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Health-Related Quality of Life in Chronic Renal Predialysis Patients Exposed to a Prevention Program – Medellín, 2007-2008

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1. Introduction

Progressive transformation of disease profiles in the world can be partially explained by the existence of chronic diseases, as they are responsible for a large part of the worldwide morbidity and mortality rates, thus becoming pandemics. One of the diseases recognized as a public health problem is chronic renal failure (CRF) because of the negative impact it has on the health and health-related quality of life (HRQOL) of its sufferers (Atkins, 2005a, 2005b).

The concept of HRQOL is still inaccurate because it has been approached from a variety of disciplines such as philosophy, economics, medicine, sociology, public health, politics, ethics, etc. (Cardona & Agudelo, 2005).

According to the World Health Organization (WHO), HRQOL is the "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." (WHO, 2002) This concept includes physical and psychological aspects as well as the degree of independence, social relationships, environment and spirituality (Cardona et al., 2003). The approximately four hundred instruments for measuring HRQOL (Cardona & Agudelo, 2005) can be grouped into four categories: the ones that measure HRQOL in terms of its global definition, the ones using component-oriented approaches, those which focus on one component, and the combinations of any of the above (Fleury & Lana Da Costa, 2004).

The relationship between HRQOL in CRF patients and the treatment after renal failure has been studied repeatedly (Amoedo et al., 2004; De Alvaro et al., 1997; García et al., 2003; Leanza et al., 2000; Pérez et al., 2007; Rebollo et al., 1999, 2000a, 2000b; Sanz et al., 2004). However, there are insufficient studies on the relationship between early progression of renal damage and well-being (National Kidney Foundation [NKF], 2007). The recommendations of the Institute of Medicine (IOM) Workshop "Assessing Health and health-related quality of life Outcomes in Dialysis" are recorded in the KDOQI guidelines and supported by scientific evidence. The IOM recommends assessing the aforementioned relationship with valid, reliable, and useful instruments such as the Medical Outcomes

Study 36-Item Short Form (SF-36). The version used in this study was adapted for the Colombian culture (Lugo et al., 2006).

To follow the WHO's recommendation (Tazeen, 2006), the Colombian Ministry of Social Protection proposed a CRF prevention and control program for Colombian healthcare providers (Martínez & Valencia, 2005). One of such institutions has been developing a renal protection program (RPP) since 2004. Besides patient uptake and follow-up, this program also assists patients in the early stages of the condition to prevent progression and renal damage, to delay the need for renal replacement therapies (RRT). The Renal Protection Program (RPP) is an interdisciplinary healthcare program. It is based on a protocol that establishes educational talks and regular medical appointments for conducting clinical examinations and laboratory tests. The program is geared toward CKD patients and welcomes them since the early stages of their condition. Likewise, the program actively searches for early-stage CKD patients and refers them to nephrologists. The professionals involved in this program are: general practitioners, internists, nutritionists, nurses, and nephrologists. Their degree of involvement varies depending on the patients' CKD stage. First, a follow-up is performed on the underlying condition. Afterwards, patients in the first and second stages of CKD are assigned to the program's first healthcare level, which offers medical appointments with internists and nutrition professionals once per year for stage 1 patients, and every semester for stage 2 patients. The second healthcare level of the program is for patients in stages 3 and 4, and offers medical appointments with internists, nephrologists, and nutritionists every three years for stage 3 patients and every two months for stage 4 patients.

In contrast, other Colombian healthcare providers offered conventional treatment (CT) in 2004. CT consists of providing healthcare through general medicine once the patients feel the need to request this service. Conventional treatment follows no healthcare guidelines, does not search for patients actively, and offers no laboratory tests or regular appointments.

This study compares changes in the HRQOL of two patient groups during the early stages of CRF (one group having been exposed to a RPP from 2007 to 2008). Its aim is to provide evidence of interventions that ease the burden this disease represents for patients, families and society.

2. Methods

A longitudinal study on two representative samples consisting of CRF patients in predialysis. The first group followed a renal protection program, and the other conventional treatment (CT). SF-36 questionnaire was applied twice for both groups, with an interval of one year. The RPP actively searches for patients and interdisciplinary standardized professional care, whereas CT consists of patient-requested medical care and follows no protocol.

The eligible population consisted of 5884 people complying with the following criteria: a. Having health insurance with either of the two healthcare promoting institutions during 2007; b. Having a CRF diagnosis that complies with the criteria established in the 2007 KDOQI guidelines (NKF,2007); c. Being older than 16, and d. Having received no dialysis or renal transplants. Exclusion criteria: being registered with both healthcare providers during the follow-up year.

A formula with repeated measurements proposed by Frison and Pocock in 1992 (Frison et al., 1992) was used to calculate the sample probabilistically. The criteria were: type 1 error: 0.05, type 2 error: 0.20 (Power: 80%), a difference of 10 in the average value of both groups, a standard deviation (SD) of 34 for both groups (the highest SD observed during the validation of the SF-36 domains (Lugo et al., 2006). The correlation between basal and follow-up measurements was fixed at 0.5.

The minimal sample size for each group was 137. There was a total of 274 patients. The researchers anticipated that locating patients would be difficult due to high mobility. Therefore, an oversampling of 50% was performed, obtaining a final sample of 411 patients, of which only 293 could be contacted. The sample for the healthcare provider offering the RPP consisted of 148 patients, and the sample for the healthcare provider offering conventional treatment consisted of 145 patients. This guaranteed the expected representativeness.

The SF-36 consists of eight domains that were calculated by transforming the ordinal scale of the form's items into the corresponding score from 0 to 100 (Lugo et al., 2006). This model has been used to define two summary scores, namely: the physical health summary score (PCS1) and the mental health summary score (MCS1). Each of these two components includes four SF-36 dimensions as follows: PCS1 includes physical functioning (PF), role-physical (RP), body pain (BP) and general health (GH); MCS1 includes: vitality (V), social functioning (SF), role-emotional (RE) and mental health (MH). Furthermore, summary scores for physical and mental health were calculated using the same method applied in a reproducibility study of the SF-36 summary scores in HRQOL assessments for Schizophrenia patients (Leese et al., 2008).

Physical functioning (PF) is measured by assessing the ability to perform different kinds of simple and strenuous activities. Role physical (RP) is measured based on how much patients can devote themselves to their jobs and other activities. Bodily pain (BP) is measured based on pain intensity and on how it hinders daily work. General Health (GH) refers to the patients' assessment of their own health. Vitality (V) is measured by assessing the perception of energy, exhaustion, or fatigue. Social functioning (SF) is measured by observing how much the patients' health problems affect their social activities. Role emotional (RE) is measured in terms of what activities the patients stop doing due to emotional problems. Mental health (MH) is measured by assessing how nervous, sad, calm, discouraged, or happy the patients feel. Change in health has a scale which is independent from the aforementioned domains and is used to assess the health state of patients. The current health state is compared with the one exhibited by the same individual one year prior to the measurement.

Upon receiving the patient's informed consent, the SF-36 was administered by qualified medicine students. Also, its correct administration was verified and double data entry was used to ensure reliability.

One year later the total number of patients surveyed with the SF-36 was 133 for the RPP and 130 for CT. For the second application of the SF-36, data analysis was carried out assigning zero to the domains of deceased patients and imputing the remaining missing values through multiple linear regression (Alisson, 2001).

After imputing the domains, summary scores were calculated and their distribution explored using the Kolmogorov-Smirnov test to verify the normality assumption. A comparison was made between the HRQOL values obtained in the two measurements for each group. For this

purpose, the t-student test for independent samples or the Mann-Whitney U test were used. Likewise, the changes in HRQOL values within each group were compared using the t test for related samples or Wilcoxon's rank sum test. The report was generated by analyzing the means in order to establish comparisons between our results and the scientific literature.

For each summary score and dimension of the HRQOL perceived after one follow-up year, the adjusted mean was calculated to compare both interventions using an analysis of covariance model (ANCOVA) and a two-way analysis of variance adjusted for gender and history of hypertension, diabetes and dyslipidemia. The ANCOVA's covariables were: the HRQOL scores obtained at the start of the study, age, and stage of the condition. Furthermore, the effect size of HRQOL differences was calculated using Cohen's effect size index and its corresponding Hedges' bias correction formula (Cohen, 1988). All analyses were conducted using the program SPSS version 15.

3. Results

3.1 Demographic and clinical characteristics

The median (Md) age was 76 for CT and 65 for the RPP. The CT group was predominantly male. A significant difference ($p=0.037$) between the age of males (Md=63) and females

Characteristic	RPP n=148 Md(Min-Max)	CT n=145 Md(Min-Max)	P value
Age	65 (18-98)	76 (31-97)	<0.001
Hemoglobin	13.6 (4.9-19.8)	14.5 (10.2-17.5)	0.001
Glomerular Filtration Rate	51 (2.1-147)	47 (16.6-115.8)	0.027
Body Mass Index	26.1 (18.2-46.5)	25.3 (15.1-39.1)	0.149
Mean Arterial Pressure	93.3 (75-123.3)	93.3 (58.3-120.7)	0.529
	n (%)	n (%)	P value
Gender			
Male	77 (52.0)	119 (82.1)	<0.001
Female	71 (48)	26 (27.9)	
Stage			
1 and 2	44 (29.7)	18 (12.4)	<0.001
3, 4 and 5	104 (70.3)	127 (87.6)	
Comorbidities			
Arterial Hypertension	141 (95.3)	133 (91.7)	0.218
Diabetes	60 (40.5)	44 (30.3)	0.068
Dyslipidemia	92 (62.2)	106 (73.1)	0.045

RPP: Renal Protection Program. CT: Conventional treatment; Md: Median. Min: minimum value. Max: maximum value.

Table 1. Distribution of demographic and clinical characteristics of predialysis patients with chronic renal failure. Medellin, 2007-2008.

(Md=68) was found in the RPP group. Clinical parameters such as arterial pressure, serum creatinine, and body mass index showed no significant differences between the study groups. For the CT group, serum hemoglobin values were significantly higher, and the glomerular filtration rate was lower. Most patients in both healthcare providing institutions had a history of arterial hypertension (90%) and dyslipidemia (60%). Distribution by stages showed that patients joined the Renal Protection Program at early stages of their condition (1 and 2=29.7 %), whereas CT patients requested treatment when their disease was at later stages (1 and 2=12.4%). See Table 1.

3.2 Perception of health-related quality of life

At the start of the study, the perception of HRQOL measured by the SF-36 showed no significant differences between the RPP and CT, except for MCS1 and role-emotional. However, the effect size (ES) was 0.08 and 0.13 respectively. The only domain exhibiting significant differences after one year was change in health, whose values favored the RPP with ES=0.11 (See Table 2).

As for the changes within each group after one year, the RPP patients showed a significant decrease only in physical functioning ($p=0.038$; ES=0.14), whereas CT patients showed a decrease in four domains: physical functioning ($p=0.027$; ES=0.14), general health ($p=0.001$; ES=0.29), social functioning ($p=0.010$; ES=0.22), and vitality ($p=0.009$; ES=0.22) and in MCS1 ($p=0.044$; ES=0.19).

Domains and summary scores	Initial			1 year		
	RPP	CT:	t-Student	RPP	CT:	t-Student
	Mean (SD)	Mean (SD)	P value	Mean (SD)	Mean (SD)	P value
PCS1:	60.9 (28.4)	58.5 (27.6)	0.470	58.9 (27.6)	54.2 (28.7)	0.160
Physical Functioning	70.0 (27.4)	68.7 (26.4)	0.662	65.8 (30.6)	64.3 (31.1)	0.684
Role-Physical	62.0 (41.4)	63.3 (42.9)	0.795	66.4 (42.3)	59.7 (45.5)	0.191
Bodily Pain	66.7 (28.6)	67.8 (27.4)	0.733	65.0 (28.3)	64.2 (29.1)	0.808
General Health	58.8 (23.6)	60.4 (22.4)	0.554	57.6 (23.5)	53.1 (26.0)	0.125
MCS1:	67.1 (33.2)	75.1 (28.1)	0.027	69.4 (27.6)	69.7 (27.4)	0.917
Mental Health	69.6 (26.8)	73.3 (23.8)	0.219	68.1 (24.5)	69.8 (23.8)	0.539
Role-Emotional	64.8 (43.1)	76.0 (37.1)	0.017	71.0 (40.9)	70.1 (40.4)	0.858
Social Functioning	76.3 (29.1)	80.9 (27.0)	0.160	77.3 (26.6)	74.5 (28.5)	0.390
Vitality	67.4 (27.0)	67.8 (24.6)	0.905	64.9 (24.9)	61.9 (26.3)	0.315
Changes in Health	66.1 (23.9)	65.9 (21.1)	0.955	68.5 (23.2)	62.6 (22.9)	0.029

RPP: Renal Protection Program. CT: Conventional treatment; PCS1: Physical health summary score. MCS1: Mental health summary score. SD: Standard deviation

Table 2. Distribution of HRQOL scores in patients with chronic renal failure in predialysis before and after an intervention. Medellín, 2007-2008.

Domains and Summary Scores	Initial		t-Student	1 year		
	Female	Male		Female	Male	t-Student
	Mean (SD)	Mean (SD)	P value	Mean (SD)	Mean (SD)	P value
RPP						
PCS1:	54.6 (27.7)	66.6 (28.0)	0.010	53.0 (26.4)	64.3 (27.8)	0.013
Physical Functioning	61.5 (27.4)	77.9 (25.1)	<0.001	57.3 (30.8)	73.6 (28.3)	0.001
Role-Physical	53.2 (41.8)	70.1 (39.5)	0.012	62.0 (44.7)	70.5 (39.9)	0.224
Bodily Pain	61.3 (28.5)	71.7 (28.0)	0.026	59.4 (27.3)	70.2 (28.3)	0.021
General Health	52.4 (22.2)	64.7 (23.5)	0.001	53.8 (22.6)	61.1 (23.9)	0.059
MCS1:	59.4 (36.1)	74.3 (28.6)	0.006	64.4 (28.7)	74.0 (25.8)	0.034
Mental Health	62.5 (29.1)	76.2 (22.7)	0.002	63.5 (23.5)	72.3 (24.9)	0.028
Role-Emotional	52.0 (45.0)	76.5 (37.9)	<0.001	64.5 (43.1)	77.0 (38.0)	0.065
Social Functioning	74.0 (29.7)	78.5 (28.6)	0.354	73.7 (28.4)	80.7 (24.6)	0.109
Vitality	59.6 (27.5)	74.6 (24.6)	0.001	56.1 (23.9)	73.0 (23.2)	<0.001*
CHANGES IN HEALTH	65.1 (23.6)	67.0 (24.2)	0.622	66.2 (21.0)	70.6 (25.0)	0.245
CT:						
PCS1:	51.3 (27.8)	60.1 (27.4)	0.142	47.6 (28.5)	55.7 (28.7)	0.198
Physical Functioning	61.5 (28.8)	70.2 (25.7)	0.130	55.6 (30.6)	66.3 (31.0)	0.112
Role-Physical	48.1 (43.0)	66.6 (42.3)	0.046	47.1 (44.9)	62.4 (45.3)	0.121
Bodily Pain	57.1 (29.0)	70.1 (26.6)	0.027	49.9 (25.7)	67.3 (29.0)	0.005+
General Health	61.9 (21.9)	60.0 (22.6)	0.700	59.6 (24.7)	51.7 (26.2)	0.162
MCS1:	65.9 (28.9)	77.1 (27.6)	0.065	61.4 (27.5)	71.5 (27.1)	0.086
Mental Health	61.5 (24.0)	75.8 (23.1)	0.005	64.5 (17.7)	70.9 (24.8)	0.213
Role-Emotional	66.6 (43.2)	78.0 (35.4)	0.216	52.5 (42.1)	74.0 (39.2)	0.013
Social Functioning	74.4 (30.2)	82.4 (26.2)	0.176	67.8 (21.5)	76.0 (29.7)	0.180
Vitality	58.5 (23.4)	69.8 (24.5)	0.033	56.9 (20.0)	62.9 (27.5)	0.292
CHANGES IN HEALTH	60.8 (21.5)	67.1 (20.9)	0.169	71.5 (18.9)	60.7 (23.3)	0.028

RPP: Renal Protection Program. CT: Conventional treatment PCS1: Physical health summary score.

MCS1: Mental health summary score. SD: Standard deviation

*: Effect size =0.69 +: Effect size =0.61

Table 3. Distribution of HRQOL scores, by gender, in patients with chronic kidney disease in predialysis before and after an intervention. Medellín, 2007-2008.

3.3 Perception of health-related quality of life in terms of gender

In both groups HRQOL was lower for women both in the initial measurement and in the final measurement after one year. At the start of the study, the female patients of the RPP showed significant differences in most domains, and CT female patients showed these only in a few domains. One year later, the HRQOL difference between men and women in the RPP group remained unchanged for PCS1 (ES=0.40) and MCS1 (ES=0.34), and for the following domains: physical functioning (ES=0.53), bodily pain (ES=0.37), mental health (ES=0.35) and vitality (ES=0.69). For the CT group, the only significant differences were in bodily pain (ES=0.61), role-emotional (ES=0.51) and change in health (ES=0.48). See Table 3.

After one year, women within each group showed no changes in HRQOL measurements. Only the men following CT showed a significant decrease in general health ($p=0.001$ ES=0.33), social functioning ($p=0.014$ ES=0.15), vitality ($p=0.007$ ES=0.13), and change in health ($p=0.012$ ES=0.09).

3.4 Perception of health-related quality of life in terms of age

In both interventions, the physical component of HRQOL was more affected in patients older than 65 than in younger individuals. This was constant throughout the study. In the RPP group, these differences at the start of the study and one year later were statistically significant for PCS1 ($p=0.001$, ES start=0.08; $p<0.001$, ES year=0.06), for the physical functioning domain ($p=0.001$, ES start=0.30; $p<0.001$, ES year=0.03) and for bodily pain ($p=0.009$, ES start=0.02; $p=0.025$, ES year=0.10). In CT, however, the differences found between the age groups at the start were in PCS1 ($p=0.025$, ES start=0.44), in the physical functioning domain ($p=0.001$, ES start=0.61) and in role-physical ($p=0.022$, ES start=0.43). One year later, differences were found in physical functioning ($p=0.022$, ES year=0.57) and general health ($p=0.021$, ES year=0.45). See Table 4.

After analyzing changes within each group and for each age group, it was observed that the RPP patients who were 65 and older showed significant changes in physical functioning ($p=0.006$, ES=0.30) after one year. Patients younger than 65 showed no changes after this time. In CT, patients younger than 65 showed significant changes in MCS1 ($p=0.044$, ES=0.34) and in the social functioning domain ($p=0.003$, ES=0.53). Patients who were 65 and older showed changes after one year in physical functioning ($p=0.050$, ES=0.15), general health ($p=0.001$, ES=0.35) and vitality ($p=0.044$, ES=0.20) See Table 4.

3.5 Health-related quality of life adjusted for previous measurements, age, and gender

After adjusting the second measurement's raw HRQOL score (See Table 2) for the initial HRQOL score, significant differences were found between the RPP and the CT groups in the following domains: general health (a difference of 5.2 points favoring the RPP) and change in health (the difference of 5.9 points continues to favor the RPP). After adjusting it for gender, differences were found in PCS1 (a difference of 7.7 points favoring the RPP) and vitality (a difference of 6.9 points favoring the RPP). When the score was adjusted for age, differences were then found in physical functioning (a difference of 7.2 points favoring CT). No significant differences were found upon adjusting HRQOL for stage, hypertension, diabetes, and dyslipidemia (See Table 5).

Domains and Summary Scores	Initial			1 year		
	65 and older	Younger than 65	t-Student	65 and older	Younger than 65	t-Student
	Mean (SD)	Mean (SD)	P value	Mean (SD)	Mean (SD)	P value
RPP						
PCS1:	53.3 (28.0)	68.9 (26.8)	0.001	51.0 (27.1)	67.2 (25.9)	<0.001
Physical Functioning	62.7 (26.1)	77.8 (26.9)	0.001	53.8 (30.7)	78.5 (24.9)	<0.001
Role-Physical	57.9 (42.5)	66.3 (40.1)	0.217	60.2 (43.8)	72.9 (40.0)	0.067
Bodily Pain	60.7 (29.5)	73.0 (26.4)	0.009	60.0 (30.6)	70.4 (24.7)	0.025
General Health	56.0 (24.3)	61.7 (22.7)	0.140	56.6 (24.9)	58.6 (22.0)	0.613
MCS1:	70.7 (32.9)	63.4 (33.2)	0.178	68.5 (31.3)	70.2 (23.2)	0.708
Mental Health	69.5 (29.1)	69.8 (24.3)	0.945	67.5 (28.2)	68.6 (20.2)	0.793
Role-Emotional	67.0 (42.7)	62.4 (43.7)	0.518	64.6 (43.7)	77.7 (36.7)	0.051
Social Functioning	76.9 (30.3)	75.7 (27.9)	0.809	73.7 (29.2)	81.2 (23.2)	0.085
Vitality	66.2 (26.8)	68.7 (27.3)	0.576	61.2 (26.5)	68.7 (22.7)	0.068
CHANGES IN HEALTH	62.4 (23.1)	70.0 (24.2)	0.052	61.3 (24.3)	76.1 (19.5)	<0.001
CT:						
PCS1:	55.7 (27.6)	67.9 (25.8)	0.025	51.9 (28.3)	62.2 (29.0)	0.068
Physical Functioning	65.2 (27.0)	80.5 (20.9)	0.001	60.5 (31.8)	77.4 (24.8)	0.002
Role-Physical	59.2 (43.8)	77.3 (37.2)	0.022	58.3 (45.2)	64.4 (46.8)	0.498
Bodily Pain	66.7 (28.1)	71.5 (25.1)	0.377	64.8 (28.5)	62.2 (31.6)	0.648
General Health	59.2 (22.8)	64.2 (21.2)	0.262	50.4 (25.7)	62.3 (25.3)	0.021
MCS1:	73.8 (28.9)	79.6 (24.8)	0.302	69.9 (27.0)	69.0 (28.9)	0.875
Mental Health	71.8 (24.5)	78.3 (20.9)	0.167	69.5 (24.3)	70.7 (22.1)	0.811
Role-Emotional	73.4 (39.1)	84.7 (27.9)	0.068	69.0 (41.4)	74.1 (37.1)	0.520
Social Functioning	79.1 (28.1)	87.1 (22.0)	0.136	74.8 (29.0)	73.7 (27.0)	0.851
Vitality	66.0 (24.9)	73.8 (23.0)	0.110	60.7 (26.8)	65.8 (24.6)	0.325
CHANGES IN HEALTH	64.3 (21.0)	71.5 (20.6)	0.084	61.4 (23.2)	66.7 (21.6)	0.249

RPP: Renal Protection Program. CT: Conventional treatment PCS1: Physical health summary score. MCS1: Mental health summary score. SD: Standard deviation

Table 4. Distribution of HRQOL scores, by age, in patients with chronic renal failure in predialysis before and after an intervention. Medellín, 2007-2008.

Domains and summary scores	Mean adjusted for initial HRQOL		Mean adjusted for gender		Mean adjusted for age	
	RPP	CT:	RPP	CT:	RPP	CT:
PCS1:	58.2	54.9	<u>58.7**</u>	<u>51.0**</u>	56.0	57.1
Physical Functioning	65.3	64.9	65.5	59.8	<u>61.5*</u>	<u>68.7*</u>
Role-Physical	66.7	59.4	66.2	56.1	64.3	61.7
Bodily Pain	65.3	64.0	64.8	60.0	63.6	65.6
General Health	<u>58.0*</u>	<u>52.8*</u>	57.6	52.6	56.6	54.2
MCS1:	70.5	68.6	69.2	66.6	69.2	69.9
Mental Health	68.7	69.1	67.9	67.2	67.7	70.2
Role-Emotional	72.5	68.6	70.7	65.1	69.2	71.9
Social Functioning	78.0	73.8	77.2	72.1	76.3	75.6
Vitality	65.0	61.8	<u>64.6**</u>	<u>57.7**</u>	63.5	63.3
CHANGES IN HEALTH	<u>68.5*</u>	<u>62.6*</u>	68.5	63.0	67.2	64.0

RPP: Renal Protection Program. CT: Conventional treatment PCS1: Physical health summary score. MCS1: Mental health summary score. The underlined values correspond to significant difference by intervention type and by adjustment variable. P value: * p<0.05 **p<0.01.

Table 5. Distribution of health-related quality of life scores in patients with chronic renal failure in predialysis after one year of treatment. Scores are adjusted for initial health-related quality of life, gender, and age. Medellín, 2007-2008.

3.6 Reasons for not participating in the study

The reasons for the unreachability of the remaining 118 patients during the first measurement were: wrong phone number = 43 (40% RPP), occupation = 33 (45% RPP), being out of geographical reach = 17 (35% RPP), and exclusion criteria = 14 (57% RPP). Only 11 patients (36% RPP) were excluded due to concomitant disease or death, which is associated with a decrease in HRQOL. One year later, of the missing RPP patients: 6 refused to participate (2 due to disease), 6 couldn't be contacted, and 3 had died. In CT: 5 refused to participate (1 due to disease), 4 couldn't be contacted, and 6 had died.

4. Discussion

This is the first report in Colombia to provide an account of the factors affecting HRQOL in patients with mild to moderate renal impairment. It is also the first to point out the advantages that a renal protection program may have over conventional treatment regarding its impact on patient HRQOL. This study's results are presented to comply with the demands that appear in international literature regarding the need to determine the impact on HRQOL in early stages of renal impairment (Chandban et al., 2003; Perlman et al., 2005) and to insist that current interventions must emphasize the preservation of renal functioning in order to decrease the negative impact of kidney failure on HRQOL (Chandban et al., 2003; Fukuhara et al., 2007; Valdebarrano et al., 2001).

The study's data were collected from 293 patients in the early stages of CRF. Patients followed two kinds of medical treatment during one year. The groups showed no differences for the main comorbidities, but it was evident that the RPP collected more patients in earlier stages of CRF due to its active search. The higher proportion of male patients in CT could be due to the faster progression of CRF in males (Silbiger & Neugarten, 1995). This could explain the gender and age disparities found between the groups at the start of the study.

One year later, the RPP group's scores for the different HRQOL domains were slightly lower, but these differences were not significant. Conversely, the CT group showed a significant decrease in four of the eight domains after the same time. This accounts for the effect of the RPP even in a short follow-up period. It is worth noting that general health was the most affected domain in both groups. After one year, the initial value for the RPP remained unchanged, but decreased drastically for CT.

The results obtained from data collected from predialysis patients confirm that HRQOL is affected from the early stages of CRF and continues to decrease as the condition evolves. Even after only one year, the scores for most domains decreased. This conclusion is shared by other studies whose patients lacked RRT. The population assessed in such studies was Japanese (Fukuhara et al., 2007), African-American (African American Study of Kidney Disease and Hypertension Trial Group [AASK], 2002), Australian (Chandban et al., 2005), Korean (Chin et al., 2008), and Dutch (Korevaar et al., 2000).

In this study, the physical health of predialysis patients was found to be more affected than their mental health. This was true for both study groups. These findings are in accordance with the conclusions reached in other publications on the same topic (Chandban et al., 2005; Fukuhara et al., 2007; AASK, 2002; Korevaar et al., 2000; Hopman et al., 2000). Regarding mental health, CT patients initially showed significantly superior values compared to the RPP patients. This result is consistent with the ideas exposed in other studies, which suggest that older patients – or those with an older diagnosis – have better mental health. This proves that mental health is worse in young or recently diagnosed individuals (Hopman et al., 2000). Nevertheless, one year later, the scores for the mental component of HRQOL increased within the RPP group, whereas CT scores decreased, and the initial differences between the RPP and CT disappeared.

Gender was a key factor for the SF-36 scores since its first application. It was observed that the scores for women were lower and had significant differences regardless of the group. However, these differences disappeared within the RPP group one year later. In CT, however, the differences remained and values in men decreased statistically. Other researchers also recognized this affectedness of HRQOL by gender. They also proposed that women may be particularly more vulnerable (Yepes et al., 2008). This was also done in the AASK study (AASK, 2002), which focused on the need for exploring the mechanisms allowing HRQOL in female CRF patients to decrease quickly. In studying the HRQOL of the Australian population suffering from kidney failure Chandban (Chandban et al., 2005) described similar worsening patterns for both genders.

After one year, women's HRQOL in most domains continued to be worse than that of men. However it is worth noting that differences between the values obtained at the start of the study and after one year could be indirectly considered as clinically important in the vitality values for the RPP (ES=0.69) and the bodily pain values for CT (ES=0.61).

Regarding age, patients older than 65 had a lower HRQOL. Physical functioning was the most affected domain for the two groups both at the start of the study and one year later. This could be explained by the strong negative association between the state of physical health and old age. Such association was reported in literature by studies on this and other chronic diseases (Chandban et al., 2005; Hopman et al., 2000; Yepes et al., 2008). The RPP patients younger than 65 showed an increase in four of the domains one year after the start of the study. The rest of the domains also decreased, but not significantly, except for the role-physical domain. For the CT group, all the domains values decreased in the second measurement, and four of them did so significantly. The difference found in physical functioning between the age groups in CT according to the effect size (> 0.60) can be considered to be clinically important. This must be corroborated for each case with the medical staff.

It is imperative to adjust the differences found in the final HRQOL scores for the variables that can influence such results. As for general health and change in health, upon adjusting for the respective value of the initial score, an increase of more than five points of HRQOL was generated in the difference that favors the RPP over CT in both domains. In the PCS1 and vitality domains, adjusting scores for gender yielded an important increase of the difference in favor of the RPP in both cases (Yepes et al., 2008). In physical functioning, adjusting scores for age increased the difference in HRQOL scores, favoring CT (Yepes et al., 2008).

In short, exposure to a RPP has a positive impact on the HRQOL of CRF patients from the early stages of their condition. The initial HRQOL score, gender, and age are fundamental characteristics to take into account for measuring the HRQOL of patients upon exposure to an intervention. It seems that early detection of CRF patients and interdisciplinary control of risk factors have a significant influence in the outcome of both physical and mental HRQOL measurements.

HRQOL values have been proposed as an important outcome in patients with high death, hospitalization, and depression risks. Measuring the HRQOL with validated instruments such as the SF-36 allows it to become a strong indicator of the health-related quality of life in ambulatory patients. In fact, it is considered a mortality and morbidity predictor in elderly and CRF patients (DeOreo, 1997; Han et al., 2009; Kalantar-Zadeh, 2005; Mapes et al., 2003). Assessing the well-being of CRF patients periodically with the SF-36 is important for measuring response to treatment and for improving healthcare. In fact, improving the HRQOL of CRF patients is a key objective in the U.S (Kalantar-Zadeh, 2005).

This study's main limitation is its short follow-up period, which could not provide an appropriate account of the characteristics of a slow, progressive disease while explaining that many changes are not significant enough. Another limitation is that demographic variables like marital status, socioeconomic level, occupation, educational level, income, etc., were disregarded. Some studies state that both PCS1 and MCS1 are closely associated with demographic characteristics that are likely to have a deeper impact than clinical characteristics themselves (AASK, 2002; Fukuhara et al., 2007).

Data loss due to patient death and other causes was expected for the second application of the SF-36 one year later. Like many other health scales, the SF-36 has no clear directions regarding how deaths within a studied population should be analyzed. This has limited the analysis in research. This issue is most frequently addressed by excluding these cases from the study or by analyzing these data separately. Paradoxically, if two study groups are compared, the

group with more diseased individuals seems to obtain better results. This is because most individuals have died and have been thus excluded from the results and from the analysis.

Due to the negative impact of CRF on HRQOL, it is necessary to determine potential areas for research and clinical intervention. Such areas include: psychological support for the most vulnerable population (women, young people, recently diagnosed patients, patients in early stages of the condition), early prescription of nephroprotectors, and complete physical therapy programs focusing on older patients and on those with high deterioration rates.

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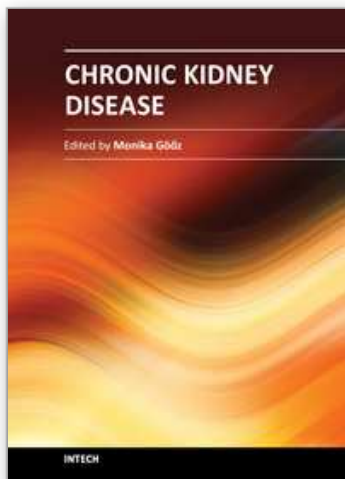
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Chronic kidney disease is an increasing health and economical problem in our world. Obesity and diabetes mellitus, the two most common cause of CKD, are becoming epidemic in our societies. Education on healthy lifestyle and diet is becoming more and more important for reducing the number of type 2 diabetics and patients with hypertension. Education of our patients is also crucial for successful maintenance therapy. There are, however, certain other factors leading to CKD, for instance the genetic predisposition in the case of polycystic kidney disease or type 1 diabetes, where education alone is not enough.

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