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Association of decreased quality of life and erectile dysfunction in hemodialysis patients

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Association of decreased quality of life and erectile dysfunction in hemodialysis patients.

Background. Quality of life in hemodialysis patients has been associated with treatment outcomes. We explored the impact of erectile dysfunction on quality of life in a cohort of hemodialysis subjects.

Methods. A random sample of 302 Philadelphia area hemodialysis (HD) subjects was enrolled using a cross-sectional design. Subjects completed a self-administered questionnaire including items on sexual function, past medical history, and quality of life. Linear regression (accounting for sampling design by weighted estimation methods) was used to examine the associations between various measures of quality of life (the dependent variables) and erectile dysfunction (ED) and other variables (the predictor variables).

Results. We found the emotional domains of the SF-36, a multi-purpose, short-form health survey with 36 questions, to be more profoundly associated with ED than the physical domains. Using the physical and mental components of the SF-12, a new 12-item short form health survey as predictors of ED, only the mental composite score (MCS) was statistically significant after adjusting for age and diabetes ($P = 0.008$). Subjects with ED had significantly lower quality of life mean scores. In particular, ED was associated with poorer social interaction (mean score difference, -10.3 , adjusted $P < 0.001$), decreased emotional well-being (-12.9 , adjusted $P = 0.005$), more role limitations due to emotional problems (-22.9 , adjusted $P = 0.01$), and poorer social function (-17.8 , $P = 0.001$).

Conclusion. Recent advances in therapies for ED warrant that the diagnosis and treatment of erectile dysfunction be included in the global health assessment by the nephrologists and primary care providers of patients with renal insufficiency, as it may improve the quality of life of patients.

The population of hemodialysis (HD) patients is growing, in part, because of longer survival [1], something that has highlighted the importance of quality of life for these

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patients. Erectile dysfunction (ED) is common, occurring in 82% of hemodialysis patients [2]. Our previous work demonstrated a prevalence of severe ED of 45% (95% CI, 36% to 55%) among HD patients using standardized self-reporting instruments. Subjects younger than 50 years had a prevalence of ED of 63% (95% CI, 53% to 71%), while in subjects 50 years or older it was 90% (95% CI, 84% to 94%). A multivariable analysis demonstrated increasing age (50 to 59 years, OR = 2.04, 95% CI, 1.3 to 3.1; 60 to 69 years, OR = 5.5, 95% CI, 1.9 to 15.6) and diabetes (OR = 2.0, 95% CI, 1.2 to 3.3) to be independently associated with the presence of any level of ED. The use of angiotensin-converting-enzyme inhibitors was inversely associated with ED (OR = 0.41, 95% CI, 0.17 to 0.98).

Although a wealth of evidence exists that addresses the multifactorial nature of ED in end-stage renal disease (ESRD) patients [2–9], the impact of ED on quality of life is not known. No prior study has specifically focused on the relationship between ED and quality of life among HD patients, despite the fact that ED is associated with poorer quality of life among men without kidney disease [10]. This study sought to identify the associations between ED and various quality-of-life domains.

METHODS**Study design and research population**

We studied men aged 18 years or older in metropolitan Philadelphia who were treated with chronic HD for at least six months. We used a two-stage cluster sampling design to create a study population from which we could make population-based inferences [11]. In the first stage, we randomly selected 16 HD facilities from the 51 facilities in the area, with the probability of each facility's inclusion approximately proportional to its size, as measured by its number of dialysis stations. In the second stage, we randomly selected from each chosen facility

20 subjects who met the eligibility criteria. Subjects were excluded if they were cognitively impaired or spoke no English. We replaced subjects who refused or were excluded with alternate subjects until we enrolled 20 individuals from each facility. Using this sampling scheme, larger facilities had a higher probability of being selected, but eligible individual patients within a facility had an approximately equal probability of selection into the study. Characterization of sexual function was the focus of an earlier publication in which additional details on methods can be found [2].

The University of Pennsylvania's Institutional Review Board and the review boards of the clinical centers caring for study subjects approved this study.

Data collection

We asked the selected subjects to complete a self-administered questionnaire that included items referring to sexual function, past medical history, and quality of life.

Sexual function

Each subject completed a self-administered five-item, previously validated questionnaire, the International Index of Erectile Function (IIEF-5) [12]. The IIEF-5 is an abridged version of the 15-item International Index of Erectile Function. [13]. The five items included in the IIEF-5 address the National Institutes of Health definition of ED, discriminate well between men with and without ED, and capture the severity of ED [12]. The subjects' ED was measured and categorized according to severity using a five-level ordinal scale based on their IIEF-5 score. A cutoff score of 21 (range of scores, 5 to 25) was used to define ED. Subjects with scores of 21 or less were considered to have ED. ED was classified likewise into five validated severity levels, ranging from none (22 to 25) to severe (5 to 7). Subjects also categorized their ED on a supplemental single-item scale as not impotent, minimally impotent, moderately impotent, or completely impotent as defined by the responses "always," "usually," "sometimes," or "never" able to get and keep an erection sufficient for sexual intercourse, respectively [14].

Comorbidity

We obtained medical and demographic data for each subject from abstraction of dialysis records. Medical data collected included measures of: health status; time on dialysis; comorbid conditions; laboratory studies such as hemoglobin, creatinine, albumin, and parathyroid hormone; adequacy of dialysis; compliance with dialysis; prior transplantation; and current medications.

The Index of Co-Existing Disease (ICED) was used to categorize patients' comorbidities. ICED classifies subjects with ESRD on a four-point scale based on the presence and severity of 19 medical conditions and 11

physical impairments [15]. These two components are summarized in the Index of Disease Severity (IDS) and the Index of Physical Impairment (IPI). The IDS reflects the severity of each of a selected list of 19 disease categories. The disease categories are rated using an explicit list of symptoms, signs, and diagnostic tests indicating the presence and increasing severity of each identified condition. Level 1 characterizes a condition with little or no morbidity. Level 2 is asymptomatic controlled disease. Level 3 is an uncontrolled disease with moderate or severe manifestations. Level 4 refers to an uncontrolled, life-threatening disease. The IPI is intended to act as a snapshot of the impact of all the conditions on the patients' functional abilities, where level 0 is normal function, level 1 is mild-to-moderate impairment, and level 2 is serious-to-severe impairment. The IDS and IPI are combined to yield a single ICED score. Higher scores reflect greater severity of disease or impairment.

Quality of life

The Kidney Disease Quality of Life-Short Form (KDQOL-SF) [16] questionnaire was administered at the same time as the IIEF-5. This questionnaire, which includes the SF-36 [17], is an abridged version of the KDQOL, [18] a validated disease-specific tool that assesses issues related to quality of life for patients with ESRD. Scores on the KDQOL-SF can range from 0 to 100; higher scores represent higher quality of life. The elements selected for the KDQOL-SF have been shown to demonstrate good reliability and validity in quantifying quality of life among HD patients [16]. When subjects could not complete the KDQOL independently, study personnel administered the SF-12. The SF-12 is a 12-item subset of the original 36 items of the SF-36 that can reproduce the physical and mental component summary scale score of the SF-36 without substantial loss of information [19]. We calculated the summary scores using the SF-36 summary measures manual. There were three major steps, including standardization of scales (z-scores), aggregation of scale scores, and transformation of summary scores.

Depression

Depression was evaluated using two questions from the KDQOL. Patients were asked to indicate how much time during the previous four weeks they had felt (a) "so down in the dumps that nothing could cheer you up," and (b) "downhearted and blue." A response of "a good bit," "most," or "all" of the time was considered an indication of depression.

Statistical methods

Our analyses sought to identify the associations between the presence or absence of ED and various quality-of-life domains. Because of the two-stage sampling

Table 1. Demographic and clinical characteristics of study cohort

Variable	% Among patients with ED (N)	% Among patients without ED (N)	P value
Age group			
<50	20.6 (39)	59.7 (26)	<0.01
50–59	20.2 (50)	29.0 (15)	
60–69	24.3 (58)	11.3 (6)	
70+	34.8 (83)	0 (0)	
Race ^a			
White	39.8 (97)	19.2 (10)	0.07
Black	56.9 (130)	77.3 (35)	
Other	3.3 (4)	3.4 (2)	
Duration on dialysis years			
<1	15.0 (33)	8.5 (4)	0.69
1–<2	25.5 (61)	20.7 (11)	
2–<4	33.8 (81)	31.8 (13)	
4+	25.7 (59)	39.0 (19)	
Hypertension			
Yes	95.9 (223)	98.7 (46)	0.29
No	4.1 (11)	1.3 (1)	
Diabetes			
Yes	42.1 (94)	22.9 (12)	<0.01
No	57.9 (140)	77.1 (35)	
ACE inhibitors			
Yes	26.1 (61)	45.8 (18)	0.04
No	73.9 (173)	54.2 (29)	
Individual disease severity			
1	2.8 (6)	1.3 (1)	0.68
2	61.9 (143)	67.1 (33)	
3	35.3 (85)	31.7 (13)	
Index of physical impairment			
0	36.9 (83)	52.7 (26)	0.34
1	49.2 (118)	32.9 (13)	
2	13.8 (31)	14.4 (7)	
Index of coexistent disease			
1	29.6 (65)	38.1 (19)	0.44
2	29.3 (71)	22.4 (11)	
3	41.1 (97)	39.5 (17)	
Cause of ESRD			
Diabetes mellitus	38.3 (82)	19.5 (10)	<0.01
Hypertension	43.3 (105)	54.1 (23)	
Other	18.5 (41)	26.4 (14)	
Smoking status			
Never smoked	30.0 (59)	28.7 (12)	0.25
Smoked <40 packs	37.6 (75)	51.8 (21)	
Smoked ≥40 packs	32.5 (72)	19.5 (8)	
Alcohol use ^b			
Does not drink	75.3 (169)	68.4 (34)	0.73
<6 drinks/week	17.8 (44)	25.2 (8)	
6+ drinks/week	7.0 (14)	6.4 (4)	
Karnofsky index	Mean (SE) patients with ED 80.98 (2.1)	Mean (SE) patients without ED 86.46 (2.6)	0.07

^aIncludes American Indian, Asian, and Other/multiracial. There was no difference in estimates between models examining white vs. non-white; ^bQuantification of ETOH consumption was done using the Khavari Alcohol Test [37]

Note: Due to missing values, total may not always equal 302.

design, all analyses accounted for the unequal probabilities of selection of individual subjects in facilities of varying size and the clustered sampling, which affects the variability of estimates. To account for unequal selection probabilities, we used weighted estimation methods, with each subject's sampling weight inversely proportional to his probability of selection into the study. The probability of selection into the study was the probability of selecting a given dialysis unit multiplied by the probability of selection of a given subject from that unit.

We described continuous variables by their mean and standard deviations (or standard errors), and categorical variables by the proportion in each category. Linear regression (accounting for sampling design by weighted estimation methods) [11] was used to examine the associations between various measures of quality of life (the dependent variables) and ED and other variables (the predictor variables). We explored different quality-of-life measures in HD patients that we hypothesized a priori may be associated with ED. For example, the emotional do-

Table 2. Results of Kidney Disease Quality of Life (KDQOL) questionnaire in ESRD study subjects ($N = 166$)

Measure	All patients Mean (SD)	Patients with ED Mean (SD)	Patients without ED Mean (SD)
ESRD-targeted scales			
Symptom/problem	73.8 (16.0)	73.0 (15.8)	76.9 (16.9)
Effects of kidney disease	63.1 (22.2)	61.3 (22.8)	68.9 (20.7)
Burden of kidney disease	47.3 (27.3)	46.1 (27.8)	53.6 (25.3)
Work status	28.7 (38.0)	26.2 (36.4)	37.6 (43.7)
Cognitive function	84.0 (16.9)	82.4 (17.7)	90.6 (11.3)
Quality of social interaction	78.7 (16.8)	77.7 (17.8)	83.1 (12.1)
Sexual function	79.5 (26.5)	69.9 (28.1)	97.7 (6.8)
Sleep	62.3 (21.2)	61.2 (22.1)	66.7 (17.6)
Social support	73.8 (27.9)	72.6 (29.5)	76.2 (20.6)
Dialysis staff encouragement	77.9 (21.3)	77.3 (21.2)	77.0 (22.9)
Patient satisfaction	67.1 (24.3)	65.1 (24.3)	72.7 (23.5)
36-item health survey scales			
Physical functioning	54.2 (27.8)	50.6 (27.5)	73.6 (19.5)
Role-physical	33.6 (39.3)	29.8 (38.0)	52.7 (40.3)
Pain	71.4 (28.5)	69.7 (28.6)	80.6 (25.7)
General health perceptions	48.1 (21.1)	46.3 (20.9)	57.3 (20.8)
Emotional well-being	74.1 (17.6)	72.6 (18.2)	82.3 (11.8)
Role-emotional	59.8 (43.3)	55.7 (43.7)	77.2 (37.2)
Social function	65.4 (31.0)	62.7 (30.4)	80.5 (27.9)
Vitality	51.5 (19.0)	49.1 (19.2)	61.2 (16.6)
Overall health rating	61.7 (21.3)	59.9 (21.3)	65.5 (20.0)

mains of the SF-36 would be more profoundly associated with ED than the physical domains.

Subjects with missing data were not included when those variables were analyzed. For the SF-36, if a patient answered at least half of the questions for a particular domain, the mean of the nonmissing questions was used. For example, the “physical functioning” scale had 10 questions. If a patient answered five or more of the 10 questions, a “physical” score was calculated. However, for the mental and physical component summary scores, a patient needed to have nonmissing scores for each of the 8 domains (physical, physical role, emotional role, social, mental, body pain, vitality, general). For the SF-12, a patient needed to complete all questions to have a nonmissing mental component score and physical component score. Analyses were performed using the survey estimation facilities of STATA, version 7 (Stata Corporation, College Station, TX, USA) and SAS version 6.12 (SAS Institute, Cary, NC, USA).

RESULTS

We identified 482 of 705 potentially eligible men receiving hemodialysis in the 16 facilities, as has been previously reported [2]. Twenty-seven men were excluded because of cognitive impairment. Thirty-seven men were not available, 24 men were not eligible, and four men had language barriers, leaving a total of 390 subjects who were asked to participate. Of these, 88 (22.6%) subjects refused or did not complete the questionnaires. The individuals who refused did not differ from study subjects with regard to age. The proportion of subjects younger than 50 years of age was 23% among those who refused

versus 25.4% among participants. Therefore, the final study sample was made up of 302 subjects.

Table 1 summarizes the subject characteristics with and without ED. One hundred seventy-two (59%) subjects were African American. Nine patients (2.6%) were Hispanic. The mean (SD) age was 59 (15) years. Fourteen percent of subjects had been on HD for 6 months to 1 year, 26% for 1 to 2 years, 33% for 2 to 4 years, and 28% for more than 4 years. The majority of patients (97%) had hypertension and 39% had diabetes mellitus. The cause of ESRD was diabetes type 1 (17%), diabetes type 2 (18%), hypertension (46%), glomerulonephritis (2%), cystic disease (4%), and other (12%). The medical history and physiologic parameters of this study population have been described previously [2].

There were 167 subjects who completed the KDQOL-SF; 135 completed the SF-12. However, there were still some missing data for various questions. All available data were used for each calculation. For instance, data were available from 162 men for the “symptom/problem list” scale of the KDQOL, but from only 159 men for “dialysis staff encouragement.” Complete information needed to score the SF-12 was available for 266 patients. Patients who filled out the abbreviated questionnaire were older (66 vs. 55 years, $P < 0.0001$) and had a higher index of coexisting disease ($P = 0.015$). However, subjects that were interviewed were more likely to have lower mean IIEF-5 scores (14.1 vs. 10.9, $P = 0.03$) and increased severity of ED ($P = 0.001$).

Subjects’ SF-36 scores were lower in all domains except bodily pain and general health perception than those reported for an age-matched population without ESRD [20]. Table 2 summarizes the results of the KDQOL

Table 3. Unadjusted association between KDQOL measures and presence of ED

QOL measure	Patients with ED Mean (SE)	Patients without ED Mean (SE)	Mean score difference (SE)	Linear regression <i>P</i> value
PCS-12 ^a	37.9 (0.8)	43.8 (1.5)	-5.9 (1.8)	0.007
MCS-12 ^b	46.7 (1.2)	53.0 (1.5)	-6.3 (1.8)	0.005
PCS-36 ^c	36.4 (1.1)	44.2 (1.2)	-7.7 (1.7)	0.001
MCS-36 ^d	47.6 (1.5)	54.5 (1.6)	-6.9 (2.1)	0.007

There were unadjusted scores available for 266 patients for the SF-12 and 149 patients for the SF-36.

^aPCS-12 is the physical composite score of the SF-12

^bMCS-12 is the mental composite score of the SF-12

^cPCS-36 is the physical composite score of the SF-36

^dMCS-36 is the mental composite score of the SF-36

in the study population overall, in subjects with ED, and in subjects without ED. The overall health-rating question from the KDQOL was 61.7 (21.3) among all subjects.

Evaluation of the relationship between ED and depression

Using the question “Have you felt so down in the dumps that nothing could cheer you up?” to classify depression, 9.7% of the subjects were classified as depressed. Using the question “Have you felt downhearted and blue?” 14.6% of subjects were classified as depressed. There was no statistically significant association between ED and depression using either question. Depression increased to 26.2% if we used a positive response to either question as presence of depression. Although depression was found in 19.4% of individuals without ED and in 27.2% of individuals with ED, we were unable to find an association between depression and ED (OR = 1.46, 95% CI, 0.64 to 3.35, *P* = 0.3).

Evaluation of the relationship between ED and quality of life

Among the 149 patients who completed all the KDQOL items, ED was statistically and significantly associated with all individual SF-36 scales. Men with ED had significantly lower scores than did men without ED on the physical (36.4 vs. 44.2, respectively; *P* = 0.001) and mental (47.6 vs. 54.5, respectively; *P* = 0.007) scales. Among the 266 patients for whom we had complete data on the SF-12, the mean (SD) SF-12 mental score was 48 (11.0). The mean (SD) SF-12 physical score was 39 (9.3). In unadjusted analyses, lower physical and mental scores were significantly associated with ED (Table 3). Using the physical and mental components of the SF-12 as predictors of ED, only the mental composite score (MCS) was statistically significant (*P* = 0.008) after adjusting for age and diabetes.

We examined the dose-response relationship between ED and quality-of-life. Using the IIEF severity scale and the supplemental single-item scale question separately, the physical component scores of the SF-12 showed a statistically significant decline as the severity of ED increased (*P* = 0.006 and *P* = 0.003, respectively). The de-

Table 4. KDQOL measures that may be associated with ED

Domain	Mean score difference (SE) ^a	Linear regression <i>P</i> value
ESRD-targeted areas ^b		
Symptom/problem	-8.3 (2.7)	0.009
Burden of kidney disease	-11 (5.5)	0.07
Work status	-4.0 (8.9)	0.66
Cognitive function	-9.0 (3.8)	0.03
Quality of social interaction	-10.3 (1.9)	<0.001
Sleep	-12 (3.7)	0.007
Social support	-8.7 (6.3)	0.19
Dialysis staff encouragement	-3.1 (5.1)	0.56
Patient satisfaction	-15.1 (3.5)	0.001
36-item health survey scales		
Physical functioning	-16.9 (4.9)	0.004
Role-physical	-20.1 (9.5)	0.06
Pain	-15.2 (4.2)	0.004
General health perceptions	-11.5 (3.2)	0.004
Emotional well-being	-12.9 (3.7)	0.005
Role-emotional	-22.9 (7.6)	0.01
Social function	-17.8 (4.1)	0.001
Vitality	-11.3 (3.3)	0.005

^a Adjusted for diabetes, age, albumin, time on dialysis, and index of coexisting disease score.

^b Effects of kidney disease domain not included since it contains questions about sexual history.

cline in MCS-12 was also statistically significant using the IIEF severity scale (*P* = 0.005) and the MMAS question (*P* = 0.001).

The presence of ED was a statistically significant predictor of lower physical and mental composite scores even after adjusting for age, diabetes, and ICED score. In regression models for different quality-of-life measures, ED was associated with poorer social interaction, less emotional well-being, and more role limitations due to emotional problems, all adjusted for age group, presence of diabetes, albumin, time on dialysis, and ICED score (Table 4).

DISCUSSION

ED is a common, but likely underdiagnosed, health issue. We explored different quality of life measures in HD patients that we hypothesized a priori may be associated with ED: We found the emotional domains of the SF-36 to be profoundly associated with ED. This

association of ED with diminished quality of life was independent of age, presence of diabetes, and other comorbidities, as assessed by the ICED score.

Our subjects' SF-36 scores were lower than an age-matched general population in all domains except bodily pain and general health perception [17], but are similar to results found in other dialysis studies [21, 22]. For example, the mean physical functioning domain score in the HD group was 54.2 (27.8) versus 79.9 (25.5) for men between the ages of 55 to 64 in the general U.S. population [17]. Treatment of ED in patients without renal insufficiency has been associated with improvements in mental health scores [23, 24], social health scores [23], and self-esteem scores [23] using the Duke health profile, a quality-of-life questionnaire.

Other non-ESRD subjects have also demonstrated the relationship between ED and the emotional domains of the SF-36. ED may lead to depressive symptoms, low self-esteem, and decreased overall quality of life [10, 25, 26]. Although there is no accepted standard definition of what a clinically significant difference in score is, it is generally accepted that a five-point decline in quality-of-life represents an impact that prompts patients to seek medical attention [27]. As shown in Table 4, the difference in scores between subjects with ED and without ED frequently reached three to four times that difference in our cohort.

Not surprisingly, ED is a focus of considerable interest for the patient. Steele et al [28] found, in a cohort of 68 peritoneal dialysis patients, that 63% reported never having sexual intercourse. Of these, half of the subjects desired to have intercourse. This group also had significantly higher depression and anxiety scores and poorer quality of life than did patients having intercourse more than twice a month.

Diagnosis and therapy of ED should be part of routine health care practices. Physician-initiated discussion of ED is not common. For example, studies in other high-risk groups such as the elderly, diabetics, or hypertensive patients have documented discussion about ED in less than 30% of patients [29].

Despite having performed a population-based sampling of male HD patients, our study has several limitations. We measured depression using two questions from the KDQOL questionnaire. Depression is an independent risk factor for ED, even after adjustment for demographic and lifestyle factors, medication use, and hormones [25]. It is known that the dialysis population has a high prevalence of depression [30, 31], as found in this study. Recently, Lopes et al [32] found that the two simple questions from the KDQOL used as indicators of depression in this study have predictive validity for mortality and hospitalization among dialysis patients in the United States and Europe. However, the agreement with physician-diagnosed depression was low.

Furthermore, all our measures of ED were self-reported and no other physical or diagnostic tests were performed, which resembles today's clinical practice. We attempted to standardize self-report of ED by using a questionnaire that had been validated in other settings [12, 13]. Finally, because the presence of ED and associated conditions and exposures were assessed simultaneously, it was impossible to determine if we identified causal associations.

There have been new therapies developed for the treatment of ED, including oral sildenafil, which has yielded encouraging results in some studies [33–35], while others have shown poor results [36].

Recent advances in therapies of ED warrant the diagnosis and treatment of ED be included in the global health assessment by the nephrologist and primary care provider of patients with renal insufficiency, as it may improve the quality of life of our patients. However, further studies are needed that will assess changes in quality of life after ED therapy in patients with ESRD.

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