Clinical outcome of incident peritoneal dialysis patients with diabetic kidney disease

Running Title: Clinical course of diabetic PD

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Abstract

Background: Although peritoneal dialysis (PD) is becoming more widespread, PD among diabetic patients carries some concerns, such as worsened glycemic control due to constant exposure to glucose and operational errors due to diabetic complications. However, several technical advances could overcome these disadvantages. We therefore aimed to compare technical and patient survival between diabetic and non-diabetic PD patients.

Methods: We conducted a historical cohort study of 103 patients (mean age, 57±16 years; 75 males, 32 diabetic patients) who started PD between January 2011 and January 2016. Kaplan-Meier survival analysis was used to compare technical and patient survivals between diabetic and non-diabetic patients. Multivariate Cox regression analysis was used to estimate the effects of the presence of diabetes on these outcomes.

Results: Technical and patient survivals did not differ significantly between groups (P=0.62, P=0.34, respectively). In addition, presence of diabetes affected neither technical nor patient survival in multivariate analysis (hazard ratio [HR], 1.31; 95% confidence interval [CI], 0.58 - 2.82 and HR, 0.80; 95%CI, 0.22 - 2.68, respectively).

Conclusions: Technical and patient survivals of diabetic PD patients were not inferior to those of non-diabetic PD patients. These results suggest that no hesitation is warranted in initiating PD for diabetic patients with end-stage renal disease.

Key Words: diabetes, icodextrin, patient survival, peritoneal dialysis, technical survival, twin-bag system

Introduction

As in many other countries, the number of diabetic patients receiving dialysis in Japan is still increasing, and the percentages of prevalent and incident patients with diabetic nephropathy as of 2012 were 37.1% and 44.1%, respectively [1].

Peritoneal dialysis (PD) is becoming widespread as a renal replacement therapy all over the world, along with as hemodialysis (HD). Among diabetic patients, several concerns have been raised about PD management, such as worsened glycemic control due to constant exposure to glucose in the dialysate and procedural problems associated with diabetic complications such as cerebral infarction, diabetic peripheral neuropathy, and diabetic retinopathy. Indeed, the percentage of prevalent PD patients to total prevalent dialyzed patients in 2012 was only 3% in Japan, and underutilization among diabetic patients is a potential contributory factor [1]. On the other hand, coronary heart disease and cerebral infarction often develop in diabetic patients, and fluctuations in blood pressure caused by autonomic nervous system disorders and by the HD procedure itself represent risk factors. In addition, various troubles related to HD in diabetes are seen, such as vascular access failure because of severe arteriosclerosis and bleeding complications associated with the use of anticoagulants during HD. As a result of such issues, PD may be preferable to HD for diabetic patients.

Several reports have discussed clinical outcomes including mortality rate [2-5] and peritonitis rate [6-8] among diabetic PD patients, and results have ranged widely. Couchoud et al. [9] published a systematic review of 721,783 HD and 106,790 PD patients with diabetes, and found no evidence regarding whether HD or PD as first treatment improved patient survival for diabetic dialyzed patients. See et al. [10] reported that the presence of diabetes was an independent risk factor for early technical failure using Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) database including all adult patients who initiated PD in Australia and New

Zealand in 2000 through 2014.

In the last two decades, several technical advances have been made in the field of PD, such as the introduction of biocompatible PD solutions, icodextrin-containing PD solutions and twin-bag systems. Icodextrin-containing PD solution was available since 2003 in Japan and made regulation of body fluid easier especially in diabetic PD patients. Angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin II receptor blockers (ARBs) have gained wider use. Additionally, dipeptidyl peptidase-4 (DPP-4) inhibitors, launched in 2009 in Japan, facilitated better glycemic control. All these factors could affect the clinical outcomes for diabetic PD patients. We therefore conducted a historical cohort study of 103 patients who started PD after 2011, with the aim of comparing patient and technical survivals between PD patients with and without diabetes mellitus (DM).

Methods

Methods

We retrospectively reviewed the medical records of 103 patients (male, 73%; age, 57±16 years; and diabetes, 31%) who started PD at Jikei University Hospital, Tokyo, Japan or any of three branch hospitals between January 2011 and January 2016. We divided enrolled patients into diabetic and non-diabetic groups according to the presence of diabetic nephropathy, defined either by the kidney biopsy, or, in its absence, by clinical features such as long-lasting diabetes, proteinuria, and diabetic retinopathy in the absence of any other cause. The ethics committee at Jikei University Hospital approved this study protocol, and the study proceeded in accordance with the Declaration of Helsinki.

Biochemical parameters including hemoglobin, total protein, serum albumin, blood urea nitrogen, creatinine (Cr), and β2-microglobulin were measured using standard laboratory

techniques at each center. The dialysate-to-plasma ratio of creatinine (D/P Cr) was obtained from a peritoneal equilibration test.

Information about history of PD-related peritonitis, death and switches to other modalities, including HD and combined therapy with PD and HD were extracted from data as of the end of 2016. PD-related peritonitis was diagnosed using the criteria proposed by the International Society for Peritoneal Dialysis (ISPD) [11]. Cardiovascular death was defined as death caused by heart failure, pulmonary edema, acute myocardial infarction, arrhythmia, endocarditis, valvular disease, subarachnoid hemorrhage, cerebral hemorrhage, cerebral infarction or sudden death. Fourteen patients, including 1 diabetic patient and 13 non-diabetic patients, underwent kidney transplantation (median PD duration, 10.8 months).

Statistical analysis

Data are presented as mean ± standard deviation (SD) or median and range. Values of $P<0.05$ were considered significant. For comparisons between patients with and without DM, Student's *t*-test or the Wilcoxon rank-sum test were used for continuous variables when appropriate, and the chi-square test or Fisher's exact test were used for nominal variables. Kaplan-Meier survival analysis was used to compare technical and patient survivals between patients with and without DM. For the analysis of technical survival, patients were censored on receipt of kidney transplantation or death. Hazard ratios (HRs) and 95% confidence intervals (CIs) for technical and patient survivals were assessed using Cox regression analysis with the confounding factors of age, sex, presence of diabetes, and use of icodextrin. Data were statistically analyzed using JMP for Windows version 13.0.0 (SAS Institute, Cary, NC).

Results

Demographics and baseline clinical characteristics

Table 1 shows demographic and clinical characteristics for the 103 patients at the initiation of PD. Diabetic patients tended to have higher blood pressure and a higher prevalence of cardiovascular disease. The primary renal diseases among non-diabetic patients were chronic glomerulonephritis (51%), nephrosclerosis (24%), polycystic kidney disease (6%), and other or unknown (20%). Total protein, serum albumin, and Cr were lower, and D/P Cr was higher in the diabetic group compared to the non-diabetic group. On the other hand, age, body weight, urine volume, hemoglobin, and β2 microglobulin were similar among the two groups. During the follow-up period, icodextrin-containing PD solution was used among 29 patients (28%), including 9 patients in the diabetic group (31%) and 20 patients in the non-diabetic group (28%).

Patient and technical survivals

During the follow-up period, 13 patients died (5 patients in the diabetic group, 8 patients in the non-diabetic group), with death due to cardiovascular disease in 1 patient from each group (chi-square, P=0.72). Fourteen patients switched to combined therapy with PD and HD (5 patients in the diabetic group, 9 patients in the non-diabetic group), and 18 patients were switched to HD alone (5 patients in the diabetic group, 13 patients in the non-diabetic group). The causes of withdrawal from PD were underdialysis (3 patients in the diabetic group, 6 patients in the non-diabetic group), overhydration (2 patients in the non-diabetic group), PD-related peritonitis (1 patient in each group), and others or unknown (6 patients in the diabetic group, 9 patients in the non-diabetic group), and the distributions were not significantly different between two groups (P=0.70). Kaplan-Meier analysis showed that neither patient nor technical survival differed significantly between two groups (P=0.34, P=0.62, respectively; Figure 1A and 1B). The incidences of PD-related peritonitis (times per patient-years) were not statistically different

between the diabetic and non-diabetic group (0.19 vs. 0.11 per patient-years; P=0.10). The median peritonitis-free period was 23.0 months for the diabetic and 24.4 months for the non-diabetic group. Kaplan-Meier analysis revealed that the duration of the peritonitis-free period was not differed between two groups (P=0.25, Figure 1C).

Table 2 shows the results of uni- and multivariate Cox analyses using variables including age, sex, presence of diabetes, and use of icodextrin. Age was independently associated with technical and patient survivals (HR, 0.97; 95%CI, 0.95 to 1.00 and HR, 1.12; 95%CI, 1.07 to 1.19, respectively). Presence of diabetes (HR, 1.31; 95%CI, 0.58 to 2.82 and HR, 0.80; 95%CI, 0.22 to 2.68, respectively) and use of icodextrin (HR, 1.75; 95%CI, 0.71 to 3.90 and HR, 1.87; 95%CI, 0.38 to 7.10, respectively) affected neither technical nor patient survival.

Among 74 patients with a data of urine volume after 1 year of PD initiation, 69 patients continued PD therapy alone. Among these patients, urine volume reductions within 1 year were not significantly different between diabetic and non-diabetic patients (500 (-1340 to 2510) vs. 350 (-1200 to 2410); P=0.74).

Discussion

In our historical cohort study of 103 patients who started PD between January 2011 and January 2016, no significant differences in technical or patient survival were identified between diabetic and non-diabetic patients. Several previous reports have described worse patient survival [3, 2, 4] and higher prevalence of PD-associated peritonitis [6-8] among diabetic PD patients as compared to non-diabetic PD patients. Although the presence of diabetes was an independent risk factor for early technical failure among incident PD patients who started PD from 2000 to 2014 in Australia and New Zealand, the rate for early technical failure was dramatically reduced in the study period, and the change in the effect of diabetes was not assessed[10]. Furthermore, Mehrotra

et al. [12] reported that the hazards for death or transfer to HD among incident PD patients declined, whereas outcomes for HD patients remained largely unchanged.

The candidate causes underlying these changes were considered to be the spread of icodextrin-containing PD solution, ACEIs and ARBs, and twin-bag systems.

Icodextrin-containing PD solution can prevent the worsening of glycemic control seen with the use of conventional hypertonic dextrose dialysates. In addition, this conventional solution could induce peritoneal damage due to hyperglycemia, dyslipidemia and glucose degradation products (GDPs). Icodextrin, a high molecular weight glucose polymer, is an alternative osmotic agent to dextrose, and was expected to prevent various harmful effects of peritoneal glucose exposure and to ensure sufficient fluid removal [13]. PD patients with diabetes are often complicated by fluid overload, a chief cause of technical failure. Icodextrin allows not only better fluid removal and extended technical survival [14-16], but also improvement of glycemic control and lipid metabolism [17-19]. These benefits of icodextrin may be one reason underlying the improvements in clinical outcome among diabetic PD patients. Use of icodextrin affected neither technical nor patient survival in our study, presumably because the rate of icodextrin use was similar between diabetic and non-diabetic groups.

Use of ACEIs and ARBs is considered as another factor facilitating improvements to the clinical course of diabetic PD patients. Both AT1 and AT2 receptors are expressed in the peritoneal mesothelium, and stimulation by molecules such as glucose, GDPs and acid results in local activation of the renin-angiotensin-aldosterone system (RAAS). Blockade of the RAAS with the use of ACEIs and ARBs is thus thought to be important for protecting the peritoneal membrane [20]. Indeed, administration of ACEIs and ARBs for PD patients has reportedly decreased mortality including cardiovascular mortality [21, 22], the suppressive effects of peritoneal hyperpermeability [23], and the possibility of residual renal function maintenance [24]. Our study

did not specifically address the favorable effects of ACEI and ARB, because the majority of patients were already using these drugs as of the start of PD.

Twin-bag systems have also improved clinical outcomes for diabetic PD patients through the inhibition of PD-related peritonitis. The prevalence of PD-related peritonitis is known to be higher in diabetic patients compared to non-diabetic PD patients, probably due to the immunocompromised state and operational errors caused by visual disorder and peripheral neuropathy [6-8]. We recently reported that twin-bag systems have had a marked impact on reductions in PD-associated peritonitis using 33 years of data from a single-center cohort [25]. Since the development of peritonitis represents an important factor affecting both technical and patient survival among PD patients, twin-bag systems are thought to deliver clear benefits. Again, this study could not confirm the effects of twin-bag systems, as all patients were using such systems.

The present study has several limitations. First, since criteria for selection of PD or HD among the diabetic patients were not established, some degree of selection bias was unavoidable. Second, since the distinction between diabetic nephropathy and diabetes as comorbidity is difficult without diagnosis by the kidney biopsy, some cases with nephrosclerosis with diabetes could be considered as diabetic nephropathy. Third, the difference in timing of dialysis initiation, possible cause of time-lead bias, between diabetic and non-diabetic patients is not taken into account. It's well-known that glomerular filtration rate (GFR) at dialysis initiation was higher in diabetic than non-diabetic patients [26]. Additionally, not uremic symptoms such as nausea and appetite loss, oliguria or exacerbation of renal function, but fluid retention such as congestive heart failure or intractable edema were common symptoms or reasons for dialysis initiation in diabetic patients [26]. Fourth, because of the low number of outcomes, we could not take account of a sufficient number of confounding factors, including glycemic control, in multivariate analyses. Lee et al.

[27] reported that glycemic control contributed to clinical outcomes among diabetic PD patients.

Conclusions

Previously, PD therapy in diabetic patients has been recognized to show poor technical and patient survivals. However, findings from our historical cohort study of 103 patients who started PD after 2011 suggested that the clinical outcomes for diabetic PD patients were not inferior to those for non-diabetic PD patients. These results suggest that clinicians need not hesitate in initiating PD for diabetic patients.

Acknowledgments

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Compliance with ethical standards

Conflict of interest

Y.M. and M.I. have received scholarship funds from Baxter International, Inc. and Terumo Corporation. Y.T. has received research grants from Baxter International, Inc. No sources of funding had any direct involvement in the design or conduct of the study; the collection, management, analysis, or interpretation of data; or the preparation, review, or approval of the manuscript. No other authors have any conflicts of interest to declare.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee at which the

studies were conducted (IRB approval number 29-286 (8902)) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Written informed consent was not required because of the non-intervention and retrospective chart review design. We provided all individual participants a means to opt out in this study.

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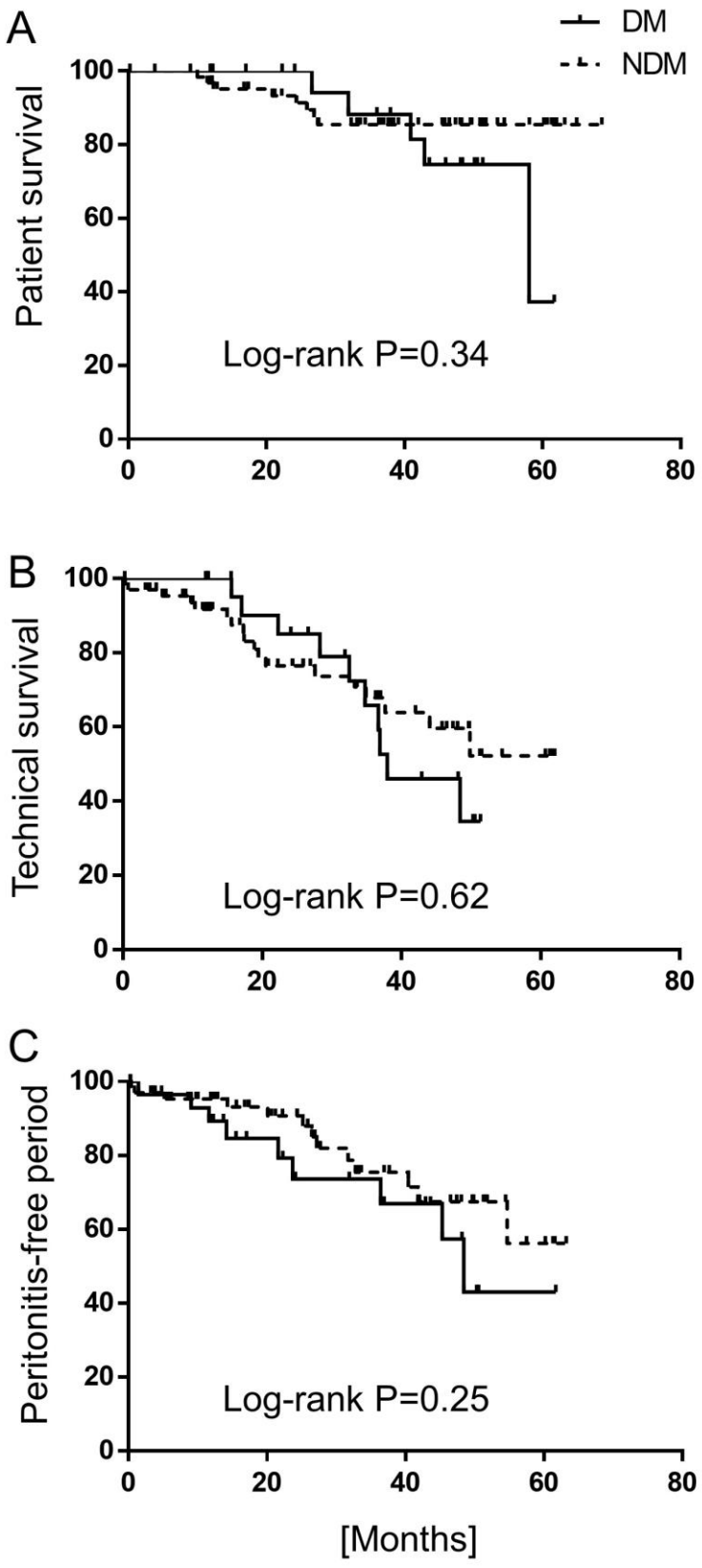
Figure Legends

Figure 1. Kaplan-Meier curve of patient survival (A), technical survival (B), and peritonitis-free period (C). These parameters were compared between DM (solid line) and NDM (dashed line) groups.

Abbreviations: DM, diabetes mellitus; NDM, non-diabetes mellitus.


A
DM
NDM
Patient survival
100
80
60
40
20
0
Log-rank P=0.34
0
20
40
60
80
B
Technical survival
100
80
60
40
20
0
Log-rank P=0.62
0
20
40
60
80
C
Peritonitis-free period
100
80
60
40
20
0
Log-rank P=0.25
0
20
40
60
80
[Months]

1

2

1

Table 1. Baseline characteristics.

	All patients	DM	NDM	*P*
N	103	32(31%)	71(69%)	
Male［%］	75 (73%)	25(78%)	50(70%)	0.48
Age［yr］	57±16	60±16	56±16	0.23
Height［cm］	164±10	165±11	164±9	0.20
Body weight［kg］	60.4±11.7	63.2±11.6	59.2±11.6	0.07
Systolic BP［mmHg］	144±21	142±23	144±20	0.83
Diastolic BP［mmHg］	79±16	74±14	82±16	0.02
Urine volume［mL/day］	1300 (400 to 4500)	1200 (400 to 4500)	1400 (500 to 3000)	0.16
Primary renal disease				
CGN	36 (35%)	0(0%)	36(51%)	
Diabetic nephropathy	32 (31%)	32(100%)	0(0%)	
Nephrosclerosis	17 (17%)	0(0%)	17(24%)	
PKD	4 (4%)	0(0%)	4(6%)	
Other or unknown	14 (14%)	0(0%)	14(20%)	
Comorbidities				
Cardiovascular disease	9 (9%)	6(19%)	3(4%)	0.02
Cerebrovascular disease	10 (10%)	4(13%)	6(8%)	0.50
Malignancy	4 (4%)	1(3%)	3(4%)	1.00
Laboratory data				
Hb［g/dL］	9.6±1.4	9.6±1.5	9.6±1.3	0.77
TP［g/dL］	6.4±0.7	6.1±0.6	6.5±0.7	<0.01
Alb［g/dL］	3.5±0.6	3.2±0.5	3.6±0.5	<0.01
BUN［mg/dL］	81.8±30.6	76.6±26.6	84.2±32.2	0.13
Cr［mg/dL］	9.1±2.5	7.8±2.2	9.9±2.4	<0.01
β2-m［mg/L］	15.7±4.5	14.7±3.8	16.2±4.8	0.10
D/P Cr	0.56±0.11	0.60±0.10	0.54±0.11	<0.01

Abbreviations: DM, diabetes mellitus; BP, blood pressure; CGN, chronic glomerulonephritis; PKD, polycystic kidney disease; Hb, hemoglobin; TP, total protein; Alb, serum albumin; BUN, blood urea nitrogen; Cr, creatinine; β2-m, β2-microglobulin; D/P Cr, dialysate-to-plasma ratio of creatinine.

2

3

1

Table 2. Hazard ratios and 95% confidence intervals of technical and patient survival.

	Univariate analysis		Multivariate analysis	
	HR and 95%CI	P	HR and 95%CI	P
Technical survival				
Age (per 1-year increase)	0.97 (0.95 to 1.00)	0.04	0.97 (0.95 to 1.00)	0.051
Male gender	1.97 (0.81 to 5.90)	0.14		
Diabetes mellitus	1.16 (0.51 to 2.46)	0.71	1.31 (0.58 to 2.82)	0.51
Use of icodextrin	1.46 (0.66 to 3.09)	0.34	1.75 (0.71 to 3.90)	0.21
Patient survival				
Age (per 1-year increase)	1.12 (1.07 to 1.19)	<0.01	1.12 (1.07 to 1.19)	<0.01
Male gender	0.64 (0.21 to 2.13)	0.45		
Diabetes mellitus	1.62 (0.49 to 4.90)	0.41	0.80 (0.22 to 2.68)	0.72
Use of icodextrin	0.65 (0.15 to 2.13)	0.50	1.87 (0.38 to 7.10)	0.41

Abbreviations: HR, hazard ratio. CI, confidence interval.

2