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Health Policies on Dialysis Modality Selection

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Abstract

Objectives: In Taiwan, end stage renal disease (ESRD) patients can freely select the dialysis modality they wish to receive. However, the utilization of peritoneal dialysis (PD) is considered to be low in Taiwan. Since 2005, four major policies have been implemented in Taiwan by the health department: (1) multidisciplinary pre-ESRD education, (2) insurance reimbursement for the rental of automated peritoneal dialysis (APD) machines, (3) insurance reimbursement for icodextrin dialysate, and (4) endorsement of PD promotion to meet hospital accreditation regulation. The effect of these policies on dialysis modality selection is currently unknown.

Setting: We analyzed data stored in the Taiwan Renal Registry Data System (TWRDS) from 2006 to 2013 focusing on PD incidence by time period stratifying the results by age, sex, or diabetes to illustrate the impact of these four policies on dialysis modality selection.

Participants: There were 115,565 patients were enrolled in this study during the period from 2006 to 2013.

Results: The mean age of hemodialysis patients who entered in the Taiwan dialysis program was 64.7 ± 13.7 years, nearly 10 years older than the mean age of PD patients, which was 54.6 ± 15.7 years. Diabetes prevalence in ESRD patients was 45%. After stratifying PD incidence by age, sex, and diabetes, the results demonstrated that PD incidence has increased since 2006 because of the effect of the four health policies listed above but decreased in 2010 because hospital accreditation was repealed in 2010.

Conclusions: Hospital accreditation for PD promotion had the greatest impact on PD as a dialysis modality selection verifying that health policy greatly affects the selection of dialysis modalities.

Article summary:

Strengths and limitation of this study:

Strengths: We used a long-term, national-wide population based ESRD registry system to report that dialysis modality selection was affected by health policy.

Limitation: no discussion about technique failure in PD patients because we omitted those who shifting treatment modality from PD to HD.

Bullet points:

- 1. In Taiwan, ESRD patients are freely to choose their dialysis modality (HD or PD)
- 2. However, the penetration of PD in Taiwan is less than 10% of overall ESRD patients.
- 3. The Taiwan government took four health policies to increase PD selection from 2006-2010.
- 4. There are four health policies for promoting PD; multidisciplinary CKD care unit; reimbursement of Icodextrin (a new PD dialysate); free access to automated PD system; and hospital accreditation.
- Among the four health policies for promoting PD, hospital accreditation is the most powerful one.

Keywords: Accreditations; Dialysis; Health policies; Health insurance reimbursement; Peritoneal dialysis; End Stage Renal Disease; Hemodialysis; Automated Peritoneal Dialysis; Taiwan

Introduction

The increasing number of people with end stage renal disease (ESRD) is a considerable burden on the Taiwanese government. According to the U.S. Renal Data System annual report, the prevalence and incidence of ESRD was the highest in Taiwan as compared with that in other countries. The health expenditure for ESRD patients consisted of 6% of the total annual National Health Insurance (NHI) budget and benefitted 0.3% of the total Taiwanese population with advanced renal replacement therapy (RRT) by receiving either hemodialysis (HD) or peritoneal dialysis (PD).

In Taiwan, HD was first administrated in 1963 while PD was first administered in 1984. The Taiwanese government has provided global coverage of dialysis costs for every citizen since 1995. At present, the number of dialysis facilities (HD or PD) is sufficient for providing quality dialysis to ESRD patients in Taiwan where patients freely select the dialysis modality they wish to receive. The spread of PD remained below 10% in 2005 with inadequate patient education being held responsible for this low pick-up rate because it is essential for ESRD patients to know all current RRT modalities available with patient-centered care. Several therapy barriers, such as peritoneal membrane longevity and hypoalbuminemia, are encountered while administering PD; this necessitates favorable health-care policies ¹ and integrated health resources to increase PD selection. ³.

Administrative interventions, such as the "PD first" policies in Thailand ⁴ and Hong Kong ⁵, are highly influential in medical practice. In Taiwan, the four following policies proposed by the Ministry of Health and Welfare concerning modality selection were implemented to increase the proportion of patients receiving PD therapy: (1) Promotion of setting multidisciplinary care (MDT) units in health care

institutes for chronic kidney disease (CKD) patients, providing more medical knowledges for PD therapy (2006), (2) Inclusion of increase PD prevalence and incidence in individual hospitals as one of key performance index (KPI) item in the hospital accreditation (2006), (3) Insurance reimbursement of icodextrin dialysate by the NHI program for high peritoneal membrane function or refractory edema in PD patients using high level of glucose PD fluid (4.25%), providing incentives for both nephrologist and hospital for relieving the patients' fluid retention and ultrafiltration failure (2007) (4) free access to automated PD machine for every PD patients, and both more satisfaction and convenience for PD therapy (2008). The above policy provisions included patient education, accreditation regulation, and incentive for patients to select RRT modality. The facts listed above prompt us to want to include the impact of PD promotional policy on actual PD dialysis selection rate in the Taiwan Renal Registry Data System (TWRDS) database.

Subjects and Methods

This study was approved by the ethics committee of the Taipei Medical University Institutional Review Board (No. 201405054) and was carried out in accordance with the Declaration of Helsinki of 1975, as revised in 2000.

Taiwan Renal Registry Data System

The TWRDS was initially established in 1987 for the accreditation of dialysis therapy, as previously described. All dialysis units in Taiwan are obligated to include relevant data in the TWRDS for NHI for appropriate reimbursement. Each dialysis unit submits a report quarterly. The data in the TWRDS forms a solid foundation for continual dialysis quality control at the national level ⁶⁻⁹. During this period, four major administrative or incentive interventions were implemented for influencing

dialysis modality selection after the 2014 annual report on kidney disease in Taiwan was issued and policy implementation was measured by the Taiwan Society of Nephrology under the surveillance of Ministry of Health and Welfare.

Patient enrollment

As of December 31, 2009, 539 HD and 113 PD units had been established in Taiwan. In comparison to the number of units in December 2005, the number of HD units increased by 78 and the number of PD units increased by 54. From 2009 to the end of 2011, the number of HD units increased by 30 but the number of PD units only increased by 4. Dialysis unit increases were submitted in both annual and quarterly reports to the TWRDS and the following data from these reports were obtained.

Patients registered with the TWRDS from 2006 to 2013 were included in the analysis (n = 115,565). Patients who had received HD or PD for >1 month were assigned to either the HD group or the PD group, respectively. After excluding 4,661 patients who changed their dialysis modality, the final sample for analysis included 110,994 patients (Figure 1). Of these patients, 101,672 (91.6%) patients selected HD and 9,232 (8.3%) patients selected PD as their initial RRT modality between 2006 and 2013. During this period, MDT certified hospital for CKD education and care increased from 9.5% (44/461) in 2006 to 15.2% (78/507) in 2008, and 22.1% (126/569) in 2012. The percentage of using APD among all PD patients increased from 11.1% (326/3237) in 2005 to 20.0% (939/4682) in 2009. Icodextrin PD fluid uptake was up to 47.45% in 2009, which was highest in nearby countries. Because only one NHI exists in Taiwan and coverage is nearly 99.6%, dialysis patients lost to follow-up were regarded as deceased. Uremia patients who were no longer registered in the TWRDS database were also regarded as deceased based on the 99.6% NHI

coverage policy for all RRT expenditures. In addition, the kidney transplantation rate, which was very small, only included 300 cases per year.

Medical policies

1. Mandatory pre-dialysis dialysis modality education

The multidisciplinary pre-dialysis education (MPE) program in Taiwan was designed and managed by the Taiwan Society of Nephrology (TSN) ¹⁰. Since 2003, the MPE program has consisted of a standard care protocol and an annual reporting system that stipulates mandatory education for modality selection. In 2003, the MPE established pre-dialysis modality education into their system. The program extended rapidly across the country from 19 (4.1%) hospitals in 2005 to 126 (22.1%) hospitals by the end of 2011 ¹¹. The MPE program in Taiwan delayed dialysis initiation, improved first year dialysis survival, and increased PD selection rate in a prospective controlled cohort study ¹². Based on the results of this prospective study, the NHI Bureau in Taiwan enforced mandatory modality selection education for all dialysis patients before beginning long-term dialysis in 2005.

2. Introduction and regulation of a glucose-free dialysate, extraneal (icodextrin)

Glucose-free dialysate is considered to be beneficial in PD management ¹³. Glucose-free dialysate was introduced in Taiwan in early 2000. However, due to the high cost, the NHI Bureau limited its use by prior review inspection. This prior review inspection resulted in infrequent glucose-free dialysate use. The NHI Bureau in Taiwan announced in 2007 that glucose-free dialysate would be regulated to encourage PD therapy. This regulation policy clearly indicated that patients with a high/high average score on the peritoneal equilibrium test and poor ultrafiltration (defined as using >2 bags of 2.5% and 4.25% dialysate to achieve adequate

ultrafiltration), and diabetes with poor glucose control (an HbA1c level > 7%) use icodextran or glucose-free dialysate consequently increasing its use. In addition, this policy increased the rate of PD selection, which may have been influenced by physicians.

3. Free access to APD

APD has also provided several quality and clinical outcome advantages for PD patients ¹⁴. The high rental cost of APD machines limits the use of this dialysis modality. In order to solve this problem, the NHI Bureau in Taiwan has covered rental fees of APD machines since 2008. Implementation of this policy has subsequently influenced PD therapy in Taiwan.

4. PD promotion in hospitals included in the KPI of accreditation

Hospital accreditation, which requires supervision by the Taiwan Joint Commission on Hospital Accreditation (TJCHA) every years, began in Taiwan in 1978. TJCHA now include revised accreditation standards, survey methods, and a surveyors system for evaluating the entire process of patient care for better quality and safety. The fulfilment of accreditation requirements is essential for any hospital in Taiwan to enter the NHI program. NHI payment will be reduced if hospitals do not pass accreditation and additional hospital degradation may occur. In 2006, promotion of PD was included in the KPI accreditation scheme as a hospital requirement. The KPI accreditation scheme was subsequently modified in 2010 to stipulate that the number of PD patients must exceed 9% of the number of HD patients in an accredited hospital. This new policy lowered the threshold for achieving favorable KPI scores, which may in fact influence the willingness of health providers to promote PD as a dialysis modality.

Statistical methods

PD incidence for all years was stratified by age intervals and gender. The descriptive statistics were expressed as either ± standard deviation of the mean, median (range), or frequency (percentage). Data was analyzed using SPSS 17.0 software for Windows XP (SPSS Inc., Chicago, IL, USA).

Results

Trend of PD incidence in stratified age intervals in TWRDS 2005–2013

The mean age of HD patients who entered the Taiwan dialysis program and participated in this study was 64.7 ± 13.7 years, which was nearly 10 years older than that of the PD patients included in this study, which was 54.6 ± 15.7 years. Table 1 shows PD incidence in TWRDS for the years 2006–2013, indicating a PD incidence increase of 12.5% to 15.1% since 2006. This trend however showed a PD incidence decrease of 15.1% to 13.8% for 2010, which continued in the year 2013, and a PD incidence decrease of 10.4%. A total of 45.1% of the incidence population consisted of patients >65 years in 2006, while patients in this age group consisted of 53.6% of the incidence population in 2013, indicating that the mean age of dialysis patients steadily increased from 2006 to 2012 (Table 1).

Diabetes prevalence in all ESRD patients and the trend of PD incidence according to diabetes stratified by age of 60

Table 2 shows data obtained from TWRDS from 2006 to 2013, which shows a consistent trend of diabetes among ESRD patients selecting PD. A similar trend of diabetes among ESRD patients selecting PD was found in stratified diabetes and age of 60. In addition, a double than higher average of 25.7% (12.5%) of PD incidence occurred among younger ESRD patients (<60 years old) without diabetes who select

PD as their long-term treatment modality. In contrast, those patients >60 years with diabetes demonstrated a PD selection rate of nearly half (5.5 %) the lower average.

Trend of PD incidence according to gender and age

Female ESRD patients had a higher PD utilization rate than male ESRD patients, although this PD utilization rate has diminished. In 2013, the incidence of PD utilization rate for female ESRD patients was 10.6%, while the PD utilization rate for male ESRD patients was 10.2%. In addition, we analyzed patients <60 years old without diabetes utilizing PD, which consisted of a large population for 2013. Both males and females exhibited a similar trend demonstrating a sudden increase of PD utilization for 2006, stable PD utilization rate from 2006 to 2009, and a decreasing PD utilization rate since 2010.

Trend of PD incidence trend by time sequence of four major health policies

Figure 2 depicts a bar chart of PD utilization rate from 2006 to 2013. After a steady increase from 2006 to 2009, the PD utilization rate decreased. In 2006, PD treatment availability and promotion was included as an essential item in the KPI used for hospital accreditation. Many hospitals therefore initiated PD programs since then. In summary, hospital accreditation for PD promotion affected the PD utilization rate most. The implementation of PD promotion policy was reflected in an increased incidence of PD utilization by patients from 2005 to 2009; however, for some reason, incentive policies did not produce a sustained effect. Therefore, PD incidence began to decrease in 2010 (Figure 3).

Discussions

The main result of this study exhibited that implementation of the four PD promoting policies created an increase in PD incidence, while the repeal of KPI

promotion regulated by hospital accreditation criteria created a decrease in PD incidence. These finding were confirmed by stratifying study data by age, gender or diabetes in our analysis. In addition, health policy or medical reimbursement provisions, including co-payment policies for outpatients and selection of different socioeconomic status for hospital inpatients in Taiwan ¹⁵ may also influence appropriate medical treatment accessibility.

Among the four implemented policies, mandatory pre-dialysis modality education created an increased number of patients selecting PD treatment. Multidisciplinary care was implemented in the Taiwanese pre-ESRD care program, and a large cohort study on this multidisciplinary care conducted in Taiwan reported more willingness among ESRD patients to select PD modality ¹⁶. According to providers, younger patients demonstrating residual renal function are generally more ideal candidates for PD therapy ¹⁷, thus making PD patients nearly 10 years younger than HD patients.

Full insurance coverage of APD rental machines provided since 2008 has substantially affected the decisions of dialysis patients regarding dialysis treatments. In addition, APD patients exhibited a decreased peritonitis rate ¹⁸. From 2006 to 2008, the PD utilization rate increased by 20% in Taiwan. The implementation of an APD rental reimbursement policy in China may have influenced the ESRD survival rate or reduced the technique failure rate among young Chinese patients ⁸. The regulatory use of icodextrin dialysate in Taiwan since 2006 may have also influenced the PD utilization rate by possible decreased mortality and the drop-out rates of PD patients ¹⁹, reflecting a prevalent increase of PD treatment modality utilization rate in Taiwan from 2006 to 2013.

Hospital accreditation inspection by the TJCHA was assigned by the

government. The promotion of PD was listed as a KPI item for hospital accreditation in 2006, therefore increasing the PD utilization rate. Insurance reimbursement for the rental of APD machines and icodextrin dialysate were found to be the most potent factors stimulating the promotion of PD treatment utilization among providers and hospitals ²⁰. However, PD incidence decreases since 2010 have occurred because accreditation requirement revisions in 2010 excluded the possibility of including these factors as KPI for hospital accreditation criteria.

Several limitations for this study exist. First, this was a retrospective study that did not include valid laboratory data or quality clinical follow up. The data used however was obtained from the TWRDS, which was the largest ESRD database in Taiwan at that time. Second, the study drop-out rate was expected to be higher among PD patients than among HD patients and this occurrence may have affected the prevalence of the dialysis modalities. However, the focus of this study was the selection of dialysis modality based on incidence and health policy influences on dialysis modality selection.

Conclusions

In summary, four major PD promotional policies were implemented in Taiwan by the Ministry of Health and Welfare during the past decade. In 2005, pre-dialysis education became mandatory, which created better patient understanding of dialysis modality treatments before undergoing long-term dialysis. In 2007, explicit regulation of reimbursements for the cost of administering glucose-free dialysate (icodextrin) was announced. In 2008, the government began providing full coverage for APD rental costs. The phenomenon of the increasing incidence of dialysis implies improvement in dialysis quality, because of dialysis programs maintenance in Taiwan. The data obtained from the TWRDS suggest that the four following factors may

stabilize dialysis incidence and increase PD use: (1) the nationwide implementation of an MPE program and (2) the introduction of APD rental payment reimbursement and (3) coverage of icodextrin dialysate has also sustained PD selection rate since 2007 and (4) promotion of PD as hospital accreditation since 2006. However, concurrent retrieval of KPI promoting PD utilization has created a decreased PD modality treatment selection rate in 2010.

At present, conducting chronic kidney disease (CKD) prevention and quality improvement programs are mandatory policies in Taiwan. Future research goals consisting of the determination of survival estimates of the dialysis patients analyzed in this study and observation of whether KPI schemes promoting PD utilization could be extended to improve ESRD outcomes should be performed. Other issues should include financial incentives and promotion of low cost dialysis modality ²¹.

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Contributorship statement

.nts: YL
(Yi-Chun Lin)
-Chung Lin); CH
.terials/analysis tools: YL(Yi-Cı.
.npt: YL (Yi-Chun Lin); MW Conceived and designed the experiments: YL (Yi-Chung Lin); YL (Yen-Chung Lin); MW

Performed the experiments: YL (Yi-Chun Lin)

Analyzed the data: YL (Yen-Chung Lin); CH

Contributed reagents/materials/analysis tools: YL(Yi-Chun Lin); HC; CK

Wrote the manuscript: YL (Yi-Chun Lin); MW

there is no funding, and no additional data available for sharing.



Reference

- 1. Oh KH, Kim YL, Lo WK, et al. Peritoneal dialysis-moving from current status to the future. International journal of nephrology 2013;**2013**:530713.
- 2. Blake PG. Integrated end-stage renal disease care: the role of peritoneal dialysis. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association 2001;16 Suppl 5:61-6.
- 3. Jha V. Peritoneal dialysis in India: current status and challenges. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis 2008;**28 Suppl 3**:S36-41.
- 4. Dhanakijcharoen P, Sirivongs D, Aruyapitipan S, et al. The "PD First" policy in Thailand: three-years experiences (2008-2011). Journal of the Medical Association of Thailand = Chotmaihet thangphaet 2011;94 Suppl 4:S153-61.
- 5. Yu AW, Chau KF, Ho YW, et al. Development of the "peritoneal dialysis first" model in Hong Kong. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis 2007;27 Suppl 2:S53-5.
- 6. Yang WC, Hwang SJ. Incidence, prevalence and mortality trends of dialysis end-stage renal disease in Taiwan from 1990 to 2001: the impact of national health insurance. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association 2008;23(12):3977-82.
- 7. Hwang SJ, Lin MY, Chen HC, et al. Increased risk of mortality in the elderly population with late-stage chronic kidney disease: a cohort study in Taiwan. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association 2008;**23**(10):3192-8.
- 8. Huang CC, Cheng KF, Wu HD. Survival analysis: comparing peritoneal dialysis and hemodialysis in Taiwan. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis 2008;**28 Suppl 3**:S15-20.
- 9. Hwang SJ, Yang WC, Lin MY, et al. Impact of the clinical conditions at dialysis initiation on mortality in incident haemodialysis patients: a national cohort study in Taiwan. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association 2010;25(8):2616-24.
- 10. Hwang SJ, Tsai JC, Chen HC. Epidemiology, impact and preventive care of chronic kidney disease in Taiwan. Nephrology (Carlton) 2010;**15 Suppl 2**:3-9.
- 11. Wu M, Wu I, Hsu K. Survival Analysis of Taiwan Renal RegistryData System (TWRDS) 2000-2009. Acta Nephrologica 2012;**26**(2):104-08.
- 12. Wu IW, Wang SY, Hsu KH, et al. Multidisciplinary predialysis education decreases the incidence of dialysis and reduces mortality--a controlled cohort study based on the NKF/DOQI guidelines. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association 2009;24(11):3426-33.
- 13. Cho Y, Johnson DW, Badve S, et al. Impact of icodextrin on clinical outcomes in peritoneal dialysis: a systematic review of randomized controlled trials. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association 2013;28(7):1899-907.
- 14. Sun CY, Lee CC, Lin YY, et al. In younger dialysis patients, automated peritoneal dialysis is associated with better long-term patient and technique survival than is continuous ambulatory peritoneal dialysis. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis 2011;31(3):301-7.
- 15. Chen LC, Schafheutle EI, Noyce PR. The impact of nonreferral outpatient co-payment on medical care utilization and expenditures in Taiwan. Research in social & administrative pharmacy: RSAP 2009;5(3):211-24.
- 16. Chen YR, Yang Y, Wang SC, et al. Effectiveness of multidisciplinary care for chronic kidney disease in Taiwan: a 3-year prospective cohort study. Nephrology, dialysis, transplantation: official publication

- of the European Dialysis and Transplant Association European Renal Association 2013;**28**(3):671-82.
- 17. Goodlad C, Brown E. The role of peritoneal dialysis in modern renal replacement therapy. Postgraduate medical journal 2013;**89**(1056):584-90.
- 18. Huang JW, Hung KY, Yen CJ, et al. Comparison of infectious complications in peritoneal dialysis patients using either a twin-bag system or automated peritoneal dialysis. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association 2001;16(3):604-7.
- 19. Kuriyama R, Tranaeus A, Ikegami T. Icodextrin reduces mortality and the drop-out rate in Japanese peritoneal dialysis patients. Advances in peritoneal dialysis Conference on Peritoneal Dialysis 2006;**22**:108-10.
- 20. Burkart J. The future of peritoneal dialysis in the United States: optimizing its use. Clinical journal of the American Society of Nephrology: CJASN 2009;4 Suppl 1:S125-31.
- 21. Cleemput I, De Laet C. Analysis of the costs of dialysis and the effects of an incentive mechanism for low-cost dialysis modalities. Health Policy 2013;110(2-3):172-9.



Year 2006		m 2006 to 2012 stratified by dialy 2007 2008			2009		2010		2011		2012		2013			
roup	HD	PD	HD	PD	HD	PD	HD	PD	HD	PD	HD	PD	HD	PD	HD	PD
45	692	337	645	353	671	366	641	341	674	362	690	343	705	288	806	90
5–64	3206	478	2927	606	3115	645	2897	605	3195	616	3371	594	3487	600	3553	412
65	3643	245	3733	333	4250	385	3860	367	4418	342	4364	279	4533	293	5227	502
otal	87.5 %	12.5 %	84.9 %	15.1	85.2 %	14.8 %	84.9 %	15.1 %	86.2 %	13.8	87.3 %	12.7 %	87.9 %	12.1 %	89.6 %	10.4 %
lean age year)	63 ± 14	51 ± 17	63 ± 14	53 ± 16	64 ± 14	54 ± 17	64 ± 14	54 ± 17	64 ± 14	53 ± 16	64 ± 15	53 ± 16	64 ± 15	54 ± 16	64 ± 15	54 ± 16

ncidence (2006 to 201	3) grouped by	sex in TWRD	S			
2006	2007	2008	2009	2010	2011	2012	2013
47.5	46.9	47.6	48.2	46.7	46.4	46.7	49.0
52.5	53.1	52.4	51.8	53.3	53.6	53.3	51.0
43.2	43.9	46.2	46.0	45.2	45.9	45.7	45.0
5.5	6.8	7.3	7.6	7.2	6.2	5.2	5.8
among pa	tients <60 ye	ears					
22.7	26.4	26.8	27.4	25.6	23.1	22.0	22.3
29.1	37.7	34.3	34.5	36.9	33.1	32.3	31.1
25.7	31.6	30.4	30.6	30.6	27.4	26.4	25.9
	2006 47.5 52.5 43.2 5.5 among pa 22.7 29.1	2006 2007 47.5 46.9 52.5 53.1 43.2 43.9 5.5 6.8 among patients <60 years 22.7 26.4 29.1 37.7	2006 2007 2008 47.5 46.9 47.6 52.5 53.1 52.4 43.2 43.9 46.2 5.5 6.8 7.3 among patients <60 years	2006 2007 2008 2009 47.5 46.9 47.6 48.2 52.5 53.1 52.4 51.8 43.2 43.9 46.2 46.0 5.5 6.8 7.3 7.6 among patients <60 years	47.5 46.9 47.6 48.2 46.7 52.5 53.1 52.4 51.8 53.3 43.2 43.9 46.2 46.0 45.2 5.5 6.8 7.3 7.6 7.2 among patients <60 years 22.7 26.4 26.8 27.4 25.6 29.1 37.7 34.3 34.5 36.9 25.7 31.6 30.4 30.6 30.6	2006 2007 2008 2009 2010 2011 47.5 46.9 47.6 48.2 46.7 46.4 52.5 53.1 52.4 51.8 53.3 53.6 43.2 43.9 46.2 46.0 45.2 45.9 5.5 6.8 7.3 7.6 7.2 6.2 among patients <60 years	2006 2007 2008 2009 2010 2011 2012 47.5 46.9 47.6 48.2 46.7 46.4 46.7 52.5 53.1 52.4 51.8 53.3 53.6 53.3 43.2 43.9 46.2 46.0 45.2 45.9 45.7 5.5 6.8 7.3 7.6 7.2 6.2 5.2 among patients <60 years

Figure legends

- Figure 1: Flow chart showing the 2006–2013 cohort established using TWRDS database
- Figure 2: PD incidence (%) in TWRDS database 2006–2013
- Figure 3: PD incidence and health policies showing in time sequences in TWRDS 2006–2013



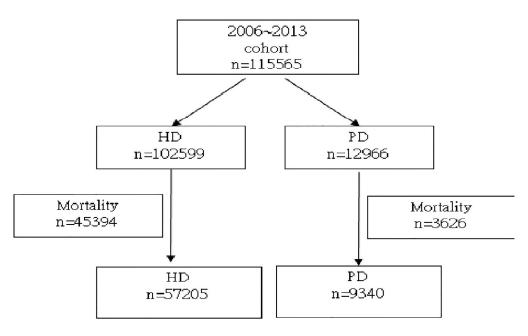


Figure 1: Flow chart showing the 2006–2013 cohort established using TWRDS database $\,$

262x158mm (300 x 300 DPI)

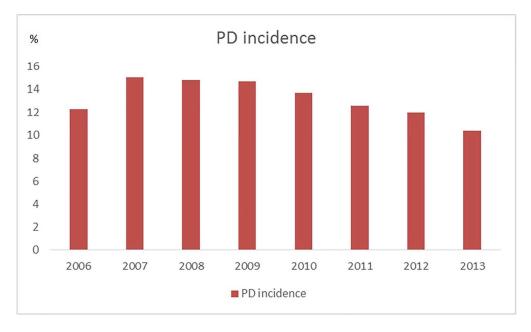


Figure 2: PD incidence (%) in TWRDS database 2006–2013
262x158mm (300 x 300 DPI)

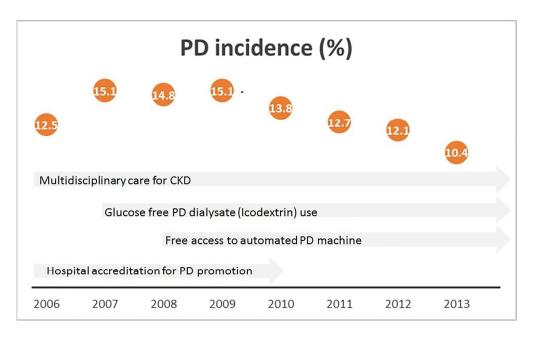


Figure 3: PD incidence and health policies showing in time sequences in TWRDS 2006–2013 $251 \times 151 \text{mm} (300 \times 300 \text{ DPI})$

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Health Policies on Dialysis Modality Selection: A Nationwide Population Cohort Study

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Keywords:	Accreditations, Health policies, Peritoneal dialysis, Health insurance reimbursement, End Stage Renal Disease

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Health Policies on Dialysis Modality Selection: A Nationwide Population **Cohort Study**

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Abstract

Objectives: In Taiwan, patients with end stage renal disease (ESRD) can freely select the dialysis modality they wish to receive. However, the utilization of peritoneal dialysis (PD) is considered to be low in Taiwan. Since 2005, four major policies have been implemented in Taiwan by the health department: (1) multidisciplinary pre-ESRD care program (2006), (2) inclusion of increased PD prevalence and incidence in individual hospitals as one of key performance index (KPI) items in hospital accreditation (2006) (3) insurance reimbursement for icodextrin dialysate (2007), and (4) insurance reimbursement for the rental of APD machines rental (2008). The aim of the study is to analyze the impact of PD promotional policies on actual PD dialysis selection rate.

Setting: We analyzed data stored in the Taiwan Renal Registry Data System from 2006 to 2013 focusing on PD incidence influenced by time sequence of these four PD-promotional policies followed by stratifying the results by age, sex, or presence of diabetes mellitus.**Participants:** There were 115,565 patients were enrolled in this study during the period from 2006 to 2013.

Results: The mean age of hemodialysis patients who enrolled in the Taiwan dialysis program was 64.7 ± 13.7 years, nearly 10 years older than that of PD patients, 54.6 ± 15.7 years. PD incidence has increased from 12.8% (2006) to 15.1% (2009) when four PD promoting policies were implemented. However, PD incidence started to drop in 2010 (13.8%) when only one of the policies (hospital accreditation) was repealed. The other three policies persisted but had a weak influence on PD incidence. In the observational analysis, the patients' age, gender, diabetes mellitus incidences were relatively stable during the period.

Conclusions: Among four health policies intended to promote PD utilization, inclusion of increased PD prevalence as one of KPI items in hospital accreditation had the greatest impact.

Keywords: Accreditations; Health policies; Peritoneal dialysis; Health insurance reimbursement; End Stage Renal Disease

Article summary:

Strengths and limitation of this study:

- 1. We used a long-term, nationwide population based ESRD registry system.
- 2. We investigated the four health policies and their effects on dialysis selection by time sequence.
- 3. There were no confounding factors from any other incentives or reimbursements for physicians or patients during the study period.
- 4. No discussion was done about technique failure in patients with PD
- 5. A lack of valid kidney transplant records in this database was observed.

Introduction

The increasing number of people with end stage renal disease (ESRD) is a considerable burden on the Taiwanese government. According to the U.S. Renal Data System annual report, the prevalence and incidence of ESRD were highest in Taiwan as compared with those in other countries. The health expenditure for patients with ESRD consisted of 6% of the total annual National Health Insurance (NHI) budget and benefitted 0.3% of the total Taiwanese population who had undergone advanced renal replacement therapy (RRT) by receiving either hemodialysis (HD) or peritoneal dialysis (PD).

In Taiwan, HD was first administrated in 1963 while PD was first administered in 1984. The Taiwanese government has provided global coverage of dialysis costs for every citizen since 1995. At present, the number of dialysis facilities (HD or PD) is sufficient for providing quality dialysis to patients with ESRD in Taiwan where patients can freely select the dialysis modality they wish to receive. The spread of PD remained below 10% in 2005 with inadequate patient education being held responsible for this low pick-up rate as it is essential for patients with ESRD to know all current RRT modalities available with patient-centered care. Several therapy barriers, such as peritoneal membrane longevity and hypoalbuminemia, are encountered while administering PD; this necessitates favorable health-care policies (1, 2) and integrated health resources to increase PD selection. (3).

Administrative interventions, such as the "PD first" policies in Thailand (4) and Hong Kong (5), are highly influential in medical practice. For the past 3 decades, dialysis reimbursement policy has been helpful in providing sufficient incentives for PD selection.(6) In Taiwan, the four following policies proposed by the Ministry of

Health and Welfare concerning modality selection were implemented to increase the proportion of patients receiving PD therapy: (1) multidisciplinary pre-ESRD care program in health care institutes for chronic kidney disease (CKD) patients, providing more medical knowledges for PD therapy (2006), (2) inclusion of increase PD prevalence and incidence in individual hospitals as one of key performance index (KPI) item in the hospital accreditation (2006), (3) insurance reimbursement of icodextrin dialysate by the NHI program for high peritoneal membrane function or refractory edema in PD patients using high level of glucose PD fluid (4.25%), providing incentives for both nephrologist and hospital for relieving the patients' fluid retention and ultrafiltration failure (2007) (4) insurance reimbursement for rentingautomated PD machines (APD) for every PD patients, and both more satisfaction and convenience for PD therapy (2008). The above policy provisions included patient education, accreditation regulation, and incentive for patients to select RRT modality. The aim of the study is to analyze the impact of PD promotional policies on actual PD dialysis selection rate.

Subjects and Methods

This study was approved by the ethics committee of the Taipei Medical University
Institutional Review Board (No. 201405054) and was carried out in accordance with
the Declaration of Helsinki of 1975, as revised in 2013.(7)Waiver of the
Requirements for Obtaining Informed Consent was approved by Taipei Medical
University Institutional Review Board because it meets all applicable regulations.

Taiwan Renal Registry Data System

The TWRDS was initially established in 1987 for the accreditation of dialysis therapy, as previously described. All dialysis units in Taiwan are obligated to upload

relevant data to the website constructed by TWRDS in 2005. This provided only a very small portion of incentives (5%) for dialysis centers and did not correlate with the medical reimbursement for overall expenditure from the NHI. Each dialysis unit submits a report quarterly, which is prepared by a special registered nurse. The data in the TWRDS makes a solid foundation for continual dialysis quality control at the national level (8-11). During this period, four major administrative or incentive interventions were implemented for influencing dialysis modality selection and policy implementation was measured by the Taiwan Society of Nephrology under the surveillance of Ministry of Health and Welfare.

Patient enrollment

As of December 31, 2009, 539 HD and 113 PD units had been established in Taiwan. As compared to December 2005, the number of HD units increased by 78 and the number of PD units increased by 54. The increasing rate of PD spots was higher than that of HD spots (91.5% vs. 16.9% in PD and HD, respectively) from 2006-2009. This information was submitted in both annual and quarterly reports to the TWRDS and the following data from these reports were obtained.

Patients registered with the TWRDS from 2006 to 2013 were included in the analysis (n = 115,565). Patients who had received HD or PD for >3 month were assigned to either the HD group or the PD group, respectively. After excluding 4,661 patients who changed their dialysis modality, the final sample for analysis included 110,994 patients. Of these patients, 101,672 (91.6%) patients selected HD and 9,232 (8.3%) patients selected PD as their initial RRT modality between 2006 and 2013. During this period, multi-disciplinary pre-ESRD care program-certified hospital increased from 9.5% (44/461) in 2006 to 15.2% (78/507) in 2008, and 22.1% (126/569) in 2011. The percentage of using APD among all PD patients increased from 11.1% in

2005 to 20.0% in 2009. Icodextrin PD fluid uptake increased from 5.9% in 2005 to 47.9% in 2009, which was highest in nearby countries. Because only one NHI exists in Taiwan and the coverage is nearly 99.6%, dialysis patients who did not follow-up were considered deceased. Uremia patients who were no longer registered in the TWRDS database were also considered deceased based on the total NHI coverage policy for all RRT expenditures. In addition, the kidney transplantation rate, which was very small, only included 300 cases per year. Of note, Taiwan is one of the countries that uremia patients are free to choose PD therapy as renal replacement therapy.

Medical policies

1. Multidisciplinary pre-dialysis care program

The multidisciplinary pre-dialysis care program in Taiwan was designed and managed by the Taiwan Society of Nephrology (TSN) (12). Since 2003, this program has consisted of a standard care protocol and an annual reporting system that stipulates mandatory education for modality selection. In 2003, pre-dialysis modality education was established into their system. The program extended rapidly across the country from 19 (4.1%) hospitals in 2005 to 126 (22.1%) hospitals by the end of 2011 (13). Based on a prospective controlled cohort study from Taiwan, this program delayed dialysis initiation, improved first year dialysis survival, and might increased the probability of selecting PD as the treatment modality. (14). Based on the results of this prospective study, the NHI Bureau in Taiwan enforced mandatory modality selection education for all dialysis patients before beginning long-term dialysis in 2005.

2. Inclusion of increase PD prevalence and incidence in hospitals included in the KPI of accreditation

Hospital accreditation, which requires supervision by the Taiwan Joint Commission on Hospital Accreditation (TJCHA) every years, began in Taiwan in 1978. TJCHA now include revised accreditation standards, survey methods, and a surveyor system for evaluating the entire process of patient care for better quality and safety. The fulfilment of accreditation requirements is essential for any hospital in Taiwan to enter the NHI program. NHI payment will be reduced if hospitals do not pass accreditation and additional hospital degradation may occur. In 2006, a scheme with promotion of PD was included in the KPI as a hospital accreditation requirement. The KPI accreditation scheme was subsequently modified in 2010 to stipulate that the number of PD patients must exceed 9% of the number of HD patients in an accredited hospital. This new policy lowered the threshold for achieving favorable KPI scores, which may in fact influence the willingness of health providers to promote PD as a dialysis modality.

3. *Insurance reimbursement of a glucose-free dialysate, extraneal (icodextrin)*

Glucose-free dialysate is considered to be beneficial in PD management (15). Glucose-free dialysate was introduced in Taiwan in early 2000. However, due to the high cost, the NHI Bureau limited its use by prior review inspection. This prior review inspection resulted in infrequent glucose-free dialysate use. The NHI Bureau in Taiwan announced in 2007 that glucose-free dialysate would be regulated to encourage PD therapy. This regulation policy clearly indicated that patients with a high/high average score on the peritoneal equilibrium test and poor ultrafiltration (defined as using >2 bags of 2.5% and 4.25% dialysate to achieve adequate ultrafiltration), and diabetes with poor glucose control (an HbA1c level > 7%) use

icodextran or glucose-free dialysate consequently increasing its use. This policy might increase the incentive of nephrologist to use Icodextrin in PD patients with refractory fluid overload by traditional glucose-based dialystates.

4. Insurance reimbursement for renting APD machines

APD has also provided several quality and clinical outcome advantages for PD patients (16). The high rental cost of APD machines limits the use of this dialysis modality. In order to solve this problem, the NHI Bureau in Taiwan has covered rental fees of APD machines since 2008. Implementation of this policy has subsequently influenced PD therapy in Taiwan. The prevalence of APD use increased from 11.1% (326/3237) in 2005 to 20.0% (939/4682) in 2009.

Statistical methods

The primary outcome is PD incidence of each year during the study period. This was further stratified by age intervals, gender, and history of diabetes mellitus. The descriptive statistics were expressed as either ± standard deviation of the mean, median (range), or frequency (percentage). Data was analyzed using SPSS 17.0 software for Windows XP (SPSS Inc., Chicago, IL, USA).

Results

Trend of PD incidence trend by time sequence of four major health policies

Reimbursement of Icodextrin might increase incentive of nephrologist to use icodextrin in PD patients with refractory fluid overload over traditional glucose-based dialystates, but this action showed a limited effect on increasing PD incidence. During 2007-2008, PD incidence did not increase (Figure 1). Nevertheless, icodextrin use in 2009 reached 47.9%, the highest level in nearby countries. In addition, number of

APD use showed a slowly increasing trend before 2008. After initiating insurance reimbursement for renting APD machine in 2008, APD use increased faster then PD incidence, showing the trend that both APD or icodextrin had weak correlations with PD incidence. Figure 2 depicts a bar chart of PD utilization rate from 2006 to 2013. After a steady increase from 2006 to 2009, the PD utilization rate decreased. In 2006, PD treatment availability and promotion was included as an essential item in the KPI used for hospital accreditation. Many hospitals therefore initiated PD programs since then. We could observe that the PD spots increased faster than HD spots during 2006 to 2009 (91.5% vs. 16.9% in PD and HD, respectively). Figure 3 showed the relation of PD incidence and health policies in time sequences in TWRDS 2006-2013. Two policies, pre-dialysis care program and hospital accreditation, were introduced in 2006, icodextrin reimbursement in 2007 and APD use in 2008. Incident PD use rose dramatically in 2007 and stayed stable until 2009. The 2 policies from 2006 were associated with an increased use of PD and this may have been causal. The subsequent withdrawal of the policy "increase PD prevalence and incidence in hospitals as the KPI of accreditation" in 2010 was associated with a fall in PD use below the level of 2006 suggesting it may have been critically important. The policies introduced in 2007 and 2008, the reimbursement of icodextrin and APD, were not associated with subsequent growth in PD suggesting that that they may have a much less critical role.

Trend of PD incidence in stratified age intervals in TWRDS 2005–2013

The mean age of patients with HD who entered the Taiwan dialysis program and participated in this study was 64.7 ± 13.7 years, which was nearly 10 years older than that of the patients with PD included in this study, which was 54.6 ± 15.7 years. Table 1 shows PD incidence in the TWRDS for the years 2006-2013, and a total of 45.1% of the incidence population consisted of patients >65 years in 2006, while patients in

this age group consisted of 53.6% of the incidence population in 2013, indicating that the mean age of dialysis patients steadily increased from 2006 to 2013.

Diabetes prevalence in all ESRD patients and the trend of PD incidence according to diabetes stratified by age of 60

Table 2 shows data obtained from TWRDS from 2006 to 2013, which shows a consistent trend of diabetes among uremiapatients selecting PD. A similar trend of diabetes among patients with ESRD selecting PD was found in stratified diabetes and age of 60. In addition, a twofold higher average of PD incidence 27.5% (12.5%) occurred among younger patients with ESRD (<60 years old) without diabetes who select PD as their long-term treatment modality.

Trend of PD incidence according to gender and age

Female patients with ESRD had a higher PD utilization rate than male patients, although this PD utilization rate has diminished. In 2013, the incidence of PD utilization rate for female patients with ESRD was 10.6%, while the PD utilization rate for male patients was 10.2%. Both males and females exhibited a similar trend demonstrating a sudden increase of PD utilization for 2006, stable PD utilization rate from 2006 to 2009, and a decreasing PD utilization rate since 2010.

In summary, hospital accreditation for PD promotion affected the PD utilization rate most. The implementation of PD incentive policies may influence the incidence of PD utilization; however, for some reason, incentive policies did not produce a sustained effect. Therefore, PD incidence began to decrease in 2010 (Figure 3).

Discussions

The main result of this study exhibited that implementation of the four PD promoting policies created an increase in PD incidence, while the repeal of KPI

promotion regulated by hospital accreditation criteria created a decrease in PD incidence. From a study of Vonesh et al. (17) using the USRDS database, they found that PD:HD death rate is strongly correlated with patient's age, gender, and presence of diabetes mellitus. This affects both physician and patient's willingness to use PD as renal replacement therapy, especially in old age or diabetes patients. In our database, the age of PD patients is nearly 10 years younger than HD patients with a slightly women predominance. However, there were no obvious changes in the age, gender and diabetes mellitus during the study period. In addition, health policy or medical reimbursement provisions, including co-payment policies for outpatients and selection of different socioeconomic status for hospital inpatients in Taiwan (18) may also influence appropriate medical treatment accessibility. Regulation or non-free of choosing PD therapy may deteriorate quality of life in literature.(19) And there was free choice of renal replacement therapy modality in Taiwan.

Among the four implemented policies, mandatory pre-dialysis modality education might increase selectivity of PD in uremia patients. since PD has advantage of home-based therapy, use of convenient equipment, and being time-saving compared with HD. Multidisciplinary care was implemented in the Taiwanese pre-ESRD care program, and a large cohort study on this multidisciplinary care conducted in Taiwan reported more willingness among patients with ESRD to select PD modality (20). According to providers, younger patients demonstrating residual renal function are generally more ideal candidates for PD therapy (21), thus making PD patients nearly 10 years younger than HD patients.

Full insurance coverage of APD rental machines provided since 2008 has substantially affected the decisions of dialysis patients regarding dialysis treatments. In addition, APD patients exhibited a decreased peritonitis rate (22). From 2006 to

2008, the PD utilization rate increased by 20% in Taiwan. The implementation of an APD rental reimbursement policy in China may have influenced the ESRD survival rate or reduced the technique failure rate among young Chinese patients (10). The regulatory use of icodextrin dialysate in Taiwan since 2006 may have also influenced the PD utilization rate by possible decreased mortality and the drop-out rates of PD patients (23). However, both two policies showed only weak impact on PD incidence from our study.

Hospital accreditation inspection by the TJCHA was assigned by the government in 1999. It is emerging and twelve of health care organizations in Taiwan have achieved the Gold Seal of Approval® as JCI-accredited entities in 2011, achieving patient-centered care.(24) The result of hospital accreditation not only affect hospital grading but also reimbursement from NHI. The promotion of PD was listed as a KPI item for hospital accreditation in 2006, therefore increased the PD utilization rate. Insurance reimbursement for the rental of APD machines and icodextrin dialysate were found to be the most potent factors stimulating the promotion of PD treatment utilization among providers and hospitals in the USA (25). However, reduced PD incidence since 2010 have resulted from accreditation requirement revisions in 2010 despite the reimbursement of APD and icodextrin policy persisted in Taiwan.

From the patient's point of view, convenient therapy is as important as treatment efficacy, where PD has advantages in being a home-based therapy and in its ability to save time. But, the number of HD spots is far more than PD spots in Taiwan, providing strong ESRD care network especially in urban areas. However, during the study period from 2005-2009, the incidence of newly set-up PD facilities is even higher than that of HD. In addition, reimbursement of facilities or physicians for PD, PD catheter, patient's medical expense were totally covered by national health

insurance. Co-pay for patients in PD or HD did not change either.

Several limitations in this study exist. First, this was a retrospective study that did not include valid laboratory data or quality clinical follow up. Howeveer, the data used r was obtained from the TWRDS, which was the largest ESRD database in Taiwan at that time. Second, we exclude those who had changed dialysis modality, some uremia patients using long-term peritoneal dialysis may use short-term hemodialysis at first. But we only excluded those who had continuously receiving HD therapy for at least 3 months and then shifted to PD; hence, the number was not large.

Currently, conducting chronic kidney disease (CKD) prevention and quality improvement programs are mandatory policies in Taiwan. Future research goals should be the determination of survival estimates of the dialysis patients analyzed in this study and observation of whether KPI schemes promoting PD utilization could be extended to improve ESRD outcomes. Other issues should include financial incentives and promotion of low cost dialysis modalities (26).

Conclusions

Among four health policies intended to promote PD utilization, inclusion of increased PD prevalence as one of KPI items in hospital accreditation had the greatest impact.

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Performed the experiments: YL (Yi-Chun Lin)

Analyzed the data: YL (Yen-Chung Lin); CH

Contributed reagents/materials/analysis tools: YL(Yi-Chun Lin); HC; CK

Wrote the manuscript: YL (Yi-Chun Lin); MW



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Reference

- 1. Oh KH, Kim YL, Lo WK, Margetts PJ. Peritoneal dialysis-moving from current status to the future. International journal of nephrology. 2013;2013:530713.
- 2. Blake PG. Integrated end-stage renal disease care: the role of peritoneal dialysis. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2001;16 Suppl 5:61-6.
- 3. Jha V. Peritoneal dialysis in India: current status and challenges. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis. 2008;28 Suppl 3:S36-41.
- 4. Dhanakijcharoen P, Sirivongs D, Aruyapitipan S, Chuengsaman P, Lumpaopong A. The "PD First" policy in Thailand: three-years experiences (2008-2011). Journal of the Medical Association of Thailand = Chotmaihet thangphaet. 2011;94 Suppl 4:S153-61.
- 5. Yu AW, Chau KF, Ho YW, Li PK. Development of the "peritoneal dialysis first" model in Hong Kong. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis. 2007;27 Suppl 2:S53-5.
- 6. Li PK, Chow KM. Peritoneal dialysis-first policy made successful: perspectives and actions. Am J Kidney Dis. 2013;62(5):993-1005.
- 7. World Medical A. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-4.
- 8. Yang WC, Hwang SJ. Incidence, prevalence and mortality trends of dialysis end-stage renal disease in Taiwan from 1990 to 2001: the impact of national health insurance. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2008;23(12):3977-82.
- 9. Hwang SJ, Lin MY, Chen HC, Hwang SC, Yang WC, Hsu CC, et al. Increased risk of mortality in the elderly population with late-stage chronic kidney disease: a cohort study in Taiwan. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2008;23(10):3192-8.
- 10. Huang CC, Cheng KF, Wu HD. Survival analysis: comparing peritoneal dialysis and hemodialysis in Taiwan. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis. 2008;28 Suppl 3:S15-20.
- 11. Hwang SJ, Yang WC, Lin MY, Mau LW, Chen HC. Impact of the clinical conditions at dialysis initiation on mortality in incident haemodialysis patients: a national cohort study in Taiwan. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2010;25(8):2616-24.
- 12. Hwang SJ, Tsai JC, Chen HC. Epidemiology, impact and preventive care of chronic kidney disease in Taiwan. Nephrology (Carlton). 2010;15 Suppl 2:3-9.
- 13. Wu M, Wu I, Hsu K. Survival Analysis of Taiwan Renal Registry Data System (TWRDS) 2000-2009. Acta Nephrologica. 2012;26(2):104-8.
- 14. Wu IW, Wang SY, Hsu KH, Lee CC, Sun CY, Tsai CJ, et al. Multidisciplinary predialysis education decreases the incidence of dialysis and reduces mortality--a controlled cohort study based on the NKF/DOQI guidelines. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2009;24(11):3426-33.
- 15. Cho Y, Johnson DW, Badve S, Craig JC, Strippoli GF, Wiggins KJ. Impact of icodextrin on clinical outcomes in peritoneal dialysis: a systematic review of randomized controlled trials. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2013;28(7):1899-907.
- 16. Sun CY, Lee CC, Lin YY, Wu MS. In younger dialysis patients, automated peritoneal dialysis is associated with better long-term patient and technique survival than is continuous ambulatory peritoneal dialysis. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis. 2011;31(3):301-7.

- 17. Vonesh EF, Moran J. Mortality in end-stage renal disease: a reassessment of differences between patients treated with hemodialysis and peritoneal dialysis. J Am Soc Nephrol. 1999;10(2):354-65.
- 18. Chen LC, Schafheutle EI, Noyce PR. The impact of nonreferral outpatient co-payment on medical care utilization and expenditures in Taiwan. Research in social & administrative pharmacy: RSAP. 2009;5(3):211-24.
- 19. Szabo E, Moody H, Hamilton T, Ang C, Kovithavongs C, Kjellstrand C. Choice of treatment improves quality of life. A study on patients undergoing dialysis. Arch Intern Med. 1997;157(12):1352-6.
- 20. Chen YR, Yang Y, Wang SC, Chiu PF, Chou WY, Lin CY, et al. Effectiveness of multidisciplinary care for chronic kidney disease in Taiwan: a 3-year prospective cohort study. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2013;28(3):671-82.
- 21. Goodlad C, Brown E. The role of peritoneal dialysis in modern renal replacement therapy. Postgraduate medical journal. 2013;89(1056):584-90.
- 22. Huang JW, Hung KY, Yen CJ, Wu KD, Tsai TJ. Comparison of infectious complications in peritoneal dialysis patients using either a twin-bag system or automated peritoneal dialysis. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association European Renal Association. 2001;16(3):604-7.
- 23. Kuriyama R, Tranaeus A, Ikegami T. Icodextrin reduces mortality and the drop-out rate in Japanese peritoneal dialysis patients. Advances in peritoneal dialysis Conference on Peritoneal Dialysis. 2006;22:108-10.
- 24. Ryan C. The Power to drive change: Working together for excellence. Creating a continuously improving consumer engagement framework for excellence in patient-centered care. World Hosp Health Serv. 2016;52(1):37-41.
- 25. Burkart J. The future of peritoneal dialysis in the United States: optimizing its use. Clinical journal of the American Society of Nephrology: CJASN. 2009;4 Suppl 1:S125-31.
- 26. Cleemput I, De Laet C. Analysis of the costs of dialysis and the effects of an incentive mechanism for low-cost dialysis modalities. Health Policy. 2013;110(2-3):172-9.

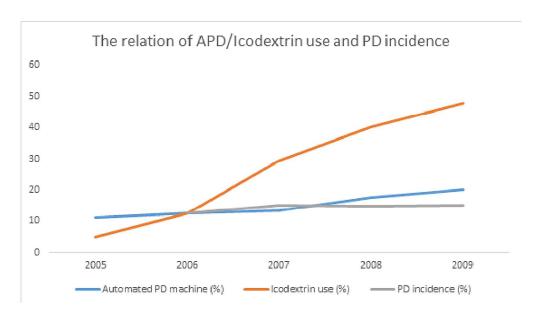
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					\pm										54 ± 16	64 ± 15	54 ± 16
																3	

Group/Year	2006	2007	2008	2009	2010	2011	2012	2013
Male (%)	47.5	46.9	47.6	48.2	46.7	46.4	46.7	49.0
Female (%)	52.5	53.1	52.4	51.8	53.3	53.6	53.3	51.0
Diabetes	43.2	43.9	46.2	46.0	45.2	45.9	45.7	45.0

(%) Old diabetes (>60 years)	5.5	6.8	7.3	7.6	7.2	6.2	5.2	5.8				
PD incidence among patients <60 years												
Male (%)	22.7	26.4	26.8	27.4	25.6	23.1	22.0	22.3				
Female (%)	29.1	37.7	34.3	34.5	36.9	33.1	32.3	31.1				
Without diabetes (%)	25.7	31.6	30.4	30.6	30.6	27.4	26.4	25.9				
Figure legends												
Figure 1: Th	Figure 1: The relation of APD/Icodextrin use and PD incidence (%)											
Figure 2: PD	Figure 2: PD incidence (%) in TWRDS database 2006–2013											

Figure 1: The relation of APD/Icodextrin use and PD incidence (%)

Figure 3: PD incidence and health policies showing in time sequences in TWRDS 2006–2013



The relation of APD/Icodextrin use and PD incidence (%)



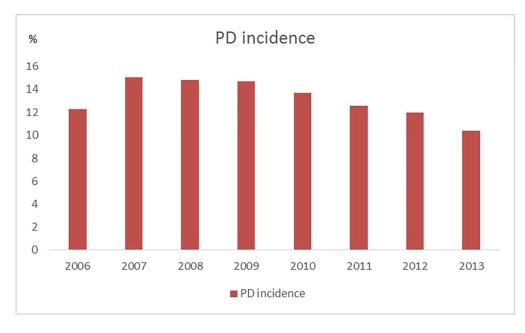


Figure 2: PD incidence (%) in TWRDS database 2006–2013

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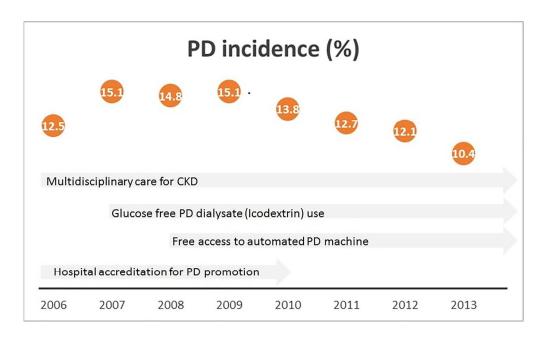


Figure 3: PD incidence and health policies showing in time sequences in TWRDS 2006–2013 $251 \times 151 \text{mm} \ (300 \times 300 \ \text{DPI})$

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Health Policies on Dialysis Modality Selection: A Nationwide Population Cohort Study

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ABSTRACT

Objectives: In Taiwan, peritoneal dialysis (PD) and hemodialysis are fully accessible to patients with end-stage renal disease (ESRD). However, the utilization of PD is considered low in Taiwan. Since 2005, four major policies have been implemented by Taiwan's Ministry of Health and Welfare, namely, a multidisciplinary predialysis care program and utilizing increasing the PD incidence as a key performance indicator (KPI) for hospital accreditation, both of which were implemented in 2006; reimbursement of the glucose-free dialystate, icodextrin that was implemented in 2007; and insurance reimbursement for renting automated PD (APD) machines that was implemented in 2008. The aim of this study was to analyze the associations between the PD promotional policies and the actual PD selection rates.

Setting: We analyzed data within the Taiwan Renal Registry Data System from 2006 to 2013, focusing on the PD incidence in relation to the timings of the four PD promotional policies; then, we stratified the results according to age, sex, and the presence of diabetes mellitus.

Participants: From 2006 to 2013, 115,565 patients were enrolled in this study. The PD patients' mean (standard deviation) age was 54.6 (15.7) years.

Results: During the timeframe in which the four PD promotional policies were implemented, the PD incidence increased from 12.8% in 2006 to 15.1% in 2009. The PD incidence started to decline in 2010 (13.8%) when the hospital accreditation policy was repealed. The three remaining policies were weakly associated with the PD incidence. The observational analysis determined that the patients' ages, sexes, and diabetes mellitus incidence rates were relatively stable from 2006 to 2013.

Conclusions: Of the four health policies intended to promote PD utilization, utilizing increasing the PD incidence as a KPI for hospital accreditation had the strongest association with the PD incidence.

Keywords: Accreditations; Peritoneal dialysis; Health policies; Health insurance reimbursement; End-stage renal disease

Article summary

Strengths and limitations of this study

- 1. This study was based on a comprehensive long-term, nationwide, population-based end-stage renal disease registry system.
- 2. Four health policies and the incidence of peritoneal dialysis (PD) according to the timings of their implementation were presented in this study.
- 3. The temporal associations between the four health policies and the PD incidence did not prove causation.
- 4. Unmeasured confounding factors, for example, a physician's experience or preference, may exist.
- 5. A lack of valid kidney transplant records in this database was observed.

INTRODUCTION

The increasing number of people with end-stage renal disease (ESRD) is placing a considerable burden on the Taiwanese government. According to the United States Renal Data System (USRDS) annual report, Taiwan had the highest prevalence and incidence of ESRD compared with other countries. The health expenditure for patients with ESRD comprised 6% of Taiwan's total annual National Health Insurance (NHI) budget, and it benefitted 0.3% of the Taiwanese population who underwent advanced renal replacement therapy (RRT) by receiving either hemodialysis (HD) or peritoneal dialysis (PD).

In Taiwan, HD was first administered in 1963 and PD was first administered in 1984. The Taiwanese government has provided global coverage of the dialysis costs for every citizen since 1995. At present, the numbers of HD and PD facilities are sufficient to provide quality dialysis to patients with ESRD in Taiwan. The monthly reimbursements to physicians and the insurance payments to healthcare institutions are similar for HD and PD patients in Taiwan. Eligible patients can select the dialysis modality they wish to receive. The utilization of PD remained at <10% in 2005, and inadequate patient education was considered to underlie this low utilization rate, because in the context of patient-centered care, it is essential that patients with ESRD are aware of all of the RRT modalities that are available. Several therapy barriers, including peritoneal membrane longevity and hypoalbuminemia, are encountered while PD is administered, which necessitates the implementation of favorable health care policies^{2 3}and integrated health resources to increase the utilization of PD.⁴

Administrative interventions, for example, the "PD first" policies in Thailand⁵ and Hong Kong,⁶ ⁷ have greatly influenced medical practice.⁸ Over the past three decades, a dialysis reimbursement policy has helped to provide sufficient incentives

for PD selection. In Taiwan, four policies proposed by the Ministry of Health and Welfare relating to modality selection were implemented to increase the incidence of patients receiving PD as their initial RRT. In 2006, a multidisciplinary predialysis care program was implemented in healthcare institutions that provided patients with chronic kidney disease (CKD) with more medical information about PD. Additionally, in 2006, increasing the PD incidence became a key performance indicator (KPI) for hospital accreditation. Reimbursements of glucose-free dialysate, icodextrin from the Bureau of NHI for PD patients with increased levels of transport of low-molecular weight solutes across the peritoneal membrane or refractory edema were implemented in 2007. thereby providing incentives for nephrologists and hospitals to relieve patients' fluid retention and ultrafiltration failures. In 2008, insurance reimbursements for renting automated PD (APD) machines were implemented, thereby ensuring greater patient satisfaction and convenience in relation to PD. These policy provisions, therefore, included patient education, accreditation, and incentives to encourage patients to select a particular RRT modality. The aim of this study was to analyze the temporal relationships between the PD promotional policies and the actual PD selection rates.

METHODS

Ethical considerations

This study was approved by Taipei Medical University's Institutional Review Board's Ethics Committee (No. 201405054), and it was carried out in accordance with the principles of the 2013 revision of the Declaration of Helsinki 1975. Taipei Medical University's Institutional Review Board waived the requirement to obtain informed consent, because the study met all of the applicable regulations.

Taiwan Renal Registry Data System

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The Taiwan Renal Registry Data System (TWRDS) was initially established in 1987 for the accreditation of dialysis therapy, as previously described. All dialysis units in Taiwan are obliged to upload relevant data to the website that was constructed by the TWRDS in 2005. This provided only a very small portion of the incentives (5%) to the dialysis centers and there were no corrections with the medical reimbursements for overall expenditure from the Bureau of NHI. Each dialysis unit submits a quarterly report that is prepared by a specially registered nurse. The data within the TWRDS provides a solid foundation for continual dialysis quality control at a national level. 10-13 From 2006 to 2008, four major administrative or incentive-based interventions were implemented to influence dialysis modality selection, and policy implementation was measured by the Taiwan Society of Nephrology (TSN) under the surveillance of the Ministry of Health and Welfare.

Patient enrollment

Data submitted to the TWRDS in annual and quarterly reports were extracted for this study.

Patients who were registered with the TWRDS from 2006 to 2013 were included in the analysis (n=115,565), and those who had received HD or PD for >3 months were assigned to the HD group or the PD group, respectively. After excluding 4661 patients who changed their dialysis modality, the final sample for the analysis comprised 110,994 patients. Of these patients, 101,672 (91.6%) patients had selected HD and 9232 (8.3%) patients had selected PD as their initial RRT modality between 2006 and 2013. Given that there is only one Bureau of NHI in Taiwan and its coverage is nearly 99.6%, dialysis patients who did not attend follow-up assessments were considered deceased. Uremia patients who were no longer registered with the TWRDS were also considered deceased, and this was based on the total NHI coverage

policy for all RRT expenditures. In addition, the kidney transplantation rate was 300 cases per year.

Health policies

Multidisciplinary predialysis care program

The multidisciplinary predialysis care program was designed and managed by the TSN.¹⁴ Since 2003, this program has consisted of a standard care protocol and an annual reporting system, and predialysis modality education was established as part of the program in 2003. The program's availability extended rapidly across the country, and it was available in 19 (4.1%) hospitals in 2005 and in 126 (22.1%) hospitals by the end of 2011.¹⁵ The results from a Taiwanese prospective controlled cohort study showed that this program delayed dialysis initiation, improved first-year dialysis survival, and that it might increase the likelihood of selecting PD as the treatment modality.¹⁶ Based on the results from this prospective study, the Bureau of NHI in Taiwan executed mandatory dialysis modality selection education for all dialysis patients before they began long-term dialysis in 2005.

Increasing the peritoneal dialysis incidence as a key performance indicator for hospital accreditation

Hospital accreditation, which requires supervision by the Taiwan Joint Commission on Hospital Accreditation (TJCHA) every year, began in Taiwan in 1978. The TJCHA now includes revised accreditation standards, survey methods, and a surveillance system to evaluate the entire patient care process to improve quality and safety. Fulfilling the accreditation requirements is essential for hospitals in Taiwan to be able to participate in the NHI program. NHI payments are reduced if hospitals do

not achieve accreditation, and additional hospital downgrades may occur. In 2006, a scheme was implemented in hospitals that involved utilizing increasing the PD incidence as a KPI for hospital accreditation. The KPI accreditation scheme was modified in 2010 to stipulate that the number of new PD patients must exceed the number of new HD patients by 9% in an accredited hospital.

Reimbursement of the glucose-free dialysate, icodextrin

Glucose-free dialysate is considered beneficial in PD management, ¹⁷ and it was introduced to Taiwan in early 2000. However, the Bureau of NHI in Taiwan limited its use by conducting inspections before use because of its high cost, which led to the infrequent use of glucose-free dialysate. In 2007, the Bureau of NHI announced that glucose-free dialysate would be reimbursed to encourage PD. This policy clearly indicated that patients with a high/high average score on the peritoneal equilibrium test, poor ultrafiltration, which was defined as using more than two bags of 2.5% and 4.25% dialysate to achieve adequate ultrafiltration, and diabetes that was characterized by poor glucose control, which was defined as a glycated hemoglobin level >7%, could use icodextrin or glucose-free dialysate, which increased its use.

*Insurance reimbursement for renting automated peritoneal dialysis machines**

APD machines offer several advantages in relation to the quality of patient's lives and PD patients' clinical outcomes. ¹⁸ The high cost associated with renting an APD machine may have limited its uptake.. To solve this problem, the Bureau of NHI in Taiwan has covered the cost of renting APD machines since 2008.

Statistical analysis

This study's primary outcome was the PD incidence during each year of the study period. The PD incidence was further stratified according to age, sex, and a history of diabetes mellitus. The descriptive statistics are expressed as the means (standard deviations), medians (ranges), or frequencies (percentages). The data were analyzed using SPSS software, version 17.0 for Windows XP (SPSS Inc., Chicago, IL, USA).

RESULTS

Peritoneal dialysis incidence trend according to the timing of the four major health policies

By December 31, 2009, 539 HD and 113 PD units had been established in Taiwan, and compared with December 2005, there were 78 more HD units and 54 more PD units. During this period, the rate at which the number of PD units increased (91.5%) was higher than the rate at which the number of HD units increased (16.9%). The proportion of multidisciplinary predialysis care program-certified hospitals increased from 9.5% (44/461) in 2006 to 15.4% (78/507) in 2008 and to 22.1% (126/569) in 2011. APD machine use among the PD patients increased from 10.1% (326/3237) in 2005 to 20.1% (939/4682) in 2009, and icodextrin PD fluid uptake increased from 5.9% in 2005 to 47.9% in 2009 (Figure 1), which was the highest rate compared with the nearby countries. The reimbursement of icodextrin dialysate might have encouraged nephrologists to use icodextrin dialysate rather than traditional glucose-based dialysates in PD patients with refractory fluid overloads, but this policy was associated with a limited increase in the PD incidence (Figure 1). From 2007 to 2008, the PD incidence did not increase. The number of APD machines rented slowly increased before 2008. After the insurance reimbursement for APD machine rental

was initiated in 2008, APD machine use increased faster than the PD incidence (Figure 1). Reimbursing the APD machine rental costs and the icodextrin dialysate costs had weak associations with the PD incidence as shown in figure 1. Figure 2 depicts the PD utilization rate from 2006 to 2013. After a steady increase in the PD utilization rate from 2006 to 2009, it declined. In 2006, increasing the PD incidence became a KPI for hospital accreditation. Consequently, many hospitals had initiated PD programs from 2006. We observed that from 2006 to 2009, the rate at which the number of PD units increased (91.5%) was higher than the rate at which the number of HD units increased (16.9%). Figure 3 illustrates the relationships between the PD incidence and the health policies based on the data from the TWRDS from 2006 to 2013. The PD incidence rose dramatically in 2007 and it remained stable until 2009. The two policies (multidisciplinary predialysis care program and and utilizing increasing the PD incidence as a key performance indicator (KPI) for hospital accreditation) that were implemented in 2006 were associated with increases in the PD incidence. The subsequent withdrawal of the policy that utilized an increase in the PD incidence as a KPI for hospital accreditation in 2010 was associated with a fall in PD incidence to a level that was below that in 2006. The policies that were implemented in 2007 and 2008, namely, the reimbursement of icodextrin dialysate costs and the reimbursement of APD machine rental costs, respectively, were not associated with increases in PD use.

Peritoneal dialysis incidence trend from 2006 to 2013 stratified according to the age intervals in the Taiwan Renal Registry Data System

The mean age of the HD patients who participated in this study was 64.7 (13.7) years, which was nearly 10 years older than that of the PD patients who participated in this study (54.6 [15.7] years). Table 1 shows the HD and PD incidence from 2006 to 2013

based on the TWRDS data. In 2006, 45.2% of the study population comprised patients aged >65 years. In 2013, 52.1% of the study population comprised patients aged >65 years. Therefore, the mean age of the patients undergoing dialysis increased between

Table 1. Annual number and percentage of incident HD and PD stratified by age groups from 2006 to 2013

2	Year	2006		2007		2008		20	09	20	10	20	11	1136
4	Group	HD	PD	н										
67	<45 years	692	337	645	353	671	366	641	341	674	362	690	343	36/bmjopeng201
9	45–64 years	3206	478	2927	606	3115	645	2897	605	3195	616	3371	594	ှာ 34 8
1 2 3	≥65 years	3643	245	3733	333	4250	385	3860	367	4418	342	4364	279	3007;jpn 11
4 5 6 7	Total (%)	87.5	12.5	84.9	15.1	85.2	14.8	84.9	15.1	86.2	13.8	87.3	12.7	Jan@ary ∞
8 9	Mean (SD) age (years)	63 (14)	51 (17)	63 (14)	53 (16)	64 (14)	54 (17)	64 (14)	54 (17)	64 (14)	53 (16)	64 (15)	53 (16)	2017 Dov

2006 and 2013.

HD, hemodialysis; PD, peritoneal dialysis, SD, standard deviation.

Peritoneal dialysis incidence trend according to the presence of diabetes stratified according to the age of 60 years

Table 2 presents the data obtained from the TWRDS from 2006 to 2013. Female patients with ESRD had a higher PD incidence than male patients. Similar percentages of patients with uremia and diabetes selected PD from 2006 to 2013. When the data were stratified according to the presence of diabetes and being aged >60 years, a much lower incident PD percentage was evident among patients with ESRD who were aged >60 years and had diabetes.

Table 2. Annual percentage of incident PD according to sex, the presence of diabetes mellitus, and being aged >60 from 2006 to 2013

Group/Year	2006	2007	2008	2009	2010	2011	2012	2013
Male (%)	47.5	46.9	47.6	48.2	46.7	46.4	46.7	49.0
Female (%)	52.5	53.1	52.4	51.8	53.3	53.6	53.3	51.0
DM(%)	43.2	43.9	46.2	46.0	45.2	45.9	45.7	45.0
Older patients with DM (>60 years) (%)	5.5	6.8	7.3	7.6	7.2	6.2	5.2	5.8

PD, peritoneal dialysis; DM, diabetes mellitus

DISCUSSION

This study's main finding demonstrated that implementing the four PD promotional policies was associated with increases in the PD incidence, while repealing the policy that utilized increasing the PD incidence as a KPI for hospital accreditation was associated with a decline in the PD incidence. The findings from a study by Vonesh *et al*¹⁹ that used data from the USRDS, showed that the PD:HD death rate was strongly correlated with a patient's age, sex, and the presence of diabetes mellitus. This affects the willingness of physicians and patients to use PD as RRT, especially when the patients are old or have diabetes. The analysis of the information in the TWRDS showed that the PD patients were almost 10 years younger than the HD patients, and that there was a slight predominance of women. However, there were no obvious changes with respect to the patients' ages and sexes, and the presence of diabetes mellitus during the study period. Moreover, health policy or medical reimbursement

provisions, including copayment policies for outpatients and the selection of hospital ²⁰ may have influenced accessibility to appropriate medical treatment. The regulation of or a lack of freedom to choose PD may negatively impact upon the quality of patients' lives. ²¹ Although individual physicians have experience and their personal preferences, a patient who is eligible for PD and HD has complete access to either dialysis modality in Taiwan. Physician and care provider incentives and reimbursements for HD are similar to those for PD, for example, physicians' fees amount to 120 USD/HD patient per month and they are up to 100 USD/PD patient per month, and the insurance payments to healthcare institutions are also comparable at 1600 USD/HD patient per month and up to 1600 USD/PD patient per month; these may vary because of the different PD dialysate doses and the different administration modalities, namely, APD machines or continuous ambulatory PD.

Of the four policies that were implemented, the multidisciplinary predialysis care program might have been associated with increases in the selection of PD by uremia patients, because PD has the advantages of being home-based therapy and using convenient equipment, and it saves time compared with HD. Multidisciplinary care was implemented in the Taiwanese predialysis care program, and a large cohort study that investigated multidisciplinary care in Taiwan reported a greater willingness among patients with ESRD to select PD.²² According to the providers, younger patients who have residual renal function tend to be more suitable candidates for PD,²³ therefore, PD patients may be almost 10 years younger than HD patients.

The provision of full insurance coverage for APD machine rental since 2008 was associated with a substantial effect on dialysis patients' decisions regarding APD machine rental. In addition, patients who used APD machines had a lower peritonitis rate.²⁴ The implementation of an APD machine rental reimbursement policy in China

Page 14 of 22

may have influenced the ESRD survival rate or reduced the rate of technique failure among young Chinese patients. ¹² In addition, the reimbursement of the costs associated with the use of icodextrin dialysate in Taiwan since 2007 may have influenced the PD utilization rate by reducing mortality and the PD patient drop-out rate. ²⁵ However, the results from our study only indicated weak associations between these policies and the PD incidence, suggesting that these policies had much less critical roles.

Hospital accreditation inspections by the TJCHA were initiated by the government in 1999, and 12 of the healthcare organizations in Taiwan had attained a Gold Seal of Approval® as Joint Commission International-accredited entities by 2011 for achieving patient-centered care.²⁶ Hospital accreditation not only affects hospital grading, but also affects reimbursements from the Bureau of NHI. Increasing the incidence of PD was utilized as a KPI for hospital accreditation, and it may have been associated with an increase in the PD utilization rate. Insurance reimbursements for APD machine rental and icodextrin dialysate were the most potent factors that stimulated PD utilization among providers and hospitals in the United States of America.²⁷ However, the reduction in the PD incidence since 2010 in Taiwan was strongly associated with the accreditation requirement revisions that took place in 2010. This new policy lowered the threshold for achieving favorable KPI scores, which may have influenced the willingness of healthcare providers to promote PD as a dialysis modality despite the continuation of the reimbursements for APD machine rental and icodextrin dialysate, which is indicative of the critical importance of this policy

From the patient's perspective, the convenience of therapy is as important its efficacy, and PD is a home-based therapy that saves time. However, the number of HD sites is far higher than the number of PD sites in Taiwan, which provides a strong

ESRD care network, particularly in urban areas. Nevertheless, from 2005 to 2009, the number of new PD facilities was higher than the number of new HD facilities. In addition, the Bureau of NHI provided complete reimbursements for PD facilities and physicians, and for PD catheters and PD patients' medical expenses. Co-pay for patients in PD or HD did not change either.

This study has some limitations that are described next. First, this was a retrospective study that did not include valid laboratory data or dialysis quality assessments. However, the study's data were obtained from the TWRDS, which was the largest ESRD database in Taiwan at the time. Second, this study only presented the timings of the PD promotional policies and the incidence of PD, which did not prove causation. Third, valid kidney transplant records were missing from the database.

Currently, it is mandatory to undertake CKD prevention and quality improvement programs in Taiwan. Future investigations should estimate the survival of the dialysis patients whose data were analyzed in this study and they should assess whether the KPI that was associated with the promotion of PD incidence could be extended to improve ESRD outcomes. Other issues to be investigated should include financial incentives and the promotion of low-cost dialysis modalities.²⁸

Conclusions

Of the four health policies that were intended to increase the PD incidence, utilizing increasing the PD incidence as a KPI for hospital accreditation appeared to have the strongest association.

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COMPETING INTERESTS The authors declare that there are no competing interests to disclose.

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AUTHORS' CONTRIBUTIONS

Conceived and designed the experiments: Yi-Chung Lin, Yen-Chung Lin, and MW; performed the experiments: Yi-Chung Lin; analyzed the data: Yen-Chung Lin and CH; contributed reagents/materials/analysis tools: Yi-Chun Lin, HC, and CK; wrote the manuscript: Yi-Chun Lin and MW.

REFERENCES

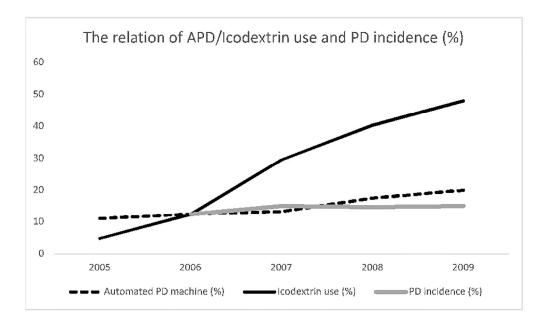
- 1. Foley RN, Collins AJ. The USRDS: what you need to know about what it can and can't tell us about ESRD. Clin J Am Soc Nephrol 2013;8:845-51 doi: 10.2215/CJN.06840712published Online First: Epub Date]|.
- 2. Oh KH, Kim YL, Lo WK, et al. Peritoneal dialysis-moving from current status to the future. *Int J Nephrol* 2013;**2013**:530713 doi: 10.1155/2013/530713published Online First: Epub Date]|.
- 3. Blake PG. Integrated end-stage renal disease care: the role of peritoneal dialysis. *Nephrol Dial Transplant* 2001;**16 Suppl 5**:61-6
- 4. Jha V. Peritoneal dialysis in India: current status and challenges. Perit Dial Int 2008;28 Suppl 3:S36-41
- 5. Dhanakijcharoen P, Sirivongs D, Aruyapitipan S, et al. The "PD First" policy in Thailand: three-years experiences (2008-2011). *J Med Assoc Thai* 2011;**94 Suppl 4**:S153-61
- 6. Yu AW, Chau KF, Ho YW, et al. Development of the "peritoneal dialysis first" model in Hong Kong. *Perit Dial Int* 2007;**27 Suppl 2**:S53-5
- 7. Li PK, Chow KM. Peritoneal dialysis-first policy made successful: perspectives and actions. *Am J Kidney Dis* 2013;**62**:993-1005 doi: 10.1053/j.ajkd.2013.03.038published Online First: Epub Date]|.
- 8. Mehrotra R, Devuyst O, Davies SJ, et al. The Current State of Peritoneal Dialysis. *J Am Soc Nephrol* 2016 doi: 10.1681/ASN.2016010112published Online First: Epub Date].
- 9. World Medical A. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;**310**:2191-4 doi: 10.1001/jama.2013.281053published Online First: Epub Date]|.
- 10. Yang WC, Hwang SJ. Incidence, prevalence and mortality trends of dialysis end-stage renal disease in Taiwan from 1990 to 2001: the impact of national health insurance. *Nephrol Dial Transplant* 2008;**23**:3977-82 doi: 10.1093/ndt/gfn406published Online First: Epub Date]|.
- 11. Hwang SJ, Lin MY, Chen HC, et al. Increased risk of mortality in the elderly population with late-stage chronic kidney disease: a cohort study in Taiwan. *Nephrol Dial Transplant* 2008;**23**:3192-8 doi: 10.1093/ndt/gfn222published Online First: Epub Date]|.
- 12. Huang CC, Cheng KF, Wu HD. Survival analysis: comparing peritoneal dialysis and hemodialysis in Taiwan. *Perit Dial Int* 2008;**28 Suppl 3**:S15-20
- 13. Hwang SJ, Yang WC, Lin MY, et al. Impact of the clinical conditions at dialysis initiation on mortality in incident haemodialysis patients: a national cohort study in Taiwan. *Nephrol Dial Transplant* 2010;**25**:2616-24 doi: 10.1093/ndt/gfq308published Online First: Epub Date]|.
- 14. Hwang SJ, Tsai JC, Chen HC. Epidemiology, impact and preventive care of chronic kidney disease in Taiwan. *Nephrology (Carlton)* 2010;**15 Suppl 2**:3-9 doi: 10.1111/j.1440-1797.2010.01304.xpublished Online First: Epub Date]|.
- 15. Wu M, Wu I, Hsu K. Survival Analysis of Taiwan Renal Registry
- Data System (TWRDS) 2000-2009. Acta Nephrologica 2012;26:104-8
- 16. Wu IW, Wang SY, Hsu KH, et al. Multidisciplinary predialysis education decreases the incidence of dialysis and reduces mortality--a controlled cohort study based on the NKF/DOQI guidelines. *Nephrol Dial Transplant* 2009;**24**:3426-33 doi: 10.1093/ndt/gfp259published Online First: Epub Date].
- 17. Cho Y, Johnson DW, Badve S, et al. Impact of icodextrin on clinical outcomes in peritoneal dialysis: a systematic review of randomized controlled trials. *Nephrol Dial Transplant* 2013;**28**:1899-907 doi: 10.1093/ndt/gft050published Online First: Epub Date]|.
- 18. Sun CY, Lee CC, Lin YY, et al. In younger dialysis patients, automated peritoneal dialysis is associated with better long-term patient and technique survival than is continuous ambulatory peritoneal dialysis. *Perit Dial Int* 2011;**31**:301-7 doi: 10.3747/pdi.2010.00072published Online First: Epub Date]|.
- 19. Vonesh EF, Moran J. Mortality in end-stage renal disease: a reassessment of differences between

patients treated with hemodialysis and peritoneal dialysis. J Am Soc Nephrol 1999;10:354-65

- 20. Chen LC, Schafheutle EI, Noyce PR. The impact of nonreferral outpatient co-payment on medical care utilization and expenditures in Taiwan. *Res Social Adm Pharm* 2009;**5**:211-24 doi: 10.1016/j.sapharm.2008.08.003published Online First: Epub Date] |.
- 21. Szabo E, Moody H, Hamilton T, et al. Choice of treatment improves quality of life. A study on patients undergoing dialysis. *Arch Intern Med* 1997;**157**:1352-6
- 22. Chen YR, Yang Y, Wang SC, et al. Effectiveness of multidisciplinary care for chronic kidney disease in Taiwan: a 3-year prospective cohort study. *Nephrol Dial Transplant* 2013;**28**:671-82 doi: 10.1093/ndt/gfs469published Online First: Epub Date]|.
- 23. Goodlad C, Brown E. The role of peritoneal dialysis in modern renal replacement therapy. *Postgrad Med J* 2013;**89**:584-90 doi: 10.1136/postgradmedj-2012-131406published Online First: Epub Date]|.
- 24. Huang JW, Hung KY, Yen CJ, et al. Comparison of infectious complications in peritoneal dialysis patients using either a twin-bag system or automated peritoneal dialysis. *Nephrol Dial Transplant* 2001;**16**:604-7
- 25. Kuriyama R, Tranaeus A, Ikegami T. Icodextrin reduces mortality and the drop-out rate in Japanese peritoneal dialysis patients. *Adv Perit Dial* 2006;**22**:108-10
- 26. Ryan C. The Power to drive change: Working together for excellence. Creating a continuously improving consumer engagement framework for excellence in patient-centered care. *World Hosp Health Serv* 2016;**52**:37-41
- 27. Burkart J. The future of peritoneal dialysis in the United States: optimizing its use. *Clin J Am Soc Nephrol* 2009;**4 Suppl 1**:S125-31 doi: 10.2215/CJN.04760709published Online First: Epub Date]|.
- 28. Cleemput I, De Laet C. Analysis of the costs of dialysis and the effects of an incentive mechanism for low-cost dialysis modalities. *Health Policy* 2013;**110**:172-9 doi: 10.1016/j.healthpol.2013.03.001published Online First: Epub Date]|.

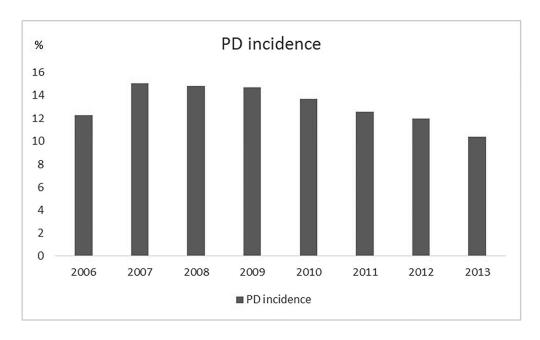
Figure legends

- Figure 1: The relationships between automated peritoneal dialysis (APD) machine use and icodextrin dialysate use and PD incidence
- Figure 2: Peritoneal dialysis incidence from 2006 to 2013 based on the Taiwan Renal Registry Data System data
- Figure 3: Peritoneal dialysis incidence from 2006 to 2013 based on the Taiwan Renal Registry Data System data and health policy timing

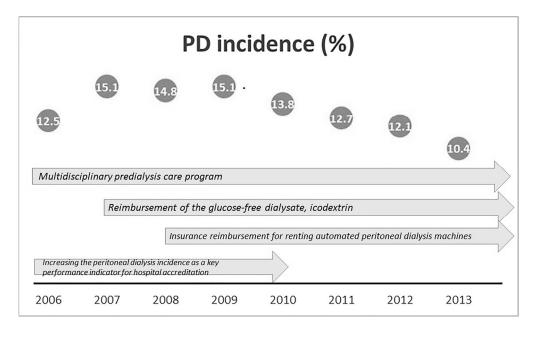


The relationships between automated peritoneal dialysis (APD) machine use and icodextrin dialysate use and PD incidence

169x102mm (300 x 300 DPI)



Peritoneal dialysis incidence from 2006 to 2013 based on the Taiwan Renal Registry Data System data $262 \times 158 \text{mm}$ (300 x 300 DPI)



Peritoneal dialysis incidence from 2006 to 2013 based on the Taiwan Renal Registry Data System data and health policy timing

194x116mm (300 x 300 DPI)