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# Health Related Quality of Life in End-Stage Renal Disease Patients

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## Abstract

**Background:** The purpose of this study is to assess the psychosocial reality of patients undergoing renal replacement therapy (RRT) with peritoneal dialysis (PD) in a level III University Hospital. This study also evaluated the prevalence of anxiety and depression in this cohort of subjects.

**Methods:** Observational, prospective and cross-sectional study conducted, from January to December 2018, on patients undergoing RRT with PD. Health related quality of life (HRQOL) was evaluated by means two different methods: A visual analogue scale (VAS) score and the Medical Outcomes Survey Short Form-36 (SF-36) questionnaire. Utility measurements were evaluated by means the EuroQol 5D (EQ-5D), the Health Utilities Index Mark III (HUI3) and the SF-6 Dimension (SF-6D). The State-Trait-Anger-eXpression-Inventory (STAXI) and the Hospital Anxiety and Depression Scale (HADS) were used as clinical scales.

**Results**: Fifty-eight patients were included in the analysis. Mean VAS score was 66.8 (16.8). Physical component of SF-36 exhibited a mean value of 40.9 (7.5), while the mental component of the SF-36 reached a mean value of 47.6 (10.2). Mean utility score observed with SF-6D [0.65 (0.20)] was significantly lower than that obtained with the EQ-5D [0.75 (0.16), p=0.0025] or the HUI3 [0.82 (0.23), p=0.0001], respectively. According to the HADS scores, a 6.8% of patients can be categorized within the category of clinical anxiety and 13.6% in the category of clinical depression.

**Conclusions:** The results of this study suggested that end-stage renal disease and RRT impact on the HRQOL, but not in all the dimensions at the same level.

Keywords: End-stage renal disease; Renal replacement therapy; Peritoneal dialysis; Health related quality of life

# Introduction

Chronic kidney failure (CKF) is defined [1] as an abnormally elevated serum creatinine for more than 3 months or calculated glomerular filtration rate below  $60 \text{ mL/min per } 1.73 \text{ m}^2$  [1]. In those situations where the patient needs a renal replacement therapy (RRT), the CRF is called end-stage renal disease (ESRD) [1].

Over the last several years there have been an increase in the prevalence of the ESRD worldwide, and that trend is expected to continue [2]. With worsening of their kidney disease, patients develop many complications that significantly impacts not only their life span but also their quality of life (QoL) [3,4]. Patients with ESRD require renal replacement therapy (RRT) for replacing the functionality of their kidneys. Kidney transplantation (KT) and dialysis, either peritoneal (PD) or hemodialysis (HD), are well established renal replacement options for ESRD. However, some patients might be not candidates for KT or they could pose important limitations, personal or technical, at the time of initiating dialysis that could complicate the decision-making process about whether or not to start a RRT

[2,5]. Moreover, patients undergoing RRT often experience a range of distressing psychological and physical symptoms [6]. PD and HD are well established dialysis options of RRT [7]. Due to the improvement of CKD care there has been delay in ESRD progression, which has made of the health-related quality of life (HRQOL) an important issue to take into account [8].

Although we have evidence suggesting that HD has a significant impact on either life expectancy and HRQOL, PD is considered as a first line therapy in only few patients [8,9]. This might be related to the fact that PD would be a difficult for elderly people or due to the belief that PD has a greater incidence of complications [10]. However, PD as initial RRT has been identified as an adequate strategy even in elderly patients when considering its advantages [11]. Moreover, the results of the BOLDE study showed that PD can be successfully managed by elderly patients [12].

There is evidence suggesting that the use of home therapies, like the PD, had similar HRQOL outcomes than those of a traditional in-center therapy [13,14]. Nevertheless, treatment satisfaction may



be higher in patients on PD [15]. This study aimed to evaluate the psychosocial conditions of patients undergoing RRT with PD in a level III University Hospital. Additionally, this study assessed the prevalence of anxiety and depression in this group of subjects.

## Methods

# Design

Observational, prospective and cross-sectional study conducted, from January to December 2018, on patients undergoing RRT with PD at the Nephrology Department of the Josep Trueta University Hospital, Girona, Spain. The study protocol was approved by the local ethics committee. All patients were fully informed about the details of the study protocol and patients provided written informed consent at the beginning of the study. The ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice was followed.

## Patients

**Inclusion criteria:** Age  $\geq$  18 years, clinical diagnosis of ESRD undergoing RRT with PD and signed the written inform consent.

**Exclusion criteria:** Patients to receive a kidney transplant within one year from the inclusion in the study and those patients with life expectancy <1 year.

## Questionnaires

**Quality of Life:** Quality of life was assessed by means two different methods. A visual analogue scale (VAS) score measuring the current state of health perceived by the patient was reported from 0 to 100 (0=no health impairment, 100=maximum health impairment).

The other method was the Medical Outcomes Survey Short Form-36 (SF-36) questionnaire (S1 Annex). The SF-36 consists of eight dimensions, generating a profile of health-related quality of life [15]. Raw scores are transformed into a score between zero and hundred for each dimension. Higher scores indicate better health [15].

## Utility measures: EuroQol 5D

Each question of the EuroQol 5D (EQ-5D) system evaluates one specific dimension of HRQOL [16] (S2 Annex). The final score is the addition of the 5-dimension individual scores and may range from -0.59 to 1.00 [17].

Health Utilities Index Mark III (HUI3): The HUI3 has into consideration eight attributes, with five to six levels [18]. Its utility scores range from -0.36 to 1.00 [18] (S3 Annex).

**Medical Outcomes Survey Short Form-6 Dimension (SF-6D):** The SF-6D has its origin in the SF-36 questionnaire [17] (S4 Annex). It assesses the level of deterioration for 6 dimensions (each between four and six levels) by means an algorithm, which uses 11 items selected from the SF-36, to generate a continuous index for health [19]. Level 1 in each dimension represents full health while levels 2 to 6 refer to a certain loss of health [20].

## **Clinical scales**

**State-Trait-Anger-eXpression-Inventory (STAXI):** The STAXI [21,22] consists of three different scales, State Anger (10 items), Trait Anger (10 items), and anger expression (24 items). A high score on each of these scales represents a high tendency or frequency to express that mode of anger.

**Hospital Anxiety and Depression Scale (HADS):** The HADS is a selfrating scale developed to evaluate psychological distress in non-psychiatric patients [23]. It evaluates separately anxiety and depression [24]. The HADS assess anxiety and depression symptoms and take into account 14 items, 7 for anxiety (HADS anxiety) and 7 for depression (HADS depression). Each item is individually score and subsequently sum to obtain the two subscales. A cut-off value of 8 or above has been shown to have the best sensitivity/specificity balance for both HADS Anxiety and HADS Depression [25].

# Statistics

Statistical analysis was performed using SPSS version 11 (SPSS Inc. in Chicago). Descriptive statistics included frequencies, means and standard deviations and median and interquartile ranges.

# Results

Fifty-eight patients were included in the analysis. Their main clinical and demographic characteristics have been summarized in table 1. Mean (standard deviation) age at diagnosis was 49.1 (16.2) years, with a mean treatment period of 10.9 (8.6) years. Information about the type of underlying kidney disease was available only in 32 patients, among whom 20 (62.5%) patients had an acquired disease, while 12 (37.5%) had a congenital one.

 Table 1: Demographic and clinical characteristics of the study sample.

Age, years Mean (SD) Range	60.7 (13.3) 18.0 to 80.0
Sex, n (%) Male Female	41 (70.7) 17 (29.3)
Weight, Kg Mean (SD) Range	75.7 (17.4) 45.0 to 123.0
Height, cm Mean (SD) Range	168.8 (7.9) 144.0 to 190.0
BMI, kg/m² Mean (SD) Range	26.2 (5.0) 15.9 to 38.4
Education level, n (%) Without studies Primary studies Secondary studies Vocational training Higher education	3 (6.0) 16 (32.0) 10 (20.0) 12 (24.0) 9 (18.0)
Marital status, n (%) Single Married Separated/Divorced Widow Other	7 (12.5) 37 (66.1) 6 (10.7) 4 (7.1) 2 (3.6)
Place of residence, n (%) Home (alone) Home (with someone) Nursing home	6 (10.5) 51 (89.5) 0 (0.0)
Employment situation, (%) Working Unemployed Laboral inability Retired	21 (36.2) 5 (8.6) 10 (17.2) 22 (37.9)



Regarding the type of PD, 40 (69.0%) patients were on APD automated method and 18 (31.0%) ones were on CAPD manual method. Although the length of CAPD treatment [3.1 (9.7) years] was longer than that of the APD method [1.9 (3.5) years)], such a difference was not statistically significant (p=0.502).

The number of comorbidities ranged from 0 to 8, with most of patients having 1 (22.0%) or two (28.8%) comorbidities. The most frequent comorbidities were systemic hypertension (85.5%), Diabetes mellitus type II (38.2%), hypercholesterolemia (32.7%), heart failure (14.5%) and peripheral vascular failure (14.5%).

Fifty-one patients were taking medical treatment. The most frequent treatments were diuretics (40.7%), calcium antagonists (44.4%), angiotensin converting enzyme inhibitors (ACEI) (38.9%) and angiotensin II receptor antagonists (AIIRA) (29.6%). Mean FKSI-DRS score was 4.6 (4.6), ranging from 0 to 21 points.

#### **HRQOL** measurements

Mean VAS score was 66.8 (16.8). Physical component of SF-36 exhibited a mean value of 40.9 (7.5), while the mental component of the SF-36 reached a mean value of 47.6 (10.2). Figure 1 shows the different sections of the quality of life according to the SF-36 questionnaire.

#### Utility measurements

Mean utility score observed with SF-6D [0.65 (0.20)] was significantly lower than that obtained with the EQ-5D [0.75 (0.16), p=0.0025] or the HUI3 [0.82 (0.23), p=0.0001], respectively. There was no significant difference between EQ-5D and HUI3, p=0.0619.

# **Clinical scales**

Mean "trait anger" score was 16.0 (4.5), while the mean "anger expression" (mean of the different 24 items) was 18.8 (8.7). Additionally, the HADS showed mean values of 6.0 (2.7) and 8.3 (2.0) for the anxiety and depression subscales, respectively. According to the HADS scores, a 6.8% of patients can be categorized within the category of clinical anxiety and 13.6% in the category of clinical depression (Figure 2).

## Discussion

Treatment of CKF is associated, in many patients, with being on dialysis for a long period of time. Patients on HD usually experience an important impairment in their life, due to the fact that they need to go to the HD-treatment-centers several times per week for 3-5 hours per treatment session [7]. Nevertheless, PD can be performed independently by the patient, either alone or in collaboration with a caregiver, in different clean places (home, work, etc.) [7]. PD can be done several times/daily, every 4-5 hours, resting a greater period during the night by means a manual method named continuous ambulatory peritoneal dialysis (CAPD) [7]. On the other hand, PD can be also performed throughout the night (8 to 10 hours) with an ambulatory peritoneal dialysis (APD) automated method [7].

Although CKF represents a prevalent condition among elderly people, only a few ESRD patients are being treated with PD [8,9,26]. Not only the ESRD but also the dialysis, either HD or PD, significantly change patients' lives. Patients with chronic disease tend to have reduced HRQOL, and PD patients are no exception. They have peculiar challenges that include body image issues, episodes of peritonitis and restricted employment options due to the need for peritoneal bag exchanges during the day. In our study both the physical and the mental components of the SF-36 showed low values when compared with healthy people [27]. The most affected SF-36 subscales were physical role limitations; General health and vitality showing almost half scores as compared with healthy people [27]. Nevertheless, Physical functioning; Bodily pain; social functioning; Emotional role limitations and mental health exhibited similar values to healthy people [27]. The finding that patients showed really low values in the physical role limitations dimension with physical functioning dimension having normal values, might support the fact that the capacity to fulfill broader physical roles (with or without assistance) may be much more important than the ability to perform specific physical functions. When compared with patients undergoing PD, the results of this study partially agreed with those of Ramos, et al. [28], who found that physical role limitations had the lowest value of the SF-36 dimensions. Regarding other dimensions of the SF-36, our study found better scores in physical functioning and emotional role limitations, but worse results in general health status [28].

## Utility measurements

The EQ-5D, SF-6D and HUI3 are health utility measures of generic HRQOL derive from health-economic approaches [29]. These scales have into account different items to create a scenario that reflects the overall HRQOL. They score ranges from 1.0 (full health) to 0.0 (death), including states worse than death (<0.0). This study found significant differences between the SF-6D scores and those observed with either EQ-5D or HUI3 [29]. Although all the HRQOL scales claim

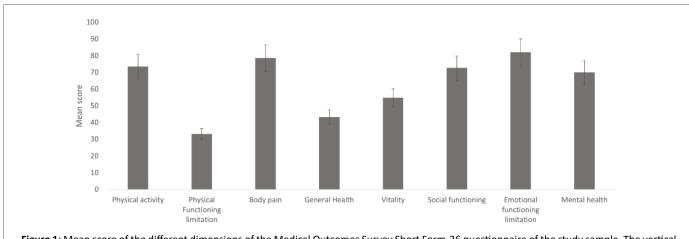
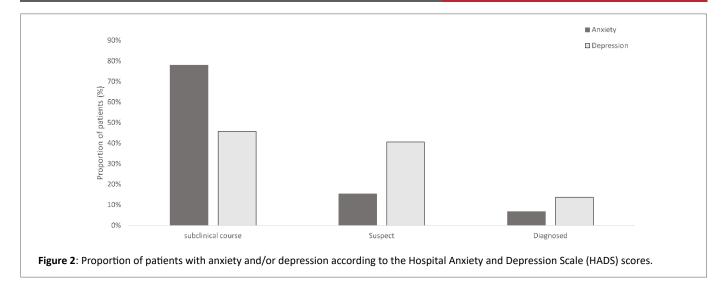


Figure 1: Mean score of the different dimensions of the Medical Outcomes Survey Short Form-36 questionnaire of the study sample. The vertical bars represent the 95% confidence interval.





to measure the same thing, they often do not. Their values usually vary, mainly because they use different strategies and algorithms to generate its overall utility score [30-32]. The EQ-5D score observed in our study [0.75 (0.16)] was greater than those reported by Manns, et al. (0.56) [32] and Lee, et al. (0.53) [33]. Similarly, the EQ-5D score found in our study was lower than that published by Yang, et al. [0.59 (0.21)] [34]. Such a difference may be explained by differences in study population. Our study was conducted on Caucasians, while Yan, et al. [34] study was conducted on Asian population; our study population had a higher educational level and none of our patients were living in public residences.

## **Anxiety and Depression**

The prevalence of depression (HADS  $\geq$  11) found in the current study (13.6%) was similar to that observed by Stasiak, et al. (14.8%) [35]. However, the prevalence of anxiety in our study (6.8%) was greater than that of the Stasiak et a study (0.0%) [35].

When considering together doubtful and definite cases (HADS  $\geq$  8) the prevalence of depression in this study (54.3%) is slightly greater than that published by Iyasere, et al. (38.8) [36]. In a similar vein, the results of our study found a prevalence of "possible depression" (HADS  $\geq$  8) significantly greater than that reported by the BOLDE study (10.0%) [12].

# Limitations

This study has several limitations. First, the analyses were based on cross-sectional data, and hence causal inferences cannot be made. Second, this was a single center study conducted on a level III University Hospital with inherent recruitment bias.

# Conclusions

Despite these limitations, the results of this study suggested that ESRD and RRT impact on the HRQOL, but not in all the dimensions at the same level. Physical role limitations; General health and Vitality seemed to be more affected than Physical functioning; Bodily pain; social functioning; Emotional role limitations and mental health. Additionally, the prevalence of depression and "possible depression" in our sample was relatively high, while prevalence of anxiety or "possible anxiety" was moderate. Further studies are needed that evaluate the potential effect of psychological interventions on these parameters.

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