DURATION OF HEMODIALYSIS FOLLOWING PERITONEAL DIALYSIS CESSATION IN AUSTRALIA AND NEW ZEALAND: PROPOSAL FOR A STANDARDIZED DEFINITION OF TECHNIQUE FAILURE

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• Background: Although technique failure is a key outcome in peritoneal dialysis (PD), there is currently no agreement on a uniform definition. We explored different definitions of PD technique failure using data from the Australia and New Zealand Dialysis and Transplant (ANZDATA) Registry.

• *Methods:* We included 16,612 incident PD patients in Australia and New Zealand from January 1998 to December 2012. Different definitions of technique failure were applied according to the minimum number of days (30, 60, 90, 180, or 365) the patient received hemodialysis after cessation of PD.

♦ Results: Median technique survival varied from 2.0 years with the 30-day definition to 2.4 years with the 365-day definition. For all definitions, the most common causes of technique failure were death, followed by infectious complications. The likelihood of a patient returning to PD within 12 months of technique failure was highest in the 30-day definition (24%), and was very small when using the 180- and 365-day definitions (3% and 0.8%, respectively). Patients whose technique failed due to mechanical reasons were the most likely to return to PD (46% within 12 months using the 30-day definition).

• Conclusions: Both 30- and 180-day definitions have clinical relevance but offer different perspectives with very different prognostic implications for further PD. Therefore, we propose that PD technique failure be defined by a composite endpoint of death or transfer to hemodialysis using both 30-day and 180-day definitions.

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Peritoneal dialysis (PD) is an important means of renal replacement therapy used throughout the world. In particular, there has been an increasing use of PD in the developing world, with an estimated 2.5-fold increased prevalence from 1997 to 2008 (1). Unfortunately, the main limitations of PD relate to technique failure and infection, particularly PD-associated peritonitis (2–7).

Despite the many studies that have examined the determinants of technique failure, or have considered technique failure as an outcome, there is wide variation on the precise definition of technique failure in the existing literature (8). For instance, some studies have defined technique failure according to the minimum duration of temporary periods of hemodialysis, ranging from 30 to 90 days (2,5,9,10). Others have defined technique failure according to whether a patient had switched to hemodialysis by a specific time point, usually at 1, 2, or 3 years, regardless of how long the patient remained on hemodialysis (3,6,11,12). Censoring for death and renal transplantation have been treated inconsistently (13). With the wide variety of definitions, comparison of studies and provision of clear prognostic information to patients about likelihood of PD technique survival is unnecessarily complex.

Among patients receiving PD, it remains uncertain as to how long a period of interruption of PD and temporary hemodialysis transfer should define "technique failure." No matter what definition is used for technique failure, some patients will return to PD for a subsequent course (14). An appropriate balance in the duration of hemodialysis therefore must be struck.

The aim of our study was to determine an empirically justified definition of PD technique failure using registry data. We also propose a framework for future reporting and research.

SUBJECTS AND METHODS

STUDY POPULATION

The study included all Australian and New Zealand patients who commenced PD for the first time between 1 January 1998 and 31 December 2012. Follow-up was until the end of 2012.

DATA COLLECTION

Data for analysis were obtained from the Australia and New Zealand Dialysis and Transplant (ANZDATA) Registry, which collects data on all patients who commence renal replacement therapy in Australia and New Zealand. Details regarding the structure and method of collection have been described previously (15). The data obtained for analysis included demographic data, cause of primary renal disease, comorbidities at the time of commencement of PD, body mass index (BMI), date of renal replacement therapy modality transfer, reasons for transferring from PD to hemodialysis, and duration of treatment on the different renal replacement therapies.

Peritoneal dialysis and hemodialysis use were reported by the individual centers. For PD technique failure to have occurred, a patient had to have both a transfer to hemodialysis and then remain on hemodialysis for the required number of days depending on the definition being analyzed. For instance, when taking the 30-day definition, a patient had to be on hemodialysis for at least 30 days before being considered to have had a technique failure. A return to PD was taken as being any period of time the patient was transferred back to PD from hemodialysis.

Death (on PD or within the required number of days following a transfer from PD to hemodialysis) was considered a technique failure. Ceasing PD due to renal transplantation was not considered a technique failure and was censored in our analysis. Deaths occurring after transplantation were not included in the analyses. Patients were also censored at loss to follow-up, end of follow-up (31 December 2012) or recovery of native kidney function.

The reasons for technique failure were classified into 7 categories for analysis. These were: 1. Infection (caused by either acute, recurrent or persistent peritonitis; a tunnel or exit-site infection; or intra-abdominal infection e.g. diverticulitis); 2. Mechanical causes (caused by either a blocked PD catheter; dialysate leak; abdominal pain or surgery; hemoperitoneum; hernia; multiple adhesions; pleural effusion; scrotal edema; or other surgery); 3. Inadequate dialysis (caused by either inadequate solute clearance; inadequate fluid ultrafiltration; excessive fluid ultrafiltration; or poor nutrition); 4. Social reasons (this was a result of either patient preference; the patient being unable to manage self-care; or geography); 5. Encapsulating peritoneal sclerosis (EPS); 6. Death; and 7. Other reasons.

STATISTICAL ANALYSIS

Results were expressed as either mean ± standard deviation (SD) for continuous normally distributed data, or median and interquartile range (IQR) for continuous non-normally distributed data. Frequencies and percentages were used for categorical data.

The Kaplan-Meier method was used to estimate technique survival by definition, and compared using the log-rank test. A competing risk survival analysis was used to estimate the cumulative incidence of cause-specific technique failure.

Time to restarting PD after technique failure was assessed using a competing risks cumulative incidence function. The start point was calculated from the time the patient had been considered to have ceased PD for a sufficient enough time period to be classified as a technique failure. For example, using the 90-day definition, time to restarting PD was calculated from the zero time point of 90 days after previously changing from PD to hemodialysis until the time that PD restarted. This was used to assess each of the different definitions and repeated for each of the individual reasons for technique failure.

Analyses were conducted in Stata/IC version 12.0 (StataCorp LP, College Station, TX USA).

RESULTS

STUDY POPULATION

There were a total of 16,612 incident PD patients in Australia and New Zealand over the duration of the study period, with a total follow-up time of 68,589 patient-years. The baseline characteristics of these patients are shown in Table 1. Data

TABLE 1	
Baseline Characteristics of the Study	Population

Characteristic	All incident PD patients (n=16,612)
Age at PD start (years), median (IQR)	61 (48–70)
Male sex	9,348 (56%)
Race	
Caucasian	11,534 (69%)
Australian Indigenous	1,012 (6%)
NZ Indigenous / Pacific Islander	2,117 (13%)
Asian	1,631 (10%)
Other	318 (2%)
Primary renal disease	
Glomerulonephritis	4,321 (26%)
Analgesic nephropathy	472 (3%)
Polycystic kidney disease	893 (5%)
Reflux nephropathy	570 (3%)
Hypertension	2,195 (13%)
Diabetic nephropathy	5,532 (33%)
Other	1,645 (10%)
Uncertain	984 (6%)
Coronary artery disease	6,350 (38%)
Diabetes mellitus	6,880 (41%)
Peripheral vascular disease	4,168 (25%)
Cerebrovascular disease	2,445 (15%)
Late referral	3,758 (23%)

PD = peritoneal dialysis; IQR = interquartile range; NZ = New Zealand.

were complete, except for comorbidity data, missing in < 1% of patients.

TECHNIQUE SURVIVAL

Peritoneal dialysis technique survival for the population was similar between the definitions (Figure 1). There was a graded increase in median technique survival from 2.0 years for the 30-day definition to 2.4 years for the 365-day definition (p < 0.0001).

REASONS FOR TECHNIQUE FAILURE

The number of patients who suffered technique failure ranged from 10,274 to 11,467 according to the definition utilized (Table 2). The most common cause of technique failure, regardless of definition, was death. Technique failure due to mechanical reasons was more common when technique failure was defined by a shorter duration of hemodialysis (Figure 2), with mechanical reasons contributing 1,380 (12%) cases of

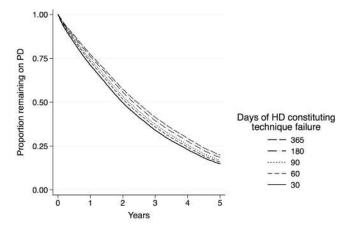


Figure 1 — PD technique survival after technique failure according to definition. The graph shows PD technique survival according to the different definitions of technique failure. PD = peritoneal dialysis; HD = hemodialysis.

technique failure when defined by being on hemodialysis for at least 30 days, compared with 853 (8%) cases of technique failure when defined by at least 180 days of hemodialysis. The

(a)

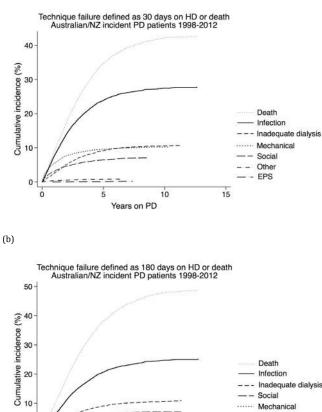


Figure 2 — Causes of PD technique failure for 30-day and 180-day

definitions. The graphs show the contribution of each of the causes of technique failure for the 30- and 180-day definitions over time. PD = peritoneal dialysis; HD = hemodialysis; NZ = New Zealand; EPS = encapsulating peritoneal sclerosis.

TABLE 2 Reasons for Technique Failure by Definition

	Definition				
	30 days	60 days	90 days	180 days	365 days
Reason for failure/cessation of PD	(<i>n</i> =11,467)	(<i>n</i> =11,217)	(<i>n</i> =11,037)	(<i>n</i> =10,695)	(<i>n</i> =10,274)
Death	4,535 (40%)	4,670 (42%)	4,788 (43%)	4,922 (46%)	4,954 (48%)
Infection	3,166 (28%)	3,104 (28%)	2,938 (27%)	2,677 (25%)	2,502 (24%)
Inadequate dialysis	1,206 (11%)	1,216 (11%)	1,206 (11%)	1,173 (11%)	1,083 (11%)
Mechanical	1,380 (12%)	1,070 (10%)	976 (9%)	853 (8%)	756 (7%)
Encapsulating peritoneal sclerosis	19 (<0.2%)	19 (<0.2%)	19 (<0.2%)	20 (<0.2%)	16 (<0.2%)
Social	907 (8%)	903 (8%)	890 (8%)	865 (8%)	819 (8%)
Other	115 (1%)	105 (1%)	100 (1%)	87 (1%)	78 (1%)
Not reported	139 (1%)	130 (1%)	120 (1%)	98 (1%)	66 (1%)

PD = peritoneal dialysis.

When looking at the cumulative incidence of the causes for technique failure within the different definitions at 1, 3, and 5 years, death and infection were the leading causes at all 3 timepoints (Table 3). Table 3 also showed that the incidence of mechanical reasons for technique failure fell as the duration of days required to be on hemodialysis increased. Inadequate dialysis and social reasons for technique failure were consistent along all the different definitions. Encapsulating peritoneal sclerosis (EPS) was of minimal significance. Cardiac death was the leading cause of death amongst all PD patients whose cause of technique failure was death, irrespective of definition.

LIKELIHOOD OF RETURNING TO PD AFTER TECHNIQUE FAILURE

The time to restarting PD after technique failure is shown in Figure 3. Twenty-four percent of patients who had technique failure defined by transferring to hemodialysis for at least 30 days returned to PD within 12 months. The percentage of patients returning to PD within 12 months after technique failure was found to be 17% and 11% for the 60-day and 90-day definitions, respectively. For the definitions requiring 180 or

Technique failure definition (minimum number of days		Technique failure cumulative incidence (%, 95% CI)		
spent on HD)	Cause of technique failure	1 year	3 years	5 years
30 days	Infection	8 (7, 8)	19 (18, 19)	24 (23, 25)
	Inadequate dialysis	3 (2, 3)	7 (7, 8)	9 (9, 10)
	Mechanical	5 (5, 6)	9 (8, 9)	10 (9, 10)
	EPS	<1 (0, <1)	<1 (0, <1)	<1 (0, <1)
	Social	3 (3, 3)	5 (5, 6)	6 (6, 7)
	Other	<1 (0, 1)	1 (1, 1)	1 (1, 1)
	Death	9 (9, 10)	25 (24, 26)	35 (34, 36)
60 days	Infection	7 (7, 8)	18 (17, 19)	24 (23, 24)
	Inadequate dialysis	3 (2, 3)	7 (7, 8)	9 (9, 10)
	Mechanical	4 (4, 4)	7 (6, 7)	8 (7, 8)
	EPS	<1 (0, <1)	<1 (0, <1)	<1 (0, <1)
	Social	3 (3, 3)	5 (5, 6)	7 (6, 7)
	Other	<1 (0, <1)	1 (1, 1)	1 (1, 1)
	Death	9 (9, 10)	26 (25, 26)	36 (35, 37)
90 days	Infection	7 (6, 7)	17 (16, 18)	22 (22, 23)
	Inadequate dialysis	3 (2, 3)	7 (7, 8)	9 (9, 10)
	Mechanical	4 (3, 4)	6 (6, 7)	7 (6, 7)
	EPS	<1 (0, <1)	<1 (0, <1)	<1 (0, <1)
	Social	3 (3, 3)	5 (5, 6)	6 (6, 7)
	Other	<1 (0, <1)	1 (0, 1)	1 (1, 1)
	Death	9 (9, 10)	26 (25, 27)	37 (36, 38)
180 days	Infection	6 (5, 6)	15 (15, 16)	21 (20, 21)
	Inadequate dialysis	2 (2, 3)	7 (7, 7)	9 (9, 10)
	Mechanical	3 (3, 3)	5 (5, 6)	6 (6, 7)
	EPS	<1 (0, <1)	<1 (0, <1)	<1 (0, <1)
	Social	3 (3, 3)	5 (5, 6)	6 (6, 7)
	Other	<1 (0, <1)	1 (0, 1)	1 (1, 1)
	Death	9 (9, 10)	27 (26, 27)	38 (37, 39)
365 days	Infection	5 (5, 6)	14 (14, 15)	20 (19, 20)
	Inadequate dialysis	2 (2, 2)	6 (6, 7)	9 (8, 9)
	Mechanical	3 (2, 3)	5 (4, 5)	5 (5, 6)
	EPS	<1 (0, <1)	<1 (0, <1)	<1 (0, <1)
	Social	3 (2, 3)	5 (5, 5)	6 (6, 7)
	Other	0 (0, 0)	0 (0, 1)	1 (0, 1)
	Death	9 (9, 10)	27 (26, 28)	39 (38, 40)

TABLE 3 Causes of PD Technique Failure for Different Definitions at 1, 3, and 5 Years

PD = peritoneal dialysis; HD = hemodialysis; CI = confidence interval; EPS = encapsulating peritoneal sclerosis.

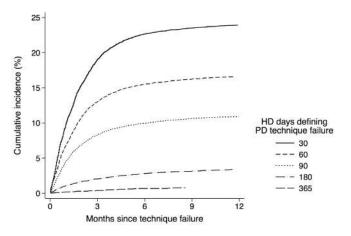


Figure 3 — Time to restarting PD after technique failure by definition. The graph shows the likelihood of patients returning to PD within 12 months according to the different definitions. Technique failure starts once the criterion for PD technique failure is reached (e.g. after 30 days on HD for the 30-day definition). PD = peritoneal dialysis; HD = hemodialysis.

365 days on hemodialysis, the patient's likelihood of returning to PD fell to 3% and 0.8%, respectively.

The likelihood of returning to PD was also assessed according to the cause of failure, as shown in Table 4. We found that patients whose technique failure was due to mechanical reasons were the most likely to return to PD within 12 months of suffering technique failure. Up to 46% of these patients returned to PD, depending upon the definition used for technique failure. Alternatively, patients who failed PD due to either inadequate dialysis or social reasons had < 10% likelihood of returning to PD within 12 months. As expected, no patients with technique failure due to EPS returned to PD.

DISCUSSION

Peritoneal dialysis technique failure is an important concept that requires a clear framework for use in both clinical practice and research. Presently, having at least 30 days of hemodialysis is most often used to define technique failure, and this is useful for assessing the burden of transfer to hemodialysis. However, our study showed that the likelihood of returning to PD after technique failure ranged from 0.8% to 24% depending upon the definition used, with the definitions requiring at least 180 or 365 days of hemodialysis being the least likely to return to PD. As such, different definitions appear to focus on different clinical aspects. We also found that after death, infection was the most likely cause of technique failure across all of the definitions, whilst patients who failed PD secondary to mechanical reasons were the most likely to return to PD within 12 months.

Our initial analysis included death as a cause of technique failure, and it was found to contribute to the cessation of PD in 40% to 48% of patients, depending upon the definition used. This is consistent with that found by Kolesnyk *et al.* who reported that death was the reason for PD discontinuation in 25% to 30% of their study population (7). In comparison, a number of other studies have censored for death when assessing technique failure (2,4,16). However, this has been identified as providing inflated risk event estimates (13,17), by leading to an overestimation of the risk of technique failure due to a cause other than death. Ideally, units should report technique failure (death plus other causes of technique failure), death-censored technique failure, and mortality to maximize the informativeness of their data and to permit adequate benchmarking between PD centers.

After death, infection was clearly the most common cause of technique failure within our study population, no matter which definition was applied. This is consistent with what has been shown previously in the literature from the United States (18,19), Asia (20), and Europe (7). Although studies have reported the increased mortality risk associated with peritonitis (21), the likelihood of returning to PD has not been reported until now.

Our study showed there to be both differences and similarities amongst the different PD technique failure groups. The proportion of deaths, as well as failures due to adequacy, infection, and social reasons, was similar by both temporal definitions and their cumulative proportions according to prior number of years on PD.

When assessing the likelihood of returning to PD after technique failure, we found a wide range in the likelihood of returning within 12 months, with very low likelihoods in 2 definitions, namely PD patients transferring and remaining on hemodialysis for at least 180 and 365 days. This implies that a return to PD should not be discounted for those who have ceased PD for shorter periods. There were also differences in this likelihood of return with different causes of technique failure. As expected, higher rates of return were seen among those with mechanical causes since these reasons (such as a blocked PD catheter) can be more easily addressed. These differences appeared to be modest.

For other major reasons for technique failure, namely inadequate dialysis and social reasons, the likelihood of patients returning to PD was relatively small across all the definitions. At the same time, a previous study examining which patient factors may predict a transfer from PD to hemodialysis found that patient factors were of limited clinical significance in predicting a transfer from PD to hemodialysis (22). These findings suggest that technique failure is not a homogenous outcome. Instead, it is dependent upon a wide range of factors, with the cause of failure being an important contributor. As such, it may not be appropriate to consider PD to have failed without considering the reason for hemodialysis transfer. Going further, the heterogeneity of technique failure makes any analysis very difficult. However, despite problems with accuracy and subjectivity, trying to better define technique failure should result in better understanding and better patient outcomes.

The main strengths of our analysis relate to the fact that it included all PD patients in Australia and New Zealand over a substantial period of time (1998 – 2012). By including a large

Technique failure definition (minimum number of days		Returning to PD (%, 95% CI)		
on HD)	Cause of technique failure	1 year	3 years	5 years
30 days	Infection	24 (23, 26)	25 (23, 26)	25 (23, 26)
	Inadequate dialysis	7 (5, 8)	7 (6, 9)	7 (6, 9)
	Mechanical	46 (43, 48)	46 (44, 49)	46 (44, 49)
	EPS	0	0	0
	Social	10 (8, 13)	11 (9, 13)	12 (9, 14)
	Other	25 (17, 33)	26 (18, 34)	26 (18, 34)
60 days	Infection	21 (19, 22)	21 (20, 23)	22 (20, 23)
	Inadequate dialysis	4 (3, 5)	5 (4, 6)	5 (4, 6)
	Mechanical	26 (24, 29)	27 (24, 29)	27 (24, 29)
	EPS	0	0	0
	Social	7 (5, 9)	8 (6, 10)	8 (6, 10)
	Other	15 (9, 23)	17 (10, 25)	17 (10, 25)
90 days	Infection	14 (13, 15)	15 (13, 16)	15 (13, 16)
	Inadequate dialysis	3 (2, 4)	4 (3, 5)	4 (3, 5)
	Mechanical	17 (15, 20)	17 (15, 20)	18 (15, 20)
	EPS	0	0	0
	Social	4 (3, 6)	5 (4, 7)	6 (4, 7)
	Other	11 (6, 19)	13 (7, 21)	13 (7, 21)
180 days	Infection	4 (3, 5)	5 (4, 5)	5 (4, 6)
	Inadequate dialysis	2 (1, 3)	2 (1, 3)	2 (1, 3)
	Mechanical	5 (21)	5 (4, 7)	5 (4, 7)
	EPS	0	0	0
	Social	2 (1, 3)	3 (1, 4)	3 (2, 4)
	Other	7 (2, 14)	7 (2, 14)	7 (2, 14)
365 days	Infection	1 (1, 2)	1 (1, 2)	2 (1, 2)
	Inadequate dialysis	0 (0, 1)	1 (0, 1)	1 (0, 1)
	Mechanical	1 (0, 2)	1 (0, 2)	1 (1, 2)
	EPS	0	0	0
	Social	1 (0, 2)	2 (1, 3)	2 (1, 4)
	Other	2 (0, 8)	2 (0, 8)	2 (0, 8)

 TABLE 4

 Percentage Returning to PD after Technique Failure at 1, 3, and 5 Years

PD = peritoneal dialysis; HD = hemodialysis; CI = confidence interval; EPS = encapsulating peritoneal sclerosis.

number of centers over 2 countries, we were able to capture a wide variety of clinical practices, improving the external validity of our results. However, these strengths should be balanced against the study's limitations. As with any registry study, it is subject to possible classification/coding bias. Additionally, as it does include a large number of centers, the practice of returning patients back to PD may not be uniform, and the generalizability of the results to global PD population may be limited due to the fact that only PD patients from Australia and New Zealand were analyzed.

CONCLUSIONS

The data from our study suggest that patients who receive a minimum of 180 days of hemodialysis are very unlikely to return to PD (i.e. 3% chance of returning to PD within the next 12 months), making this a potentially useful definition of "permanent" technique failure. However, such a definition would not be appropriate from a clinical practice perspective, given the patient and resource implications of hemodialysis for this period. Additionally, the definition involving a minimum of 30 days of hemodialysis is more able to capture PD peritonitis episodes and other intercurrent problems that require conversion to hemodialysis and likely removal and reinsertion of PD catheters. We therefore propose a framework for a standardized definition of PD technique failure incorporating three components:

- 1) Reporting of technique failure using both 30-day and 180day definitions.
- 2) Use of a composite endpoint (transfer to hemodialysis or death). Death-censored technique failure should be separately reported, clearly specified as such, and analyzed using competing risk methodologies.

TABLE 5 Proposed Standardized Approach for Defining and Analyzing PD Technique Failure According to the 30-Day Criterionª

Event	Counts as a technique failure event?	For time to technique failure analysis, PD duration extends from start of PD until date of:
 Transferred from PD to HD for ≥30 days	Yes	HD commencement
Death while on PD	Yes	Death
Death within 30 days of transfer from PD to HD	Yes	HD commencement
Transplant while on PD	No	Transplant
Transplant within 30 days of transfer from PD to HD	No	HD commencement
Lost to follow-up while on PD	No	Last follow-up
Lost to follow-up within 30 days of transfer from PD to HD	No	HD commencement
Renal recovery while on PD	No	Last PD
Renal recovery within 30 days of transfer from PD to HD	No	HD commencement
End of study / audit period while on PD	No	End of study / audit period
End of study / audit period within 30 days of transfer to HD	No	HD commencement

PD = peritoneal dialysis; HD = hemodialysis.

^a A similar approach would be used for the 180-day criterion, except that the minimum period on hemodialysis would be 180 days instead of 30 days.

3) Reports of technique failure should specify whether they include only incident patients (undergoing their first episode of PD), as was the case in the present study, or all patients undergoing PD (irrespective of previous PD exposure).

With this framework in mind, our proposed standardized approach for defining and analyzing PD technique failure according to the 30-day criterion is presented in Table 5.

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