

Sexual Dysfunction Is Associated with Depression and Anxiety in Patients with Predialytic Chronic Kidney Disease

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ABSTRACT

Objective: We aimed to determine the prevalence of sexual dysfunction and clarify the relationship between sexual dysfunction and depressive mood state, drugs, and disease activities in patients with predialytic chronic kidney disease (CKD).

Materials and Methods: In total, 150 patients with CKD who had an estimated glomerular filtration rate of 15–60 mL/min were included; 65 healthy controls were selected. A detailed medical and sexual medical history was taken from individuals in the control and patient groups by applying the Golombok–Rust Inventory of Sexual Satisfaction and Hospital Anxiety and Depression Scale.

Results: Sexual frequency ($p=0.027$), impotence ($p<0.001$), and premature ejaculation scores ($p<0.001$) in male patients and sexual frequency ($p=0.004$), communication ($p=0.004$), satisfaction ($p<0.001$), avoidance ($p=0.008$), orgasmic dysfunction ($p<0.001$), sensuality ($p=0.002$), and total sexual dysfunction scores ($p<0.001$) in female patients with CKD were found to be higher compared with the control group. In female patients, the depression scores of patients with stage 3 CKD were found to be higher than those of patients with stage 4 CKD ($p=0.028$). The avoidance scores of male patients with depression ($p=0.006$) were high. In contrast, the communication score of female patients with depression was high ($p=0.004$). It has been detected that the factors that affect the sexual dysfunction score of patients with CKD in males are age ($p=0.006$), hypertension ($p=0.008$), anxiety ($p=0.003$), and depression ($p=0.002$) and those in female patients are age ($p=0.034$), anxiety ($p<0.001$), and depression ($p=0.001$).

Conclusion: Patients with predialytic CKD substantially have sexual dysfunction. The most important factors that affect sexual dysfunction are age, hypertension, anxiety, and depression.

Keywords: Chronic kidney disease, depression, anxiety, predialysis, sexual dysfunction

Introduction

Chronic kidney disease (CKD) is a worldwide public health issue. CKD is a chronic and progressive disease affecting every organ system of the body. It also affects the social, economic, and psychological status of patients [1-3]. In patients with impaired renal function, depression and anxiety disorders may develop because of loss of physical and mental capabilities and their roles in the business life, family, and society; depression may thus be triggered in these patients by their initial disease. In studies investigating the psychiatric effects of organ failure in patients with CKD, the most frequently reported psychiatric disorder was depression [4-6].

Sexual function disorders are also frequently encountered in patients with CKD. However, these complaints are generally not reported to the physician mainly because of social and traditional reasons. Only 22% of patients with sexual dysfunctions inform their physicians about these complaints [4, 7-11].

Studies investigating sexual dysfunction in patients with CKD are quite limited, particularly during the predialysis period of the disease. In the present study, our aim was to determine the frequency of sexual dysfunctions in patients with predialytic CKD of stages 3, 4, and 5 and to determine the relation between sexual dysfunctions with depressive mood and anxiety.

Materials and Methods

This study was performed with a total of 150 sexually active patients (90 males and 60 females) with their partners who were followed up at the nephrology clinic for at least 6 months, who

had an estimated glomerular filtration rate (eGFR) of 10–60 mL/min/1.73 m², who were capable of understanding the study questions and expressing their thoughts, and who voluntarily participated in the study. A healthy control group of 65 individuals (30 males and 35 females) was selected from volunteers without any systemic disease, with a regular sexual life, and matching age and gender characteristics with the patient group. Participants in both groups were informed about the study, and written consent was obtained. The study was approved by the local ethics committee (ethics committee decision date and number: 03 April 2014, 38/10).

Complete blood count and ferritin, proteinuria, blood urea nitrogen, glucose, creatinine, uric acid, total protein, albumin, parathyroid hormone, total cholesterol, triglyceride, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, carbon dioxide, sodium, potassium, calcium, and phosphorus levels were assessed.

The detailed sexual history of subjects in both groups was evaluated using the Golombok–Rust Inventory of Sexual Satisfaction (GRISS) scale. GRISS is a 28-item, Likert-type, self-report scale that evaluates the presence and severity of sexual dysfunctions. Two separate forms are developed for men and women. It not only provides overall scores of the quality of sexual functioning but also examines seven dimensions of sexual activity. Sexual frequency, communication, avoidance, sensuality, and satisfaction are the shared dimensions among both men and women. Men are additionally assessed for impotence and premature ejaculation. Vaginismus and orgasmic dysfunction are dimensions specific to women. High scores indicate greater severity of sexual dysfunctions [12].

The severity of anxiety and depression symptoms of the participants was evaluated using the Hospital Anxiety Depression Scale (HADS). HADS is a 14-item, Likert-type, self-report scale. Seven items of HADS measure depressive symptoms severity and seven items assess the severity of anxiety symptoms. Higher scores indicate greater psychopathology [13].

Statistical Analysis

Statistical analyses were performed using the SPSS 22.0 (IBM Corp.; Armonk, NY, USA) software package. Descriptive parameters were expressed as frequency, percentage, mean, standard deviation (SD), median, minimum (min), and maximum (max). Relations between categorical variables were analyzed

using the Fisher's exact test or Pearson's chi-square test.

To test normality, the Shapiro–Wilk test was used when the number of samples in the group was less than 50, whereas the Kolmogorov–Smirnov test was used when the number of samples was greater than 50. Normality hypothesis was controlled using the Shapiro–Wilk test to analyze the differences between the measured values of the two groups. The Mann–Whitney U test was used for non-normally distributed data, whereas the Student's t test was used for normally distributed data. The Kruskal–Wallis test was used for non-parametric comparisons between more than two groups, whereas the Bonferroni–Dunn test was used in the post-hoc analysis of significant cases. Analysis of Variance (ANOVA) test was used for comparison between groups when the assumption of normal distribution was met, and the Šidák test was used for paired comparisons. Linear regression analysis was used to predict sexual dysfunction scores by including variables that exhibited significant differences in the single-variable analysis. A p value of <0.05 was considered as statistically significant.

Results

The comparison of the demographic parameters between patients with CKD and the control group are shown in Table 1. The location of residence and level of education was statistically significantly different between the groups (p<0.001 and p<0.001, respectively). A greater ratio of patients with CKD lived in the rural areas compared with the control subjects (p<0.001). Patients with CKD also had a higher ratio of elementary school graduates (p<0.001) and a lower ratio of higher education graduates (p<0.001) compared with the control subjects (Table 1).

The most frequent causes of CKD were hypertension (HT) (32%), diabetes mellitus (DM) (25.3%), and glomerulonephritis (GN) (22%). The rate of comorbidity among patients with CKD was 76.7%. The most common comorbidities were HT (64%) and DM (13.3%). Calcium channel blockers (CCBs) (59.3%) and angiotensin-converting enzyme inhibitors (ACEIs; 42%) were the most commonly used drugs by the patients. The rates of comorbid diseases (HT and DM) were not different between the kidney failure stages (p>0.05). Moreover, there was no significant difference between the types of drugs (beta-blockers, CCBs, and ACEIs) used between the kidney failure stages (p>0.05).

Male patients with CKD had higher sexual frequency (p=0.027), impotence (p<0.001), and premature ejaculation (p<0.001) scores. Female patients with CKD had higher sexual frequency (p=0.004), communication (p=0.004), satisfaction (p<0.001), avoidance (p=0.008), sensuality (p=0.002), orgasmic disorders (p<0.001), and total sexual dysfunction (p<0.001) scores, while also having lower vaginismus scores (p=0.018; Table 2).

In the CKD group, patients aged below and above 50 years were compared with regard to anxiety, depression, and sexual dysfunction parameters. The test results indicated significant differences in the depression scores between males of the two age groups and in the communication scores between females of the two age groups. Male patients aged below 50 years had lower depression scores (p=0.032), whereas female patients aged above 50 years had higher communication scores (p=0.027).

The anxiety, depression, and sexual dysfunction parameters did not significantly differ among

Table 1. Demographic parameters of patients and control groups

		Control		CKD		p
		n	%	n	%	
Sex	Male	30	46.2	90	60.0	0.06
	Female	35	53.8	60	40.0	
Age	Female	Mean±SD	48.51±7.1	50.42±8.94		0.066
		Med (min-max)	47 (40-64)	51 (27-65)		
	Male	Mean±SD	50.2±8.67	53.61±8.61		0.145
		Med (min-max)	48 (40-65)	56 (35-65)		
Place of residence	Rural	4	6.2	43	28.7	<0.001
	Urban	61	93.8	107	71.3	
Educational status	Illiterate	0	0.0	8	5.3	<0.001
	Primary school	18	27.7	73	48.7	
	Secondary school	8	12.3	22	14.7	
	High school	15	23.1	32	21.3	
	Academy	24	36.9	15	10.0	

CKD: chronic kidney disease; SD: standard deviation

male patients with CKD with respect to education level; however, among female patients with CKD, the anxiety ($p=0.014$), satisfaction ($p=0.022$), and orgasmic disorder ($p=0.034$) scores as well as the total score ($p=0.033$) significantly differed with respect to education. These scores were lower among patients with high school level of education or higher compared with those with secondary school level of education or below ($p<0.001$).

The anxiety, depression, and sexual dysfunction parameters were also compared with respect to the patients' location of residence. These parameters did not significantly differ among male patients; in contrast, the communication score was higher ($p=0.013$) among female patients and the satisfaction score was lower ($p=0.009$) among those living in rural areas.

When comorbidities were independently evaluated, it was determined that the total sexual dysfunction score was higher in male patients with DM than in those without DM ($p=0.038$). Among male patients with HT, the avoidance ($p<0.001$) and sensuality ($p=0.003$) scores as well as the general total score ($p=0.003$) were determined to be higher than those of patients without HT. In male patients with coronary artery diseases (CAD), the mean satisfaction score was found to be lower than that of patients without CADs ($p=0.042$). Female patients could not be similarly compared because of insufficient sample size.

When CKD causes were independently evaluated, it was observed that the avoidance ($p=0.005$), sensuality ($p=0.008$), impotence ($p=0.02$), and total ($p=0.002$) scores among males significantly differed in at least one of the groups. The results of the paired comparisons indicated that patients whose CKD was due to HT had lower avoidance scores than those with DM ($p=0.005$) and GN-related CKD ($p=0.044$). Furthermore, patients whose CKD was due to HT had lower sensuality scores than those with DM-related CKD ($p=0.008$); patients whose CKD was due to HT had lower impotence score than those with DM-related CKD ($p=0.017$). The evaluation of the total scores indicated that patients with CKD due to HT had lower total scores than those with DM-related CKD ($p=0.002$). The sexual function parameters were not different in female patients in terms of CKD causes ($p>0.05$).

The anxiety, depression, and sexual dysfunction parameters were also compared with respect to the drugs used by the patients. The premature ejaculation score was found to be

Table 2. Anxiety, depression, and sexual dysfunction parameters of male and female patients in the CKD and control group

	n	Mean	SD	Median	Min	Max	p	
Anxiety	Control	30	6.23	3.87	6.00	.00	14.00	0.426
	CKD	90	5.84	4.33	5.00	.00	21.00	
Depression	Control	30	5.30	3.75	4.00	.00	16.00	0.775
	CKD	90	5.59	3.95	5.50	.00	21.00	
Sexual frequency	Control	30	3.63	2.04	4.00	.00	8.00	0.027
	CKD	90	4.54	1.86	4.00	.00	8.00	
Communication	Control	30	3.67	2.55	3.50	.00	8.00	0.746
	CKD	90	3.50	2.62	3.00	.00	8.00	
Satisfaction	Control	30	6.67	3.28	7.00	.00	12.00	0.053
	CKD	90	5.69	2.82	6.00	.00	13.00	
Avoidance	Control	30	3.47	2.89	3.00	.00	10.00	0.094
	CKD	90	2.44	2.40	2.00	.00	9.00	
Sensuality	Control	30	3.37	2.74	2.50	.00	9.00	0.881
	CKD	90	3.29	2.72	3.00	.00	13.00	
Impotence	Control	30	3.77	2.14	4.00	.00	8.00	<0.001
	CKD	90	5.96	2.99	6.00	.00	14.00	
Premature ejaculation	Control	30	4.93	2.90	5.00	.00	11.00	<0.001
	CKD	90	7.98	3.09	8.00	.00	14.00	
Male total sexual dysfunction score	Control	30	33.00	11.68	32.00	11.00	56.00	0.076
	CKD	90	37.84	13.20	39.00	6.00	72.00	
Anxiety	Control	35	7.34	4.98	7.00	.00	21.00	0.126
	CKD	60	8.70	4.81	8.00	.00	20.00	
Depression	Control	35	6.66	4.87	6.00	.00	20.00	0.477
	CKD	60	7.42	4.75	7.00	.00	20.00	
Sexual frequency	Control	35	4.14	2.22	4.00	.00	8.00	0.004
	CKD	60	5.43	1.77	6.00	1.00	8.00	
Communication	Control	35	3.80	2.22	3.00	.00	8.00	0.004
	CKD	60	5.23	2.39	5.00	.00	8.00	
Satisfaction	Control	35	5.34	3.66	5.00	.00	12.00	<0.001
	CKD	60	8.45	3.79	8.00	.00	16.00	
Avoidance	Control	35	3.89	3.08	3.00	.00	12.00	0.008
	CKD	60	6.35	4.28	5.50	.00	16.00	
Sensuality	Control	35	4.60	3.55	4.00	.00	12.00	0.002
	CKD	60	7.30	4.07	7.00	.00	16.00	
Vaginismus	Control	35	6.43	2.75	7.00	.00	10.00	0.018
	CKD	60	5.25	3.02	5.00	1.00	16.00	
Orgasmic dysfunction	Control	35	5.57	3.41	4.00	.00	14.00	<0.001
	CKD	60	8.10	3.09	8.00	2.00	16.00	
Female total sexual dysfunction score	Control	35	39.29	18.16	38.00	4.00	70.00	<0.001

CKD: chronic kidney disease; SD: standard deviation

higher among male patients receiving beta-blockers ($p=0.005$), whereas the communication ($p=0.003$), satisfaction ($p=0.002$), and sensuality ($p=0.028$) scores were determined

to be lower among female patients receiving beta-blockers. Among males receiving CCBs, only the anxiety ($p=0.025$) and depression ($p=0.019$) scores were statistically significantly

higher. The satisfaction ($p=0.042$) and total sexual dysfunction scores ($p=0.024$) were higher among female patients using diuretics. The avoidance ($p=0.015$), sensuality ($p=0.006$),

and impotence ($p=0.001$) scores as well as the general total score ($p=0.006$) were higher among male patients receiving insulin; as for female patients, insulin use was associated with

a lower vaginismus score ($p=0.01$). Among patients using statin, it was observed that males exhibited higher impotence scores ($p=0.034$), whereas females had lower communication scores ($p=0.04$).

Table 3. Predictors of sexual dysfunction score in male patients (Model 1)

	Unstandardized coefficients		Standardized coefficients		p	95% Confidence interval	
	Beta	Standard error	Beta	t		Lower limit	Upper limit
(Constant)	9.536	7.416		1.286	.201	-5.157	24.230
Age	.367	.130	.247	2.827	.006	.110	.624
Diabetes mellitus	6.224	3.731	.145	1.668	.098	-1.168	13.615
Hypertension	7.604	2.813	.294	2.703	.008	2.031	13.176
Insulin	2.586	3.060	.079	.845	.400	-3.476	8.649
Anxiety	.810	.267	.263	3.035	.003	.281	1.338

Table 4. Predictors of sexual dysfunction score in male patients (Model 2)

	Unstandardized coefficients		Standardized coefficients		p	95% Confidence interval	
	Beta	Standard error	Beta	t		Lower limit	Upper limit
(Constant)	8.797	7.487		1.175	.242	-6.035	23.629
Age	.388	.131	.261	2.954	.004	.128	.648
Diabetes mellitus	5.911	3.735	.137	1.583	.116	-1.488	13.310
Hypertension	7.664	2.805	.297	2.732	.007	2.106	13.221
Insulin	3.069	3.033	.094	1.012	.314	-2.940	9.078
Depression	.894	.289	.269	3.095	.002	.322	1.467

Table 5. Predictors of sexual dysfunction score in female patients (Model 1)

	Unstandardized coefficients		Standardized coefficients		p	95% Confidence interval	
	Beta	Standard error	Beta	t		Lower limit	Upper limit
(Constant)	3.510	14.883		.236	.814	-26.066	33.086
Educational status	1.535	4.197	.038	.366	.716	-6.807	9.876
Age	.473	.220	.203	2.151	.034	.036	.911
CCBs	6.734	4.687	.172	1.437	.154	-2.581	16.049
Diuretic	5.511	5.959	.088	.925	.358	-6.333	17.354
Anxiety	1.416	.383	.357	3.693	<.001	.654	2.178

CCBs: calcium channel blockers

Table 6. Predictors of sexual dysfunction score in female patients (Model 2)

	Unstandardized coefficients		Standardized coefficients		p	95% Confidence interval	
	Beta	Standard error	Beta	t		Lower limit	Upper limit
(Constant)	14.766	13.991		1.055	.294	-13.037	42.570
Educational status	-.859	4.124	-.021	-.208	.835	-9.055	7.337
Age	.357	.218	.153	1.635	.106	-.077	.790
CCBs	4.916	4.753	.126	1.034	.304	-4.529	14.361
Diuretic	3.556	6.113	.056	.582	.562	-8.591	15.703
Depression	1.288	.384	.317	3.354	.001	.525	2.051

CCBs: calcium channel blockers

When the anxiety, depression, and sexual dysfunction parameters were compared with respect to disease stage, the premature ejaculation score was found to be higher among male patients with stage 5 CKD compared with those with stages 3 ($p=0.018$) and 4 ($p=0.037$) CKD. The number of female patients with stage 5 CKD was not sufficient to perform a similar evaluation ($n=2$). The depression score of patients with stage 3 CKD was found to be higher than those with stage 4 CKD ($p=0.028$).

Anxiety and depression scores were found to be highly inter-related; hence, in the regression models developed to predict sexual dysfunction scores in the patients, these two variables were not included in the same model to avoid multicollinearity problems. Therefore, two models were developed for both males and females. All variables included in the model were primarily determined by considering the significant results obtained in the single-variable analysis. When anxiety was included into the model for male patients, age, HT, and anxiety were determined to be significant parameters (Table 3). When depression was included in the model, age, HT, and depression were determined to be significant parameters (Table 4). When anxiety was included in the model for female patients, age and anxiety were determined to be significant parameters (Table 5), and when depression was included in the model, only the depression parameter was found to be significant (Table 6).

Discussion

Sexual dysfunction is frequently observed in both male and female patients with chronic uremia, as observed in our study [4, 9-11, 14]. Furthermore, many patients believed that their sexual lives had to end with the beginning of dialysis, whereas patients who continued having an active sexual life had lower sexual satisfaction levels than the normal population [11]. A meta-analysis published by Navaneethan et al. [9] comprising 50 studies with a total of 8343 patients described that almost all studies reported a higher prevalence of erectile dysfunction. The ratio of erectile dysfunction was estimated to be 70%, whereas the rate of sexual dysfunction in female patients was determined to be 30%–80%. Erectile dysfunction is reported to be the most frequent problem among male patients, whereas decreased satisfaction and orgasm is most frequently reported among

female patients [4]. In our study, sexual frequency, impotence, and premature ejaculation scores among male patients with CKD were found to be higher than those of the control group. In female patients with CKD, sexual frequency, communication, satisfaction, avoidance, and orgasmic disorder scores as well as the total sexual dysfunction score were comparatively higher, whereas the vaginismus score was lower compared with the control subjects.

It is still unclear whether sexual dysfunction is related with organic or psychogenic causes in the natural course of CKD. This is a natural consequence of the metabolic and hormonal disorders caused by uremia [7, 8, 10, 15]. Sexual dysfunction in patients with CKD was determined to be associated with the stage of CKD, dialysis treatment, advanced age, DM, and depression [10, 14-19]. In our study, patients in the predialysis period were evaluated. When anxiety, depression, and sexual dysfunction parameters of the patients were compared between the stages of the disease, the premature ejaculation score was found to be higher in male patients with stage 5 CKD than in those with stages 3 and 4 CKD. These results show that sexual dysfunction might be affected as the kidney disease progresses, albeit at a limited level.

The number of female patients with stage 5 CKD was not sufficient for evaluation ($n=2$); however, the depression score of patients with stage 3 CKD was found to be higher than that in female patients with stage 4 CKD. This result can be associated with the adaptation of CKD progression in female patients.

Advanced age is an important factor of sexual dysfunction in patients with CKD [10, 14-19]. Age-related physiological and psychological changes in women mainly occur during menopause. Decreases in libido, sexual responsiveness, comfort level, and sexual frequency may accompany the changes in sexual function. Low testosterone levels during the premenopausal period may cause decreased libido, decreased touch sensibility, and fatigue [20]. In addition, age-related changes in males include decreases in ejaculation frequency, erection, and sexual willingness as well as decreases in the level of testosterone production [21]. We also determined that age was one of the factors that affected sexual dysfunction.

Sexual dysfunction in patients with CKD was determined to be associated with anxiety and depression [10, 14-19]. The following factors accounted for the causes of depression in male patients with CKD: job loss, loss of male self-

image, shame due to social pressures (leading to the avoidance of help-seeking behavior), and difficulty in urination. In the general population, there is the established notion that men are and should always be ready for sexual intercourse, which has the effect of lowering performance and causing significant anxiety. This in turn may lead to sexual unwillingness and avoidance of sexual intercourse. Such a cycle of unrealistic expectations and avoidance may create a depressive state in the individual [22-24]. In the study by Kurdoğlu et al. [25], depressive symptoms in predialysis patients was found to be 6 and 3.8 times more prevalent, respectively, compared with control subjects and hemodialysis patients. Moreover, sexual dysfunction was 24 times more common in predialysis patients with depressive symptoms compared with patients without depressive symptoms [25, 26]. In our study, male patients with anxiety had lower sexual frequency scores and higher avoidance scores, whereas female patients with anxiety had higher avoidance and sensuality scores as well as higher total scores. Male patients with depression had higher avoidance scores, whereas female patients with depression had higher communication scores. In addition, in our study, anxiety and depression were determined to be independent factors that affect sexual dysfunction in both males and females.

In an epidemiological study conducted in the Netherlands with 7076 patients, it was determined that anxiety and depression disorders are correlated to female, age of 25–34 years, low level of education, living alone, unemployment, family history of psychiatric diseases, and traumas during childhood [24]. When the anxiety, depression, and sexual dysfunction parameters were compared with respect to the level of education, no differences were identified in males, whereas the anxiety, satisfaction, and orgasmic dysfunction scores and the total scores significantly differed among female patients according to their level of education. These scores were found to be lower in patients with high school level education and above compared with patients with secondary school level education or below. These results indicated that sexual dysfunction decreases with increasing level of education.

A high ratio of patients with CKD, approximately 80%–85%, had HT. Many recent studies have demonstrated that sexual dysfunction develops as a consequence of comorbidities, such as HT, CAD, and DM [27-29]. In our study, the avoidance and sensuality scores, as well as the general total scores, were higher among male

patients with HT compared with those without HT. Moreover, in our study, HT was determined to be another factor that affects sexual dysfunction in males.

Sexual dysfunction is highly frequent in male and female patients with DM. Diabetic genitourinary autonomic neuropathy causes serious disorders, such as bladder dysfunction, retrograde ejaculation, erectile dysfunction, and dyspareunia (due to decreased vaginal lubrication). Loss of trabecular smooth muscle, particularly in the cavernous tissue, is believed to be responsible for this condition in males. The development of cardiovascular complications has also been reported to be a possible cause [28, 30, 31]. Consistent with the findings of previous studies, we determined that total sexual dysfunction scores were higher in both male and female patients with DM.

In addition to coexisting diseases in patients with CKD, certain cardiovascular and antihypertensive medications (beta-blockers, thiazide diuretics, etc.) may also play a role in the development of sexual dysfunction [32]. In our study, the premature ejaculation score was higher in male patients receiving beta-blockers, whereas the communication, satisfaction, and sensuality scores were lower in female patients using beta-blockers. Only the anxiety and depression scores were found to be higher in male patients receiving CCBs. In female patients using diuretics, the satisfaction score and the total sexual dysfunction score were determined to be higher.

One of the limitations of our study is the relatively small size of the study population, particularly females and patients with stage 5 CKD. Another limitation of this study is that the diagnosis of anxiety and depression is solely based on self-reported scales.

In conclusion, it is observed that patients with predialytic CKD substantially have sexual dysfunction. The most important factors that affect sexual dysfunction are age, HT, anxiety, and depression.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Antalya Training and Research Hospital Ethic Committee (03 April 2014, 38/10).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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