OUTCOME COMPARISONS BETWEEN PATIENTS ON PERITONEAL DIALYSIS WITH AND WITHOUT POLYCYSTIC KIDNEY DISEASE

A Nationwide Matched Cohort Study

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Abstract: Polycystic kidney disease (PCKD) is the most common hereditary cause of end-stage renal disease. The complications associated with this disease may affect the performance of peritoneal dialysis (PD). The aim of this study was to compare the outcomes between patients on PD with PCKD and without PCKD.

We extracted an incident cohort of adult (≥20 years old) patients on long-term PD from the Taiwan National Health Insurance Research Database. Patients with PCKD were identified by specific diagnosis codes. We recorded baseline comorbidities, socioeconomic status, timing of referral to a nephrologist, prior hemodialysis history before PD, and the type of PD modalities. We compared the risk of death, technique failure, peritonitis, hospitalization, and outpatient visiting as well as overall medical expenditure between the patients with PCKD and a group of patients without PCKD who were propensity-score matched (1:3). The analysis was carried out by various Cox regression models that considered competing risk and time-varying coefficients.

We enrolled 139 patients with PCKD and 7739 patients without PCKD who started long-term PD between 1999 and 2010. Patients with PCKD were less comorbid and more often treated with automated PD. In the propensity-score matched analysis, both overall survival and technique survival did not differ between the patients and the result was similar after adjusting for comorbidity and peritoneal dialysis type. Furthermore, the overall annual medical expenditures were similar between the patients with and without PCKD. PD patients with PCKD are comparable to PD patients without PCKD in terms of risk of death, peritonitis, technique failure, and hospitalization in the present study. Furthermore, the medical expenses of the 2 groups after initiation of PD are also indistinguishable.

INTRODUCTION

Polycystic kidney disease (PCKD) is the fourth leading cause of end-stage renal disease (ESRD) worldwide. The disease results in enlarged kidneys as well as various intra-abdominal complications, such as cystic rupture, cyst infection, diverticulitis, and abdominal wall hernia. Therefore, there are concerns about the applicability of peritoneal dialysis (PD) when patients have PCKD. However, PD is not a rare option for patients with PCKD. Up to 15% of PCKD patients chose PD as their dialysis modality in the United States, compared to 7.4% among the whole kidney replacement population.

Previous studies have not detected any significant difference regarding overall survival, technique survival, and risk of peritonitis when PD patients with PCKD and without PCKD are compared. However, most studies involved only small sample sizes or explored limited parameters and outcome measurements. In addition to the risks of death, technique failure, and peritonitis, patients with PCKD might suffer from other PD related complications that increase medical resource consumption and impair their quality of life. Thus there is a need to include more outcome measurements when evaluating whether patients with PCKD are able to tolerate PD to the same extent as non-PCKD patients.

Taiwan launched its National Health Insurance (NHI) program in 1995. Around 90% of all healthcare organizations in Taiwan provide healthcare in the NHI, and nearly all residents of Taiwan are protected under the NHI. The Taiwan National Health Interview Survey data reveal that there is some NHI care to almost every outpatient visit and each hospital stay. Since the launch of NHI, the NHI Administration (NHI) has been the single buyer. Almost all patients with ESRD in Taiwan have access to the NHI program. The Taiwan National Health Insurance Research Database (NHIRD) is a reliable data resource.
that allows rigorous investigation of outcomes among patients with ESRD. We built a national PD subcohort from the NHIRD and compared comprehensive outcomes between patients undergoing PD with PCKD and without PCKD.

**METHODS**

**Data Source and Quality**

The NHIRD contains deidentified registration files and origin claim data for reimbursements from the Taiwan NHI program. For a project on diseases in kidneys and the brain, the National Health Research Institutes (NHRI) of Taiwan have used the NHIRD to construct a cohort of 2 million patients who ever used dialysis care, or ever had major diagnoses on chronic kidney disease (CKD), acute kidney injury (AKI), or severe neurological diseases between 1997 and 2011. To comply with an NHIA policy that regulates the maximal proportion of data extracted from the population data, the NHRI set the number of patients at 2 million. The cohort is a random sample from all individuals having aforementioned conditions or diagnoses, and the sampling fraction was 71%. Each patient’s longitudinal registration and claims data for 1997 to 2011 were collected.

The quality of NHI data has been recognized, and the data have been used in many projects on clinical epidemiology and health services research.9 The reliability of NHI data has been demonstrated in a body of literature on validation of specific disease diagnoses in the NHI data.8,10,11 Because the NHIA has an auditing system for preventing fraud, the quality of NHI records is also guaranteed in regard to expensive procedures and health services, as well as medications.12 The NHIA also operates an auditing system for the NHI catastrophic illness registry system, because enrollees in this special system receive additional benefits in healthcare.

**Study Population**

On the basis of the cohort with 2-million patients, we further constructed a sample for the study, starting from extracting patients ever using PD care. Adult patients (≥20 years old) who initiated PD for more than 3 months between 1999 and 2010 were included such that there was at least 1-year observation after dialysis started and at least 2-year observation before dialysis started for each patient.

We identified PCKD patients registered on the catastrophic illness system with the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code 753.1X (cystic kidney disease). Since patients with PCKD are eligible but do not necessarily register on catastrophic illness system in Taiwan, we also defined PCKD patients using the specific ICD-9-CM codes 753.12 (polycystic kidney, unspecified type) or 753.13 (polycystic kidney, autosomal dominant) based on at least 3 outpatient claims or at least 1 inpatient claim between 1997 and 2011.

We conducted propensity-score (PS) matched cohort study to adjust for different distributions of baseline characteristics between PD patients with and without PCKD. All available predictors (Table 1) were used to calculate the PS. For each PD

| TABLE 1. Baseline Characteristics of Patients With Polycystic Kidney Disease (PCKD) and Propensity-Score Matched Patients Without Polycystic Kidney Disease |
|---------------------------------|---------------------------------|----------------|
| **PCKD (n = 139)**              | **Non-PCKD (n = 417)**          | **P-Value**    |
| Age, years, mean (STD)          | 53.4 (14.7)                     | 53.8 (14.7)    | 0.78 |
| Male, n (%)                     | 72 (51.8)                       | 229 (54.9)     | 0.49 |
| Comorbidity index, mean (STD)   | 2.9 (1.4)                       | 3.0 (1.4)      | 0.50 |
| Late referral to a nephrologist, n (%) | 23 (16.6)                   | 69 (16.6)      | 1    |
| Prior hemodialysis history, n (%) | 76 (54.7)                      | 207 (49.6)     | 0.28 |
| Economic status                 |                                |                |      |
| Low                             | 52 (37.4)                       | 156 (37.4)     | 0.96 |
| Intermediate                    | 83 (59.7)                       | 250 (60.0)     |      |
| High                            | 4 (2.9)                         | 11 (2.6)       |      |
| Institute level                 |                                |                |      |
| Medical center                  | 101 (72.7)                      | 298 (71.5)     | 0.53 |
| Metropolitan hospital           | 34 (24.5)                       | 99 (23.7)      |      |
| Others                          | 4 (2.9)                         | 20 (4.8)       |      |
| Comorbidity                     |                                |                |      |
| Hypertension                    | 99 (71.2)                       | 305 (73.1)     | 0.66 |
| Diabetes                        | 19 (13.7)                       | 69 (16.6)      | 0.25 |
| Coronary artery disease         | 21 (15.1)                       | 67 (16.1)      | 0.78 |
| Cerebral vascular disease       | 2 (1.4)                         | 7 (1.7)        | 0.85 |
| Heart failure                   | 15 (10.8)                       | 53 (12.7)      | 0.52 |
| Arrhythmia                      | 13 (9.4)                        | 34 (8.2)       | 0.65 |
| Valvular heart disease          | 4 (2.9)                         | 12 (2.9)       | 1    |
| Peripheral vascular disease     | 2 (1.4)                         | 10 (2.4)       | 0.49 |
| Chronic obstructive pulmonary disease | 7 (5.0)                       | 18 (4.3)       | 0.71 |
| Chronic liver disease           | 20 (14.4)                       | 68 (16.3)      | 0.58 |
| Gout                            | 42 (30.2)                       | 149 (35.7)     | 0.17 |
| Dyslipidemia                    | 21 (15.1)                       | 60 (14.4)      | 0.82 |
| Cancer                          | 4 (2.9)                         | 11 (2.6)       | 0.88 |

PCKD = polycystic kidney disease.
patient with PCKD, we randomly selected 3 PS-matched PD patients without PCKD.

**Study Outcomes**

The primary outcome of interest was mortality. The date of death was defined using the records in the registry of catastrophic illness or based on the discharged status (death or critically ill discharge). Lost to follow-up was identified if there was neither a registry record nor a claim record for more than 1 year. Patients were censored after they had undergone a successful renal transplantation, when they were lost to follow-up or on December 31, 2010.

The secondary outcomes included peritonitis free survival (considering only first episode of peritonitis), peritonitis rate (taking recurrent events into consideration), technique survival (defined by undergoing maintenance hemodialysis for at least 60 days after discontinuation of PD), hospitalization rate, frequency of nondialysis outpatient visits, incidence of abdominopelvic hernia requiring surgical intervention, and incidence of subarachnoid hemorrhage (SAH). We defined a PD peritonitis episode by excluding concurrent diagnosis of hallow organ perforation or obvious focus of intraabdominal inflammation. At least 2 eligible diagnoses of peritonitis on different days within 14 days were requisite if the patient was not hospitalized for the peritonitis. In addition, if 2 episodes of peritonitis occurred within 30 days, we defined them as the same single episode. We further probed into the severity of the peritonitis, which was indicated by a requirement for transient hemodialysis, by a requirement for hospitalization and by the 30-day mortality rate after peritonitis.

To further address issues on healthcare costs, which are usually major concerns for policy makers, we calculated the average annual expenditure of each patient after the initiation of dialysis according to the payment schedule of the NHI global budgeting system based on the Consumer Price Index of Taiwan. All expenditures were expressed in Taiwan dollars based on the value on the December 31, 2013 when the exchange rate to 1 US dollar was 29.997.

**Candidate Predictors**

The definition of the covariates was consistent with our previous work. Age, sex, socioeconomic status (SES), and hospital levels were defined by the registry data during the 6 months from the initiation of PD. Late referral to a nephrologist was defined if the duration between the first nephrologist visiting to dialysis was less than 180 days. We also identified if a patient had undergone hemodialysis before the initiation of PD. Comorbidity status and the Deyo’s Charlson comorbidity index were defined by the claims data over the 2 years before the initiation of dialysis.

Since the application of automated PD (APD) is time varying, we defined APD users as ever users, initial users (prescription of APD within 90 days of initiating PD), and constant users (prescription of APD more than 50% PD periods).

**Statistical Analysis**

In order to compare continuous variables t tests and Wilcoxon signed-rank tests were used before and after matching. We used Chi-square tests or Fisher exact tests (when the expected number were small) to compare the proportions of nominal variables. Cochran–Mantel–Haenszel (CMH) test were applied to compare categorical variables after matching.

Analyses were done both on an “in intention to treat” basis (regardless of whether or not a patient switched dialysis modality during the followed period) and by considering a modality switch to bring about censoring, except when there was technique failure and/or peritonitis ( censoring modality switch only).

The association between potential risk factors and event-free survival were evaluated by Cox regression analysis. Death was treated as a competing risk with respect to other than mortality or hospitalization. Since those patients with PCKD died after at least 1 episode of hospitalization, we could not fit the competing risk model successfully while analyzing risk of hospitalization. In the other way, a condition leading to death would be indicated for hospitalization in case timely before death happened. Therefore, we treated death as an event while analyzing risk of hospitalization.

Negative binomial models were applied to estimate the relative risk for all episodes of hospitalizations and peritonitis. Unadjusted and multivariable-adjusted hazard ratios (HRs), risk ratios (RR), or subdistribution HR (SHR) and corresponding 95% confidence intervals (CIs) for each outcome are reported. In cases where the assumption of proportional SHR was violated, we divided each patient’s total length of follow-up into 2-year or shorter periods (with each patient’s last period being shorter than or equal to 2-year long), and generated multiple records for each patient in order to further conduct competing-risks regression using time-varying SHR.

All analyses were performed using SAS 9.3 software (The SAS Institute, Inc., Cary, NC) and Stata Version 13 (StataCorp, College Station, TX). This work was approved by the Institutional Review Board of National Taiwan University Hospital (20131107RINC).

**RESULTS**

The process used to establish the subcohorts is shown in Figure 1. A total of 8176 patients started long-term PD between 1999 and 2010, among which 234 (2.9%) patients were excluded because they started dialysis at age younger than 20 years old or with missing data for sex or birth date. Another 10 patients were excluded due to ever being coded eligible ICD-9 for less than 3 outpatient claims. The final 2 subcohorts consisted of 139 PD patients with PCKD and 7793 PD patients without PCKD.

The average age of the PD cohort was 54.1 ± 15.1 years, of which 44.8% were male. Characteristics of the 2 study populations are shown in Appendix, http://links.lww.com/MD/A536. Compared to patients without PCKD, PD patients with PCKD had lower comorbidity index and less late referral to a nephrologist. Most patients with PCKD received PD at medical centers. Otherwise the patients forming the 2 groups had similar distributions in terms of age, sex, economic status, and a prior hemodialysis history. There was no significantly different baseline characteristic between patients with PCKD and the PS-matched patients without PCKD (Table 1).

The risks of mortality and of technique failure were similar between the patients with PCKD and the PS-matched patients without PCKD (Figs. 2 and 3). As the assumption of proportional subhazards failed for the analyses of technique failure and of peritonitis (Figs. 3 and 4), we used estimated models to obtain time-varying subhazard ratios, which allowed each 2-year period having a separate subhazard ratio. The results (Appendix, http://links.lww.com/MD/A536) indicate that PCKD patients had comparable risk of peritonitis and technique
failure to non-PCKD patients during each periods. Furthermore, the proportion of patients experienced peritonitis and severity of peritonitis did not differ between patients with PCKD and the matched patients without PCKD (Table 2).

The risk of hospitalization was similar for the patients with PCKD and the PS-matched patients without PCKD, regardless of when the first episode of hospitalization took place (Fig. 5) or the patient undergoing recurrent hospitalizations (Table 3). We did not find any significant difference in the risk of developing a hernia requiring surgical intervention between the 2 groups using the PS-matched analysis. As expected, the risk of SAH was higher for patients with PCKD (Table 3). The 2 groups also showed similar rates of nondialysis outpatient visits as well as similar levels of medical expenditure (Table 3).

As expected, patients with PCKD were more often treated with APD to reduce intraabdominal pressure (Table 4). Estimates of risks for death, technique failure, peritonitis, and hospitalization after additionally adjusted for APD users did not materially change.

**DISCUSSION**

This is the first population-based study focusing on outcomes comparison between PD patients with and without PCKD. Our findings are in agreement with previous comparisons that involved single centers in terms of similar risks for mortality, peritonitis, and technique failure between the 2 groups. We further demonstrate statistically indistinguishable risks for hospitalization and medical resource consumptions between the patients with and without PCKD.

Due to the higher risk among patients with PCKD of colonic diverticulitis, of the rupture of cysts and of cystic infection, a higher peritonitis rate would be expected among PCKD patients on PD. Recent observational cohort studies using traditional
FIGURE 2. Survival curves for patients on peritoneal dialysis with polycystic kidney disease and without polycystic kidney disease. Panel A: Intention to treat (test for proportional hazard assumption: 0.16, \( P \)-value for log-rank test: 0.74). Panel B: Modality switch as censor (test for proportional hazard assumption: 0.11, \( P \)-value for log-rank test: 0.83).
TABLE 2. Risk of Peritonitis for Polycystic Kidney Disease Patients and Propensity-Score Matched Nonpolycystic Kidney Disease Patients on Peritoneal Dialysis (Censoring Modality Switch)

|                                | PCKD (n = 139) | Non-PCKD (n = 417) | P-Value |
|--------------------------------|----------------|--------------------|---------|
| Peritonitis cases              | 49 (35.3)      | 133 (31.9)         | 0.47    |
| Peritonitis episodes           | 76             | 203                |         |
| Peritonitis rates, mean, per person-year | 0.19 | 0.17 |         |
| SHR for first episode of peritonitis\(^1\) | 1.10 (0.78–1.55) | Reference | 0.60    |
| RRR for peritonitis\(^1\)     | 1.06 (0.75–1.51)| Reference         | 0.73    |
| Severe peritonitis episodes, n (%) |                   |                    |         |
| Transient or permanent hemodialysis | 13 (17.1)     | 36 (17.7)          | 0.90    |
| Intensive care unit            | 4 (5.2)        | 9 (4.4)            | 0.76    |
| Hospitalization                | 45 (59.2)      | 119 (58.6)         | 0.93    |
| Hospitalization > 30 days      | 7 (9.2)        | 13 (6.4)           | 0.42    |
| 30 days mortality after peritonitis | 3 (4.0)      | 7 (3.5)            | 0.84    |
| Technique failure after peritonitis | 8 (10.5)     | 19 (9.4)           | 0.77    |

PCKD = polycystic kidney disease, RRR = relative risk ratio, SHR = subdistribution hazard ratio.
\(^1\) P-value equals to 1.
FIGURE 5. Survival curves with respect to the incidence of the first episode of hospitalization among polycystic kidney disease and nonpolycystic kidney disease patients on peritoneal dialysis. Panel A: Intent to treat (test for proportional hazard assumption: 0.30; death was considered as an event, $P$-value for log-rank test: 0.52). Panel B: Modality switch as censor (test for proportional hazard assumption: 0.33; death was considered as an event, $P$-value for log-rank test: 0.43).
proportional hazard regression have not found there to be different risks of peritonitis among patients on PD with and without PCKD. However, the risk ratio for PD peritonitis between patients with and without PCKD might be not proportional, as what was observed in our case (Fig. 4). It is possible that the mechanisms associated with peritonitis are different among the patients with PCKD and without PCKD, thus the risk ratio for peritonitis varies between the groups in a time-dependent manner. The specific etiologies and timing of peritonitis among patients with PCKD deserve further investigation.

Most literature identified a survival benefit to patients that occurred after starting dialysis among patients with PCKD; however, recent studies that have focused on the patients receiving PD did not demonstrate similar survival superiority. However, the risk ratio for PD peritonitis between patients with and without PCKD might be not proportional, as what was observed in our case (Fig. 4). It is possible that the mechanisms associated with peritonitis are different among the patients with PCKD and without PCKD, thus the risk ratio for peritonitis varies between the groups in a time-dependent manner. The specific etiologies and timing of peritonitis among patients with PCKD deserve further investigation.

In addition to mortality, technique survival, and the risk of peritonitis, it is of concern that patients with PCKD may have a higher chance of developing other PD related complications, especially those related to increased intraabdominal pressure. In our subcohorts, the risk of suffering from a hernia that requires surgery was similar between the patients with and without PCKD. Furthermore, the patients with PCKD did not consume more medical resources, which was supported by indistinguishable hospitalization risks, outpatient visit frequencies, and overall annual medical expenditure after initiation of PD. Based on the above findings, it is possible to speculate that PD patients with PCKD are able to tolerate PD as well as PD patients without PCKD.

### Table 3. Other Outcomes Comparison Between Polycystic Kidney Disease and Propensity-Score Matched Nonpolycystic Kidney Disease Patients on Peritoneal Dialysis

|                | PCKD (n = 139) | Non-PCKD (n = 417) | P-Value |
|----------------|---------------|-------------------|---------|
| Transplantations | 13 (9.4)      | 41 (9.8)          | 0.87    |
| Technique failure | 34 (24.5)    | 94 (22.5)         | 0.64    |
| Intention to treat analysis |           |                   |         |
| Median followed years, median | 2.7 (1.2–5.3) | 2.8 (1.3–5.1) | 0.79    |
| Hernia requiring surgical intervention | 10 (7.2)     | 33 (7.9)          | 0.78    |
| Subarachnoid hemorrhage | 3 (2.2)       | 2 (0.5)           | 0.10    |
| Hospitalization cases | 110 (79.1)   | 308 (73.9)        | 0.20    |
| Crude hospitalization rates, median, per person-year | 2.2 (0.4–10.3) | 1.6 (0–6.2) | 0.25    |
| HR for first episode of hospitalization | 1.07 (0.86–1.33) | Reference | 0.53    |
| RRR for hospitalizations | 1.23 (1.00–1.52) | Reference | 0.05    |
| Rate for non-dialysis outpatient visits, mean (STD), per person-year | 22 (14) | 21 (14) | 0.48    |
| Medical expense (1000 NTS/py), median (Q1–Q3) | 595 (503–717) | 585 (504–692) | 0.42    |

### Table 4. Applications of Automatic Peritoneal Dialysis Among Patients With and Without Polycystic Kidney Disease

|                | APD Ever Users | APD Initial Users | APD Constant Users |
|----------------|---------------|-------------------|--------------------|
| PCKD (N = 139) | 65 (46.8%)    | 37 (26.6%)        | 26 (18.7%)         |
| Non-PCKD (N = 7793) | 2929 (37.6%) | 1785 (22.9%)    | 914 (11.8%)        |
| P value | P = 0.03 | P = 0.3 | P = 0.01 |
| Matched non-PCKD (N = 417) | 169 (40.5%) | 93 (22.3%) | 43 (10.3%) |
| P-value | P = 0.20 | P = 0.30 | P < 0.01 |

APD = automated peritoneal dialysis, PCKD = polycystic kidney disease.
The strengths of this study include comprehensive pre-dialysis and postdialysis medical resource information that was obtained from a reliable national database; this has allowed adjustments of plenty confounding factors and assessment of multidimensional outcomes. The cohort is representative with a sampling fraction as high as 71%. There is a significant selection bias between patients with and without PCKD, thus we applied PS-matched analysis. Compared to PD patients without PCKD, the PD patients with PCKD had lower comorbidity index “before” match. After PS matching, the comorbidity index and other baseline characteristics are similar between the patients with PCKD and their matches (Table 1). In addition, we applied Cox regression with competing risk and/or time-varying coefficients in order to deal with the distinctive features of the different clinical outcomes. Although NHI data do not contain direct information about quality of life, we used hospitalization and prescription of psychological medications as surrogate indicators.

FIGURE 6. Subgroup analysis by incident year.
However, there are inherent limitations to the use of administrative data such as that used in the present study. Laboratory results are not available from the NHIRD thus the diagnosis of PCKD or other events of interest rely only on ICD-9-CM diagnosis and procedure codes. We could not measure quality of life or adjust for certain well recognized parameters such as kidney size, residual renal function, dialysis adequacy, serum albumin level, or nutritional index. Details of PD regimen regarding filling volumes, total volumes, or dwell time are lacking in the registry. Certain time varying variables, such as APD users, were difficult to be attributed adequately. There might be still significant differences between groups regarding unmeasured covariates. Further probing into the causes of mortality, technique failure, and leading pathogens of peritonitis was also limited by the contents of the dataset. The stringent criteria to identify PCKD may have introduced under-reporting bias. Using the same algorithm, the prevalence of PCKD among the incident ESRD cohort in Taiwan is 1.9%. Furthermore, we observed only those patients who underwent PD successfully for 3 months or longer. It might raise a concern that PD technique failure in the first 3 months due to complications of raised intraabdominal pressure may be higher in patients with PCKD.

In conclusion, differences regarding risks of death, peritonitis, and technique failure were not proven to be significant between PD patients with PCKD and without PCKD in the present study. The hospitalization rate, nondialysis outpatient visit frequency, and overall annual medical expense of the patients with PCKD after initiation of PD are indistinguishable to those of patients without PCKD.

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