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Epidemiological profile of patients on renal replacement therapy in Brazil, 2000-2004

ABSTRACT

OBJECTIVE: To describe the clinical and epidemiological profile of patients under renal replacement therapies, identifying risk factors for death.

METHODS: This is a non-concurrent cohort study of data for 90,356 patients in the National Renal Replacement Therapies Database. A deterministic-probabilistic linkage was performed using the Authorization System for High Complexity/Cost Procedures and the Mortality Information System databases. All patients who started dialysis between 1/1/2000 and 12/31/2004 were included and followed until death or the end of 2004. Age, sex, region of residence, primary renal disease and causes of death were analyzed. A proportional hazards model was used to identify factors associated with risk of death.

RESULTS: The prevalence of patients under renal replacement therapies increased an average of 5.5%, while incidence remained stable during the period. Hemodialysis was the predominant initial modality (89%). The patients were majority male with mean age 53 years, residents of the Southeast region and presented unknown causes as the main cause of chronic renal disease, followed by hypertension, diabetes and glomerulonephritis. Of these patients, 42% progressed to death and 7% underwent kidney transplantation. The patients on peritoneal dialysis were older and had higher prevalence of diabetes. The death rate varied from 7% among transplanted patients to 45% among non-transplanted patients. In the final Cox proportional hazards model, the risk of mortality was associated with increasing age, female sex, having diabetes, living in the North and Northeast region, peritoneal dialysis as a first modality and not having renal transplantation.

CONCLUSIONS: There was an increased prevalence of patients on renal therapy in Brazil. Increased risk of death was associated with advanced age, diabetes, the female sex, residents of the North and Northeast region and lack of renal transplant.

DESCRIPTORS: Renal Insufficiency, Chronic, epidemiology. Renal Replacement Therapy. Hospital Information Systems. Mortality Registries.

INTRODUCTION

The aging of the population and increased life expectancy, resulting from the demographic transition over the last decades in Brazil, contributed to changes in the morbidity and mortality profile and the increase in the prevalence of chronic diseases, including chronic kidney disease (CKD).[7] Hypertension and diabetes are the main risk factors for CKD and are becoming more common in the general population, contributing to the increased incidence of CKD.[4]

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CKD is global public health problem. Urinal tract and renal diseases account for approximately 850 thousand deaths every year and 15 million disability-adjusted life years lost, constituting the 12th leading cause of death and 17th cause of disability.[23] The final stage of CKD is called end-stage renal disease (ESRD), when the patient needs a renal replacement therapy (RRT) to survive. The available RRT methods are dialysis (hemodialysis [HD] and peritoneal dialysis [PD]) and renal transplantation (RT). The prevalence of ESRD in the global population increased 6% between 2003 and 2004.[7] At the end of 2004, approximately 1.8 million patients were undergoing RRT in the world, a prevalence of 280 patients per 1 million of population (pmp). Of those, 77% were undergoing some form of dialysis and 23% were renal transplanted.[7]

The growth of the population with CKD has substantial implications on public policies in health, especially due to the high cost of patients on RRT, with 85% to 95% of this therapy subsidized by the National Health System (SUS).[18] The systematic collection of information about dialysis patients has been a challenge for the majority of countries. In Brazil, there is a lack of national-level data to assist the monitoring of the population on RRT.[18] A possibility for overcoming this difficulty is the use of information from administrative data systems, whose primary objective is the documentation of payments for procedures performed by the SUS for patients on RRT.

The objective of the present study was to describe the clinical and epidemiological profile of patients on RRT in Brazil, identifying risk factors for death.

METHODS

This is a non-concurrent cohort study, stemming from a large study called the "RRT Project – Economic-epidemiological evaluation of renal replacement therapies in Brazil" conducted by the Research Group in Health Economics of the Universidade Federal de Minas Gerais.[5] The data source was the National RRT Database, developed by probabilistic linkage performed on the Authorization System for High Complexity/Cost Procedures (APAC) database from the SUS Ambulatory Information System (SIA) and on the Mortality Information System (SIM) database, with the goal of following a cohort.[5,15]

Considering that RRT procedures are continuous, a process was developed for inputting information in the documentation gaps in RRT modality between the first month of observation, the occurrence of death or the end of follow up, due to project end (12/31/2004) or by loss of follow up. The data entry was done randomly when dealing with intervals between different treatment modalities, and when the same modality was at the either end of the interval, the modality was repeated.

The population studied included all the patients registered for RRT in the National Database, who began dialysis in the period from 1/1/2000 to 12/31/2004, with at least three consecutive months of procedure registered. For the survival analysis, patients who died in the first three months under RRT and patients under 18 years were excluded.

The dependent variable was the elapsed time between the day the first treatment modality began until the day of patient death. The independent variables were: demographic (age, sex, municipality and region of residence); clinical (initial diagnosis of cause for chronic kidney disease [International Classification of Diseases – 10th Edition – ICD 10]; treatment modality [HD, PD and RT)], length of treatment) and outcome (death, continued treatment or loss to follow up). The initial treatment modality was defined as the first modality in which the patient remained for at least three consecutive months, without considering the subsequent changes to modality.

A descriptive analysis was performed through frequency distributions, measures of central tendency and variability of the characteristics studied. The χ^2 test was used to verify differences of proportion between categorical variables, and the Student's t test used for comparison of continuous variables.

The analysis of survival considered the total time in RRT (HD or PD) and the length of survival after performing renal transplantation, independent of changes between modalities. Death was considered as a final event, and the patients were only censored through loss of follow up or at the end of the study period.[10]

In order to indentify an effect independent of the explanatory variables for survival, a multivariate Cox proportional hazard model was used. The proportionality assumption was evaluated by the graphic log-minus-log method. The quality adjustment for the final model was evaluated by graphic analysis of martingale and deviance residuals. The analyses were done using the survival package[a] of the open software R[b] 2.7.2, with a significance level of 5%.

The RRT Project was approved by the Research Ethics Committee of the Universidade Federal de Minas Gerais (Process: ETIC 397/2004).

[a] Therneau T. Survival analysis, including penalized likelihood: package version 2.34-1 [internet]. R-Forge Statistics. [cited 2008 Oct 20]. Available from: https://r-forge.r-project.org/search/?type_of_search=soft&group_id=0&atid=0&forum_id=0& group_project_id=0&words=package+version+2.34-1&Search=Search

[b] R Development Core Team (2008). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051- 07-0, URL http://www.R-project.org.

RESULTS

In Brazil, 68,467 patients underwent RRT in 2000, of which 8,501 progressed to death and 1,190 were lost to follow up until 12/31/2004. Among the 58,746 patients in RRT at the end of the year, there was a prevalence of 354 pmp (Table 1). Another 17,114 patients began treatment in 2000, which corresponds to an incidence rate of 103 pmp. Between 2000 and 2004, the prevalence of patients on RRT increased by a mean of 5.5%. The incidence rate was stable during this period, and the lethality rate increased.

Between 2000 and 2004, 90,356 patients began dialysis in Brazil, with hemodialysis being the most common treatment (Table 2). The main primary cause of CKD was indeterminate for the majority of patients, followed by hypertension and other cardiovascular diseases, diabetes and glomerulonephritis. Of these patients, 7% underwent renal transplantation (live or deceased donor) and 42% progressed to death. The three main causes of death among these patients were related to CKD. A gradual increase in mean age at initiation of RRT was observed over the study period, from 52 years in 2000 to 54 years in 2004. In the five years of follow up, the mean time on RRT was 19 months.

In the five regions of the country, the youngest age at initiation of RRT was found among patients in the Central-West region (mean=51; SD 17.2 years) and the greatest age in the South region (mean=55; SD=17.5 years), which also had the greatest percentage of elderly patients (31%). In all five regions, the majority of patients (from 60% to 69%) began RRT at an intermediate age (20 to 64 years).

The main cause of CKD at enrollment was hypertension and other cardiovascular diseases (ranging from 42% to 54%), except for the North region where the most frequent cause was diabetes (36%). In all regions, the majority of patients with ESRD began RRT with hemodialysis, with the greatest percentage in the Northeast region (92%). The highest percentage of PD occurred among patients residing in the Southeast (12%). In the North region, 4% of the patients underwent transplant, while the greatest percentages were observed in the Southeast and Central-West regions (both 8%). The North region had the greatest percentage of deaths (47%), and the Central-West region had the lowest (39%). The longest mean time on RRT was in the Southeast region (20 months), and the lowest was in the North region (16 months).

The majority of the patients that initiated RRT with hemodialysis (Table 2) were men, with mean age of 53 years, at the age group of 45 to 64 years. For those who began with PD, the sex distribution was similar, with mean age of 55 years and the majority of patients in the age group above 65 years. A greater number of patients were observed in the Southeast, Northeast and South regions.

Of the patients beginning on hemodialysis, 10% began RRT with an access point through an arteriovenous fistula. In PD, 28% performed the training procedures recommended at treatment enrollment. At the end of the follow up period, 47% of the patients on PD and 42% on hemodialysis progressed to death, principally do to diabetes mellitus and cardiovascular diseases. The mean time on RRT was similar for both modalities.

In Table 3, a greater percentage of male patients can be observed in the transplanted group. The mean age was 37 years, and 2% were above 65 years. Among patients that did not undergo transplantation, the mean age was 55 years and 28% of them were above 65 years old.

Among the transplanted patients, the main causes of CKD were glomerulonephritis, hypertension and other cardiovascular diseases and diabetes. For the non-transplanted patients, hypertension and other cardiovascular diseases, diabetes and glomerulonephritis were observed. Forty-five per cent of the non-transplanted and 7% of the transplanted patients progressed to death. The mean duration of treatment was 19 months among the non-transplanted and 41 months for the transplanted.

The 76,949 patients for the survival analysis were selected from a total of 90,356 patients that initiated dialysis in Brazil between 2000 and 2005, excluding 2,727 patients under 18 years and 10,680 who died in the first three months of treatment.

Table 1. Prevalence, incidence and lethality rate of patients on renal replacement therapy. Brazil, 2000 to 2004.

Year	Estimated Population IBGE	Prevalence		Incidence		Lethality	
	(millions)	n	Rate (pmp)	n	Rate (pmp)	n	Rate (%)
2000	166,113	58,746	354	17,114	103	8,501	12.4
2001	172,386	64,005	371	17,362	101	10,401	13.7
2002	174,633	69,052	395	18,275	105	12,050	14.6
2003	176,871	73,370	415	19,075	108	13,218	15
2004	181,581	78,260	431	18,530	102	14,751	16.1

Source: National Database of RRT
IBGE: Instituto Brasileiro de Geografia e Estatística; pmp: patients per million population

Table 2. Demographic and clinical characteristics of incident patients on renal replacement therapy according to initial treatment modality. Brazil, 2000-2004.

Variable	Initial Modality				Total	
	PD		HD			
	n	%	n	%	n	%
Total	9.506	11	80.850	89	90.356	100
Sex*						
Male	4.722	50	46.474	57	51.196	57
Female	4.784	50	34.376	43	39.160	43
Age at enrollment in RRT[a,]*						
Average (Standard deviation)	55 (22)		53 (17)		53 (18)	
Median	59		54		55	
Age group at enrollment in RRT (years)*						
0 to 19	984	10	2.649	3	3.427	4
20 to 44	1.534	16	21.779	27	21.963	24
45 to 64	3.369	35	34.581	43	35.609	39
Over 65	3.551	37	21.482	27	23.584	29
Region of residence at first enrollment*						
Southeast	5.584	59	39.394	49	44.978	50
Northeast	1.690	18	20.283	25	21.973	24
Central West	513	5	4.164	5	4.677	5
South	1.334	14	13.074	16	14.408	16
North	385	4	3.935	5	4.320	5
Procedure category at enrollement*						
Hemodialysis	750	8	71.405	88	72.155	80
Peritoneal Dialysis	4.254	45	721	1	4.975	6
Definitive access to PD	1.662	17	162	0	1.824	2
Definitive access to HD	205	2	8.382	10	8.587	10
Training PD	2.635	28	177	0	2.812	3
Cause of CKD at enrollment*						
Diabetes Mellitus/renal complications	1.725	18	12.429	15	14.154	16
Glomerulonephritis	809	9	8.282	10	9.091	10
Hypertension and other cardiovascular diseases	1.769	19	19.533	24	21.302	24
Indeterminate	4.715	50	34.963	43	39.678	44
Other diseases	488	5	5.643	7	6.131	7
Renal transplantation during the period						
Yes	707	7	5.666	7	6.373	7
Deaths during the observation period*						
Diabetes Mellitus/renal complications	689	15	4.108	12	4.797	13
Hypertensive renal disease with CKD	232	5	2.258	7	2.490	7
CKD not specified	640	14	4.580	14	5.220	14
Cause of death not reported	719	16	4.662	14	5.381	14
Other causes of death	2.227	49	18.080	53	20.307	50
Total	4.507	47	33.688	42	38.195	42
Duration of RRT[a,] *						
Mean (standard deviation)	18 (15)		19 (17)		19 (17)	
Median	14		14		14	

Source: National Database of RRT
[a] Test by independent sample assuming unequal variance
* p<0.001
RRT: Renal Replacement Therapy; HD: Hemodialysis; PD: Peritoneal Dialysis; CKD: Chronic Kidney Disease

Table 3. Demographic characteristics of transplanted and non-transplanted patients. Brazil, 2000-2004.

Variable	Non-transplanted		Transplanted		Total	
	n	%	n	%	n	%
	83.983	93	6.373	7	90.356	100
Sex*						
Male	47.378	56	3.818	60	51.196	57
Female	36.605	44	2.555	40	39.160	43
Age at RRT enrollment[a,*]						
Mean (standard deviation)	55 (17)		37 (15)		53 (16)	
Median	56		37		55	
Age group at RRT enrollment* (years)						
0 to 19	2.567	3	860	13	3.427	4
20 to 44	18.423	22	3.540	56	21.963	24
45 to 64	33.821	40	1.788	28	35.609	39
Over 65	23.449	28	135	2	23.584	26
Region of residence at first enrollment*						
Southeast	41.248	49	3.730	59	44.978	50
Northeast	20.955	25	1.018	16	21.973	24
Central West	13.281	16	1.127	18	14.408	16
South	4.368	5	309	5	4.677	5
North	4.131	5	189	3	4.320	5
Modality at first enrollemnt						
PD	75.184	90	5.666	89	80.850	89
HD	8.799	10	707	11	9.506	11
Cause of CCKD at enrollment*						
Hypertension – Cardiovascular diseases	19.969	24	1.333	21	21.302	24
Diabetes Mellitus/renal complications	13.743	16	411	6	14.154	16
Glomerulonephritis	7.702	9	1.389	22	9.091	10
Indeterminate	36.924	44	2.754	43	39.678	44
Other diseases	5.645	7	486	8	6.131	7
Deaths during the observation period*						
Diabetes Mellitus/renal complications	4.779	13	18	4	4.797	13
Hypertensive renal disease with CKD	2.469	7	21	5	2.490	7
CKD not specified	5.157	14	63	14	5.220	14
Cause of death not reported	5.335	14	46	10	5.381	14
Other cause of death	20.004	52	303	67	20.307	52
Total	37.744	45	451	7	38.195	42
Duration of RRT (month)[a,*]						
Mean (standard deviation)	19 (16)		41 (14)		19 (17)	
Median	15		42		17	

Source: National Database of RRT
[a] The test for independent samples was used assuming different variance.
* p>0.001
RRT: Renal Replacement Therapy; HD: Hemodialysis; PD: Peritoneal Dialysis; CKD: Chronic Kidney Disease

The Figure shows the survival curves for the patients that initiated RRT between 2000 and 2004 in Brazil, according to selected characteristics. The graphic (b) with the Kaplan-Meier cumulative survival probabilities by region showed an intersection in the curves for the Southeast and Central-West regions. Since there was not a difference in the Log-rank test (p = 0.66) for these regions, they were grouped in order to avoid violating the supposition of risk proportionality, thus producing curves that did not cross and that were significantly different.

Table 4. Cox proportional risk model for survival analysis of patients on renal replacement therapy according to demographic and clinical variables. Brazil, 2000-2004.

Variable	Hazard ratio	95% CI	p*
Age (years)			
18 to 44	1		
45 to 64	1.83	1.77;1.89	<0.0001
≥ 65	3.12	3.01;3.24	<0.0001
Sex			
Male	1		
Female	1.08	1.05;1.11	<0.0001
Diabetes			
No	1		
Yes	1.23	1.20;1.27	<0.0001
Region of residence			
Southeast/ Central West	1		
South	1.09	1.05;1.13	<0.0001
North	1.38	1.31;1.46	<0.0001
Northeast	1.22	1.18;1.25	<0.0001
Initial treatment modality			
HD	1		
PD	1.22	1.18;1.27	<0.0001
Renal transplantation			
Yes	1		
No	6.91	6.27;7.62	<0.0001

Source: National Database on RRT
* Cox Model
HD: Hemodialysis; PD: Peritoneal Dialysis

Shorter mean durations were observed until death for the patients with 65 or more years; female sex; diabetics; residents in the Northeast region and who had PD as the initial modality. It was not possible to calculate the median time until death among the transplanted patients.

In the final Cox proportional risk model, risk of mortality was associated with increased age, female sex, diabetes, residing in the North and Northeast region, PD as the enrollment modality and not having undergone renal transplant (Table 4).

The analysis of the plots for the Martingale and Deviance residuals suggests that there were no outliers in the analysis, which could influence the relative risk estimate. There were no residuals greater than 3 or less than -3 in any of the plots.

DISCUSSION

The current study was performed with population data of patients in renal replacement therapy through the SUS and showed an increased prevalence in the number of patients on RRT, even though the incidence has remained constant. The majority of the patients initiated hemodialysis treatment at a productive age, are residents of the Southeast region and have hypertension and diabetes as the primary cause of ESRD. At the end of the follow up period, 42% of patients progressed to death and only 7% were transplanted. Greater survival was found for patients who underwent renal transplantation.

The mean increase in the prevalence ESRD, estimated at 5% in Brazil, also follows the internationally observed trend (6%) for the world population.[7] The prevalence of 431 pmp found for Brazil is greater than the average of Latin American countries (349 pmp in 2001),[6] but less than in developed countries (700 pmp in Europe and 1403 pmp in the USA)[3] and even those described in countries like Uruguay (809 pmp), Chile (662 pmp) or Argentina (571 pmp).[6] These figures suggest that in Brazil a portion of people with ESRD have not been diagnosed or do not have access to health services.[12] Besides this, it is probable that many patients with CKD died from complications of diabetes and hypertension before reaching end stage renal disease. The incidence rate remained stable in the period, as has occurred in the USA and in several developed countries.[20] The small

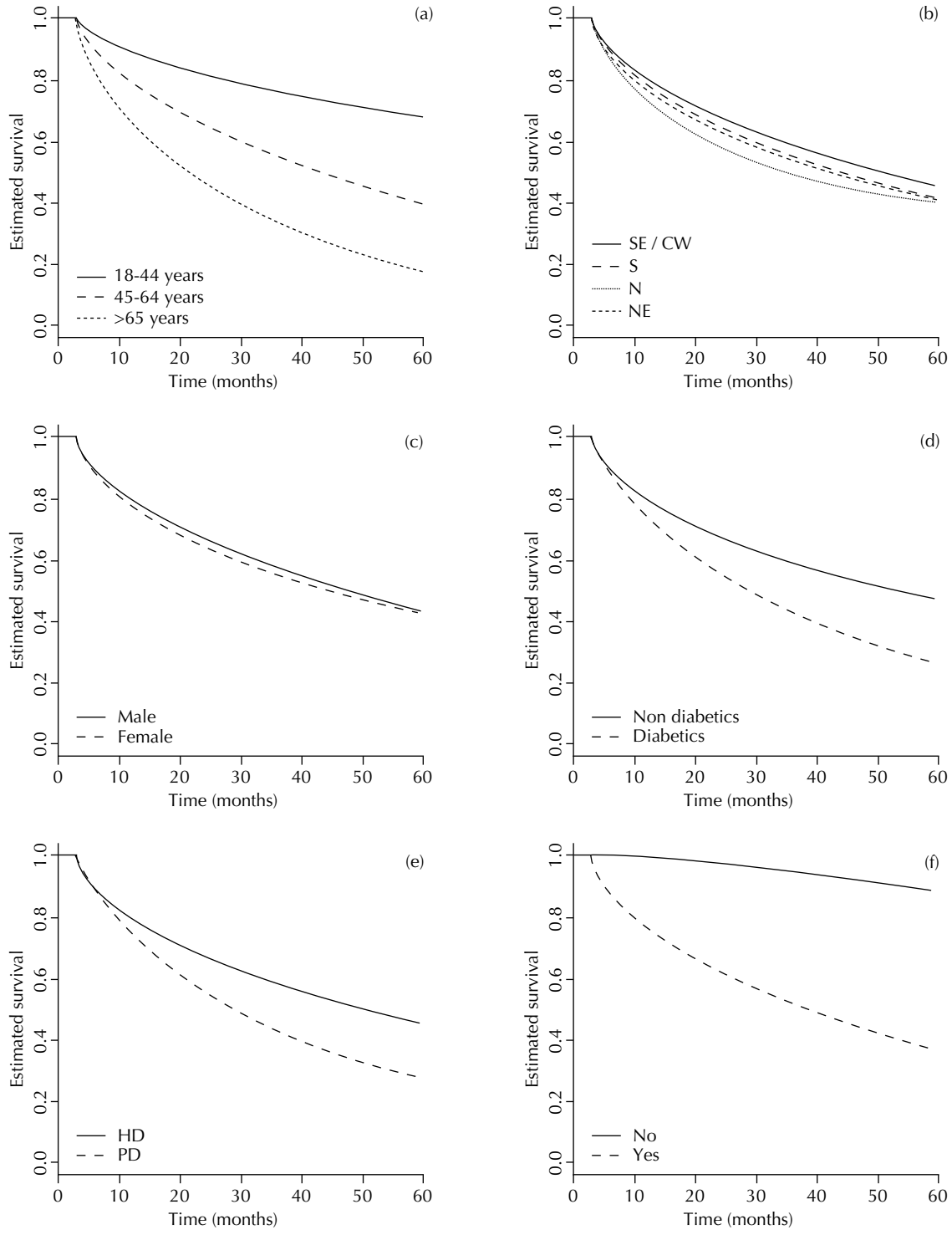

Figure. Survival curves for patients on RRT in Brazil from 2000 to 2004, according to selected characteristics: (a) Age group, (b) Region of residence, (c) Sex, (d) Cause of CKD, (e) Initial treatment modality and (f) Renal transplantation (curves with $p<0.05$ for Long-Rank test).

increase in the lethality rate between 2000 and 2004 can be attributed to the under notification of identifying patient data in the Mortality Information System (SIM), as reported by Queiroz et al (2009).[15]

In Brazil, men represent the majority (57%) of new patients, a finding similar to international studies.[8,9,19] The main cause of CKD identified by our study was hypertension, followed by diabetes, in contrast to other

studies performed in countries of America,[6,8,9,19] in which diabetes was identified as the leading cause. The differences observed between the studies may be the result of difficulties in establishing a precise diagnosis of this disease in Brazil, which can be inferred from the high percentage of indeterminate causes. There was an important proportion of glomerulonephritis observed, which can be associated with infectious agents,[c] with the Brazilian profile approaching the profile of African countries and diverging from what occurs in more developed countries.[1]

The greater concentration of RRT patients in the Southeast and South regions may be the result of the greater population density of these regions and the greater availability of health services of high technological complexity, which favors patient access.[21] Moura et al,[11] only used the enrollment archive of the APAC for analysis and found similar prevalence, incidence rate and primary cause for ESRD, as well as a similar distribution of patients between the Brazilian regions.

The distribution of the patients between the modalities of hemodialysis and PD, respectively 89% and 11%, is in accordance with the global experience.[7] In agreement with the global picture, the results of our study showed that the population in dialysis has become more elderly. In the United States, in 1996, patients with 65 years or more were 46% of new patients on renal replacement therapy.[10]

Despite not being the main primary cause of CKD, diabetes accounts for a greater proportional contribution for patients that began PD than those that in hemodialysis, suggesting a differential allocation of patients between these modalities. In developed countries, the patients on PD are more autonomous, have higher schooling, perform better preparation before initiating RRT and have less comorbidities.[19] The majority of patients with ESRD can be treated with any RRT, according to their clinical conditions, with each one having advantages and disadvantages. Nonetheless, it is thought that in Brazil, as in other countries, the choice of RRT modality is based on clinical condition, as well as on non-medical reasons such as: financial compensation, lack of consistent information to the patient regarding the options, availability of resources and moral, social and cultural aspects.[3]

In the present study, 10% of patients began hemodialysis did so with definitive vascular access (arteriovenous fistula); in European countries this rate was 66% and in the USA 15%.[14] In Brazil, the high percentage of people initiating hemodialysis with temporary access suggests the possibility of difficult access to nephrologists before the end stage of the disease, late diagnosis or even under diagnosis of CKD.[12]

In Brazil, 7% of new patients were transplanted in five years of follow up, in the United Kingdom this percentage was 6.2%,[17] 5.7% in Australia and 3.7% in New Zealand.[d] The transplanted population initiated RRT at a younger age and with a greater proportion of glomerulonephritis (47%) as the primary cause of CKD. Despite the existence of a single waiting list, patients residing in the Southeast region had greater access to renal transplant, revealing geographic disparities reported in other studies.[13] Despite the increased demand for kidney transplantation and the marked growth of the waiting list, it has been reported that access to renal transplant is very unequal between regions in the country, especially for the low income population without private health insurance plans and that live far from transplantation centers, mainly concentrated in the South and Southeast regions.[e]

In accordance with other studies,[9,16] we found greater survival for patients that underwent renal transplant. In addition, greater mortality of patients on RRT was associated with increased age and the presence of diagnosed diabetes. International studies show that besides these factors, a long time on the transplant wait list contributes to greater mortality.[22] Besides this, a long-term survival advantage has been reported for transplanted patients, even in diabetic patients.[9]

In this study, lower survival was observed for patients who initiated RRT on PD compared to those on HD. This finding may be due to the probable selection bias in the allocation of patients to PD as an initial modality, since a greater proportion of patients beginning on this modality were of older mean age and diabetic, as previously described. There is no consensus in the literature about the benefits to survival between the different dialyses. Nonetheless, recent studies suggest greater survival on PD in the first year of RRT, followed by an equivalent survival between the modalities.[8,22]

It is necessary to have reliable and available databases about RRT in Brazil, since they are fundamental for recognizing various aspects of chronic renal disease, such as prevalence, incidence, mortality and factors that influence its development. The systematic collection of data about the patients on dialysis remains a challenge in the majority of countries. Besides this, they can provide data to characterize the reality of dialysis

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treatment, the identification of problems in the provisioning of therapy and the analysis of patient survival, morbidity and quality of life. The combination of this information can inform the planning of actions and support the more rational use of financial resources devoted to this high cost therapy.[18]

Despite the possibilities that the National Database of RRT provides, the utilization of an administrative database, whose purpose is billings and not research, results in some incomplete, inconsistent and inexistent information. These characteristics limit the possibility of making larger inferences. For example, the lack of financial, social (race, education and income) and clinical (comorbidity) data deserves mention, since these are fundamental for evaluating the equity in access to RRT, as well as associated risk factors. Besides this, we highlight the high proportion of indeterminate causes (44%), which negatively impacted the distribution of causes of CKD; in developed countries this percentage is at most 19%.[2] Other important information that are also missing from this database concern hospitalization (cause, duration of stay) and type of donor for the renal transplant (live or deceased).

In conclusion, there was an increase in the prevalence of patients on renal therapy in Brazil, with a high mortality during the five year study period. The factors associated with increased mortality risk were increased age, female sex, diabetes, living in the North and Northeast regions, peritoneal dialysis as an initial modality and not having renal transplant. These findings can contribute to improved care for people with chronic kidney disease in the country.

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