42	26.33±4.68	0.306
Duration of dialysis [months]	20.41±20.95	31.67±18.94	0.084**
Systolic BP [mmHg]	131.29±21.15	137.67±13.01	0.243
Diastolic BP [mmHg]	81.71±9.57	83.22±4.27	0.491
Residual diuresis [ml/24 h]	542.35±649.03	644.44±406.54	0.463
Hb [g/dl]	11.37±1.00	11.38±1.35	0.403
CRP [mg/l]	17.55±22.89	6.30±5.98	0.306
IL-6 [pg/ml]	8.85±8.66	7.52±7.16	0.914
Serum albumin [g/dl]	3.33±0.54	3.36±0.48	0.893
Cholesterol [mmol/l]	5.88±1.32	5.29±0.84	0.388
Pro-ANP [nmol/l] 1-98	22.62±12.34	22.88±13.96	1.000
NT-proBNP [nmol/l] 1-76	0.26±0.18	0.30±0.30	0.746

* P<0.05 statistically significant; ** 0.05<P<0.1.

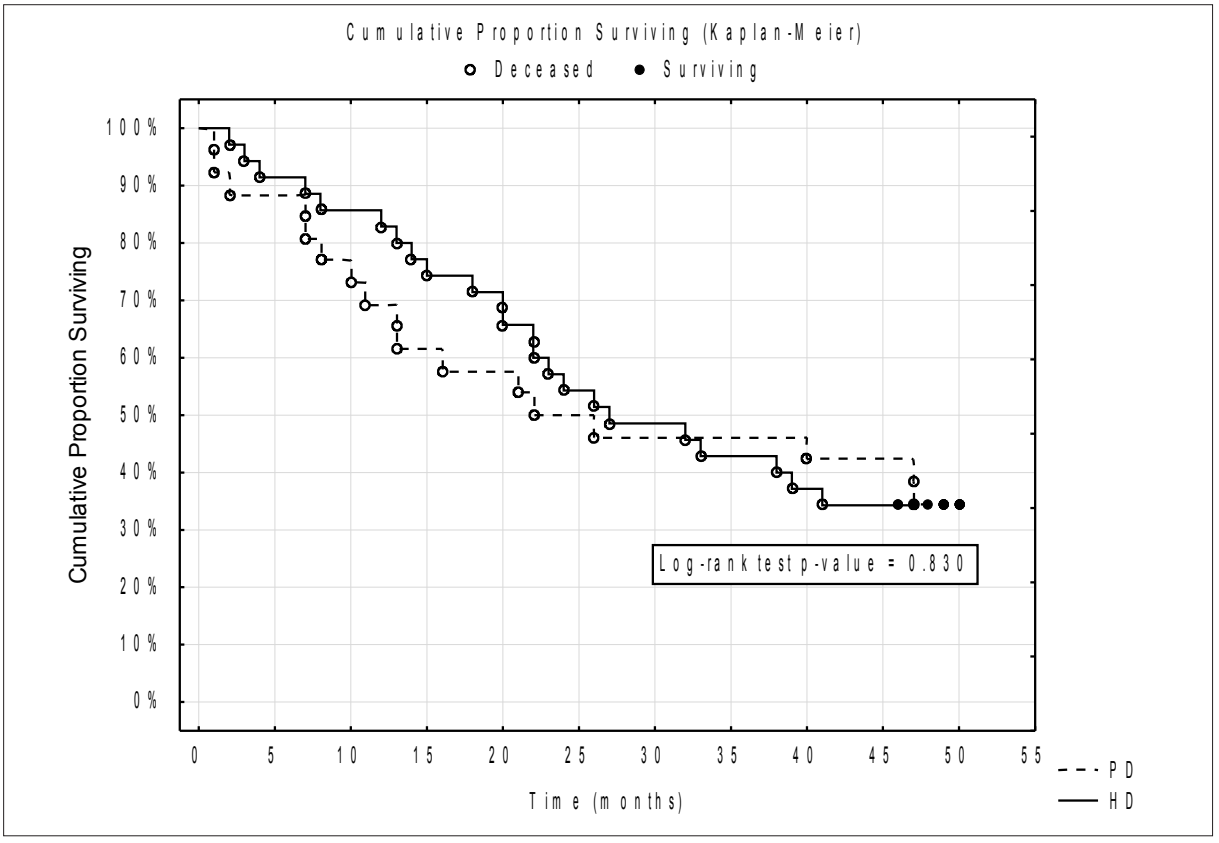

Fig. 1. Kaplan Meier Survival Function. The difference in mortality between the diabetic patients during 4- year observation period according to modality of dialysis treatment - PD versus HD

The mean annual mortality rate was 23.2%, equal in HD (22.8%) and PD (23.1%).

After the end of the 4-year observation period, type of dialysis modality (HD vs. PD) did not exert a significant impact on patient survival (Fig. 1); the log-rank test p-value equals 0.83.

However, in the detailed analysis a tendency to higher mortality appeared in the PD group in the first observation year, in which 8 patients died (30.8%) compared with 5 deceased patients in the HD group (14.3%), although the difference did not reach significance.

It is worth noting that after 4 years of follow-up surviving PD patients were significantly younger than HD survivors (58.22 ± 10.50 y versus 69.83 ± 8.38 y; p+0.017), although at baseline HD and PD patients did not differ in respect of age. Additionally, the PD survivors exhibited significantly lower albumin level than HD survivors (3.36±0.48 versus 3.98±0.45; p=0.012).

Table 4. Cox proportional hazard regression model. Dependent variable: survival time from beginning of investigation

Variable	Parameter Estimate	Wald statistics	p-value	Hazard ratio HR	Hazard ratio 95% lower	Hazard ratio 95% upper
All patients (n=61)						
Serum albumin [g/dl]	-0.588	3.962	0.047*	0.556	0.311	0.991
HD patients (n=35)						
Cholesterol [mmol/l]	-0.597	8.15	0.004*	0.551	0.365	0.829
PD patients (n=26)						
Age [years]	0.050	3.93	0.047*	1.051	1.001	1.104

The most common cause of death was cardiovascular complications – 18 pts (45% of all deaths) (7 PD/11 HD), followed by infection – 12 pts (30%) (6 PD/6 HD), malignancy – 5 pts (12.5%) (1 PD/4 HD) and other reasons (gastrointestinal bleeding) – 5 pts (12.5%) (3 PD/2 HD).

In the backward stepwise selected multivariate Cox proportional hazard regression model (Table 4) low serum albumin concentration was the only factor with a significant negative impact on 4-year survival in the whole diabetic cohort (p=0.047). Referring to dialysis modality the significant mortality predictor in the HD group was low cholesterol level (p=0.004), and exclusively older age (p=0.047) in the PD group.

Discussion

The results of our study clearly indicate the gloomy long-term outlook of dialysis treatment in high cardiovascular risk diabetic patients, without a significant difference between PD and HD effect on survival. Two thirds of patients died during four-year prospective observation (at a median time of 65 months from the beginning of dialysis treatment), with an annual mortality rate of 23.2% during the study period.

In the Cox proportional hazard regression model (Table 4) low serum albumin concentration was the only factor with a significant negative impact on 4-year survival in the whole diabetic cohort (Table 4; p=0.047). Referring to dialysis modality in the multivariate analysis the significant mortality predictor in the HD group was low cholesterol level (p=0.004), and exclusively older age (p=0.047) in the PD group. Despite general equality between PD and HD in terms of survival, the separate analysis of both groups revealed differences of particular clinical importance. First, during the median time of 16.5 months between dialysis start and study onset a drop of serum albumin in the PD group occurred, whereas in the similar time of 17 months no change of albumin level appeared in the HD group. This tendency to lowering of albumin concentration with time on PD was responsible for a significantly inferior albumin level in the PD compared to the HD group at the study onset. This negative event appeared in PD diabetic patients without augmentation of the inflammatory process, which was not different in PD and HD groups, exhibiting similar CRP and Il-6 values (Table 1). It shows that most patients with diabetes are not able to compensate for the peritoneal and urinary albumin loss. The occurrence of a lower albumin level was a universal feature in the PD group, losing due to this high distribution the impact on survival. This was the reason that the only significant difference between PD survivors and deceased patients was more advanced age in those who died (67.65±10.15 y versus 58.22±10.50 y; p=0.05). Older age retained its negative effect on PD patient survival as the only independent factor in the Cox proportional hazard regression model (Table 4; p=0.047). The association of older age with mortality in the PD group was also revealed by significantly younger age of PD survivors compared to HD survivors (58.22 ± 10.50 y versus 69.83 ± 8.38 y, p=0.017). Additionally, the PD survivors exhibited a significantly lower albumin level than HD survivors (p=0.012), which in turn reflects common hypoalbuminemia presence under PD treatment.

A different pattern of survival predictors appeared in patients with diabetes treated by HD. The HD survivors were characterized by a lower IL-6 level (p=0.04), higher albumin concentration (p=0.03), and increased cholesterol (p=0.004). This shows that long-term survival in HD pts is associated with two categories of variables, reflecting inflammation (IL-6, albumin) and nutrition (cholesterol), whereas age had no influence. In this context the different significance of hypercholesterolemia in PD patients versus HD should be emphasized. Elevated cholesterol was a universal finding in PD patients, with very significantly higher values (p<0.0001) compared to the HD group, and a slight tendency to lower values in PD survivors. In PD patients hypercholesterolemia seems to appear as an element of atherosclerotic dyslipidemia, whereas in maintenance HD its occurrence is probably more connected with good nourishment. This difference may explain the failure to prove the advantage of statin application in HD populations in randomized control trials [3]. It also suggests more potential benefits from statin therapy in PD patients. In addition, it is noteworthy that IL-6 appeared to be a more sensitive inflammation indicator than CRP. In the Cox proportional hazard regression model low cholesterol level remained as the independent mortality predictor in HD pts (Table 4; p=0.004), again indicating a possible connection between cholesterol and nourishment in HD treatment. It should be mentioned that the other considered parameters – systolic blood pressure, residual diuresis, Hb, CRP, serum pro-ANP and NT-proBNP – did not exert an effect on survival. This is different to the situation observed in our previous study [9] encompassing elderly dialysis patients (median age 77 y) in whom paramount for survival appeared to be adequate extracellular volume control and as independent mortality predictors were found higher plasma pro-ANP, lower residual diuresis and lower systolic blood pressure.

The literature on the effects of dialysis modality on survival in patients with diabetes is equivocal [10,15,16], with a study suggesting better outlook under PD treatment [2,5,8,11,18], and others signifying more beneficial results in HD programs [1,4,12]. Our study confirms the crucial importance of the initial characteristics of the diabetic cohort [6,14,17,18], which may be responsible for contradictory results and is also in line with the United States and Canadian registries showing that HD is associated with better survival for diabetics aged 45 and older [16,19].

While conscious of our study limitations connected with the small number of included patients, we believe that it provides a couple of clinically important indications for appropriate application of dialysis treatment in diabetics. A strength of the study derives from the fact that the observed diabetic patients formed a homogeneous group

with pronounced cardiovascular risk (Monckeberg type intravascular calcifications in all persons, with 26 patients (43%) over 70 years old). The association between the serum albumin level and mortality is well known from the seminal paper published by Lowrie and Lew [7]. However, in the current interpretation more emphasis is put in HD on the connections between hypoalbuminemia and inflammation than on the nutrition state. This relationship also appeared in the multivariate analysis in the present study when all patients were collectively considered independently of dialysis modality type. The division according to dialysis modality reveals clearly that distinct categories of metabolic disorders occur under PD and HD treatment. Therefore, from the methodological point of view the evaluations of morbidity and mortality risk factors are more appropriate when they consider PD and HD separately.

In summary, the PD modality is more suitable for younger patients with diabetes mellitus below 60 y of age with albumin concentration in the upper half of the normal range; for those not fulfilling such characteristics, HD seems to be the preferred option. During performance of the HD program in diabetics, particular attention should be concentrated on maintaining appropriate nutrition with simultaneous inflammation control.

Conclusions

1. There is a difference in the mortality predictor pattern in high risk cohort diabetic patients dependent on dialysis modality.

2. In the PD program more advanced age has a decisive negative impact on survival, whereas during HD therapy the outlook is associated with variables reflecting nutrition and inflammation.

3. Elevated cholesterol level has different prognostic significance depending on the dialysis mode, exhibiting a survival advantage in HD patients.

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