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## CLINICAL STUDY

## The impact of diabetes mellitus on peritoneal dialysis: the Turkey Multicenter Clinic Study

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### Abstract

**Purpose:** It is well established that diabetic peritoneal dialysis (PD) patients have a higher mortality rate than the other PD population. This study was designed to determine the overall predictors of survival and compared mortality and morbidity between diabetic and non-diabetic Turkish PD patients. **Methods:** We conducted a multicenter retrospective study with 915 PD patients [217 had diabetes mellitus (DM)]. Serum albumin, PTH, HbA1c, co-morbid diseases, dialysis adequacy (Kt/V), and peritoneal transport characteristics as well as peritonitis episodes and ultrafiltration failure during the follow-up period were recorded. **Results:** DM patients were older and had more co-morbidities than non-DM patients. Peritonitis rates were higher in DM patients (one episode per 35.9 patient months) compared to non-DM patients (one episode per 41.5 patient months) ( $p < 0.001$ ). On Kaplan–Meier analysis, patient survival was significantly lower in DM patients with the 2-, 3- and 5-year patient survival rates of 90.8%, 87.8% and 78.2% in non-diabetics and 80.9%, 70.4% and 61.2% in diabetics, respectively. On Cox regression analysis, DM (HR 1.5,  $p = 0.022$ ), age (HR 1.03,  $p < 0.001$ ), baseline serum albumin (HR 0.39,  $p < 0.001$ ), heart failure (HR 0.038,  $p = 0.038$ ), peripheral artery disease (HR 1.83,  $p = 0.025$ ) and amputation (HR 4.1,  $p = 0.009$ ) at baseline were significant predictors of overall mortality. **Conclusions:** Patient survival is lower in diabetic compared to non-diabetic patients on PD. Peritonitis rates were also higher in diabetic PD patients. DM, older age, albumin level and cardiovascular co-morbidities are predictors of mortality

### Keywords

Diabetes mellitus, mortality, peritoneal dialysis, peritonitis rate

### History

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### Introduction

Peritoneal dialysis (PD) patients with diabetes mellitus have worse prognosis and survival is significantly lower due to high prevalence of cardiovascular diseases and infections.<sup>1–5</sup> As most other countries in the world, type 2 diabetes mellitus is an important cause of end-stage renal disease also in Turkey. According to the 2009 Registry of Turkish Society of Nephrology, the prevalence and incidence of diabetes was 24% and 31.6%, respectively, among peritoneal dialysis patients (<http://www.tsn.org.tr>)

Most previous studies from different countries or ethnicity reported an increased peritonitis risk in diabetic peritoneal dialysis patients compared to non-diabetic counterparts.<sup>6–8</sup> More recently, in a large prospective Canadian cohort,

however, higher peritonitis rate was reported only among female patients with diabetes.<sup>9</sup> On the contrary, a prospective study showed that diabetes had no significant impact on peritonitis rates.<sup>10</sup>

The effect of peritoneal dialysis modality on peritonitis rates is also controversial after continuous ambulatory peritoneal dialysis patients started to use the Y-disconnect system.<sup>7,11,12</sup>

Diabetes is a strong risk factor for peripheral vascular disease which is a powerful predictor of an increased rate of morbidity and mortality in end-stage renal disease population.<sup>5</sup> The rates of peripheral vascular disease in dialysis patients were varied from 16.9% in Japan<sup>13</sup> to 35% in USA<sup>14</sup> when ankle–brachial index (ABI)  $< 0.9$  was used as criteria for diagnosis.

There was no large-scale data to show the overall predictors of survival and to compare morbidity and mortality between diabetic and non-diabetic Turkish peritoneal dialysis patients. We conducted a multicenter retrospective study on behalf of Turkish Multicentre Peritoneal Dialysis Study Group (TULIP) including 915 peritoneal dialysis patients with an aim to compare demographics, survival and co-morbidities of peritoneal dialysis patients with and without diabetes mellitus.

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## Methods

### Patients

The study included peritoneal dialysis patients from 11 centers across Turkey. The data on incident patients since 1 February 2000 were retrospectively entered into the database in 2010. Approval was obtained from the research ethics board at Marmara University.

### Data collection

Demographic and clinical data that were collected for this study include age, gender, cause of ESRD, diabetes status at baseline, peritoneal dialysis modality (CAPD vs. APD), co-morbidities (hypertension, cardiovascular diseases, and amputation), peritonitis episodes, ultrafiltration failure (UFF) and icodextrin usage. Cardiovascular disease was recorded if one of the following conditions was present: coronary heart disease, cerebrovascular disease, congestive heart failure class III–IV, peripheral vascular disease. Hypertension was defined as a systolic blood pressure >140 and/or diastolic pressure >90 mmHg and/or the use of antihypertensive medications. Claudication, gangrene or amputation was used as criteria for diagnosis for peripheral vascular disease. Net ultrafiltration of <400 ml during a 4-h dwell using 3.86% glucose was defined as UFF. Peritonitis rates were calculated as follows: months of peritoneal dialysis at risk (total number of months each patient has spent on dialysis), divided by number of episodes (total number of episodes experienced by all patients), and expressed as interval in months between episodes.

Total weekly  $Kt/V_{urea}$ , peritoneal transport characteristics, serum albumin, PTH and HbA1c were recorded at baseline and at the last visit. Data on adequacy and peritoneal kinetics calculated after 4 to 6 weeks following the start of the peritoneal dialysis treatment were accepted as baseline values.

Peritoneal membrane characteristics were determined based on results of the available PET test performed according to Twardowski.<sup>15</sup>

### Statistical analysis

Primary outcome was death on peritoneal dialysis. The intent-to-treat model was used to determine the association between the presence of diabetes as a co-morbidity and mortality.

In statistical analysis, chi-squared test was used for categorical variables, and *t* test was used for the continuous variables. The significance was set to  $p < 0.05$ . In multivariate analysis, a model of Cox regression was performed which included age, gender, and the presence of diabetes, coronary artery disease, hypertension, cerebrovascular disease, congestive heart failure, peripheral artery disease, amputation and albumin at baseline. Kaplan–Meier survival estimation curve was made for the patients with and without diabetes mellitus. Statistical analysis was performed by STATA 11 (College Station, TX).

## Results

### Patient demographics

The study sample consisted of 915 patients (mean age  $49.5 \pm 15.8$  years) on peritoneal dialysis with a mean duration of  $30.1 \pm 22.7$  months (ranging from 3 to 107 months). Twenty-two patients had type 1 DM and 195 patients had type 2 DM. The clinical and some of the demographic characteristics of patients with diabetes mellitus ( $n = 217$ ) were significantly different from non-diabetic patients ( $n = 698$ ) (Table 1). The patients with diabetes mellitus were older and had more co-morbidities and amputations than their non-diabetic counterparts. About 46% and 44% of the patients had at least one peritonitis episode during follow-up in diabetics and non-diabetics, respectively ( $p = 0.699$ ). However, the

Table 1. Characteristics of diabetic peritoneal dialysis patients compared with non-diabetic counterparts.

Characteristics	Diabetics ( $n = 217$ )	Non-diabetics ( $n = 698$ )	<i>p</i> Value
Age (years)	$55.8 \pm 13.5$	$47.4 \pm 16$	<0.001
Female— <i>n</i>	89 (41%)	338 (48%)	0.056
BMI ( $\text{kg}/\text{m}^2$ )	$25.9 \pm 4.1$	$26.5 \pm 4.9$	0.199
Smoking status			
Current	22 (10%)	108 (15%)	<0.001
Former	79 (36%)	235 (34%)	0.579
Non-smoker	116 (53%)	355 (51%)	0.601
ACE inh. or ARB usage	80 (37%)	231 (33%)	0.204
PD modality			
APD	139 (66%)	459 (67%)	0.740
CAPD	78 (34%)	239 (33%)	
Patients who have at least 1 peritonitis episode	99 (46%)	308 (44%)	0.699
Patients who have multiple peritonitis episodes	43 (20%)	153 (22%)	0.509
Peritonitis rate (1 episode per patient months)	35.9	41.5	<0.001
Ultrafiltration failure	19 (9%)	43 (6%)	0.184
Icodextrin usage	138 (64%)	312 (45%)	<0.001
Follow-up time (months)	$26 \pm 21.7$	$32 \pm 23.2$	0.002
Comorbid conditions			
Coronary heart disease	24 (11%)	30 (4%)	<0.001
Congestive heart disease	38 (18%)	46 (7%)	<0.001
Peripheral vascular disease	32 (14.7%)	26 (3.7%)	<0.001
Cerebrovascular accident	7 (3%)	14 (2%)	0.295

Notes: ACE inh., angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; CAPD, continuous ambulatory peritoneal dialysis; APD, automated peritoneal dialysis. Values expressed as mean  $\pm$  SD or number (%).

duration on peritoneal dialysis treatment was longer in non-diabetic patients. Consequently, peritonitis rates were significantly higher in diabetics (one episode per 35.9 patient months) compared to non-diabetics (one episode per 41.5 patient months) ( $p < 0.001$ ) (Table 1). UFF and peritoneal dialysis modality were not significantly different between patients with and without diabetes mellitus. Icodextrin use was more frequent in diabetic peritoneal dialysis patients (Table 1).

### Patients' clinical parameters at baseline and at the end of follow-up

In diabetic peritoneal dialysis patients, total Kt/V urea and serum albumin levels were not significantly different compared to non-diabetic peritoneal dialysis patients at baseline and at the end of follow-up. PTH values were significantly lower in diabetic patients at both time points ( $p = 0.009$  at baseline,  $p < 0.001$  at the last visit). As expected, HbA1c levels were higher in diabetes mellitus patients. In patients with diabetes mellitus no significant changes in HbA1c levels were observed at the last visit compared to baseline whereas mean HbA1c levels were significantly higher at the last visit compared to baseline in non-diabetic PD patients (Tables 2 and 3).

There was no difference in transport status between diabetic and non-diabetic peritoneal dialysis patients either at baseline or at the end of study. In addition, similar changes were observed in transport status during the follow-up in both groups on peritoneal dialysis (Tables 2 and 3).

### Survival

Intention-to-analysis of mortality from day 0, cumulative survival was significantly lower for patients with diabetes mellitus, as shown in Figure 1 (log-rank test,  $p < 0.001$ ). The 2-, 3- and 5-year patient survival rates were 90.8%, 87.8% and 78.2% in non-diabetics and 80.9%, 70.4% and 61.2% in diabetics, respectively. The exact numbers of deaths for

Table 2. Laboratory parameters at baseline and at the last visit in diabetic peritoneal dialysis patients ( $n = 217$ ).

Parameter	Baseline	At the last visit	<i>p</i> Value
Total Kt/V <sub>urea</sub>	2.3 ± 0.7	2.1 ± 0.4	0.096
Serum albumin (g/dL)	3.9 ± 0.3	3.9 ± 0.4	0.899
Parathormone (ng/L)	251 (47–941)	270 (11–1179)	0.097
Glycated hemoglobin (%)	7.4 ± 1.5	7.2 ± 1.3	0.242

Note: Values expressed as mean ± SD; as median (ranges) for parathormone.

Table 3. Laboratory parameters at baseline and at the last visit in non-diabetic peritoneal dialysis patients ( $n = 698$ ).

Parameter	Baseline	At the last visit	<i>p</i> Value
Total Kt/V <sub>urea</sub>	2.2 ± 0.3	2.2 ± 0.3	0.893
Serum albumin (g/dL)	4.1 ± 0.3	4.0 ± 0.4	0.542
Parathormone (ng/L)	317 (59–965)	451 (51–1380)	<0.001
Glycated hemoglobin (%)	5.2 ± 0.7	5.4 ± 0.7	0.038

Note: Values expressed as mean ± SD; as median (ranges) for parathormone.

5 years were 152 deaths in non-diabetic patients, 84 deaths in diabetics.

The causes of deaths were cardiovascular diseases (51.2%), infections (17.9%), cerebrovascular accidents (9.5%), malignancies (3.6%) and other causes (17.8%) in diabetic patients. In non-diabetic patients, cardiovascular diseases (39.5%), infections (19.1%), cerebrovascular accidents (3.9%), malignancies (3.9%) and other causes (33.6%) were the causes of deaths. Cardiovascular diseases and cerebrovascular accidents as the causes of death were significantly higher in diabetics compared to non-diabetics ( $p < 0.01$ ).

The impact of diabetes was further analyzed by Cox regression analysis, in which diabetes mellitus was an independent predictor for mortality in our peritoneal dialysis population (HR 1.5,  $p = 0.022$ ). Other independent indicators for mortality were older age (HR 1.03,  $p < 0.001$ ), presence of congestive heart failure (HR 1.65,  $p = 0.038$ ), peripheral vascular disease when amputation was excluded (HR 1.83,  $p = 0.025$ ), amputation (HR 4.1,  $p = 0.009$ ) and the baseline albumin level (HR 0.39,  $p < 0.001$ ) (Table 4).

### Discussion

Among the 4626 peritoneal dialysis patients in Turkey, 1126 had diabetes mellitus (<http://www.tsn.org.tr>) and there have been no reports on the long-term survival of peritoneal dialysis in Turkish diabetic patients. We included a total of 915 peritoneal dialysis patients into our analysis, 217 of which were diabetic as a good representative to the whole peritoneal dialysis population in Turkey.

Diabetics had worse prognosis compared to non-diabetics in reports from other countries.<sup>1–5</sup> The results of our study were in concordance with these previous studies. In our Turkish peritoneal dialysis population, the probability of survival at 2-, 3- and 5-years were 90.8%, 87.8% and 78.2% in non-diabetics while in patients with diabetes mellitus the probability of survival were 80.9%, 70.4% and 61.2%, at the same time points. These survival rates are better than that of some Western countries<sup>2,16–18</sup> and comparable with reports from Asian countries.<sup>8,19</sup>

Data from Spain revealed that 2-year patient survival was only 68% in diabetics.<sup>2</sup> However, Spanish diabetic PD patients were older compared with Turkish counterparts (64.3 ± 9.3 vs. 55.8 ± 13.5 years, respectively). Three years survival was found as 63.5% in 106 Swedish peritoneal dialysis patients. About 30 of 106 patients were diabetic.<sup>16</sup> The United States Renal Data System (USRDS) data of 2003 showed a 5-year patient survival rate in peritoneal dialysis patients of ~33%.<sup>18</sup> On the other hand, a higher 5 years patient survival rate was reported as 69.8% in 1656 Korean peritoneal dialysis patients (30.5% of the patients were diabetic)<sup>8</sup> which could be comparable to our results.

As mentioned in the introduction section, it is reported that peritoneal dialysis patients with diabetes mellitus have higher peritonitis risk compared to non-diabetics in both genders in previous studies<sup>6–8</sup> though not all.<sup>9,10</sup> In our study, diabetic PD patients had also higher peritonitis risk compared to non-diabetics. Overall peritonitis rate was that one episode per 39.7 patient months. Varied peritonitis rates were reported from different regions on the world: one episode every 32.7

Figure 1. Survival of diabetic peritoneal dialysis patients compared with non-diabetic counterparts, calculated by Kaplan–Meier method (log-rank:  $p < 0.001$ ).

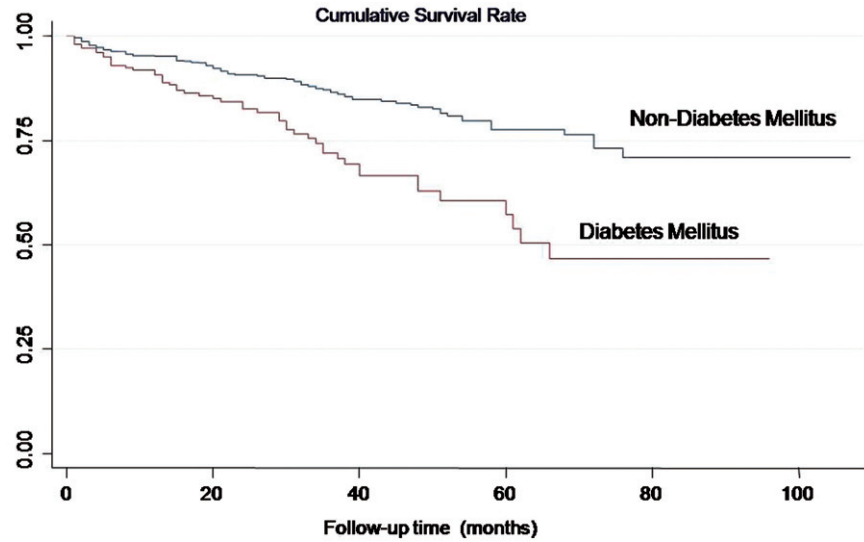


Table 4. Multivariate Cox regression for death.

Covariate	Hazard ratio	95% confidence interval	<i>p</i> Value
Age (per decade increase)	1.03	1.02–1.05	<0.001
Female gender	1.06	0.74–1.53	0.726
Diabetes mellitus	1.5	1.06–2.25	0.022
Coronary heart disease	1.14	0.64–2.64	0.643
Cerebrovascular accident	1.45	0.65–3.23	0.362
Congestive heart disease	1.65	1.02–2.64	0.038
Peripheral vascular disease excluded amputation	1.83	1.07–3.13	0.025
Amputation	4.1	1.41–11.92	0.009
Hypertension	0.94	0.64–1.36	0.752
Baseline serum albumin (per 10 g/L increase)	0.39	0.3–0.51	<0.001

patient months in USA, 1 episode every 36–45 patient months in Hong Kong, 1 episode every 30 patient months in Korea, 1 episode every 14.7–18.1 patient months in UK and 1 episode every 19.4 patient months in Australia.<sup>20–25</sup> All peritoneal dialysis centers which participated to our study were tertiary care hospital centers, more experienced and educated physicians and nurses might have provided better patient's care and education to protect peritonitis episode. There was also no difference in terms of peritoneal dialysis modality (CAPD vs. APD) in diabetics compared to non-diabetics in our study. Thus, any potential effect of peritoneal dialysis modality on peritonitis rates was already eliminated in our study.

Definition and diagnosis of peripheral vascular disease is not uniformly characterized and diagnostic measurements can significantly alter prevalence estimation.<sup>5</sup> In our study, clinical criteria was used to define peripheral vascular disease and the prevalence of peripheral vascular disease was found as 14.7 in diabetic and 3.7% in non-diabetic patients (7.1% in whole patients). These ratios are lower than the data of published studies from western countries which have also used clinical criteria for defining peripheral vascular disease.<sup>7,26</sup> Database from U.S. Renal Data System revealed a 35.5% prevalence of peripheral vascular disease in peritoneal dialysis patients.<sup>7</sup> The prevalence of peripheral vascular disease was also noted as 29.4% in the study from Spain.<sup>26</sup> ABI is a more sensitive method to detect peripheral vascular disease compared to clinical criteria<sup>27</sup> and a 16.9% prevalence of peripheral vascular disease was reported from Japan<sup>5</sup> when

ankle-brachial index <0.9 was used as the diagnostic criteria. Thus, the prevalence of peripheral vascular disease in Japanese peritoneal dialysis patients seems to be closer to our prevalence.

The associations between age, albumin or cardiovascular diseases and mortality were well documented in dialysis patients.<sup>1,3,16,28</sup> Similarly, the independent factors for the patient survival were lower serum albumin, older age and cardiovascular diseases in addition to presence of diabetes mellitus based on multivariable regression with the Cox proportional hazard model in our study.

There are conflicting data about the effect of obesity on survival in peritoneal dialysis patients. Several studies in different patient populations reported that obesity did not significant impact on patient survival in PD patients.<sup>29</sup> However, obesity is found to be a risk factor for mortality in small number of peritoneal dialysis patients.<sup>30</sup> We did not found any associations between BMI values or obesity ( $\text{BMI} \geq 30 \text{ kg/m}^2$ ) and mortality.

Recent studies were reported that higher glycated hemoglobin levels were associated with increased mortality in diabetic<sup>31</sup> or non-diabetic PD patients<sup>32</sup> even in non-diabetic adults.<sup>33</sup> It was suggested that renal anemia affects the accuracy of the HbA1c assay.<sup>26</sup> Moreover, HbA1c-mortality association was only demonstrated in non-anemic patients.<sup>34</sup> We did not find any association between baseline or final HbA1c levels and survival in our peritoneal dialysis patients (Table 3) either in diabetic and non-diabetic subgroups (data

not shown). We know that 10.1% of Turkish PD patients had hemoglobin levels <11 g/dL according to the 2009 Registry of Turkish Society of Nephrology.

This study has a retrospective design which is mainly responsible from the major limitations of this study. The important ones are the lack of data about technical survival and time to first peritonitis episode in our diabetic and non-diabetic peritoneal dialysis patients. Other factors that affect mortality, such as the patient's inflammatory state and the causes of mortality could also not be evaluated.

In summary, our data shows that Turkish diabetic patients with peritoneal dialysis have worse prognosis than non-diabetic counterparts similar to reports from other countries. Survival rates of Turkish peritoneal dialysis patients seem to be better than that of some western countries and similar to Asian countries. Peritonitis rates are higher in our diabetic peritoneal dialysis patients compared to non-diabetic ones. We need prospective multicenter studies to evaluate the factors associated with morbidity and mortality in continuous peritoneal dialysis patients in Turkey.

### Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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