

Outcomes of Assisted Peritoneal Dialysis; a Multicentre Experience

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Abstract

Background: Peritoneal Dialysis (PD) is one of the options for renal replacement therapy in patient with End Stage Renal Disease (ESRD) apart from haemodialysis and renal transplant. Patients who are physically independent are capable of self-care PD while those with multiple co-morbidities, peritoneal dialysis could be still performed with the aid of a trained assistant. There are limited data regarding the outcomes of patient undergoing assisted PD. The objective of this study is to observe the outcomes of assisted PD compared to self-care PD in term of patient's survival, peritonitis free survival and catheter survival.

Method: All incident ESRD patients initiated on PD from 1st January 2011 until 31st December 2015 in Malaysia East Coast region involving Hospital Universiti Sains Malaysia Kubang Kerian Kelantan, Hospital Raja Perempuan Zainab II, Kota Bharu Kelantan and Hospital Tengku Ampuan Afzan Pahang were recruited. Minimal observation data was 2 years. The cohort of patients was divided into self-care PD group and assisted PD group. The demographic, clinical and laboratory data from patient's file were recorded and the outcomes of patient's survival, peritonitis free survival and catheter survival were analyzed.

Result: A total of 211 PD patients were recruited from 3 different centers with 91 in self-care PD and 120 in assisted PD. Assisted PD patients were significantly older (mean 58.0 years, SD 9.08 vs mean 40.5 years, SD 13.34). There were no significant differences in peritonitis free survival (p -value=0.1) and catheter survival (p -value=0.1) between assisted PD and self-care PD. Patient's survival was lower in assisted PD as compared to self-care PD (p -value<0.001). Multiple Cox Proportional Hazards Regression Model showed that age was the only significant variable in prognosticating death among PD patients with a p -value of <0.05.

Conclusion: Patients who need assistance can receive PD treatment safely in our country as the overall outcomes of peritonitis free survival and catheter survival were similar between assisted PD and self-care PD.

Introduction

Peritoneal Dialysis (PD) accounted for 10% of all prevalent dialysis patients in Malaysia [1]. Peritoneal dialysis offers many advantages including independence from hospitals, simplicity of access, good control of hypertension, better cardiovascular stability and slow solute removal [2,3].

According to 22nd Report of the Malaysian Dialysis and Transplant Registry 2014, the number of patients treated with Peritoneal Dialysis (PD) in Malaysia has grown by approximately 2.7 times over the last decade. The proportion of new patients accepted into chronic PD program had shown a gradual but steady increase from 10% in 2005 to 13% in 2014 [1]. In the recent 24th Report of the Malaysian Dialysis and Transplant Registry 2016, there were 4633 patients receiving PD at the end of 31st December 2016 in all centers around Malaysia [4].

Most of the ESRD patients are in the elderly group with multiple co-morbidities. Obstacles for PD in elderly patients include vascular disease, impaired vision, deafness, poor mobility, arthritis and poor cognitive functions [2,3]. These obstacles causing difficulties for patients to perform PD independently, hence assisted PD provides a good alternative in this group.

Technique failure remains a major problem with peritoneal dialysis [5]. Several studies done showed variable outcomes between assisted and self-care PD. This study was intended to observe

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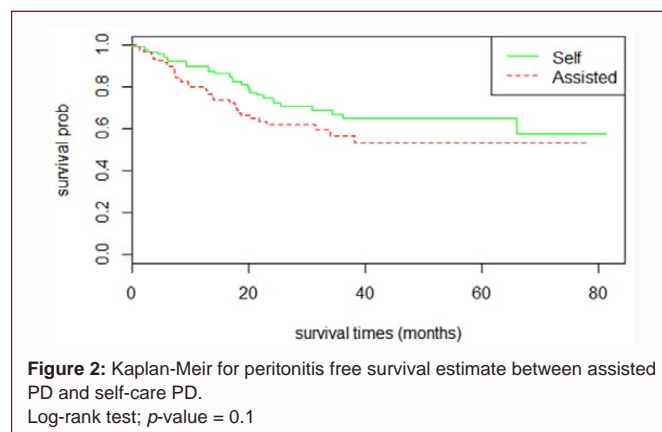
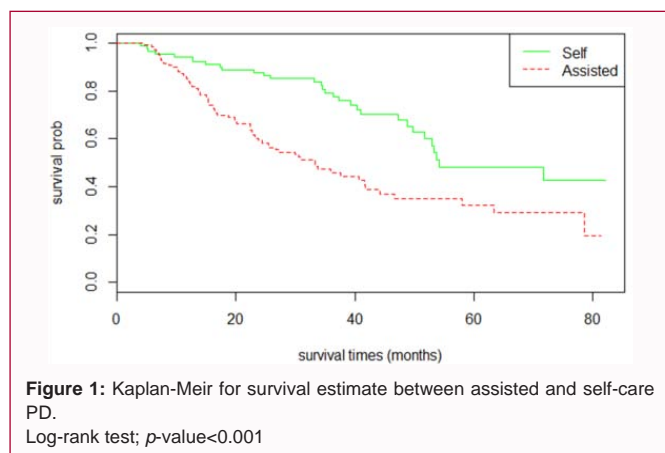
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the outcomes of assisted PD for our populations among Malaysia East Coast region in all three aspects of the patient’s survival, catheter survival and peritonitis free survival. We hypothesized that in Malaysia, assisted PD by well-trained and compliant assistants can be as good as self-care PD.

Methodology

Study population

This was a retrospective cohort study of incident ESRD patients initiated on PD either Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) from 1st January 2011 until 31st December 2015 in Malaysia East Coast region involving Hospital Universiti Sains Malaysia Kubang Kerian Kelantan, Hospital Raja Perempuan Zainab II, Kota Bharu Kelantan and Hospital Tengku Ampuan Afzan Pahang. This study ended on 31st December 2017 in which minimal observation data was 2 years.

The study cohort was divided into two groups of self-care PD group and assisted PD group.

The demographic, clinical and laboratory data from patient’s file were recorded.

The outcomes of patient’s survival (in month), peritonitis free survival (in month) and catheter survival (in month) were then analyzed. Exclusion criteria’s were patient’s age of less than 18 years old or patients with history of kidney transplant or expected to receive a transplant in the next 3 months.

Definition of outcome events

Patient’s survival was defined as duration of time from initiation of PD to the time of death. Peritonitis free survival was a duration of time from initiation of PD to the first episode of peritonitis in which was diagnosed if two of the following three criteria were present; clinical symptoms, cell count>100/ml with>50% polymorph leucocytes and positive culture. Catheter survival was defined as duration of time from initiation of PD to the time of catheter failure due to catheter malfunction or catheter removal for any reasons.

Statistical analysis

Data entry was performed and analyzed using R Software, version 1.1.447. Data exploration was done to check for missing values and distribution of numerical data. All continuous variables were expressed as mean with standard deviation or median with inter quartile range. Meanwhile, frequencies (n) and percentages (%) were obtained for categorical variables. The Kaplan-Meier method and log-rank test were used to examine patient’s survival, peritonitis free

Table 1: Demographic details, clinical characteristics and outcomes for assisted PD and self-care PD groups.

Characteristics	Self		Assisted	
	Mean (SD)	n (%)	Mean (SD)	n (%)
Age	40.5 (13.34)	-	58.0 (9.08)	-
Sex				
Male		49 (44.1)		62 (55.9)
Female		41 (41.0)		59 (59.0)
Race				
Malay		83 (42.8)		111 (57.2)
Non-Malay		7 (41.2)		10 (58.8)
Clinical Characteristics:				
Diabetes Mellitus				
Yes		36 (30.3)		83 (69.7)
No		83 (69.7)		38 (41.3)
Hypertension				
Yes		74 (39.8)		112 (60.2)
No		16 (64.0)		9 (36.0)
IHD				
Yes		16 (38.1)		26 (61.9)
No		74 (43.8)		95 (56.2)
Haemoglobin (g/dl)	9.9 (1.50)		9.9 (1.57)	
Albumin (g/dl)	35.6 (6.66)		32.1 (6.00)	
Calcium (mmol/L)	2.1 (0.27)		2.0 (0.26)	
Phosphate (mmol/L)	3.7 (17.63)		1.56 (0.47)	
KTV	1.9 (0.43)		1.9 (0.35)	
Peritonitis				
Yes		29 (42.0)		40 (58.0)
No		61 (43.0)		81 (57.0)
Catheter Removal				
Yes		14 (41.2)		20 (58.8)
No		76 (42.7)		101 (57.1)

survival and catheter survival at 12, 36 and 60 months, comparing assisted PD with self-care PD. Multiple Cox Proportional Hazards Regression Model was used to identify the important prognostic factor of death. At univariable analysis, variables with p -value pf less than 0.25, clinically important and biologically plausible were considered and included in the multivariable analysis. At multivariable analysis, preliminary main effect model was obtained using the Enter method. All possible two-way interaction was checked using multiplicative method. Hazard Functions plot and Log-Minus-Log plot was used to check the assumption of proportional hazard. A p -value of less than 0.05 was considered to represent a statistically significant difference and 95% confidence interval was used for statistical inference of the relative hazards and to represent the uncertainty of the relative hazards.

Results

Patient sociodemographic and clinical characteristics

A total of 295 ESRD patients on peritoneal dialysis were recorded in all three centers participated in this study from January 2011 until December 2015. From this total, only 270 patients were eligible for the inclusion in this study however another 59 patients were discarded due to a large amount of missing data and 211 patients participated and analyzed this study.

Among the 211 PD patients in the study group, 121 were treated with assisted PD and 90 were on self-care PD. Assisted PD patients were significantly older (mean 58.0 years, SD 9.08 vs mean 40.5 years, SD 13.34). Sixty two out of 121 assisted PD patients were males and 59 were female's vs 49 males and 41 females in self-care PD.

Prevalence of diabetes mellitus was higher in the assisted PD group (69.7% vs 30.3%). Patients on assisted PD were also noted to have higher numbers of hypertension (60.2% vs 39.8%) and ischemic heart disease (61.9% vs 38.1%). Mean Hb, albumin, calcium and KT/V were almost similar in these two groups. All characteristics were tabulated in (Table 1).

Estimation of patient's survival

Survival outcomes were observed in term of patient's survival, peritonitis free survival and catheter survival for both assisted PD and self-care PD groups in three intervals (12 months, 36 months, 60 months; Table 2). At 12 months of observation, the probability for patient's survival was 0.85 (95% CI:0.784, 0.914) in assisted PD group vs 0.94 (95% CI:0.898,0.993) in self-care PD group; probability for peritonitis free survival was 0.80 (95% CI: 0.729,0.876) in assisted PD vs 0.90 (95% CI: 0.836,0.963) in self-care PD and probability for catheter survival was 0.96 (95% CI: 0.926,0.999) in assisted PD groups vs 0.98 (95% CI: 0.947, 1.000) in self-care PD.

At 36 months interval, probability for patient's survival was 0.46 (95% CI: 0.370,0.567) vs 0.79 (95% CI: 0.708, 0.887); probability for peritonitis free survival was 0.56 (95% CI:0.464,0.696) in assisted PD vs 0.67 (95% CI: 0.571,0.786) in self-care PD group and probability for catheter survival was 0.77 (95% CI: 0.672, 0.874) in assisted PD vs 0.83 (95% CI: 0.746,0.924) in self-care PD group.

At 60 months interval, probability for patient's survival was 0.32 (95% CI: 0.229,0.454) in assisted group vs 0.48 (95% CI: 0.354,0.655) in self-care group; probability for peritonitis free survival was 0.53 (95% CI: 0.420,0.677) in assisted PD vs 0.65 (95% CI: 0.546, 0.770) and probability for catheter survival was 0.65 (95% CI: 0.498,0.848) in assisted PD vs 0.79 (95% CI: 0.689,0.913) in self-care PD group.

Patient's survival was higher in the self-care PD group compared to assisted PD group as showed in Figure 1 with p -value<0.001. There was no significant difference in peritonitis free survival for both groups (p -value=0.1; Figure 2) throughout this study. Catheter survival probability was also similar without significant difference in assisted PD and self-care PD group (p -value=0.1; Figure 3).

Prognostic factors for patient's survival

From the Simple Cox Proportional Hazards Regression Model, significant variables for prognostic factors of death were age, gender (female), type of assistance (assisted vs self-care), diabetic co-morbidity, IHD co-morbidity, pre-dialysis albumin level, 5th year of phosphate level with p -value of<0.25 (Table 3). Other parameters were not statistically significant to prognosticate death in patient with

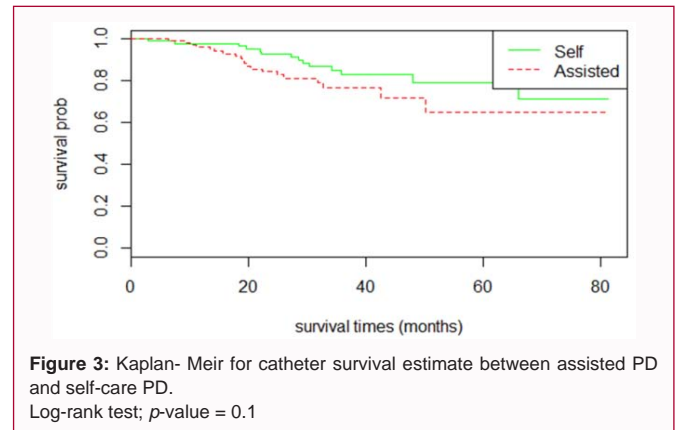


Table 2: Survival outcomes between assisted PD and self-care PD in time intervals.

Survival Outcomes	Assisted PD	Self-care PD
	Probability (95% CI)	Probability (95% CI)
Patient's Survival:		
12 months	0.85 (0.784, 0.914)	0.94 (0.898,0.993)
36 months	0.46 (0.370, 0.567)	0.79 (0.708, 0.887)
60 months	0.32 (0.229, 0.454)	0.48 (0.354, 0.655)
Peritonitis Free Survival:		
12 months	0.80 (0.729, 0.876)	0.90 (0.836, 0.963)
36 months	0.56 (0.464, 0.696)	0.67 (0.571, 0.786)
60 months	0.53 (0.420, 0.677)	0.65 (0.546, 0.770)
Catheter survival:		
12 months	0.96 (0.926, 0.999)	0.98 (0.947, 1.000)
36 months	0.77 (0.672, 0.874)	0.83 (0.746, 0.924)
60 months	0.65 (0.498, 0.848)	0.79 (0.689, 0.913)

CAPD. However, further analysis using Multiple Cox Proportional Hazards Regression Model showed significant variable in prognostic factor of death among CAPD patients were age with p -value of<0.05 (Table 4).

Discussion

CAPD is considered an appropriate renal replacement therapy for elderly and patient with multiple co-morbidities [6]. Assisted PD is an evolving dialysis modality in many parts of the world [7]. Many studies were done to compare the outcomes of assisted PD and self-care PD worldwide. This study was done to estimate patient's survival, peritonitis free survival and catheter survival among assisted PD and self-care PD.

Our study involved three centers in Malaysia East Coast region, with 211 incident CAPD patients. 57.34% of patients were on assisted PD and another 42.65% were on self-care PD. Based on sociodemographic and biochemical characteristics, our study showed that patient on assisted PD has more prevalence of underlying co-morbidities; diabetes mellitus, hypertension, ischemic heart disease and generally older than patients on self-care PD with mean age of 58 years old vs 48 years old respectively.

In this study, patient on assisted PD has lower survival rate as compared to self-care PD. This outcome of patient survival was similar the study done by Lobbedez [8] as they conclude that those

Table 3: Prognostic factors of death among CAPD patients by Simple Cox Proportional Hazards Regression Model.

Variables	Regression coefficient (b)	Crude HR (95% CI)	Wald Statistic	p-value
Age	0.04	1.04 (1.02, 1.03)	23.17	<0.001
Sex				
Male	0	1	-	-
Female	-0.46	0.63(0.42, 0.95)	4.93	0.026
Race				
Malay	0	1	-	-
Non-Malay	-0.19	0.83 (0.36, 1.89)	0.20	0.652
Mode of PD				
CAPD	0	1	-	-
APD	-1.61	0.20 (0.03, 1.43)	2.57	0.109
Type of Assistance Self Assisted	0	1	-	-
Assisted	0.88	2.41 (1.57, 3.70)	16.21	<0.001
Medical History:				
Diabetes:				
No	0	1	-	-
Yes	0.65	1.92 (1.26, 2.9)	9.5	< 0.001
Hypertension:				
No	0	1	-	-
Yes	0.40	1.49 (0.75, 2.97)	1.31	0.252
IHD:				
No	0	1	-	-
Yes	0.54	1.72 (1.07, 2.76)	5.12	0.023
Blood parameters:				
HB (Pre)	0.04	1.04 (0.90, 1.20)	0.34	0.559
HB (5 th year)	-0.20	0.81 (0.43, 1.54)	0.39	0.531
Albumin (Pre)	-0.04	0.96 (0.93, 1.04)	7.76	0.005
Albumin (5 th year)	-0.11	0.89 (0.76, 1.04)	1.91	0.167
Calcium (Pre)	-0.34	0.71 (0.34, 1.48)	0.83	0.362
Calcium (5 th year)	0.45	1.57 (0.63, 78.11)	0.05	0.820
Phosphate (Pre)	-0.09	0.90 (0.64, 1.28)	0.29	0.592
Phosphate (5 th year)	2.07	8.90 (1.22, 52.32)	4.69	0.050
KTV (1 st)	-0.33	0.72 (0.40, 1.31)	1.16	0.281
KTV (5 th year)	0.83	2.30 (0.05, 116.3)	0.17	0.678

Table 4: Prognostic factors of death among CAPD patients by Multiple Cox Proportional Hazards Regression Model.

Variables	Adjusted HR (95% CI)	Wald Statistic	p-value
Age	1.03(1.01, 1.05)	24.87	0.001
Type of Assistance Self Assisted	1		-
Assisted	1.5 (0.91, 2.49)		0.104

with assisted PD had a lower risk for transfer to haemodialysis, a higher risk for death, and a lower risk for transplantation. Result of patient survival in our study was also similar as the study done by Sara Querido [9]. They evaluated clinical outcomes of an assisted peritoneal dialysis program developed in a Portuguese centre. Their study showed that assisted-care PD patients had a poorer outcome in terms of patient survival (12th, 24th, and 48th months). A report from the French Peritoneal Dialysis Registry (RDPLF) also demonstrated that patients under assisted PD had a poorer survival rate than self-care PD [6].

Although patient survival was significantly lower than self-care PD, there are several factors affecting this outcome. From both Simple Cox Proportional Hazards Regression Model and Multiple Cox Proportional Hazards Regression Model, prognostic factors of death among CAPD patients are age and medical history of diabetes. For 1-year increase in age has 1.03 times risk of death after adjusting for types of assistance and diabetes history. Patient with assisted PD has 1.4 times risk of death compared to self-care PD when adjusted

for age and diabetes history. A person with diabetes has 1.64 times risk of death compared with no-diabetic when adjusted for age and types of assistance. From this study, we conclude that prognostic factors affecting the lower rate of patient survival are due to patient's age and diabetes co-morbidity. Overall biochemical parameters are not a prognostic factor for survival in both groups.

In a recent study from Canada using the cause specific RH approach, patient age was associated with an increased risk for death, an increased risk for technique failure and a lower risk for renal transplantation [10]. Lobbedez [8] also reported in their study that older age was associated with an increased risk of death.

In term of peritonitis free survival and catheter survival, results from other international study from different regions has variable outcomes [8,9,11]. Lobbedez [8] conclude that assisted PD was associated with a lower risk for technique failure. On the other hand, Sara Querido [9] reported a better performance of peritonitis incidence and catheter survival in assisted PD as compared to self-care PD.

In contrast to both studies, our study showed no significant difference in peritonitis free survival and catheter survival between assisted PD and self-care PD. This result is similar to a study done by Xu R [12]. They reported a similar rate of peritonitis between assisted PD and self-care PD. As most of our assisted PD patients are assisted

by family members and not by healthcare personnel, this could be the reason of not having a better peritonitis free survival and catheter survival in our setting. Lack of training among family members could also be a contributing factor for this outcome. Therefore, regular training and assessment by CAPD staffs is needed to overcome this issue.

However, comparing to a study done by Cheng [11], we have better outcomes in our population. Cheng conclude that elderly assisted PD had a poorer survival and technique survival rates than those of the self-care PD but our study showed no significant difference of peritonitis free survival and catheter survival between two groups. This could be explained by a high dedication level of family members in assisted PD patients. This result clearly demonstrates that patients who need assistance can receive PD treatment safely in our country.

There are several limitations in our study. This study involved three HD centers in East Coast region of Malaysia. Although the sample size calculated is met, more sample size is needed to represent overall population in Malaysia, to prevent potential bias and to increase reliability. Apart from that, a complete documentation is needed in order to gain complete information regarding patient's data which might affect the overall results.

In conclusions, patients who need assistance can receive PD treatment safely in our country as the overall outcomes of peritonitis free survival and catheter survival were similar between assisted PD and self-care PD.

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