Dialysis outcomes in Colombia (DOC) study: A comparison of patient survival on peritoneal dialysis vs hemodialysis in Colombia

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The goal of the Dialysis Outcomes in Colombia (DOC) study was to compare the survival of patients on hemodialysis (HD) vs peritoneal dialysis (PD) in a network of renal units in Colombia. The DOC study examined a historical cohort of incident patients starting dialysis therapy between 1 January 2001 and 1 December 2003 and followed until 1 December 2005, measuring demographic, socioeconomic, and clinical variables. Only patients older than 18 years were included. As-treated and intention-to-treat statistical analyses were performed using the Kaplan–Meier method and Cox proportional hazard model. There were 1094 eligible patients in total and 923 were actually enrolled: 47.3% started HD therapy and 52.7% started PD therapy. Of the patients studied, 751 (81.3%) remained in their initial therapy until the end of the follow-up period, death, or censorship. Age, sex, weight, height, body mass index, creatinine, calcium, and Subjective Global Assessment (SGA) variables did not show statistically significant differences between the two treatment groups. Diabetes, socioeconomic level, educational level, phosphorus, Charlson Co-morbidity Index, and cardiovascular history did show a difference, and were less favorable for patients on PD. Residual renal function was greater for PD patients. Also, there were differences in the median survival time between groups: 27.2 months for PD vs 23.1 months for HD ($P = 0.001$) by the intention-to-treat approach; and 24.5 months for PD vs 16.7 months for HD ($P < 0.001$) by the as-treated approach. When performing univariate Cox analyses using the intention-to-treat approach, associations were with age $\geqslant$65 years (hazard ratio (HR) = 2.21; confidence interval (CI) 95% (1.77–2.755); $P < 0.001$); history of cardiovascular disease (HR = 1.96; CI 95% (1.58–2.90); $P < 0.001$); diabetes (HR = 2.34; CI 95% (1.88–2.90); $P < 0.001$); and SGA (mild or moderate–severe malnutrition) (HR = 1.47; CI 95% (1.17–1.79); $P = 0.001$); but no association was found with gender (HR = 1.03, CI 95% 0.83–1.27; $P = 0.786$). Similar results were found with the as-treated approach, with additional associations found with Charlson Index (0−2) (HR=0.29; CI 95% (0.22−0.38); $P < 0.001$); Charlson Index (3−4) (HR=0.61; CI 95% (0.48–0.79); $P < 0.001$); and SGA (mild-severe malnutrition) (HR=1.43; CI 95% (1.15–1.77); $P < 0.001$). Similarly, the multivariate Cox model was run with the variables that had shown association in previous analyses, and it was found that the variables explaining the survival of patients with end-stage renal disease in our study were age, SGA, Charlson Comorbidity Index 5 and above, diabetes, healthcare regimes I and II, and socioeconomic level 2. The results of Cox proportional risk model in both the as-treated and intention-to-treat analyses showed that there were no statistically significant differences in survival of PD and HD patients: intention-to-treat HD/PD (HR 1.127; CI 95%: 0.855–1.484) and as-treated HD/PD (HR 1.231; CI 95%: 0.976–1.553). In this historical cohort of incident patients, there was a trend, although not statistically significant, for a higher (12.7%) adjusted mortality risk associated with HD when compared to PD, even though the PD patients were poorer, were more likely to be diabetic, and had higher co-morbidity scores than the HD patients. The variables that most influenced survival were age, diabetes, comorbidity, healthcare regime, socioeconomic level, nutrition, and education.

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In the past three decades, a substantial body of evidence has been built around the outcomes of dialysis therapies. Among them, survival is one of the most significant, and in spite of the large number of studies, there is a considerable controversy about which therapy provides a better survival. Survival can be attributed to the therapy itself or to other factors such as age, diabetes, history of cardiovascular disease, residual renal function (RRF), gender, comorbidity at the start of therapy, geographical location, and race.[1–21]

Assignment of the patients to different treatments varies by country and the type of dialysis center. There are some factors that increase the likelihood that peritoneal dialysis (PD) will be used for renal replacement therapy (RRT). Among these are white race, employed, low comorbidity score, good RRF, and normal albumin levels at the start of the therapy.[9,11] Among the different racial groups, there are differences in dialysis survival, which are demonstrated after adjusting for comorbidity risk factors, possibly associated with genetic and environmental factors,[14] justifying further research in different countries and ethnic groups.

Colombia is a country of 42.1 million inhabitants,[22] with an unemployment rate of 11%, a monthly minimum wage of 223 USD,[23] a projected gross domestic product per capita of 2.574 USD, with 52.4% of the population under the poverty line and health expenses equivalent to 7.7% of the GDP.[24] In 2005, the estimated dialysis prevalence was 355 patients per million (p.p.m.) population, of which 40% were on PD and 60% on HD.[25] Approximately 2% of the national health expenses is allocated to the management of the renal disease.[26]

The Colombian General Social Security and Health System has defined three basic regimes with different financing frameworks that guarantee patients with end-stage renal disease (ESRD) access to the different types of RRT with dialysis. Regime I, also known as the 'contributive regime,' which covered 36.3% of the population in 2006, guarantees overall health insurance. Regime II, called the 'subsidized regime,' is financed by both state resources and crossover subsidies, and is intended for people who do not have formal employment and are classified as part of the poor population (43%). Regime III, 'under a subsidized regime,' provides coverage to a poor population group that is not favored with regime II and gets medical assistance through a structure of public welfare financed with state resources (20.7%). The remaining 4.8% of the population is covered by special regimes with greater accessibility and a larger number of benefits.[27]

The goal of the Dialysis Outcomes in Colombia (DOC) study is to compare the survival of hemodialysis (HD) patients and PD patients in a cohort of incident patients getting dialysis in Colombia, taking into account all the aforementioned demographic and socioeconomic factors and assessing variables of interest in the patients studied.

RESULTS

Characteristics of the patients

Of 1094 patients eligible to enter the DOC study, data from 923 patients who started RRT with dialysis between 1 January 2001 and 1 December 2003 were recorded retrospectively. For the remaining 171 (15.6%) eligible patients, complete baseline and outcome data were not available; these patients were therefore excluded from the study. Of the 923 patients enrolled, 437 (47.3%) were started on HD and 486 (52.7%) on PD, defining the intention-to-treat group. The as-treated group was defined as the sum of the patients who remained on the initial therapy modality until the end of the follow-up period, those who died or were censored (751 patients, 81.3%), and those who switched from HD to PD (85 patients) from PD to HD (87 patients) censored 60 days after the switch (Figure 1).

Statistically significant differences in the continuous variables were not found between PD and HD patients upon entering the cohort, except for RRF (higher in PD when compared to HD, $P=0.006$) and phosphorus level (higher in PD when compared to HD, $P=0.01$) (Table 1). It should be stressed that only 55.1% (509) of the records actually recorded RRF, the reason why this variable was not included in the multivariate analyses.

PD and HD patients were compared for gender, social security regime, education, socioeconomic level, ESRD etiology, Subjective Global Assessment (SGA), history of cardiovascular disease, and Charlson Comorbidity Index. A larger proportion of PD patients was found for the following variables: socioeconomic level 1 ($P=0.03$), healthcare regime II ($P<0.001$) and III ($P<0.001$), diabetes mellitus (DM) ($P=0.0049$), history of cardiovascular disease ($P<0.001$), and Charlson Comorbidity Index $\geqslant 5$ ($P=0.0037$) (Table 2).

Intention-to-treat analysis

By the Kaplan–Meier method with the log-rank test, statistically significant differences were found in patient survival by therapy, with a better survival for PD patients compared to HD patients ($P<0.001$; Figure 2a). The median survival time was 27.2 months for patients on PD and 23.1 months for patients on HD, with a statistically significant difference (Mann–Whitney test $P=0.001$).

Survival curves of PD vs HD with the Cox proportional hazard model adjusting by covariates did not show statistical differences (HD/PD HR = 1.12, CI 95% (0.855–1.484) $P=0.396$; Figure 2b).

Survival adjusted for age and DM did not show statistically significant differences for PD vs HD patients (Figure 3), except for the group of nondiabetic patients

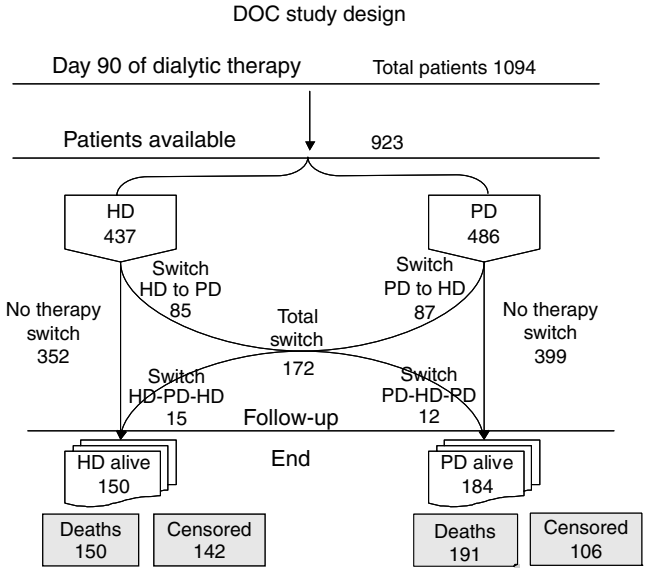

Figure 1 | DOC study patients flowchart.

Table 1 | Summary for quantitative variables

	HD	PD	*P*-value
N	437	486	
Age (years)			
Mean (range)	54.5 (18–87)	52.6 (18–95)	
s.d.	15.8	15.6	NS
Median	57	54	
Weight (kg)			
Mean (range)	59.5 (33–107)	69.4 (34–104)	
s.d.	11.1	11.3	NS
Median	58	60	
Height (m)			
Mean (range)	1.60 (1.35–1.82)	1.60 (1.36–1.82)	
s.d.	0.09	0.09	NS
Median	1.61	1.61	
BMI (kg m^{-2})			
Mean (range)	23.1 (14.1–44.1)	23.5 (15–39.2)	
s.d.	3.9	3.8	NS
Median	22.8	23.1	
RRF[a] *(ml min^{-1})*			
Mean (range)	2.03 (0–14.7)	2.67 (0–26)	
s.d.	2.71	3.5	0.006
Median	0.790	1.61	
Creatinine (mg%)			
Mean (range)	7.21 (2.0–18.6)	7.15 (1.7–29)	
s.d.	3	3.5	NS
Median	6.9	6.5	
Calcium (mg%)			
Mean (range)	8.8 (3.3–14.4)	8.7 (3.4–15)	
s.d.	1.6	1.9	NS
Median	9.0	8.9	
Phosphorus (mg%)			
Mean (range)	4.35 (1.0–12)	4.6 (1.6–13.8)	
s.d.	1.4	1.4	0.01
Median	4.1	4.4	

BMI, body mass index; HD, hemodialysis; N, number of patients; NS, not significant; PD, peritoneal dialysis; RRF, residual renal function; s.d., standard deviation.
[a]*N*=509.

Table 2 | Summary for qualitative variables

	HD		PD		
	N	%	N	%	*P*-value
Gender					
Male	258	59	267	54.9	NS
Female	179	41	219	45.1	
Regime of health coverage					
I	274	62.7	300	61.7	NS
II	145	33.2	111	22.8	0.0000
III	18	4.1	75	15.4	0.0000
Education					
Illiterate	31	7.1	35	7.2	NS
Elementary	266	60.9	282	58	NS
High school	95	21.7	128	26.3	NS
University	37	8.5	27	5.6	NS
Postgraduate	8	1.8	14	2.9	NS
Socioeconomic level					
1	78	17.8	116	23.9	0.0308
2	182	41.6	203	41.8	NS
3	130	29.7	119	24.5	NS
4	38	8.7	33	6.8	NS
5	7	1.6	6	1.2	NS
6	2	0.5	9	1.9	NS
Cause of ESRD					
Diabetes	157	35.9	220	45.3	0.0049
Hypertension	140	32.0	128	26.3	NS
Glomerulonephritis	43	9.8	50	10.3	NS
Polycystic kidney disease	7	1.6	10	2.1	NS
Obstructive uropathy	29	6.6	15	3.1	NS
Others	33	7.6	21	4.3	NS
Unknown cause	28	6.4	42	8.6	NS
SGA					
Well nourished	253	57.9	239	49.2	NS
Mild or moderate malnutrition	138	31.6	193	39.7	NS
Severe malnutrition	38	8.7	40	8.2	NS
No data	8	1.8	14	2.9	
Cardiovascular history					
Yes	112	25.6	149	30.7	0.0003
No	325	74.4	333	68.5	
Charlson Comorbidity Index					
0–2	180	41.2	187	38.5	NS
3–4	143	32.7	150	30.9	NS
5–10	92	21.1	144	29.6	0.0037

ESRD, end-stage renal disease; HD, hemodialysis; NS, not significant; PD, peritoneal dialysis; SGA, Subjective Global Assessment.

younger than 65 years, in whom survival was better on PD ($P = 0.03$).

In the univariate Cox model, non-survival risk was associated with age $\geqslant 65$ years (hazard ratio (HR) = 2.21, confidence interval (CI) 95% (1.77–2.755); $P < 0.001$); history of cardiovascular disease (HR = 1.96, CI 95% (1.58–2.90); $P < 0.001$); diabetes (HR = 2.34, CI 95% (1.88–2.90); $P < 0.001$); and SGA (mild or moderate–severe malnutrition) (HR = 1.47, CI 95% (1.17–1.79); $P < 0.001$), whereas there was no association with gender (HR = 1.03, CI 95%, 0.83–1.27; $P = 0.786$).

In the multivariate Cox proportional risks model, age, SGA, Charlson Comorbidity Index 5 and above, diabetes, regimes I and II, and socioeconomic level 2 showed statistical significance in explaining survival of ESRD patients. There was no difference in survival between HD and PD patients when adjustments were made for other confounding risk factors (Table 3).

As-treated analysis

With the Kaplan–Meier method, survival in PD patients was better when compared to HD patients (log-rank test, $P = 0.0237$) (Figure 4a). When comparing the median survival times using this approach (Mann–Whitney test), there was a difference in the median survival time of 7.8 months ($P < 0.001$) in favor of PD.

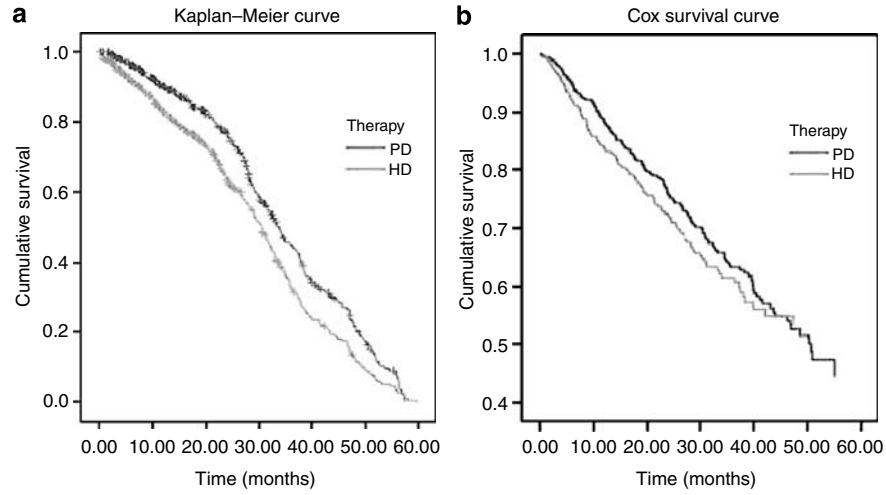

Figure 2 | Survival analysis by intention-to-treat. (**a**) Kaplan–Meier curves for HD (light line) and PD (dark line) patients, follow-up in months (log-rank test: $P<0.001$) (**b**) Cox survival curves adjusted for covariates for HD (light line) and PD (dark line) patients, follow-up in months.

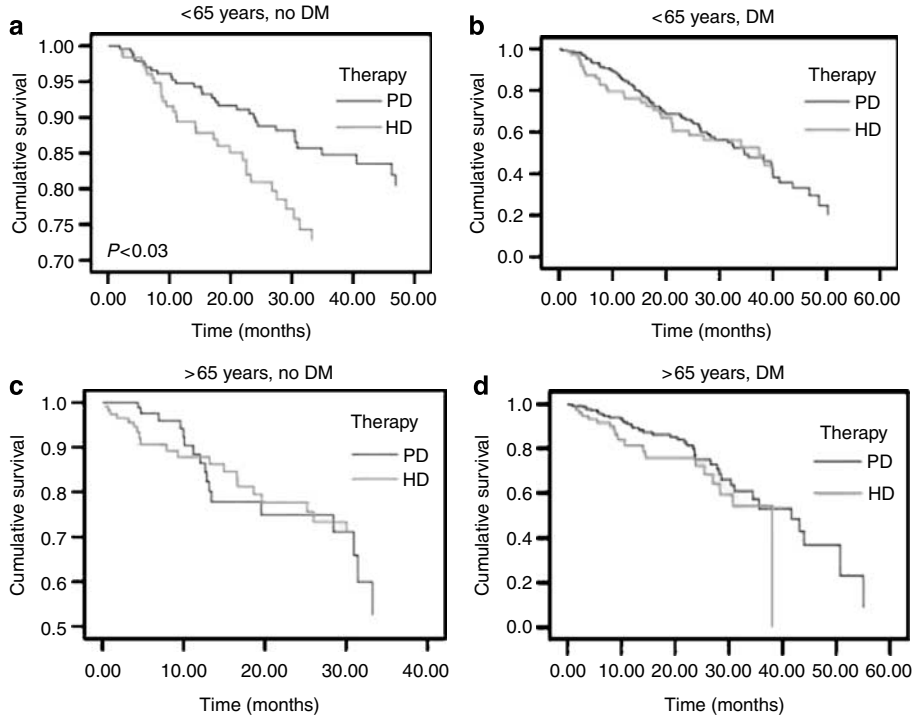

Figure 3 | Survival analysis by intention-to-treat adjusted for age and DM. (**a–d**) Cox survival curves adjusted for covariates of age and DM for groups of HD (light line) and PD (dark line) patients, follow-up in months.

Survival curves for PD vs HD with the Cox proportional hazard model adjusting by covariates did not show statistical differences (HD/PD HR = 1.23, CI 95% (0.976–1.553); $P = 0.079$; Figure 4b).

In univariate Cox model, non-survival risk was associated with age ⩾65 years (HR = 2.22, CI 95% (1.79–2.77); $P<0.001$); history of cardiovascular disease (HR = 1.97, CI 95% (1.59–2.45); $P<0.001$); diabetes (HR = 2.19, CI 95% (1.77–2.73); $P<0.001$); regime I (HR = 0.75, CI 95% (0.52–1.06); $P = 0.107$); regime II (HR = 0.67, CI 95% (0.45–1.00); $P = 0.054$), Charlson Index (0–2) (HR = 0.29, CI 95% (0.22–0.38); $P<0.001$); Charlson Index (3–4) (HR = 0.61, CI 95% (0.48–0.79); $P<0.001$); SGA (mild or moderate–severe malnutrition) (HR = 1.43, CI 95% (1.15–1.77); $P<0.001$), whereas there was no association with gender (HR = 0.92, CI 95% (0.74–1.14); $P = 0.46$).

The multivariate Cox proportional risks model showed that the variables that were significant in the intention-to-treat analysis also influenced survival under the as-treated approach, except for the regime II (HR = 0.66, CI 95% (0.433–1.00); $P = 0.055$); and socioeconomic level 2 (HR = 2.28, CI 95% (0.87–5.95); $P = 0.092$).

When conducting the analysis adjusted for age and DM, statistically significant differences were obtained only for patients younger than 65 years and nondiabetic, favoring PD ($P = 0.021$; Figure 5a).

DISCUSSION

The current study constitutes the first large initiative in Colombia to compare survival results of HD and PD patients. Socioeconomic status of patients who were included in the study was similar to that of the Colombian population with ESRD on dialysis therapy.[25]

In contrast with studies from other regions,[5,9,13,16,21] 53% of the patients included in the DOC study were being treated with PD, a higher proportion than reported for Colombia by the Asociación Colombiana de Nefrología in the year 2005[25] and for the rest of Latin America. PD utilization is reported to be about 30% in such countries as Brazil, Argentina, Uruguay, Salvador, and Guatemala.[28] This may possibly be due to a larger acceptance of PD therapy in those units that contributed patients for this study. In addition, dialysis therapy trends have historically shown a preference for PD in Colombia.

Gender, age, and comorbidity distribution is similar to the ones in other comparative studies found in the literature. However, regarding the demographic variables (regime, education, and socioeconomic level), there are clear differences specific to a developing country like Colombia.[9,11,18,29]

Table 3 | Cox proportional hazard model (intention-to-treat)

	β	HR	CI 95% for HR Lower	Upper	*P*-value
Age (⩾65 years)	0.688	1.989	1.500	2.637	0.000
SGA (mild–severe malnutrition)	0.282	1.325	1.005	1.748	0.046
Charlson Comorbidity Index (0–2): (⩾5)	−1.016	0.362	0.243	0.538	0.000
Charlson Comorbidity Index (3–4): (⩾5)	−0.534	0.586	0.430	0.799	0.001
Diabetes mellitus	0.570	1.768	1.301	2.402	0.000
Regime (I): (III)	−0.526	0.591	0.387	0.901	0.015
Regime (II): (III)	−0.505	0.603	0.377	0.966	0.036
Socioeconomic level (1): (6)	0.936	2.550	0.939	6.928	0.066
Socioeconomic level (2): (6)	1.022	2.779	1.036	7.454	0.042
Cardiovascular history	0.256	1.292	0.980	1.704	0.069
Therapy HD/PD	0.119	1.127	0.855	1.484	0.396

CI, confidence interval; HD, hemodialysis; HR, hazard ratio; PD, peritoneal dialysis; SGA, Subjective Global Assessment.

Table 4 | Cox proportional hazard model (as-treated)

	β	HR	CI 95 % for HR Lower	Upper	*P*-value
Age (⩾65 years)	0.626	1.871	1.470	2.380	0.000
SGA (mild–severe malnutrition)	0.283	1.327	1.057	1.665	0.015
Charlson Comorbidity Index (0–2): (⩾5)	−0.852	0.426	0.289	0.610	0.000
Charlson Comorbidity Index (3–4): (⩾5)	−0.385	0.680	0.521	0.888	0.005
DM	0.328	1.389	1.066	1.809	0.015
Regime (I): (III)	−0.541	0.582	0.394	0.859	0.006
Regime (II): (III)	−0.414	0.661	0.433	1.008	0.055
Socioeconomic level (1): (6)	0.841	2.318	0.879	6.114	0.089
Socioeconomic level (2): (6)	0.825	2.282	0.875	5.951	0.092
Cardiovascular history	0.349	1.418	1.118	1.798	0.004
Therapy HD/PD	0.208	1.231	0.976	1.553	0.079

CI, confidence interval; DM, diabetes mellitus; HD, hemodialysis; HR, hazard ratio; PD, peritoneal dialysis; SGA, Subjective Global Assessment.

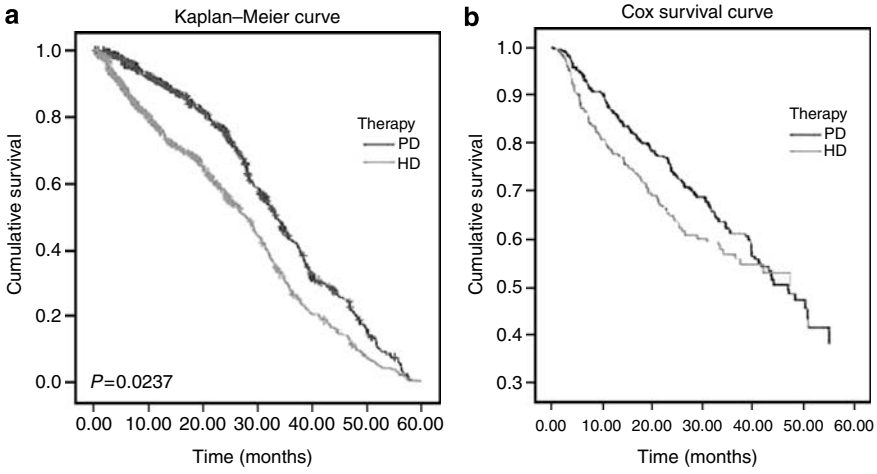

Figure 4 | Survival analysis, as-treated. (**a**) Kaplan–Meier curves for HD (light line) and PD (dark line) patients, follow-up in months (log-rank test: $P < 0.0237$) (**b**) Cox survival curves adjusted for covariates for HD (light line) and PD (dark line) patients, follow-up in months.

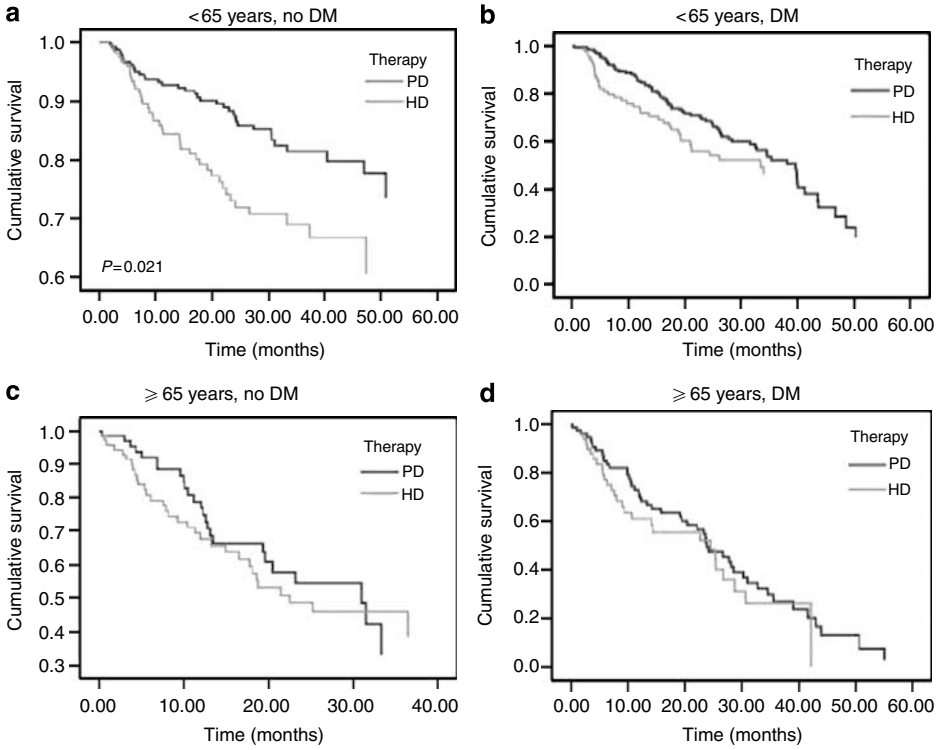

Figure 5 | Survival analysis, as-treated, adjusted for age and DM. (**a–d**) Cox survival curves adjusted for covariates of age and DM for HD (light line) and PD (dark line) patients, follow-up in months.

Health system insurance modality is an important variable with regard to access to dialysis therapy, and equally could be associated with poverty and with final outcomes.[24] In the DOC study the proportion of patients in the 'under subsidized' regime III, that is to say, those with more barriers to access to healthcare services, was larger in the PD group (15.4%) vs those on HD (4.1%). These patients could have worse health conditions associated with their poverty level. At the same time, the proportion of patients from socioeconomic stratum 1 (level with more unsatisfied basic needs) was 23.9% in PD in comparison to 17.8% in HD. This result shows a therapy pattern different from the other developed countries where the patients assigned to PD have better socioeconomic conditions.[9,11,30,31] Despite those conditions, the survival of our PD patients is similar to that of HD patients.

Analysis of ESRD primary causes showed a larger proportion of diabetic patients on PD (45.3%) compared to HD (35.9%) and similar to that reported in other studies.[8,11,13,32]

We have also found that the proportion of patients with positive cardiovascular history and a Charlson Comorbidity Index of 5 and above in our study is greater in PD patients when compared to those in HD, contrasting with the trends seen in other studies.[5,8,16,21]

In this cohort of incident patients, statistical analysis was conducted following two approaches, intention-to-treat and as-treated, and using the Cox proportional risks model, adjusted for age and DM, to control the biases and limitations suggested by other investigators who compared survival on HD and PD. Results from both approaches are consistent and show no statistical differences in survival between PD and HD adjusting for covariates, over time on dialysis, in contrast to the results found in other studies in which survival is better in the first 2 years for the PD group, being later equal or improved in the HD group.[3,5,6,8,9,29,33]

The multivariate analysis conducted with the Cox proportional risks model using the intention-to-treat approach showed that DM, malnutrition, age $\geqslant$65 years, and belonging to socioeconomic level 2 were risk factors for poorer survival. Furthermore, having a comorbidity index less than 5 and being covered by healthcare services of regimes I and II were considered as protective factors. These results are consistent with the as-treated approach where having a history of cardiovascular disease is also a risk factor. The latter shows that having high comorbidity, low-level insurance, age $\geqslant$65 years, and being diabetic diminish survival, but this is not related to the type of dialysis therapy prescribed. These facts would support the statement that these are not barriers for the election of PD as RRT.

The limitations of this study are a lack of analysis of dialysis adequacy data, the fact that almost half of the patients (44.9%) did not have RRF data at the start of therapy and also that the peritoneal membrane transport characteristics of the patients were not evaluated.[19,34]

Among the strengths of the study, we can point out the fact that is a multicenter cohort of incident patients with a

minimum time of 2 years and up to 5 years follow-up, the therapy being provided by a single dialysis supplier with a wide network around the country, the statistical analysis being conducted under the intention-to-treat and as-treated approaches; a relatively low ratio of patients who switched therapies,[9,33] and the thorough quality control used for collecting data and handling the database.

In the younger than 65 years of age and nondiabetic population, when adjusting for age and DM, survival is better on PD than on HD. The variables associated with poverty and insurance do not limit access to PD. Risk factors for a reduced survival are DM, age, cardiovascular disease history, regime III – 'under subsidized,' and a Charlson Comorbidity Index of 5 or above. Educational level did not have a significant effect on survival.

In conclusion, even though PD patients were poorer, more likely diabetic, and had higher co-morbidity scores than HD patients, no differences were found in the survival of patients on PD vs HD in this cohort of Colombian dialysis patients when adjusting for covariates. In nondiabetic patients younger than 65 years, survival was better on PD than on HD. Further studies are required to improve the understanding of the association of other variables with outcomes as well as to study other variables of interest such as quality of life.

MATERIALS AND METHODS

Patients

All incident patients on RRT with dialysis between 1 January 2001 and 1 December 2003 who reached the 90th day of therapy, were older than 18 years, and were from 13 facilities in a network of renal units in Colombia were included. Patients whose records were not reliable, in terms of quality of the clinical history (Figure 1), were excluded.

Assessment of the minimum sample size required to estimate survival was performed[35] using an α-level of 0.05, a power of 0.8, a PD/HD death risk of 1.39,[9] an expected censorship value ψ of 0.6, and a ratio of renal patients treated with PD in Colombia of 0.45,[25] with a result of 731 patients.

Design

A multicenter study of a historical cohort of patients with follow-up to 1 December 2005, or until the occurrence of the outcome of interest (death) or censorship for all those events in which the patient was alive but could not conclude the follow-up period. Causes of censorship were kidney transplantation, recovery of the residual renal function, loss to follow-up, change of renal unit, conclusion of the follow-up period without the occurrence of death, and therapy switch censored after 60 days.

The Committee of Ethics and Research of the Universidad del Rosario approved this study. All the patients were requested to provide a written informed consent allowing the use of their clinical information, and for patients who died, their relatives were requested to mail the written informed consent to the specific renal unit.

Data collection

The following demographic, socioeconomic, and comorbidity variables were recorded upon entrance of patients into the cohort: (1) age; (2) gender; (3) socioeconomic level (1 being the poorest and 6 being those with the highest income); (4) education (illiterate, elementary school, high school, university, and postgraduate study); (5) regime (I – contributive (full covering), II – subsidized (partial covering), III – under subsidized (charity covering)); (6) SG (well nourished, mild or moderate malnutrition, and severe malnutrition); (7) Charlson Comorbidity Index (Grade 0–2 (mild comorbidity), 3–4 (moderate comorbidity), and 5 (severe comorbidity)); (8) positive or negative cardiovascular disease history; and (9) cause of the ESRD (diabetes, hypertension, glomerulonephritis, polycystic kidney disease, obstructive uropathy, other, unknown cause). In addition, other variables such as weight, height, body mass index, RRF, creatinine, calcium, and phosphorus were recorded.

Data were gathered directly from the clinical history. They were registered in hard copy form, clinically checked *in situ* with co-investigators from each center, and then loaded to a central database designed using the World Health Organization and Centers for Disease Control Epi Info V.6.04d. Later, they were customized in a check routine with data quality controls and electronic typing aids, triple backup in different servers as well as automatic and clinical verification routines on the file copies.

Statistical analysis

The statistical analyses were conducted with SPSS (Statistical Package for Social Sciences) V.15 and EPIDAT V.3.0 PAHO (Pan American Health Organization) software.

Qualitative variables ratios were calculated and comparison tests performed using the χ^2 test; quantitative variables were assessed by calculating central tendency measures; T and Mann–Whitney tests were also used, depending on the case. Median survival time was compared in both treatment groups with the Mann–Whitney test. Survival analyses were conducted with the Kaplan–Meier method and with the log-rank test for comparison by dialysis modality. Later, an analysis of the variables related to survival in PD and HD patients was carried out using the Cox proportional risks model, calculating for all the significant variables ($P<0.05$), their respective HR and CI 95%.[34] Survival analyses were adjusted for diabetes and age group.

The statistical analysis was conducted using intention-to-treat and as-treated approaches.[34,36,37]

DISCLOSURE

This is a collaborative study between the Universidad del Rosario School of Medicine and Baxter Colombia. The researchers are members of working teams from both institutions. The DOC study was financed by a research grant from Baxter Colombia. No senior staff members of Baxter were involved either in the study design or in the data analyses. Drs Ardila, Camargo, Gonzalez, Lopera, Muñoz, Murad, Rivera, Rodriguez and Sanabria are Baxter employees.

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