M Phil (Nephrology) research assignment

Peritoneal dialysis technique survival at Tygerberg Hospital in Cape Town, South Africa

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Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

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Abstract

Background: Peritoneal dialysis (PD) technique failure invariably occurs in patients with end-stage renal disease who are treated with this modality and results in increased morbidity and mortality. Various factors have been associated with the development of technique failure. Identifying such factors in a PD program is important to minimize the rates of technique failure and maintain patients on PD.

Methods: In this retrospective study at Tygerberg Hospital in Cape Town, South Africa, we studied 170 patients who were started on CAPD and determined rates of technique and patient survival. Demographic, clinical and laboratory data were assessed to identify risk factors for these outcomes.

Results: The median age of the patients was 36 years with the commonest cause of ESRD being glomerulonephritis. Only one patient had diabetes mellitus. Technique survival at 1, 2, 3 and 5 years was 78.5%, 60.4%, 54.5% and 39.6% respectively while patient survival was 90.8%, 86.8%, 83.6% and 63.5%. Peritonitis was the most common cause of technique failure. On multivariate analysis, the occurrence of peritonitis (OR 57.41, CI 11.19- 294.70, $p < 0.001$) and Black race (OR 6.43, CI 1.58-26.14, $p = 0.009$) increased the likelihood of technique failure. Other clinical and social factors were not significantly associated with the occurrence of technique failure.

Conclusion: In our ESRD patients on PD, Black race and peritonitis were important factors in the development of technique failure. Concerted efforts are required to reduce peritonitis rates at our centre as this is the main cause of technique failure.

Introduction

Chronic kidney disease is an important non-communicable disease (NCD) and ranks 12th as the commonest cause of death [1]. The true extent of CKD and end-stage renal disease (ESRD) is not fully appreciated worldwide due to lack of established renal registries, especially in developing countries. Patients with ESRD who have access to renal replacement therapy (RRT) are assigned to one of three RRT modalities, namely kidney transplantation, haemodialysis (HD) or peritoneal dialysis (PD). Worldwide, however, the majority of patients with ESRD die without receiving any form of RRT due to scarcity of resources.

Each of the RRT modalities has their pros and cons, with failure of the treatment modality a downside of all. The modalities should be considered complimentary, such that patients failing one modality could be switched to another.

Peritoneal dialysis has several advantages for patients requiring chronic dialysis. It can be performed in the comfort of the home or workplace, avoiding the thrice-weekly hospital visits required for patients on haemodialysis. The impact on patients' lifestyle is less and it is more likely that patients will continue working or going to school if they are on PD than on HD. Compared to haemodialysis, peritoneal dialysis has been shown to preserve residual renal function better than haemodialysis [2- 5]. Mortality rates in the first one to two years after initiation of dialysis has been shown to be lower for PD than HD [6- 11]. However, peritoneal dialysis can become ineffective with technique failure occurring due to recurrent peritonitis, peritoneal membrane failure, psychosocial factors as well as mechanical factors.

Peritoneal dialysis is underutilized worldwide, and especially so in Africa [12, 13]. In countries where RRT is available, haemodialysis is by far the commonest form of RRT provided. Worldwide, out of approximately 3 million people on RRT at the end of 2012, only 8.4% were on peritoneal dialysis [12]. Only four countries in the world, namely Hong Kong, El Salvador, Mexico and Guatemala have a higher proportion of patients on dialysis using PD. In absolute terms, the top three countries offering peritoneal dialysis were Mexico, USA and China while Hong Kong had the highest prevalence of PD patients at 489 patients per million population (pmp) followed by Mexico (378 pmp) and El Salvador (324 pmp) [14]. In Africa, the proportion of patients on RRT receiving PD was even lower, with only 2.9% out of 69800 patients on dialysis in 2007 on peritoneal dialysis [15] whereas, in South Africa, out of 9591 people that were on RRT in 2014, most of the patients were on haemodialysis (71.8%), with only 13.5% on peritoneal dialysis and the remainder being transplanted patients [16].

In spite of the many benefits that PD may hold, it is under-utilized due to multiple and sometimes complex factors which mainly promote the use of haemodialysis [17, 18]. A complex inter-play of physician reimbursement policies, technology factors, patient perceptions of PD and the nephrology training curriculum has tended to favour HD use [17] [18, 19]. In most dialysis programs, physicians providing HD are better remunerated than those providing PD and this has tended to promote HD [20, 21]. The investment in state of the art HD technology promotes their use and the ready availability of HD facilities tend to

limit the use of PD [17, 22]. The nephrology training curricula in many centres tends to mirror the dialysis services at these centres, and produces new nephrologists that are more familiar and comfortable with HD than PD [17]. Patient education on modality choice is also biased towards HD, with a perception among both physicians and patients that HD is a superior dialysis modality [19].

Peritoneal dialysis technique failure is one of the reasons for the low prevalence of PD. There is no clearly accepted definition of peritoneal dialysis technique failure and this has resulted in differences in this important outcome as reported in various studies and registries. PD technique failure has been variably defined as a switch from peritoneal dialysis to haemodialysis for a continuous period of more than thirty days [24], sixty days [25,26], or a permanent switch to haemodialysis [27-29]. One aim of the on-going international PDOPPS study [23] is the establishment of consensus definitions for technique failure and other PD-related data, including the standardization of the causes of technique failure. PDOPPS recommends examining cause-specific PD failure, in addition to composite end-points such as those that combine death while on PD with technique failure.

Once technique failure occurs, patients may switch to haemodialysis, be transplanted, or withdraw from renal replacement therapy altogether. Maximizing PD technique survival contributes to reducing morbidity and mortality. It is thus imperative to monitor peritoneal dialysis outcomes in centres where this RRT modality is employed and to implement measures aimed at improving technique survival.

Technique survival differs among countries, regions and centres. Since the inception of PD over 40 years ago, technique failure rates have been declining [28,30,32]. Death-censored technique survival at five years was 73% and 88% in Canadian and Chinese cohorts respectively [28]. This improvement in technique survival could be a reflection of advances in peritoneal dialysis techniques as well as experience gained in use of PD within particular centres. The “flush before fill” technique, in particular, has improved technique survival in patients on peritoneal dialysis by significantly reducing peritonitis rates [33].

The main causes of technique failure are generally similar with peritonitis the commonest cause. Other causes include ultrafiltration failure, PD catheter-related problems (tunnel infection, leaks, herniation and catheter migration), as well as psycho-social factors [29, 34]. Ultrafiltration failure becomes more frequent with increasing time on peritoneal dialysis.

The factors thought to favour PD technique survival include preserved residual renal function (RRF), a large PD program, better patient educational level and good social circumstances such as access to clean running water. Maintenance of RRF, defined by urea and creatinine clearance or simply as urine output more than 200 ml/24h, has been associated with less morbidity and mortality among PD patients [35]. RRF allows improved fluid and small- and middle-molecule removal and is essential for optimal outcomes, as was shown by Bargman et al. in the reanalysis of the CANUSA study [36]

In one South African study [37], peritonitis was the major cause of technique failure. Interestingly, peritonitis rates were not affected by socio-economic factors. Factors associated with good outcomes in a study from the Limpopo province, South Africa, were

treatment of anaemia and malnutrition, and training and retraining of patients and staff to reduce the rates of peritonitis [38].

It is good clinical practice to evaluate peritoneal dialysis programmes regularly and to compare outcomes with international standards and those reported at other South African centres. The aim of this study was to determine our PD technique survival rates at Tygerberg Academic Hospital and to examine the main causes and risk factors associated with that important outcome. The information will be useful in planning interventions and improving protocols to decrease rates of technique failure and maximize the use of peritoneal dialysis.

Methods

We conducted a descriptive, retrospective study at the Division of Nephrology, Tygerberg Academic Hospital (Cape Town, South Africa). Tygerberg Hospital is a large public-sector teaching hospital which provides RRT to patients in the region, although the numbers are limited by resource constraints. There are approximately 70 patients on haemodialysis and 60 on peritoneal dialysis. Only transplantable patients are accommodated on the RRT program and PD is usually the first treatment modality.

A total of 170 adult patients with ESRD initiating peritoneal dialysis between January 2008 and July 2014 were included, and the end date for observation was 31 October 2014, allowing for a minimum follow-up period of 3 months. Demographic and clinical data as well as laboratory data were collected to assess the technique survival rates and the risk factors for technique failure. This included information on access to running water, diabetes status, residual renal function and the occurrence of peritonitis. Laboratory tests done within the week prior to initiating renal replacement therapy were recorded, including haemoglobin, serum creatinine and serum albumin concentrations. Tests were performed at the National Health Laboratory Service at Tygerberg Hospital on a Roche/Hitachi Cobas® c 501 system. Creatinine concentrations were determined using a kinetic colorimetric assay based on the Jaffe reaction, with the assay calibrated to the isotope-dilution mass spectrometry (IDMS) reference method.

Definitions

Technique failure was defined as a permanent switch to haemodialysis, withdrawal from RRT due to inability to perform PD successfully, or any PD-related death (such as peritonitis with septicaemia). This definition is similar to that used in other studies [39]. We censored patients at recovery of renal function, kidney transplantation, transfer to another centre while on PD, death unrelated to PD, and at the end of the study while still on PD.

Distinct from technique failure was the probability of patients to "stay on PD". Failure events were a permanent switch to haemodialysis or death from any cause, with censoring events being kidney transplantation, recovery of renal function, transfer to another centre and remaining on PD at the end of the study. This analysis has been used in the paper on the NECOSAD study [29] and is useful when the aim is expanding the size of a PD programme and one needs to examine all the factors that lead to patients no longer continuing PD.

For patient survival, the failure events were death from any cause or withdrawal from RRT, and patients were censored at kidney transplantation, recovery of renal function, permanent switch to hemodialysis, transfer to another center and remaining on PD at the end of the study.

Initial RRT modality refers to the intended first dialysis modality and was the modality recorded on day 91 of RRT. Patients who presented late and needed urgent haemodialysis but were then established on PD within 3 months had PD recorded as their initial modality.

Late presenters were patients who required RRT within 90 days of first being seen by a nephrologist and urgent start refers to patients who had ESRD on first presentation to our hospital and required dialysis during that admission.

Recovery of renal function was defined as being independent of any form of RRT for more than three months.

Data management

Information was extracted from patient files and entered directly into REDCap (Research Electronic Data Capture) [40], a secure web application designed to support data capture for research studies. REDCap provides user-friendly web-based case report forms, real-time data entry validation, audit trails and a de-identified data export mechanism in formats used by common statistical packages. Only authorised personnel were allowed access to the raw data, which was password-protected. Data was de-identified for further processing, including statistical analysis.

Statistical analysis

Stata (STATACORP, version 13, College Station, Texas, USA) was used for the statistical analysis. Patient and technique survival was assessed by the use of proportions and survival analysis. The association with risk factors was assessed using Chi-squared tests (and Fischer's exact test for small numbers). Cox logistic regression was used to assess potential associations and multiple regression analysis performed on significant factors found at the bivariate level. A p-value of <0.05 represented statistical significance in hypothesis testing and 95% confidence intervals were also used. Kaplan-Meier curves were used to express technique survival and the log rank test for equality of survival functions.

Ethical aspects

This was a retrospective study and a waiver of individual informed consent was granted by the University of Stellenbosch Health Research Ethics Committee, (reference #X14/10/021).

Results

During the study period, 172 patients were initiated on CAPD and 170 were included in the study. Their outcomes are summarised in the study flow chart (Figure 1).

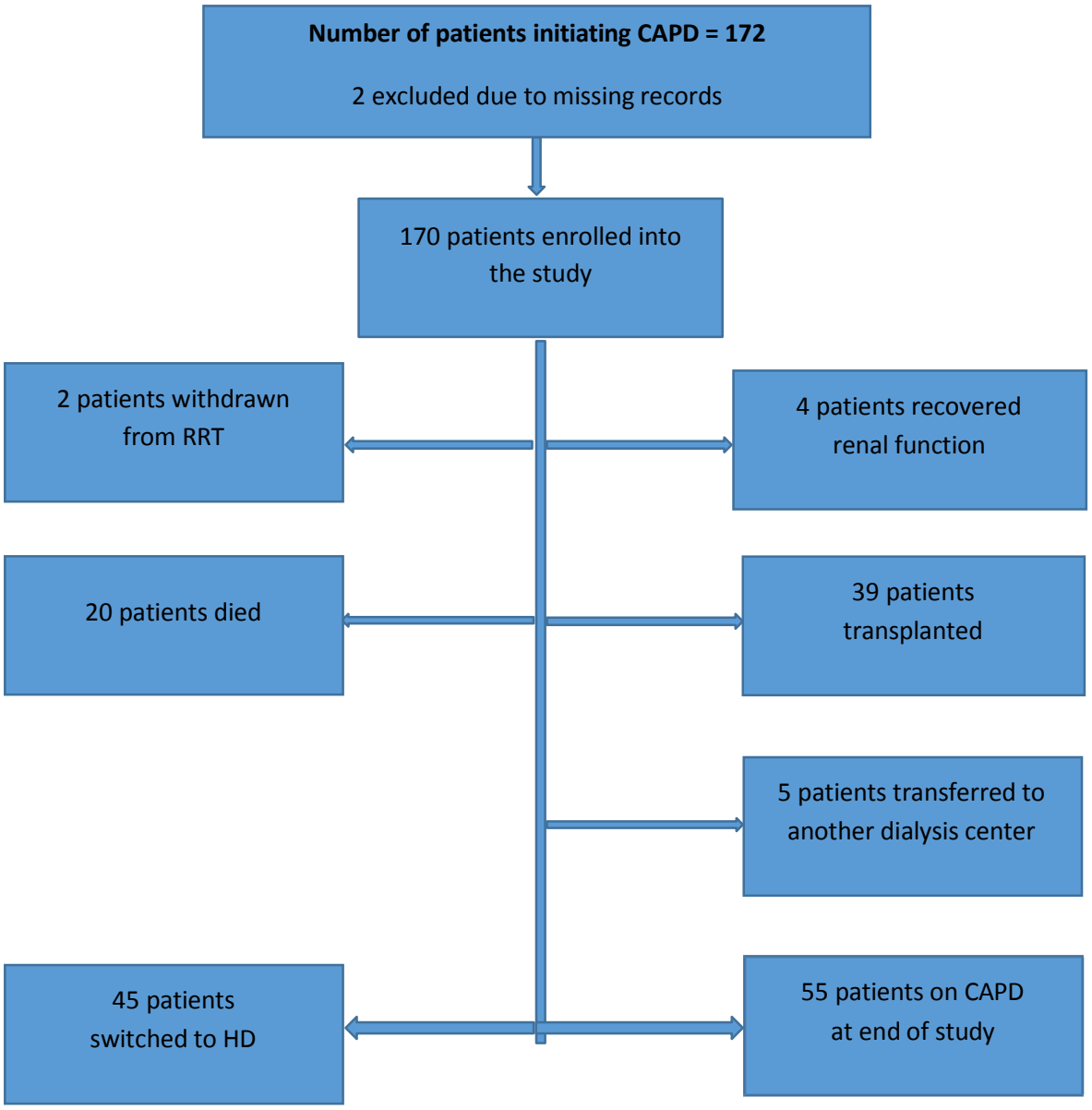

Figure 1. Study flow chart for the study period.

Baseline characteristics of the study participants

Approximately half of the participants were females (51.8%). The median age (IQR) was 36 years (27-43). Most of the participants were of mixed ancestry (68.8%), had at least secondary school education, and lived in brick houses with access to running water (Table 1).

Table 1: Socio-demographic characteristics of study participants (n = 170)

Variable	Frequency	Percentage
Gender		
Female	88	51.8
Male	82	48.2
Ethnicity		
Mixed ancestry	117	68.8
Black	41	24.1
White	8	4.7
Indian	1	0.6
Unknown	3	1.8
Educational level		
≥ Secondary	87	51.2
≤ Primary	41	24.1
Unknown	42	24.7
Type of dwelling		
Brick house	113	66.5
Wendy house*	11	6.5
Shack	8	4.7
Unknown	38	22.3
Water		
Yes	113	66.5
No	19	11.2
Unknown	38	22.3

* In the context of this study, a Wendy house refers to a prefabricated wooden structure which commonly serves as informal housing in South Africa. It is often erected in the back yard of a property and the occupants often rely on the bathroom facilities and water supply of the main house.

Glomerulonephritis was the commonest cause of ESRD (69.4%). Most patients had been followed up for more than 3 months prior to initiating RRT and peritoneal dialysis was the initial modality in 95.9%, with 74.0% of the Tenckhoff PD catheters inserted at the bedside by the nephrology team. Most of the patients (71.8%) used only one PD catheter during their time on peritoneal dialysis (Table 2).

Table 2: Clinical characteristics of the study participants (n = 170)

Variable	Frequency	Percentage (%)
Primary renal disease		
Glomerulonephritis	118	69.4
ESRD cause unknown	22	12.9
Malignant hypertension	14	8.2
Polycystic kidney disease	11	6.5
Other	5	3.0
Late presenter		
No	58	34.1
Yes	23	13.5
Unknown	89	52.4
Urgent start		
No	62	36.5
Yes	27	15.9
Unknown	81	47.6
Initial RRT modality		
Peritoneal dialysis	163	95.9
Haemodialysis	4	2.3
Kidney transplant	3	1.8
Catheter insertion method		
Percutaneous bedside	125	74.0
Surgical	31	18.0
Unknown	14	8.0
Number of catheters		
1	122	71.8
≥2	48	28.2
Peritonitis		
No	64	37.6

Yes	63	37.1
Unknown	43	25.3

Follow-up

The maximum follow-up period was 81 months with a median follow-up of 12 months (IQR 7-26 months).

Technique survival, patient survival and "stay on PD"

Of the 170 patients enrolled into the study, technique failure occurred in 53 patients (31.2%) during the 81 months of follow up. Technique survival at 1, 2, 3 and 5 years was 78.5%, 60.4%, 54.5% and 39.6% respectively while patient survival was 90.8%, 86.8%, 83.6% and 63.5%, and "stay on PD" was 68.8%, 48.4%, 29.2% and 8.1% (Figures 2-4).

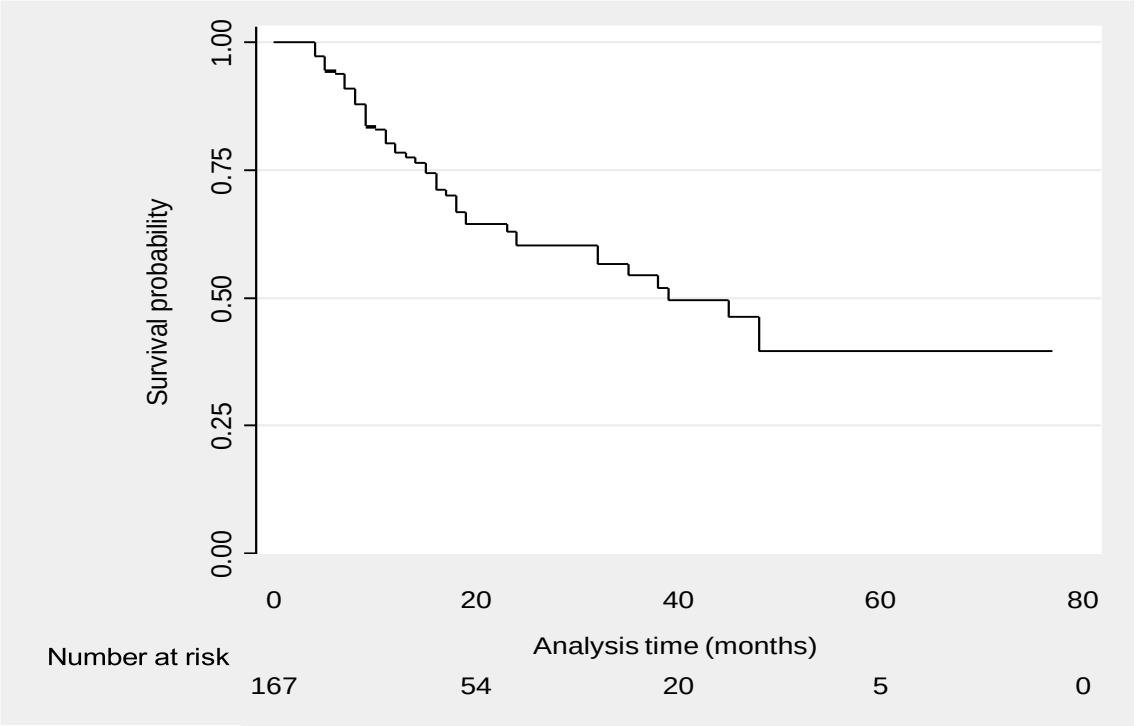

Figure 2: Technique failure for study participants. The 1, 2, 3 and 5 year PD technique survival was 78.5%, 60.4%, 54.5% and 39.6% respectively.

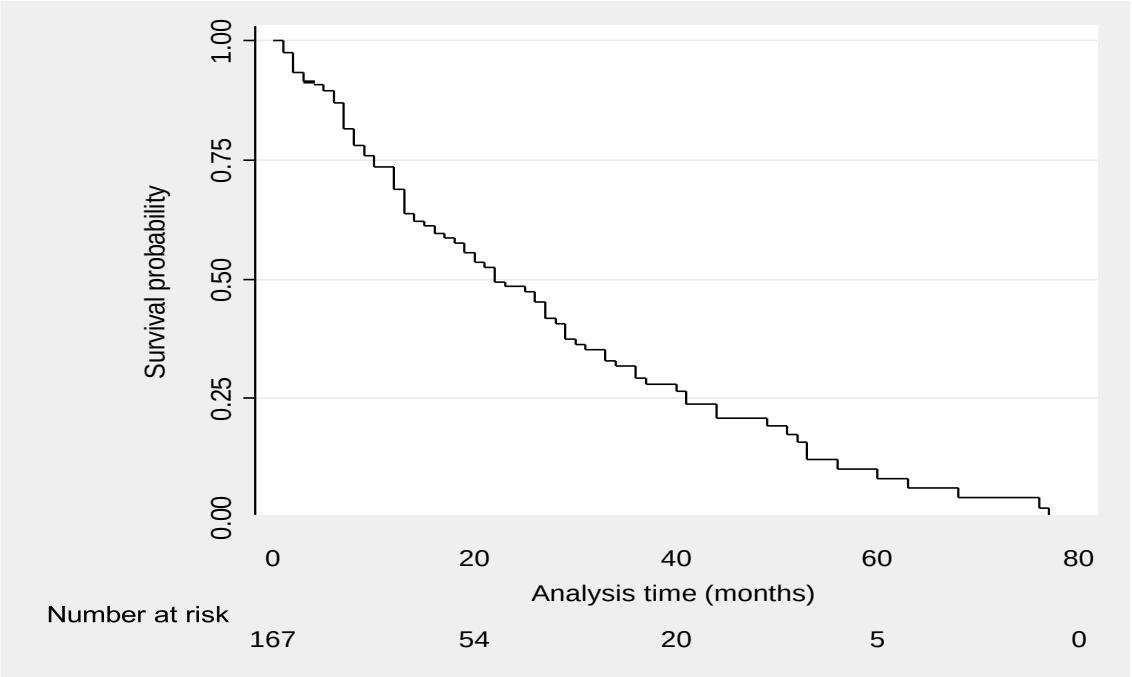

Figure 3: "Stay on PD" for study participants. The 1, 2, 3 and 5-year probability of remaining on PD was 68.8%, 48.4%, 29.2% and 8.1% respectively.

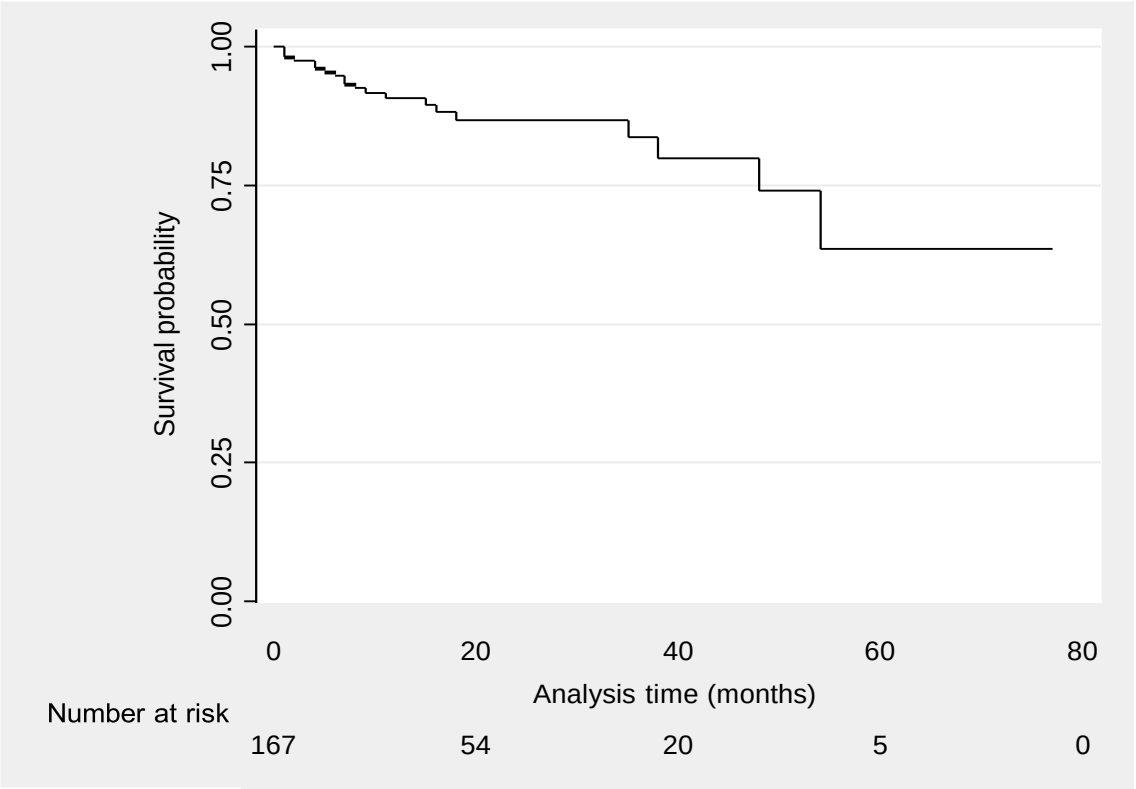

Figure 4: Patient survival for study participants. Survival at 1, 2, 3 and 5 years was 90.8%, 86.8%, 83.6% and 63.5% respectively.

Peritonitis was the main cause of technique failure, accounting for 71.6% of the cases. Patients who experienced technique failure were older (42 vs. 33 years, p=0.005) and, as expected, were more likely to have had episodes of peritonitis (Table 3). On stepwise regression analysis, peritonitis increased the risk of technique failure (OR 57.41 CI 11.19-294.70, p= <0.001) while black race had an increased risk of technique failure relative to other races (OR 6.43, CI 1.58- 26.14, p= 0.009) as illustrated in Table 4 and Figures 5 and 6.

Table 3: Comparison of potential risk factors in patients who experienced technique failure with those who did not.

	Technique failure, n (%)				
Characteristics	**Yes (n=53, 26.5%)**	**No (n=117, 73.5%)**	**P-value**	**OR**	**95%CI**
Age in years (IQR)	42 (31-47)	33 (25-42)	**0.005**	1.05	1.01- 1.08
Haemoglobin (IQR)	7.5 (6.1-8.2)	7.4 (6.5-8.6)	0.710	0.95	0.79- 1.15
Albumin (SD)	34.2 (6.0)	34.0 (6.2)	0.598	1.01	0.95- 1.06
Follow-up months (IQR)	11 (7-18)	13 (6-28)	0.744		
Male	29 (54.7)	53 (45.3)	0.255		
Ethnicity					
Mixed ancestry, White, Indian	35 (68.6)	91 (78.4)	0.174	R	R
Black	16 (31.4)	25 (21.6)		1.66	0.79- 3.48
Educational level					
≥ Secondary	30 (75.0)	57 (64.8)	0.250	R	R
≤ Primary	10 (25.0)	31 (35.2)		1.63	0.70- 3.77
Dwelling					
Brick house	35 (85.4)	78 (85.7)	0.923	R	R
Wendy house	3 (7.3)	8 (8.8)		0.84	0.21- 3.34
Shack	3 (7.3)	5 (5.5)		1.33	0.30- 5.91
Running water inside home					
Yes	35 (85.4)	81 (85.7)	0.958	R	R
No	6 (14.6)	13 (14.3)		0.46	0.18- 1.21
Initial RRT modality					
Peritoneal dialysis	51 (96.2)	112 (95.7)	0.461		
Haemodialysis	2 (3.8)	2 (1.7)			
Kidney transplant	0 (0.0)	3 (2.6)			
Method of catheter insertion					
Bedside	40 (85.1)	85 (78.0)	0.306	R	R
Surgical	7 (14.9)	24 (22.0)		0.62	0.25- 1.56
Late presentation					
No	14 (77.8)	44 (69.8)	0.570	R	R
Yes	4 (22.2)	19 (30.2)		0.87	0.27- 2.78

Urgent start					
No	16 (66.7)	49 (70.8)	0.709	R	R
Yes	8 (33.3)	19 (29.2)		1.21	0.44- 3.30
Number of catheters					
1	34 (64.1)	88 (75.2)	0.138	R	R
≥2	19 (35.9)	29 (24.8)		1.69	0.84- 3.42
Peritonitis					
No	2 (4.9)	62 (72.1)	**<0.001**	R	R
Yes	39 (95.1)	24 (29.5)		50.38	11.27- 225.11

HR: hazard ratio; CI: confidence interval: R: reference group

Table 4: Multivariate analysis of risk factors associated with technique failure.

Characteristic	**OR**	**95%CI**	**P-value**
Age (years)	1.03	0.98- 1.08	0.245
Black ethnicity	6.43	1.58- 26.14	**0.009**
Occurrence of peritonitis	57.41	11.19- 294.70	**<0.001**

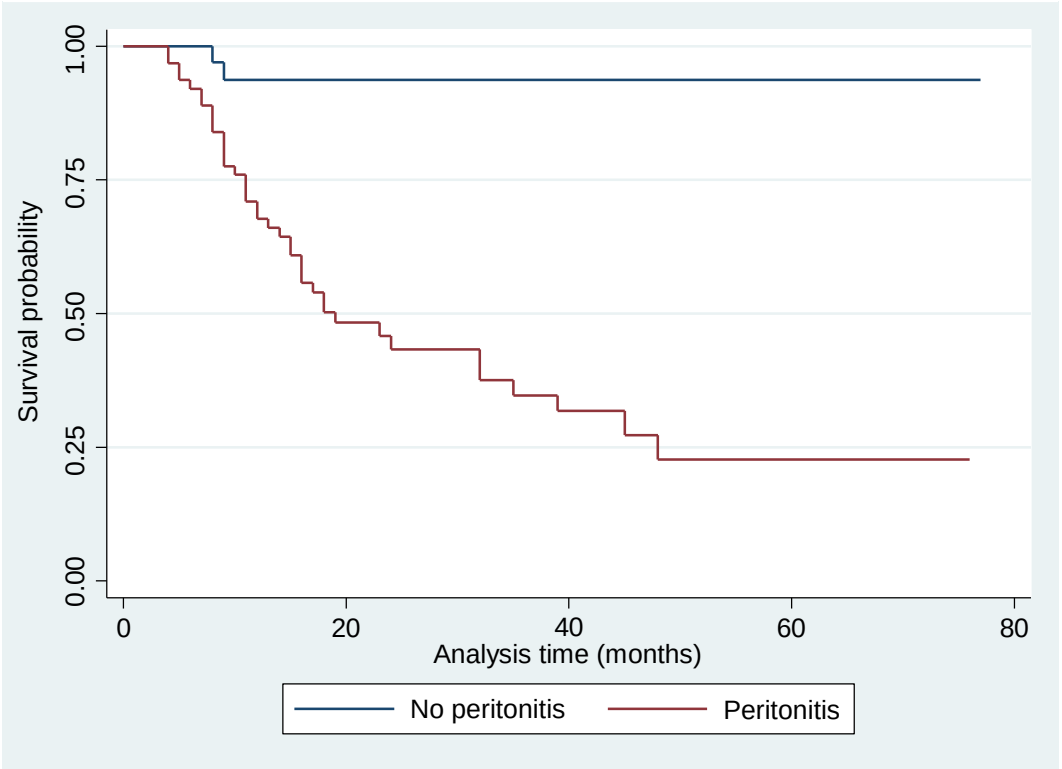

Figure 5: Technique survival by peritonitis (p<0.001).

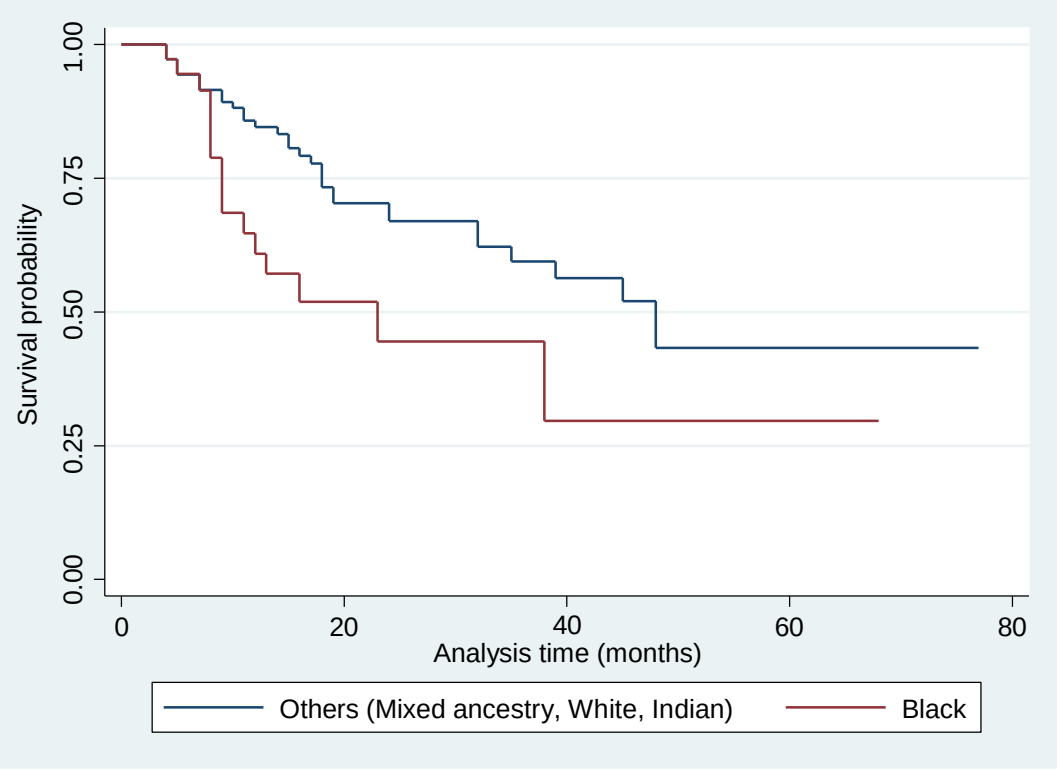

Figure 6: Technique survival by ethnicity (p= 0.017)

Twenty patients died during the period of follow-up, with cardiovascular disease and infection being the main causes of death. Six other patients on PD died at home and their cause of death was not ascertained (Table 5).

Table 5: Causes of technique failure and of death during the course of the study

Variable	Frequency	Percentage (%)
Technique failure (n=53)		
Peritonitis	38	71.6
Death due to PD related infection	6	11.3
Tunnel infection	2	3.8
Withdrawn due to non-compliance	2	3.8
Encapsulating peritoneal sclerosis	2	3.8
Calciphylaxis	1	1.9
Abdominal hernia	1	1.9
Recurrent outflow failure	1	1.9
Deaths (n=20)		
Cardiovascular	8	40.0

Infection	6	30.0
Other	6	30.0

Discussion

At Tygerberg Hospital the rate of technique survival at 1, 2, 3 and 5 years were 78.5%, 60.4%, 54.5% and 39.6% respectively. This is lower than those seen in countries such as China [28, 41- 43], Japan [44] and Canada [28] but similar to those reported from another South African centre [38] and a centre in Mexico [45]. See Table 6. We included all patients who were started on peritoneal dialysis and did not exclude those who had PD for less than three months as has been done in some studies. We considered it important to include the first few months on PD as positive interventions made during this period may improve overall outcomes.

Table 6: Summary of studies reporting technique survival in peritoneal dialysis

Study	Year	Country	N	Age	*DM	1 yr	2 yr	3 yr	5 yr
Present study	**2016**	**South Africa**	**170**	**36±11**	—	**78.5%**	**60.4%**	**54.5%**	**39.6%**
Isla [38]	2014	South Africa	152	36.8 ± 11.4	9.9%	83.3%	71.7%	—	62.1%
Yang [41]	2011	China	841	48.1±15.9	22.9%	98.0%	95.0%	91.0%	—
Fang *et al.* [28]	2008	China	240	54.4±16.2	12.9%	97.0%	93.0%	85.0%	88.0%
Wei Fang [42]	2013	China	339	55.4±17.2	23.3%	96.0%	94.0%	92.0%	82.0%
Zhang [43]	2014	China	712	52.0±19.3	15.7%	95.1%	—	87.7%	79.6%
Nakamoto [44]	2006	Japan	139	49.6±14.9	—	93.6%	86.4%	79.1%	68.2%
Fang [28]	2008	Canada	256	58.8±17.8	27.7%	92.0%	88.0%	85.0%	73.0%
Cueto-Manzano [45]	2001	Mexico	627	45.2±18.2	37%	82.0%	—	61.0%	40%
Shen [24]	2012	USA	1587	56.2±15.3	49%	80.2%	61.2%	45.2%	—

*DM, percentage of diabetic patients.

Peritonitis was the commonest cause of technique failure, in keeping with many other studies [31, 37, 45- 48]. This may explain our lower technique survival as compared to the Chinese, Japanese and Canadian studies where rates of peritonitis were low. Our patients were mostly switched to HD following recurrent episodes of peritonitis or upon finding a “frozen abdomen” with multiple adhesions on attempting to reinsert the PD catheter. Two patients developed encapsulating peritoneal sclerosis and were switched to HD.

Mechanical complications were a rare cause of technique failure. Most of our patients had bedside percutaneous insertion of their first Tenckhoff catheter. Subsequent catheters were inserted by the surgical team in theatre as well as first catheters in patients with previous abdominal surgery. There was no significant difference in technique survival based on the

method of the catheter insertion and we would recommend continuing bedside insertion for all suitable patients.

Black race was another risk factor for technique failure; this has been reported previously [24, 49]. In studies from the USA, the worst outcomes were seen in African-Americans [24, 49]. Poor compliance was more common in Black Americans [50] and was suggested as a reason for higher rates of technique failure [24,49]. In our study, non-compliance did not emerge as a major issue. In this study, it was not clear why black patients did poorly compared to mixed race patients and whites. However, it is possible that the home environment had a role to play in this outcome based generally on experience from interactions with patients in the PD clinic where most black patients tended to have poor family support and lacked privacy for PD exchanges at home in that there usually was no separate room reserved for PD exchanges that resulted in either contamination of the procedure or in patients deferring their PD exchanges. Interestingly, a study from the province of Limpopo in South Africa that predominantly included Black Africans had good technique survival rates despite the poor socio-economic circumstances of the patients [38].

In our study, too, educational status, housing and access to running water did not seem to influence technique survival. This is similar to the findings of Katz et al. [37] and Isla et al. [38] in other studies done in South Africa.

Other factors that have been noted to be associated with technique failure such as sex, age and diabetes mellitus were not independently associated with an increased risk of technique failure in our patients.

There were several limitations associated with our study. The retrospective study design meant that we had to contend with missing data and we have reported data from a single centre which necessarily limited the sample size.

Conclusion

In our cohort, Black race and the occurrence of peritonitis were important factors in the development of PD technique failure. Further studies are required to investigate the reasons for the increased rates of technique failure in our Black patients. Concerted efforts are needed to reduce peritonitis rates as this is the main cause of technique failure.

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