

available at [www.sciencedirect.com](http://www.sciencedirect.com)

SCIENCE @ DIRECT®

journal homepage: [www.elsevier.com/locate/jval](http://www.elsevier.com/locate/jval)

## Health-Related Quality of Life of Patients Receiving Hemodialysis and Peritoneal Dialysis in São Paulo, Brazil: A Longitudinal Study

Mirhelen Mendes de Abreu, MD,<sup>1,\*</sup> David R. Walker, PhD,<sup>2,†</sup> Ricardo C. Sesso, MD, PhD,<sup>3</sup> Marcos B. Ferraz, MD, PhD<sup>4</sup>

<sup>1</sup>Universidade Federal de São Carlos, São Carlos, Brazil; <sup>2</sup>Baxter Healthcare Corp., McGaw Park, IL, USA, at the time of study; <sup>3</sup>Nephrology Division, Universidade Federal de São Paulo, São Paulo, Brazil; <sup>4</sup>São Paulo Centre for Health Economics, Universidade Federal de São Paulo, São Paulo, Brazil

### ABSTRACT

**Objectives:** The aim of this study was to evaluate quality of life in patients undergoing hemodialysis (HD) or peritoneal dialysis (PD) in São Paulo, Brazil. **Methods:** Inclusion criteria for this is a 1-year prospective study included being 18 years of age or older and clinically stable receiving chronic dialysis. Quality of life was measured using the SF-12 and the Kidney Disease Quality of Life questionnaires at baseline, 6 months, and 12 months. Patients who completed the surveys for all three periods were evaluated. Differences in quality of life scores were measured using univariate and multivariate regression analyses. **Results:** One hundred eighty-nine of 249 (76%) HD patients and 161 of 228 (71%) PD patients completed all three surveys. The PD group was older and a larger number had diabetes. PD patients consistently had higher scores than HD patients at all three measurement periods for patient satisfaction ( $P = 0.002$ ,  $P = 0.005$ , and  $P = 0.005$ , respectively), encouragement/support from staff ( $P = 0.003$ ,  $P = 0.017$ , and  $P = 0.029$ ,

respectively), and burden of kidney disease ( $P = 0.003$ ,  $P = 0.017$ , and  $P = 0.057$ , respectively). The HD group had a greater percent of patients who clinically improved from baseline to 12 months compared to PD patients for sleep quality, social support, encouragement/support from staff, and overall health. Scores for other dimensions of the Kidney Disease Quality of Life and SF-12 questionnaires were not significantly different between the PD and HD groups. **Conclusions:** The results provide evidence that PD and HD patients have equivalent health-related quality of life in several domains, although the former performed better in some quality of life domains despite being older and having more comorbidities.

**Keywords:** chronic disease, hemodialysis, peritoneal dialysis, quality of life.

Copyright © 2011, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc.

### Introduction

Health status and health-related quality of life (HRQoL) are core components of health outcomes. HRQoL measures can be assessed with both generic and disease-specific instruments [1]. Renal replacement therapy (RRT) is a life-saving treatment for patients with end-stage renal disease. The two main treatment modalities are transplantation and dialysis (i.e., hemodialysis [HD] or peritoneal dialysis [PD]) [2,3]. Because of an increase in survival rates for patients with end-stage renal disease, HRQoL has become increasingly important as an outcome measure in the evaluation of dialysis treatments. [4] It has also been suggested that for patients receiving RRT, quality of life measures can be used to predict future morbidity and mortality [5]. Studies examining the difference in quality of life outcomes associated with HD and PD have mixed results [4,5].

More than 77,000 patients in Brazil were receiving chronic dialysis during January 2009 [6]; ranking the country among the top three in the world in terms of absolute number of dialysis patients. However, in Brazil, as in most developing countries, there have been no known prospective studies completed comparing HRQoL in HD and PD populations. This study is part of a larger one eval-

uating economic aspects of dialysis therapy, and aims to investigate the impact of PD and HD on HRQoL.

### Patients and Methods

#### Study Population

This study recruited PD and HD patients older than age 18 years who had been on the same dialysis modality for at least 1 month. Patients were identified from six dialysis centers in São Paulo, Brazil. Exclusion criteria included hospitalized patients at time of study initiation and patients who planned to transfer from their modality within six months.

A similar number of PD and HD patients were selected. HD patients were randomly selected and matched to PD counterparts who started dialysis during the 9-month enrollment period, by sex, age group (< 45 years, 45–59 years, and ≥ 60 years), and dialysis center. At the beginning of the enrollment period, we assessed all patients receiving dialysis and selected new patients meeting the inclusion criteria who started dialysis during the 9-month enrollment period. All PD patients at each center meeting the inclusion criteria were se-

<sup>†</sup> Employee at Baxter Healthcare Corporation at the time of the study.

Conflict of interest: The authors indicated that this study was sponsored by Baxter Healthcare Corporation.

\* Address Correspondence to: Mirhelen Mendes de Abreu, Federal University of São Carlos, Medicine Department, Av. Washington Luis, Km 235, SP 310, São Carlos, Brazil 13565-905.

E-mail: [mirhelen@ufscar.br](mailto:mirhelen@ufscar.br)

1098-3015/\$36.00 – see front matter Copyright © 2011, International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Published by Elsevier Inc.

doi:10.1016/j.jval.2011.05.016

lected, then, using a systematic random sampling method within the prespecified strata of sex and age, the HD patients were subsequently selected. This allowed us to reach the desired sample size of approximately 150 patients per group, which provided 80% power to detect a 10% or greater between-group difference in the mean scores of the quality of life dimensions.

This was a prospective multicenter study with 1 year of follow-up. For the purpose of this article, only patients who completed 12 months of follow-up were included in the analysis.

### Assessment of HRQoL

The SF-12 (mental component summary and physical component summary scores) and the Kidney Disease Quality of Life Short Form (KDQoL-SF) questionnaires were used to assess HRQoL.

Originally, the KDQoL-SF is a self-reported measure that assesses the functioning and well-being of people with kidney disease and receiving dialysis [7]. The questionnaire consists of 80 items divided into 19 dimensions: SF-36 (eight dimensions/36 items): physical functioning (10 items), role limitations caused by physical problems (four items), role limitations caused by emotional problems (three items), pain (two items), general health perceptions (five items), social functioning (two items), emotional well-being (five items), energy/fatigue (four items), and one item about health status compared to 1 year ago; kidney-disease-targeted items (11 dimensions/43 items): symptom/problem list (12 items), effects of kidney disease (eight items), burden of kidney disease (four items), cognitive function (three items), quality of social interaction (three items), sexual function (two items), sleep (four items), social support (two items), work status (two items), overall health rating (one item scored separately), patient satisfaction (one item), and dialysis staff encouragement (two items). In this study, we used the SF-12, instead of SF-36. The SF-12 health survey is designed to be quick to use while retaining the validity of the parent SF-36 and the capacity to distinguish between the health of groups of subjects of different age and sex, and with different conditions. The loss of reliability associated with fewer defined health levels was regarded as an acceptable trade-off with practicality and length in the context of large group studies [8]. The scales range from 0 to 100, with a higher score representing better HRQoL [8,9]. From the specific KDQoL domains, we also derived a kidney disease component summary score [8,9].

### Other Data Sources

Medical, clinical, and laboratory data were collected at baseline by direct interview with the patient and their charts. All clinical and HRQoL data were collected at baseline, and at 6 and 12 months of follow-up.

### Statistical Analysis

To compare differences in the means between HD and PD for the three time periods, *t* tests were used. Benjamini and Hochberg procedures were applied to evaluate changes in quality of life [10]. Clinically significant changes in quality of life for the individual domains were defined as a difference of  $\pm 5$  points [10]. Clinically significant changes for the physical component scores and mental component scores are defined as  $\pm 5.7$  points and  $\pm 6.3$  points, respectively [10]. Potential independent variables included age category, sex, race, comorbidities, lab values, comorbidities (0 and 1 were dummy variables), dialysis modality (0 = PD, 1 = HD) and years receiving dialysis. A *P* value less than 0.05 was considered statistically significant and was retained in the final regression model. We used one multivariate regression to compare the influence of dialysis modalities on the quality of life domains for all three time periods and another to examine the impact of PD and HD on the change in quality of life scores from baseline to 12 months [10,11]. Adjusters used in the analysis included demographics, comorbidities, lab values (albumin and hemoglobin), time receiving dialysis (in years), and type of health insur-

ance (public or private). The baseline score was included as an adjuster in the regression analyses evaluating the change in score from baseline to 12 months.

Statistical analyses were conducted using SAS software, version 9.1.3, 2009 (SAS Institute Inc., Cary, NC).

The study was approved by the Committee for Ethics in Research at the Federal University of São Paulo.

### Results

Between April 2007 and February 2009, 249 HD patients and 228 PD patients were interviewed. 189 (76%) HD patients and 161 (71%) PD patients completed the 12-month study. Of the whole sample, 60 HD patients did not participate in the study due to the following reasons: 14 died, three received a transplant, six changed dialysis modality, 28 had less than 12 months of follow-up, four moved to a different dialysis center, and five were lost to follow-up. Among PD patients nonparticipation reasons were 12 died, three received a transplant, 17 changed dialysis modality, 26 had less than 12 months of follow-up, three moved to a different dialysis center, and six were lost to follow-up. Demographic and socioeconomic profiles of patients completing all three quality of life surveys are shown in Table 1 in Supplemental Materials found at: doi:10.1016/j.jval.2011.05.016. PD patients were older ( $P = 0.009$ ), had fewer years on dialysis ( $P = 0.003$ ) and have higher rates of diabetes ( $P = 0.04$ ). Quality of life scores for PD patients at baseline were significantly higher than for HD patients for several domains, including effects and burden of kidney disease, work status, encouragement from dialysis staff, patient satisfaction with care, and kidney disease component score. Analysis after 6 months showed that burden of kidney disease, encouragement/support from staff, and patient satisfaction with care scores remained significantly in favor of PD and, at the end of 12 months, encouragement/support from staff and patient satisfaction with care domains continued to be significantly higher in PD compared to HD patients (Table 2 in Supplemental Materials found at: doi:10.1016/j.jval.2011.05.016). A greater percent of patients receiving HD compared to PD had clinically significant improvements in HRQoL from baseline to 12 months ( $P = 0.004$ ). Regression analyses showed that at baseline, burden of kidney disease, effects of kidney disease, dialysis staff encouragement, overall health rating, patient satisfaction with care, work status, and kidney disease component summary score were significantly better for the PD group. At 6 and 12 months, burden of kidney disease, staff encouragement/support, and patient satisfaction continued to be better in PD patients (Table 3 in Supplemental Materials found at: doi:10.1016/j.jval.2011.05.016).

Finally, a further multivariate regression analysis regarding the change in quality of life from baseline to 12 months showed that HD significantly improved by 4.86 points ( $P = 0.0285$ ) compared to PD on quality of social interaction. For patient satisfaction, PD patients improved by 4.85 points ( $P = 0.0275$ ) compared to HD patients from baseline to 12 months. There was no other significant influence of dialysis modality on the other HRQoL domains.

### Discussion

Dialysis care has increased in importance throughout the world because of the growing prevalence of patients receiving RRT and its related morbidity and mortality and high social and financial costs [12]. There is limited prospective evidence analyzing the burden of both dialysis modalities on HRQoL. This study aimed at describing HRQoL within the context of dialysis care. At baseline, both study groups were similar in sex, race, and several comorbidities, but PD patients were older, had higher rates of diabetes and hypertension, and were on dialysis for a shorter time period than HD patients. Although this could be considered a limitation of our study, these differences correspond to the reality of the

patients allocated to these modalities in Brazil [12]. The selection of the patients in this study intended to preserve their main characteristics observed in the general dialysis population in Brazil, namely the greater age and comorbidity in the PD group [12]. Therefore, patients' matching between the groups at the enrollment was not too strict. In addition, an extensive multivariate linear regression analysis was performed, adjusting for a number of baseline characteristics. Patients receiving PD had better scores in several quality of life domains throughout the study period, even after adjusting for several factors, including age and comorbidity. However, considering that dialysis treatment is chronic, maybe these statistically significant results could need more time of observation to have better comprehension regarding the clinical significance results.

Previous research has found little difference in the HRQoL between patients using HD and PD [5,12]. Liem et al. [5] conducted a systematic review on HRQoL of HD and PD, as well as transplant patients. They did not find statistically or clinically significant differences between dialysis modalities. So far, we know of no prospective study that looked at HRQoL in both dialysis modalities in a developing country. Because only 10% of all chronic dialysis patients in Brazil are receiving PD, we increased the representativeness of this group to better evaluate it [12]. HD is the most commonly used dialysis modality in many developing countries [12]. In Brazil, the reasons for the predominant allocation of patients on HD involve clinical, political, social, and economic factors [12].

Our findings show that several QOL dimensions were systematically better for PD patients during the follow-up, particularly burden of kidney disease, encouragement from staff, and satisfaction with care. Considering the clinically significant changes over time, HD had greater improvement in sleep, social support, and health status and did worse in cognitive status compared to PD. However, these results should be interpreted with caution because HD patients started with an overall lower quality of life evaluation. Literature on the responsiveness of different quality of life measures is growing, but this evidence is not available for all quality of life instruments [13]. To minimize potential floor and ceiling effects, the literature recommends the inclusion of the baseline quality of life measure as a covariate in the selected statistical model (as we did in this study), in which the contribution of the baseline to the follow-up scores is directly estimated. In general, this will result in a more powerful test of the treatment effect and an unbiased estimate of change [13]. In addition, we applied the Benjamin and Hochberg method, which is suitable for multiple comparisons [10]. From the methodologic perspective, we used the absolute change to analyze significant clinical changes between the groups over time [10]. Another limitation is that this is an observational study and some other confounding factors may not have been completely adjusted in the comparative analysis between PD and HD. Finally, the cases analyzed with complete follow-up corresponded to about 75% of the whole sample; nonetheless the patients not included in this report did not have significant differences in clinical and demographic parameters compared with those analyzed.

A strength of this study is the prospective design, which has been rarely used in previous studies on this issue. As such, it shows how quality of life is subject to variation over time due to ageing, development of complications, changes in comorbidity, or due to a patient's adjustment to the treatment.

The HRQoL tools were applied at baseline, 6 months, and 12 months. For the purpose of this article, we analyzed patients who participated during the full study period. This study is a first step in the development of more comprehensive evidence of the HRQoL benefits of PD compared to HD in developing countries.

Finally, this study was carried out in São Paulo, which is the main region for RRT in the country. Census data indicate that the distribution of demographic characteristics of São Paulo, com-

pared with other major metropolitan areas in Brazil, are similar [14]. Despite the mentioned limitations, this study contributes to the emergent investigation of quality of life and its consequences to decisions in clinical practice and health policy in RRT. This prospective study provides evidence that quality of life is, in general, similar for PD and HD patients with some domains favoring PD. These findings could be used in the planning of health care services and patient management.

## Conclusions

There was no difference between PD and HD patients' scores on the SF-12 instrument. PD consistently performed better than HD on burden of kidney disease, patient satisfaction, and staff encouragement/support domains. HD had greater clinical improvements on several variables but they had started lower at baseline and thus had more room for improvement. However, these differences are not clinically significant. Future analyses should compare incident HD and PD patients and use more sophisticated matching techniques.

Source of financial support: Baxter Healthcare Corporation.

## Supplemental Materials

Supplemental material accompanying this article can be found in the online version as a hyperlink at doi:10.1016/j.jval.2011.05.016, or if hard copy of article, at [www.valueinhealthjournal.com/issues](http://www.valueinhealthjournal.com/issues) (select volume, issue, and article).

## R E F E R E N C E S

- [1] Garratt A, Schmidt L, Mackintosh A, et al. Quality of life measurement: bibliographic study of patient assessed health outcome measures. *BMJ* 2002;324:1417–21.
- [2] Smith KW, Avis NE, Assmann SF. Distinguishing between quality of life and health status in quality of life research: a meta-analysis. *Qual Life Res* 1999;8:447–59.
- [3] Evans RW, Manninen DL, Garrison LP Jr, et al. The quality of life of patients with end-stage renal disease. *N Engl J Med* 1985;312:553–9.
- [4] Cameron JI, Whiteside C, Katz J, Devins GM. Differences in quality of life across renal replacement therapies: a meta-analytic comparison. *Am J Kidney Dis* 2000;35:629–37.
- [5] Liem YS, Bosch JL, Arends LR, et al. Quality of life assessed with the Medical Outcomes Study Short-Form 36-Item Health Survey of patients on renal replacement therapy: a systematic review and meta-analysis. *Value Health* 2007;10:390–97.
- [6] Sesso R, Lopes AA, Thomé FS, et al. Relatório do censo brasileiro de diálise [Brazilian dialysis survey report], 2009. *J Bras Nefrol* 2010;30:233–8.
- [7] Duarte PS, Ciconelli RM, Sesso R. Cultural adaptation and validation of the Kidney Disease and Quality of Life—Short Form (KDQOL-SF 1.3) in Brazil. *Braz J Med Biol Res* 2005;38:261–70.
- [8] Ware JE, Kosinski M, Keller SD. A 12-item short-form health survey. *Med Care* 1996;34:220–3.
- [9] Ciconelli RM, Ferraz MB, Santos W, et al. Brazilian-Portuguese version of the SF-36: a reliable and valid quality of life outcome measure. *J Rheumatol* 1999;39:143–50.
- [10] Thissen D, Steinberg L, Kuang D. Quick and easy implementation of the Benjamin-Hochberg procedure for controlling the false positive rate in multiple comparisons. *J Educ Behav Stat* 2002;27:77–83.
- [11] Zhang J, Quan H, Ng J, Stepanavage ME. Some statistical methods for multiple endpoints in clinical trials. *Control Clin Trials* 1997;18:204–21.
- [12] Andrade MV, Junoy JP, Andrade EI, et al. Allocation of initial modality for renal replacement therapy in Brazil. *Clin J Am Soc Nephrol* 2010;5:637–44.
- [13] Guyatt GH, Osoba D, Wu AW, et al. Clinical Significance Consensus Meeting Group. Methods to explain the clinical significance of health status measures. *Mayo Clin Proc* 2002;77:371–83.
- [14] Brazil travel. The history of Sao Paulo. Available from: <http://lanic.utexas.edu/project/etext/llilas/outreach/fulbright07/kintz.pdf>. [Assessed March 31, 2011].