Ownership Patterns of Dialysis Units and Peritoneal Dialysis in the United States: Utilization and Outcomes

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Background: Peritoneal dialysis (PD) provides outcomes similar to hemodialysis, but its use has decreased in the United States despite its potential for substantial taxpayer savings. We undertook this study to determine the relationship between dialysis unit ownership with PD use and outcomes.

Study Design: Observational study.

Setting & Participants: All incident dialysis patients (1996 to 2004) from the US Renal Data System.

Predictor: Large dialysis organization (LDO), defined as corporations owning 20 or more freestanding dialysis units located in more than 1 state.

Outcomes & Measurements: Odds for an incident dialysis patient undergoing PD and hazards for death on follow-up in incident PD patients for each of the 5 LDOs (non-LDO as reference).

Results: During the 9-year period, 785,531 patients started maintenance dialysis therapy; the proportion receiving care in LDOs increased from 39% to 63%. There were consistent differences in PD use. It was significantly lower in LDO 2 (adjusted odds ratio [OR], 0.66; 95% confidence interval [CI], 0.64 to 0.68), LDO 3 (OR, 0.82; 95% CI, 0.80 to 0.85), and LDO 4 (OR, 0.96; 95% CI, 0.92 to 0.995) and higher in LDO 1 (adjusted OR, 1.06; 95% CI, 1.02 to 1.11) and LDO 5 (adjusted OR, 1.09; 95% CI, 1.06 to 1.12). Between 2000 and 2004, LDO 2 had the least use and greatest risk of death (hazard ratio, 1.08; 95% CI, 1.02 to 1.14); LDO 1 had greater use and the lowest death risk (hazard ratio, 0.87; 95% CI, 0.78 to 0.96).

Limitations: Only cross-sectional associations can be described.

Conclusions: Three of the 5 LDOs had consistently lower PD use. Patients treated in the LDO with the lowest use of PD had the greatest risk of death. Understanding relationships among providers, physicians, and dialysis modality use may help devise strategies for increasing PD use in appropriate patients. This has the potential to reduce the cost of renal replacement therapy and further improve outcomes.

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INDEX WORDS: Peritoneal dialysis; hemodialysis; end-stage renal disease; modality selection; mortality; technique failure; leading dialysis organizations; chains.

Editorial, p. 194

In 2005, there were 341,319 patients with end-stage renal disease (ESRD) in the United States undergoing maintenance dialysis therapy. The entire ESRD program has an annual cost of $32 billion.[1] Although patients with ESRD accounted for 1.2% of the Medicare population, they represented 8.2% of expenses for the agency.[1] By 2020, the number of maintenance dialysis patients is projected to exceed 500,000 and thus the costs of ESRD therapy are expected to increase substantially.[1] With increasing constraints of the federal and state health care budgets, it would be reasonable to suggest that use of dialysis therapy modalities that decrease overall costs without compromising patient outcomes should be encouraged.

Of the different dialysis modalities, home dialysis is associated with the lowest costs.[2] Even after accounting for younger age, lower burden of other associated diseases, and greater probability of switching dialysis modalities, average ad-

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justed per-patient annual Medicare payments for peritoneal dialysis (PD; the dominant form of home dialysis) are significantly lower than for in-center maintenance hemodialysis (MHD).[3] Most patients do not have medical or social contraindications to dialyze at home.[4] However, in 2005, only 6.6% of incident patients with ESRD were treated with PD.[1] The vast majority of incident patients with ESRD report in surveys that PD is not offered to them as a treatment modality.[5] What is more concerning is that PD use has decreased substantially since 1996. Recent analyses also suggest that the decreases in PD use cannot be explained by such medical causes as increasing age, disease burden, or body size.[6] During the period that PD use has decreased, ownership patterns of dialysis units have changed dramatically, such that now most patients with ESRD receive their care in outpatient facilities owned by large dialysis organizations (LDOs). We undertook this study to test the hypothesis that there are consistent differences in PD use among different LDOs that cannot be explained by differences in patient characteristics. We also sought to test the null hypothesis that there was no relationship between unit ownership and outcomes of PD patients.

METHODS

Data Source

The study protocol was reviewed and approved as exempt by the Institutional Review Board at Los Angeles Biomedical Research Center (Torrance, CA). Data for all incident patients during the 9-year period 1996 through 2004 were obtained from the Patient and MEDEVID files of the US Renal Data System (USRDS). Data were linked to the RXHIST60 file to assign treatment modality. Data also were linked to the Facility File to identify LDO affiliation, if any.

Definitions

According to convention, the dialysis modality 90 days after the first service date and continuous treatment for at least 60 days (60-day rule) was considered to be the initial modality.[1] Similarly, unit affiliation was defined as the dialysis facility at which the patient was being treated on day 90 of ESRD. Organizations were defined as LDOs by using the USRDS definition of corporations owning 20 or more freestanding dialysis units located in more than 1 state.[1] The following 10 affiliations were identified during the study period; none, DaVita, Dialysis Clinics Inc, Everest, Fresenius, Gambro, National, Renal Care Group, Renal Treatment Centers, and Vivra. Four LDOs existed for only part of the study period (Everest, National, Renal Treatment Centers, and Vivra) and accounted for only 20,889 (2.7%) incident patients during 9 years. Thus, although each of the 9 LDOs was included in the multivariable models, presentation of results here is limited to 5 LDO providers and the non-LDO group. LDOs in this report were assigned random codes from LDO 1 through LDO 5. The presence/absence of various coexisting illnesses was determined from Medical Evidence Form 2728. The number of patients undergoing PD in the dialysis unit on December 31 of the calendar year of incidence of ESRD was defined as the PD census for the unit for the patient. To create categorical variables, data for census for all units with at least 1 PD patient on December 31, 2000, were divided into quartiles: fewer than 5, 5 to 10, 11 to 21, and more than 21 patients. These categories were used to define the PD census for the unit for the entire study period considered for survival analyses (2000 to 2004).

Statistical Analyses

Continuous data are expressed as mean ± SD, and categorical data, as percentages. Complete data were available for each covariate for at least 95% of the study population, except for serum albumin level (missing 26%) and hemoglobin level (missing 12%). Individuals with missing serum albumin values had a lower prevalence of each selected comorbid condition listed in Table 1 and were less likely to be treated with PD (PD use during 9-year study period, 8.0% versus 9.2% with albumin values available). Individuals with missing hemoglobin values had a slightly lower prevalence of each selected comorbid condition and risk factor listed in Table 1, but starting with 1998, were more likely to be undergoing PD on day 90 compared with individuals for whom the hemoglobin value was available.

In our previous studies using USRDS data, limiting analyses to only patients with complete data available did not materially change hazard ratios (HRs).[6] To use the data for all incident patients, missing covariate data were imputed by using the mean or median of the existing values, as appropriate. PD use was determined by the proportion of incident maintenance dialysis patients undergoing treatment with PD on day 90 of ESRD. Adjusted odds ratios (ORs) for PD use by unit ownership were calculated for each of the 9 incident cohorts and for the entire 9-year period by using logistic regression analysis. For these analyses, dummy variables were created for each of the 9 LDOs and entered into the model, with non-LDO units as the reference group. The other variables included in the models were age, sex, race, ethnicity, employment status, insurance, each of the 20 reported coexisting illnesses, body mass index, geographic location (18 ESRD networks), and laboratory data (hemoglobin, serum albumin, and estimated glomerular filtration rate). For the analysis using data for the entire 9-year period, incidence years were entered as additional covariates. The ORs for PD use in LDOs were similar regardless of whether laboratory variables were entered into the multivariate models; only the fully adjusted models are presented here.

Two different time-to-event analyses were performed using Cox proportional hazards models. In analyses of time to death, individuals were censored at the time of transplantation, transfer to MHD therapy or to a unit with a different affiliation, or last follow-up (September 27, 2006). In analyses of time to composite outcome of death or transfer to MHD therapy, participants were censored at the time of

Table 1. Characteristics of 764,642 Incident Dialysis Patients Between 1996 and 2004 Based on Dialysis Unit Ownership

	Non-LDO	LDO 1	LDO 2	LDO 3	LDO 4	LDO 5
Age (y)	62.0 ± 15.4	60.7 ± 15.5	61.7 ± 15.2	61.5 ± 15.5	62.0 ± 15.3	61.5 ± 15.4
Men (%)	54	53	52	47	52	53
Race (%)						
White	67	63	64	62	67	60
African American	26	33	31	28	28	35
Asian	4	2	2	6	1	4
Other	3	2	2	4	3	2
Hispanic ethnicity (%)	11	5	14	18	11	11
Employment status (%)						
Unemployed	20	17	18	25	18	25
Employed	10	10	11	11	10	10
Homemaker	5	6	6	5	5	4
Retired	60	62	62	55	64	58
Other/unspecified	5	5	3	4	4	3
Insurance coverage (%)						
Medicare, primary or secondary	55	57	55	50	57	52
Medicaid	24	25	25	27	25	27
Employer group	22	22	26	24	22	24
Department of Veterans Affairs	1	1	1	1	1	1
Other	34	32	30	32	34	30
None	7	8	7	8	7	9
Primary cause of ESRD (%)						
Diabetes	44	45	46	46	46	45
Hypertension	26	25	29	28	28	30
Others	30	30	25	26	26	26
Selected coexisting conditions or risk factors (%)						
Congestive heart failure	33	31	32	30	31	32
Ischemic heart disease	27	25	23	21	24	23
Myocardial infarction	10	10	8	7	8	8
Tobacco use (current smoker)	5	8	5	5	5	5
Inability to ambulate	5	5	4	4	3	4
Inability to transfer	2	2	1	1	1	1
Weight (kg)	74.3 ± 20.3	75.5 ± 21.2	75.7 ± 20.4	74.6 ± 20.4	77.5 ± 21.0	75.0 ± 20.3
Body mass index (kg/m^2)	26.7 ± 7.0	27.0 ± 7.2	27.3 ± 7.4	27.0 ± 7.0	27.6 ± 7.3	26.8 ± 7.0
Predialysis erythropoietin use (%)	29	32	30	29	29	28
Hemoglobin (g/dL)	9.8 ± 1.8	9.8 ± 1.8	9.8 ± 1.8	9.9 ± 1.8	9.9 ± 1.8	9.8 ± 1.7
Serum albumin (g/dL)	3.1 ± 0.7	3.1 ± 0.7	3.1 ± 0.7	3.1 ± 0.7	3.2 ± 0.7	3.1 ± 0.7
Serum creatinine (mg/dL)	7.6 ± 3.7	7.5 ± 3.6	7.5 ± 3.7	7.3 ± 3.6	6.9 ± 3.5	7.5 ± 3.7
Glomerular filtration rate (mL/min/1.73 m^2)	9.0 ± 4.4	9.0 ± 4.3	9.0 ± 4.4	9.3 ± 4.5	9.7 ± 4.6	9.2 ± 4.5
Patients undergoing PD on day 90 (%)						
1996	15	19	10	11	9	21
1997	14	15	9	11	12	12
1998	12	15	8	9	10	10
1999	11	13	7	8	10	11
2000	10	11	7	8	11	11
2001	9	10	8	9	11	11
2002	9	8	7	8	11	10
2003	9	10	6	7	10	10
2004	8	8	6	7	9	10

Note: All trends were statistically significant. Conversion factors for units: hemoglobin and serum albumin in g/dL to g/L, ×10; serum creatinine in mg/dL to mmol/L, ×88.4; glomerular filtration rate in mL/min/1.73 m^2 to mL/s, ×0.0167.

Abbreviations: ESRD, end-stage renal disease; LDO, large dialysis organization; PD, peritoneal dialysis.

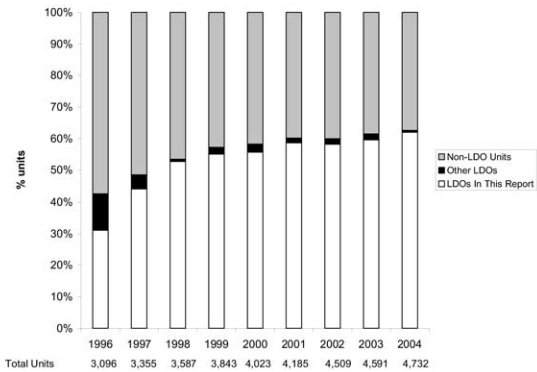

Figure 1. Change in proportion of dialysis units owned by large dialysis organizations (LDOs) in the United States from 1996 (43%) to 2004 (63%).

transplantation, transfer to a unit with a different affiliation, or last follow-up. Survival analyses were limited to the 5-year period from 2000 through 2004 because in the first 4 years of the study period (1996 to 1999), there were marked changes in ownership patterns of dialysis units in the country. Adjusted HRs were calculated for each of the 5 incident cohorts and for the entire 5-year period. Multivariate models were built by using the same variables as described for logistic regression analyses; however, PD census for the unit was added as an additional covariate. Only the fully adjusted models are presented here.

All analyses were performed using SAS, version 9.1 (SAS Institute, Cary, NC).

RESULTS

Patient Characteristics by Unit Ownership

During the 9-year period, the number of dialysis units in the country increased by 53% (Fig 1). This was a result of an increase in the number of LDO units from 1,320 in 1996 to 2,961 in 2004; the number of non-LDO units was largely unchanged (1,776 in 1996 and 1,771 in 2004). The increase in the proportion of LDO units was steep from 1996 (43%) to 1999 (57%), followed by a more gradual increase from 2000 (58%) to 2004 (63%; Fig 1). There was a parallel increase in the number of patients undergoing dialysis treatment in LDO units (1996, 39%; 2004, 63%).

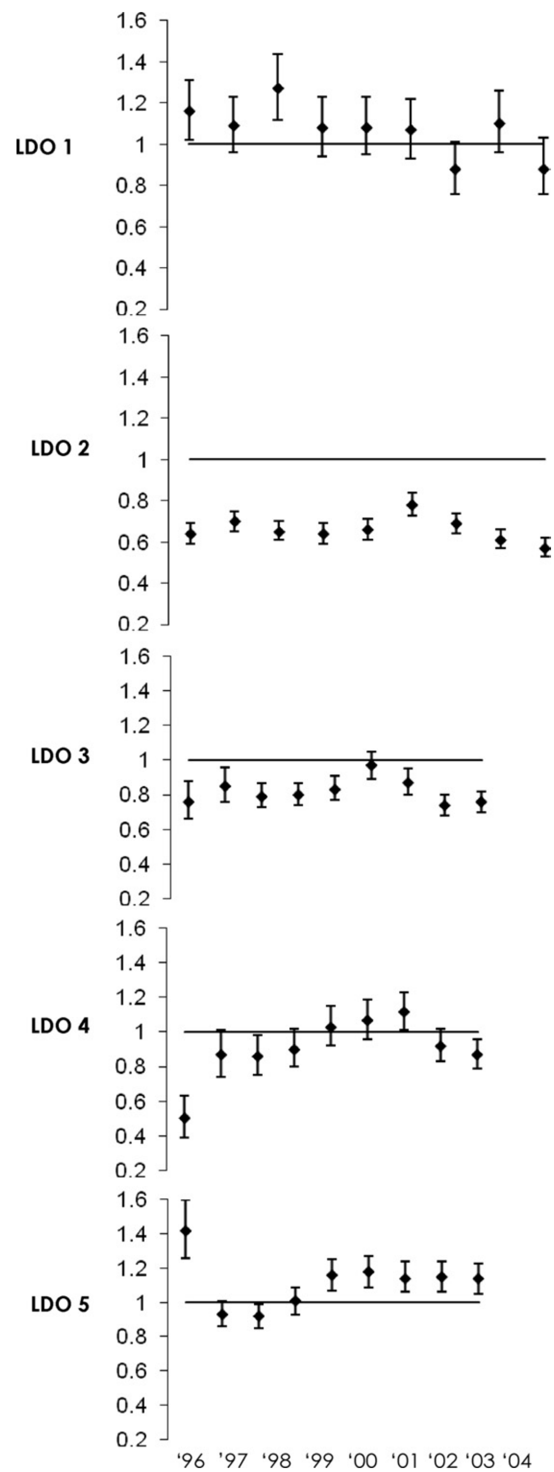

Figure 2. Adjusted odds ratios and 95% confidence intervals for use of peritoneal dialysis in 5 large dialysis organizations (LDOs) for each year from 1996 through 2004, using non-LDO units as reference. Data adjusted for LDO identification (up to 9, depending on year), age, sex, race, Hispanic ethnicity, end-stage renal disease (ESRD) network, employment status, medical insurance at start of dialysis therapy, cause of ESRD, 20 comorbidities from Medical Evidence Form 2728, serum albumin level, plasma hemoglobin level, and estimated glomerular filtration rate.

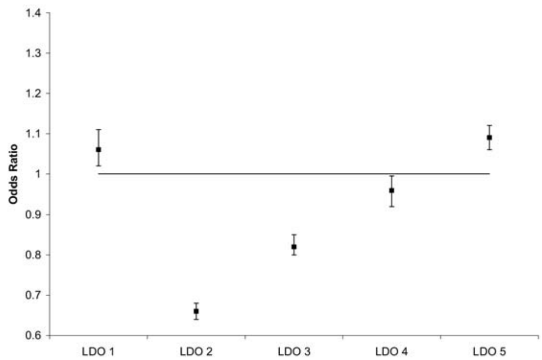

Figure 3. Odds ratios (ORs) for an incident patient to be undergoing peritoneal dialysis on day 90 in 5 large dialysis organizations (LDOs) in the United States, using non-LDO units as the reference, during the entire 9-year period (1996 to 2004). Data adjusted for LDO identification (up to 9, depending on year), age, sex, race, Hispanic ethnicity, end-stage renal disease (ESRD) network, employment status, medical insurance at the start of dialysis therapy, cause of ESRD, 20 comorbidities from Medical Evidence Form 2728, serum albumin level, plasma hemoglobin level, and estimated glomerular filtration rate. ORs were: LDO 1, 1.06 (95% confidence interval [CI], 1.02 to 1.11); LDO 2, 0.66 (95% CI, 0.64 to 0.68); LDO 3, 0.82 (95% CI, 0.80 to 0.85); LDO 4, 0.96 (95% CI, 0.92 to 0.995); and LDO 5, 1.09 (95% CI, 1.06 to 1.12).

Characteristics of incident dialysis patients are listed in Table 1. During the study period, there were 785,531 incident maintenance dialysis patients, of whom 346,104 were treated in non-LDO units. The number of incident patients in the 5 LDO units ranged from 25,949 to 95,197.

Use of PD by Unit Ownership

During the 9-year period, PD use decreased irrespective of ownership of the dialysis units (Table 1). PD use was significantly lower in LDO units than non-LDO units, with an adjusted OR of 0.77 (95% confidence interval [CI], 0.76 to 0.79). Most LDO units are for profit; classifying differently, PD use was significantly lower in for-profit units (OR, 0.86; 95% CI, 0.84 to 0.87) compared with not-for-profit units.

Systematic differences in PD use were seen in units owned by different LDOs, and trends for each LDO were similar in most years (Fig 2). Using non-LDO units as a reference, the odds for use of PD was consistently greater in patients treated in LDOs 1 and 5 and consistently lower in those treated in LDOs 2, 3, and 4 (Fig 2). Pooling the 9-year data, adjusted odds for use of PD on day 90 of ESRD were significantly greater in LDOs 1 and 5. The lowest odds for use of PD were in patients treated in LDO 2, followed by LDO 3 and LDO 4 (Fig 3).

Less than one-half of dialysis units provided care for PD patients; the lowest proportion was for LDO 4 (Table 2). Although there was a decrease in center size for PD programs in non-LDO and LDO units, there were some systematic differences. LDO 2 consistently had the smallest center sizes, whereas LDOs 4 and 5 had the largest (Table 2).

Outcomes of PD Patients by Unit Ownership

Characteristics of incident PD patients during the 5-year period (2000 to 2004) are listed in Table 3. LDO 1 PD patients had the youngest mean age and were least likely to be Hispanic. The greatest proportion of Hispanic incident PD patients was treated in LDO 3, and it had the lowest proportion with a previous

Table 2. Proportion of Units Providing Care to Patients Undergoing PD and Size of PD Programs Based on Ownership Status

	Units With PD Patients (%)						Median PD Patients/PD Program					
	Non-LDO	LDO 1	LDO 2	LDO 3	LDO 4	LDO 5	Non-LDO	LDO 1	LDO 2	LDO 3	LDO 4	LDO 5
1996	50	42	37	45	17	52	16 (1, 198)	22 (1, 130)	12 (1, 123)	12 (1, 79)	30 (2, 86)	18.5 (1, 91)
1997	48	43	34	53	23	49	15 (1, 191)	17 (1, 116)	11 (1, 122)	12 (1, 60)	25 (2, 84)	10 (1, 94)
1998	45	43	35	48	27	47	13 (1, 143)	15 (1, 123)	9 (1, 113)	12 (1, 159)	17 (1, 76)	10.5 (1, 96)
1999	42	36	34	48	29	45	12 (1, 130)	17 (1, 93)	9 (1, 115)	11 (1, 145)	21 (2, 107)	11 (1, 70)
2000	41	37	34	47	28	42	11 (1, 128)	14.5 (1, 82)	9 (1, 132)	10.5 (1, 143)	21 (1, 121)	11 (1, 80)
2001	38	33	33	45	26	42	11 (1, 126)	13 (1, 95)	10 (1, 122)	12 (1, 107)	21 (1, 132)	13 (1, 86)
2002	37	39	34	43	29	43	9 (1, 127)	7.5 (1, 97)	8 (1, 144)	12 (1, 74)	21 (1, 120)	13 (1, 88)
2003	38	37	32	39	27	44	10 (1, 126)	8 (1, 81)	8 (1, 126)	12 (1, 82)	20 (1, 108)	13 (1, 85)
2004	37	34	32	38	30	45	10 (1, 123)	9.5 (1, 87)	8 (1, 105)	12 (1, 93)	14.5 (1, 90)	14 (1, 98)

Note: Values expressed as percent or medium (minimum, maximum).
Abbreviations: LDO, large dialysis organization; PD, peritoneal dialysis.

Table 3. Characteristics of 35,653 Incident Peritoneal Dialysis Patients Between 2000 and 2004 Based on Dialysis Unit Ownership

	Non-LDO	LDO 1	LDO 2	LDO 3	LDO 4	LDO 5
Age (y)	58.0 ± 15.3	55.1 ± 15.0	56.6 ± 15.2	57.1 ± 15.2	57.4 ± 15.4	56.8 ± 15.0
Men (%)	55	54	54	53	52	54
Race (%)						
White	75	71	73	69	74	67
African American	17	24	21	20	21	27
Asian	5	2	4	7	2	3
Other	3	3	3	4	3	2
Hispanic ethnicity (%)	12	5	15	18	8	11
Employment status (%)						
Unemployed	16	14	14	19	17	20
Employed	21	25	25	24	22	22
Homemaker	5	4	6	6	5	5
Retired	46	47	49	45	49	47
Other/unspecified	12	11	6	7	7	7
Primary cause of ESRD (%)						
Diabetes	41	42	44	46	43	45
Hypertension	20	19	23	23	22	24
Others	39	39	33	32	35	31
Selected coexisting conditions or risk factors (%)						
Congestive heart failure	20	17	19	18	19	22
Ischemic heart disease	20	18	18	15	20	18
Myocardial infarction	7	7	7	6	6	6
Current tobacco use	6	7	5	5	6	6
Inability to ambulate	2	1	1	1	1	1
Inability to transfer	0.5	0.3	0.3	0.2	0.4	0.4
Weight (kg)	77.1 ± 19.6	78.1 ± 19.2	77.7 ± 18.4	76.9 ± 18.8	79.3 ± 19.5	78.8 ± 19.0
Body mass index (kg/m^2)	27.0 ± 6.6	27.2 ± 6.2	27.5 ± 6.3	27.2 ± 6.2	28.0 ± 6.7	27.7 ± 6.3
Predialysis erythropoietin use (%)	48	51	47	44	43	46
Hemoglobin (g/dL)	10.5 ± 1.8	10.5 ± 1.7	10.5 ± 1.8	10.6 ± 1.8	10.6 ± 1.8	10.5 ± 1.8
Serum albumin (g/dL)	3.4 ± 0.7	3.5 ± 0.7	3.5 ± 0.7	3.5 ± 0.7	3.6 ± 0.7	3.5 ± 0.7
Serum creatinine (mg/dL)	7.0 ± 3.3	7.4 ± 3.3	7.3 ± 3.2	7.0 ± 3.2	6.9 ± 3.1	7.2 ± 3.3
Glomerular filtration rate (mL/min/1.73 m^2)	9.7 ± 4.4	9.1 ± 4.0	9.1 ± 4.0	9.5 ± 4.1	9.7 ± 4.2	9.4 ± 4.1

Note: All trends were statistically significant. Conversion factors for units: hemoglobin and serum albumin in g/dL to g/L, ×10; serum creatinine in mg/dL to mmol/L, ×88.4; glomerular filtration rate in mL/min/1.73 m^2 to mL/s, ×0.0167.

Abbreviations: ESRD, end-stage renal disease; LDO, large dialysis organization.

diagnosis of congestive heart failure, ischemic heart disease, and myocardial infarction. The proportion of African Americans was greatest in LDO 5.

There was no significant difference in risk of death (adjusted HR, 1.03; 95% CI, 0.99 to 1.07) or a composite outcome of death or transfer to MHD therapy (HR, 1.03; 95% CI, 0.99 to 1.06) in PD patients treated in LDO units compared with non-LDO units. However, risk of death was significantly greater in for-profit units compared with not-for-profit units (HR, 1.06; 95% CI, 1.02 to 1.11). Similarly, there was a significantly greater risk of a composite outcome of death or transfer to MHD therapy in for-profit units compared with not-for-profit units (HR, 1.07; 95% CI, 1.03 to 1.11).

With non-LDO units as a reference, there was no significant difference in hazards for death between incident PD patients in each of the LDOs examined for each year, with the following exceptions: significantly lower death hazards for LDO 1 in 2000 and significantly higher hazards for LDO 2 in 2002 and 2003 and LDO 4 in 2003 (Fig 4). Pooling the 5-year data, hazards for death in incident patients in LDO 1 were 13% lower and for LDO 2 were 8% higher compared with non-LDO units (Fig 5). The effect of PD census of the dialysis unit on patient's risk of death is listed in Table 4.

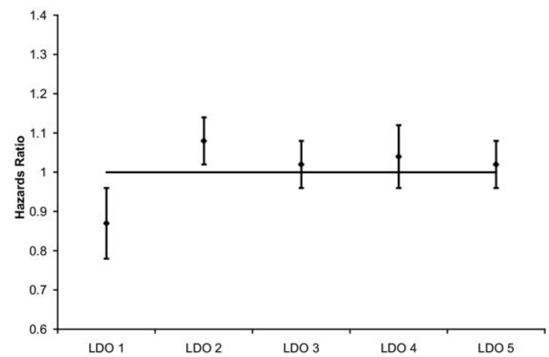

Figure 5. Adjusted hazard ratios (HRs) for death for incident peritoneal dialysis patients during the entire 5-year period (2000 to 2004) in 5 large dialysis organizations (LDOs) in the United States, using non-LDO units as the reference. Data adjusted for LDO identification (up to 9, depending on year), age, sex, race, Hispanic ethnicity, end-stage renal disease (ESRD) network, employment status, medical insurance at the start of dialysis therapy, cause of ESRD, 20 comorbidities from Medical Evidence Form 2728, serum albumin level, plasma hemoglobin level, and estimated glomerular filtration rate. HRs were: LDO 1, 0.87 (95% confidence interval [CI], 0.78 to 0.96); LDO 2, 1.08 (95% CI, 1.02 to 1.14); LDO 3, 1.02 (95% CI, 0.96 to 1.08); LDO 4, 1.04 (95% CI, 0.96 to 1.12); and LDO 5, 1.02 (95% CI, 0.96 to 1.08). Data were censored at the time of transfer to maintenance hemodialysis therapy, transplantation, or transfer to a unit with a different affiliation.

Similar trends were noted for adjusted HRs for reaching a composite outcome of death or transfer to MHD therapy (data not shown). Incident PD patients treated in LDO 2 were significantly more likely to reach the composite outcome in 3 of the 5 years studied, using non-LDO units as reference; greater risk of reaching the composite outcome was seen in 1 of the 5 years for LDOs 3 and 4. Pooling the 5-year data, hazards for death or transfer to MHD therapy in incident PD patients in LDO 2 were 13% greater compared with non-LDO units (Fig 6); HRs for none of the other

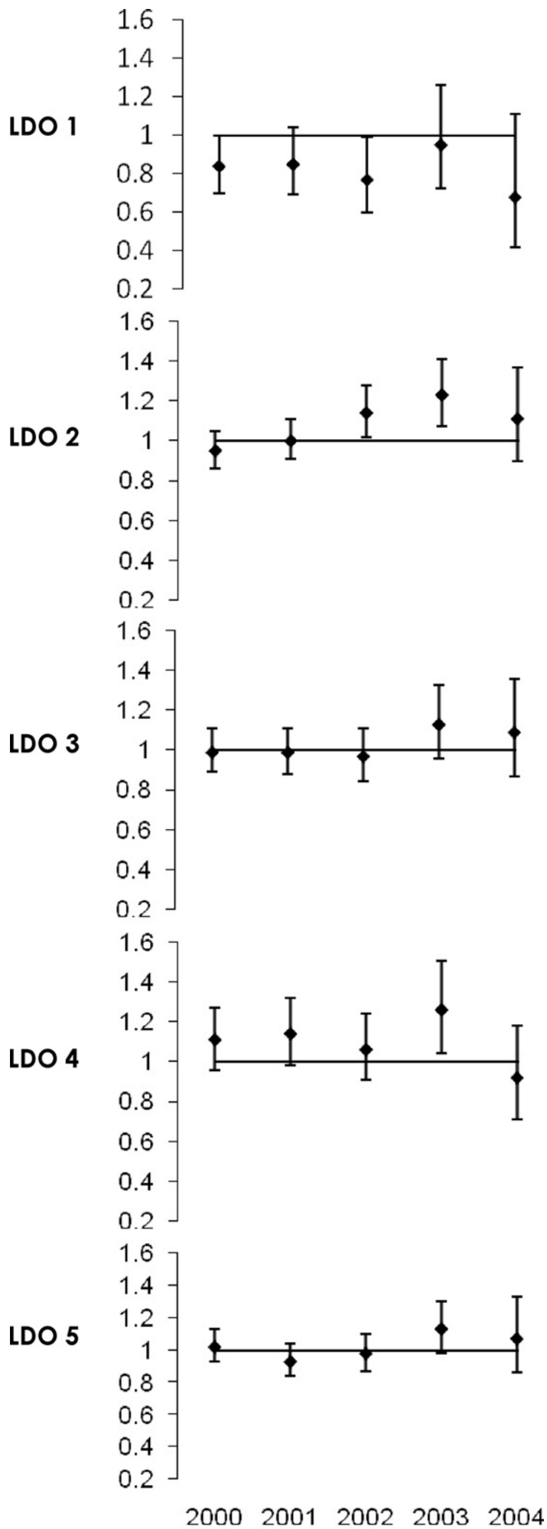

Figure 4. Adjusted hazard ratios and 95% confidence intervals for death in incident peritoneal dialysis (PD) patients in 5 large dialysis organizations (LDOs) for each year from 2000 through 2004, using non-LDOs as reference. Data adjusted for LDO identification (up to 9, depending on year), age, sex, race, Hispanic ethnicity, end-stage renal disease (ESRD) network, employment status, medical insurance at start of dialysis therapy, cause of ESRD, 20 comorbidities from Medical Evidence Form 2728, serum albumin level, plasma hemoglobin level, estimated glomerular filtration rate, and PD unit census. Data were censored at the time of transplantation, transfer to maintenance hemodialysis therapy, or transfer to a unit with a different affiliation.

Table 4. Effect of PD Unit Census on Patient Outcomes

	Hazard Ratio (95% confidence interval)	
PD Unit Census	Death	Death or Transfer to Maintenance Hemodialysis
>21	1.00	1.00
11-21	1.04 (0.99-1.09)	1.07 (1.03-1.10)
5-10	1.05 (0.99-1.12)	1.12 (1.07-1.18)
<5	1.23 (1.14-1.32)	1.32 (1.03-1.10)

Note: Analyses performed in the cohort of incident patients from 2000 through 2004 (n = 36,115). Data adjusted for LDO identification (up to 9, depending on year), age, sex, race, Hispanic ethnicity, ESRD network, employment status, medical insurance at the start of dialysis therapy, cause of ESRD, 20 comorbidities from Medical Evidence Form 2728, serum albumin level, plasma hemoglobin level, and estimated glomerular filtration rate.

Abbreviations: ESRD, end-stage renal disease; LDO, large dialysis organization; PD, peritoneal dialysis.

LDOs reached statistical significance. The effect of PD census of the dialysis unit on patient risk of the composite outcome is listed in Table 4.

DISCUSSION

Since the introduction of PD therapy, many observational studies have compared its outcomes with those seen with MHD therapy. Differences in outcomes have been described among some patient subgroups and over time, but it is hard to ascertain whether these are attributable to the dialysis modality or a result of residual confounding. The preponderance of evidence indicates that overall, the 2 therapies are associated with equivalent risk of death.[7] However, unlike some other developed countries, a much smaller proportion of maintenance dialysis patients in the United States uses PD.[7] Earlier studies, some from our group, have identified some of the following factors as important contributors to low PD use: limited opportunities for physicians to learn about the therapy in training programs, challenges from lack of infrastructure to support home dialysis in most units, and concerns (arguably misplaced) about who can or should perform home dialysis and its outcomes.[7,8] As a result, most incident dialysis patients report that they are not aware of dialysis modalities other than in-center MHD.[5]

Starting in 1996, there has been a precipitous decrease in the proportion of maintenance dialysis patients undergoing PD.[1] Our previous analyses indicate that medical characteristics of the incident dialysis population have not changed sufficiently to account for the steep decrease in PD use.[6] Additional analyses of USRDS data presented here build on the existing knowledge in the field. During the 9-year period, the prevalent dialysis population increased 47% and the number of dialysis units increased by 53%. However, the growth in number of dialysis units was limited to those owned by LDOs. We sought to determine whether the ownership pattern of dialysis units was associated with PD use. During the period studied, PD use decreased in non-LDO units and each of the LDOs. Thus, the increase in proportion of patients undergoing care in LDOs cannot be the only reason for the decrease in PD use. However, it may be an important determinant of the progressively lower PD use. As clearly shown here, there are systematic differences in PD use by incident maintenance dialysis patients receiving care in different LDOs. Even adjusted for patient characteristics, the odds for undergoing PD in LDOs 2 and 3 were consistently lower than in non-LDO units in each of the

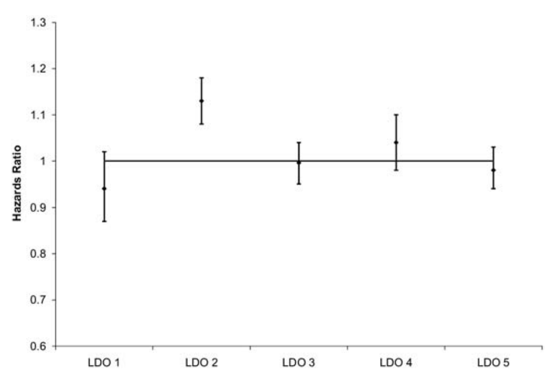

Figure 6. Hazard ratios (HRs) for death or transfer to maintenance hemodialysis therapy for incident peritoneal dialysis patients during a 5-year period (2000 to 2004) in 5 large dialysis organizations (LDOs) in the United States, using non-LDO units as the reference. Data adjusted for LDO identification (up to 9, depending on year), age, sex, race, Hispanic ethnicity, end-stage renal disease (ESRD) network, employment status, medical insurance at the start of dialysis therapy, cause of ESRD, 20 comorbidities from Medical Evidence Form 2728, serum albumin level, plasma hemoglobin level, and estimated glomerular filtration rate. HRs were: LDO 1, 0.94 (95% confidence interval [CI], 0.87 to 1.02); LDO 2, 1.13 (95% CI, 1.08 to 1.18); LDO 3, 0.996 (95% CI, 0.95 to 1.05); LDO 4, 1.04 (95% CI, 0.98 to 1.10); and LDO 5, 0.98 (95% CI, 0.94 to 1.03). Data were censored at the time of transplantation or transfer to a unit with a different affiliation.

9 years examined; in LDO 4, PD use was lower than in non-LDO units in 6 of the 9 years examined. However, incident dialysis patients in LDOs 1 and 5 were more likely to use PD in 7 of the 9 years studied. Given the consistency of these differences in PD use, they are unlikely to be random. A lopsided increase in number of units over time owned by LDOs with systematically lower PD use is expected to result in an overall decrease in PD use.

Our study design does not allow us to identify the differences in LDO policy, if any, that may impact on PD use. However, some of these may be related to varying investments in PD programs, such as hiring nurses, providing support for them to be available on call during evenings and weekends, or requiring PD nurses to work in MHD units. Our study also indicates there has been a significant increase in "hemodialysis capacity" with an increase in the number of new dialysis units; the need to fill this increased capacity may be another potential reason that may have led to lower PD use. Furthermore, different LDOs may have arrived at different conclusions regarding the profitability of providing care for PD patients. Relative to MHD, costs for supplies (dialysis solutions) for PD patients are greater, but the staffing (nursing) and capital (building and plumbing) costs are lower. As a result, per-patient profits in PD programs increase with a larger patient population. However, as listed in Table 2, significant proportions of PD programs provide care to fewer than 10 patients and have limited potential to be profitable. Thus, it is possible that the decrease in PD use may be part of a vicious cycle in which lower profitability of PD programs may lead to lower support by some LDOs. Breaking this vicious cycle of lower support for PD programs can translate into significant cost-savings to taxpayers. The cumulative savings are likely to be substantially greater with the projected increase in the maintenance dialysis patient population.

Other than economic consequences, the systematic differences in PD may have tangible implications on patient outcomes. Thus, LDO 2, which had the lowest use of PD, had the worst outcomes for these patients. However, LDO 1 had greater PD use and the outcomes were consistently better. The relationship between proportions of patients undergoing PD and outcomes in an LDO are not entirely unexpected. The relationship between procedural volume and outcomes has been reported previously for cardiothoracic surgeons and hospitals.[9] Greater cumulative experience in the care of PD patients previously has been associated with better outcomes.[10] Thus, the association between PD use in an LDO may be a surrogate for the experience of health care providers. Similarly, a strong association between center size and outcomes of PD patients has been reported previously.[11,12] Consistent with these observations, LDO 2 had the smallest PD programs and the worst outcomes. However, this can explain only part of the association. PD census of the dialysis unit was noted to be an independent predictor of outcome; however, differences in outcomes of patients treated in different LDOs persisted, even after adjusting data for the PD census of the unit where they were treated. Consistent with this observation, the median number of patients in each PD program was one of the lowest in LDO 1, yet patients treated in these units generally had the best outcomes. Similarly, LDO 4 had the highest median number of patients per program for most of the study period, but this did not translate into better survival. Differences in corporate policies in providing support to PD programs may be an additional, albeit untested, explanation for the relationship.

There are several limitations of the study. First, we were unable to ascertain the effect of change in ownership of dialysis units on the change in PD use. During the study period, many non-LDO units were acquired by LDOs, but at the time of change in ownership of the dialysis unit, a new facility identification number is assigned, making it impossible to study the effect of change in ownership. Second, based on our analyses, we cannot exclude residual confounding, particularly because the coexisting conditions or risk factors may be underreported on Medical Evidence Form 2728.[13] Moreover, no information was available for severity of the individual coexisting conditions or risk factors. However, this problem is likely to be randomly distributed for the different LDOs and thus unlikely to have biased results. Third, data for several laboratory variables was incomplete and we used imputed values for the analyses. However, similar estimates were obtained regardless of whether laboratory variables were included in the multivariate models. Therefore, the missing data are unlikely to have biased our results. Fourth, there has been additional consolidation in providers with the acquisition of Renal Care Group and Gambro by Fresenius and DaVita in 2005, respectively. Thus, our results may not be applicable to the consolidated entities as they exist today, and for this reason, we chose to de-identify the LDOs. However, this study provides crucial information regarding the relationship between changing patterns of ownership of dialysis units to PD use in the United States and its effects on patient outcomes.

To conclude, an increasingly larger proportion of patients with ESRD in the United States is being treated in dialysis units owned by LDOs. There are systematic differences in PD use in different LDOs. A lopsided increase in the number of units owned by LDOs with lower PD use likely is one, although not the only, reason for the decrease in use of PD in the country. There is a relationship between PD use and patient outcomes such that the organizations with the lowest use of the therapy generally have the worst outcomes. Understanding the relationship between provider characteristics and PD use and outcomes may allow policy makers to devise strategies to reverse the trend of decreasing PD use. The success in reversing the trend of decreasing PD use in part may dictate the ability to stem the increase in expenditures for patients with ESRD.

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REFERENCES

1. US Renal Data System: Annual Data Report. US Department of Public Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD, 2007

2. Just PM, Riella MC, Tschosik EA, Noe LL, Bhattacharyya SK, de Charro F: Economic evaluations of dialysis treatment modalities. Health Policy (Amsterdam, Netherlands) 86:163-180, 2008

3. Shih YC, Guo A, Just PM, Mujais S: Impact of initial dialysis modality and modality switches on Medicare expenditures of end-stage renal disease patients. Kidney Int 68:319-329, 2005

4. Mehrotra R: Peritoneal dialysis penetration in the United States: March toward the fringes? Perit Dial Int 26:419-422, 2006

5. Mehrotra R, Marsh D, Vonesh E, Peters V, Nissenson A: Patient education and access of ESRD patients to renal replacement therapies beyond in-center hemodialysis. Kidney Int 68:378-390, 2005

6. Mehrotra R, Kermah D, Fried L, et al: Chronic peritoneal dialysis in the United States: Declining despite utilization improving outcomes. J Am Soc Nephrol 18:2781-2788, 2007

7. Khawar O, Kalantar-Zadeh K, Lo WK, Johnson D, Mehrotra R: Is the declining use of long-term peritoneal dialysis justified by outcome data? Clin J Am Soc Nephrol 2:1317-1328, 2007

8. Mehrotra R, Blake P, Berman N, Nolph KD: An analysis of dialysis training in the United States and Canada. Am J Kidney Dis 40:152-160, 2002

9. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL: Surgeon volume and operative mortality in the United States. N Engl J Med 349:2117-2127, 2003

10. Schaubel DE, Blake PG, Fenton SS: Effect of renal center characteristics on mortality and technique failure on peritoneal dialysis. Kidney Int 60:1517-1524, 2001

11. Huisman RM, Nieuwenhuizen MG, Th de Charro F: Patient-related and centre-related factors influencing technique survival of peritoneal dialysis in The Netherlands. Nephrol Dial Transplant 17:1655-1660, 2002

12. Mujais S, Story K: Peritoneal dialysis in the US: Evaluation of outcomes in contemporary cohorts. Kidney Int Suppl 103:S21-S26, 2006

13. Longenecker JC, Coresh J, Klag MJ, et al: Validation of comorbid conditions on the end-stage renal disease medical evidence report: The CHOICE Study. Choices for Healthy Outcomes in Caring for ESRD. J Am Soc Nephrol 11:520-529, 2000