



## PREVALENCE OF FIBROMYALGIA SYNDROME AND ITS EFFECT ON QUALITY OF LIFE IN HEMODIALYSIS PATIENTS

### HEMODİYALİZ HASTALARINDA FİBROMİYALJİ SENDROMU PREVALANSI VE YAŞAM KALİTESİNE ETKİSİ

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#### Abstract

**Objective:** We evaluated the prevalence of fibromyalgia syndrome (FM) in hemodialysis patients and whether this syndrome was associated with gender, age, duration of hemodialysis, or other laboratory parameters.

**Methods:** The study included 248 patients with chronic kidney disease (CKD) undergoing hemodialysis. The patients were stratified into two groups: patients with FM based on the 2010 American College of Rheumatology diagnostic criteria and patients not meeting these criteria without FM. Quality of life (QOL) was assessed using the Short Form-36 (SF-36) and Kidney Disease Quality of Life-36 (KDQOL-36) questionnaires. Sociodemographic data, laboratory parameters and a marker for adequacy of hemodialysis (Kt/V) were recorded.

**Results:** FM was detected in 33/248 (13.3%) of patients included. All patients diagnosed as FM were female. When all sub-parameters of SF-36 and KDQOL-36 were compared, QOL was lower in the FM group compared to patients without FM ( $p<0.05$ ). When laboratory parameters, dialysis duration, Kt/V, marital status and BMI were compared, no difference was detected between groups ( $p>0.05$ ). FM frequency was higher in cases of advanced age, presence of systemic disease and/or hepatitis B and C infection in patients undergoing hemodialysis ( $p<0.05$ ). In addition, FM frequency was inversely proportional to education level ( $p<0.05$ ).

**Conclusion:** FM, associated with a significant decrease in QOL, is more commonly seen in CKD patients undergoing dialysis compared to the general population. Thus, it will be helpful to keep FM in mind and to improve QOL in these patients by early diagnosis and treatment.

**Keywords:** Hemodialysis, fibromyalgia syndrome, prevalence, quality of life

#### Öz

**Amaç:** Bu çalışmada, hemodiyaliz hastalarında fibromiyalji sendromu (FM) prevalansını ve bu sendromun cinsiyet, yaş, hemodiyaliz süresi veya diğer laboratuvar parametreleri ile ilişkili olup olmadığını değerlendirdik.

**Yöntem:** Çalışmaya, hemodiyaliz tedavisi alan kronik böbrek hastalığı (KBH) olan 248 hasta dahil edilmiştir. Hastalar, Amerikan Romatoloji Derneği (ACR) 2010 FM tanı kriterlerine göre FM olan 33 bireyden oluşan hasta grubu ve FM olmayan 215 bireyden oluşan hasta grubu olarak ikiye ayrıldı. Hastaların yaşam kalitelerini değerlendirmek için Short Form-36 (SF-36) ve Kidney Disease Quality of Life-36 (KDQOL-36) kullanıldı. Ayrıca FM olan hastalarda fonksiyonel durumu ölçmek için Fibromiyalgiya İmpact Questionnaire (FIQ) kullanıldı. Hastaların sosyodemografik verileri, laboratuvar parametreleri ve diyaliz yeterliliği göstergesi olan Kt/V değerleri kaydedildi.

**Bulgular:** Çalışmaya katılan bireylerin 33'ünde (%13,3) FM saptandı. FM tanılı 33 hastanın hepsi kadındı. SF-36 ve KDQOL-36 tüm parametreleri yönünden karşılaştırıldığında FM olan grupta, FM olmayan gruba göre yaşam kalitesi anlamlı olarak daha düşüktü ( $p<0,05$ ). Hastaların laboratuvar parametreleri, diyaliz süresi, Kt/V, medeni durum ve vücut kitle indeksi karşılaştırıldığında gruplar arasında anlamlı bir farklılık saptanmadı ( $p>0,05$ ). Diğer yandan hemodiyaliz tedavisi alan hastalarda ileri yaş, kadın cinsiyet, sistemik hastalık ve/veya hepatit B ve C enfeksiyonu varlığında FM sıklığı anlamlı olarak daha fazlaydı ( $p<0,05$ ). Ayrıca hemodiyaliz tedavisi alan hastalarda eğitim düzeyi azaldıkça FM sıklığı anlamlı bir şekilde artmaktaydı ( $p<0,05$ ).

**Sonuç:** Hemodiyaliz hastalarında yaşam kalitelerini önemli ölçüde azaltan FM, bu hastalarda normal popülasyona göre daha sık görülmektedir. Bu nedenle FM'nin erken tanı ve etkili tedavisiyle yaşam kalitesini iyileştirmek için hastalara ek yarar sağlayacaktır.

**Anahtar Kelimeler:** Hemodiyaliz, fibromiyalji sendromu prevalansı, yaşam kalitesi

## Introduction

Fibromyalgia (FM) syndrome is a nonarticular rheumatic disease characterized by chronic diffuse musculoskeletal pain.<sup>1</sup> Common body pain in patients is accompanied by signs and symptoms such as morning stiffness, headache, irritable bowel and bladder disease, anxiety, depression, Raynaud's phenomenon, dry eye, dry mouth, sleep disorders, swelling of hands, and paresthesia. The etiology and pathophysiology of FM are not known, but genetic, psychological, and environmental factors and peripheral and central mechanisms have been suggested as possible causes.<sup>2-4</sup>

The prevalence of FM is reported to be between 2-8%.<sup>5</sup> The prevalence of FM in females in the 20-64 age group was found to be 3.6% in a screening study conducted in Turkey.<sup>6</sup> Although FM is seen in all ethnic groups of all ages and genders, it most frequently affects women in the 40-60 age group.<sup>7</sup>

Chronic kidney disease (CKD) is defined as a condition where objective kidney damage and/or glomerular filtration rate (GFR) of at least three months standing is less than 60 ml/min/1.73 m<sup>2</sup>, regardless of the underlying etiology of renal disease. Evidence of kidney damage may be of a structural or functional nature; these findings can be obtained from urine, blood tests, imaging studies and/or renal biopsy.<sup>8</sup>

There are a limited number of studies into FM in specific populations. Some of these studies have focused on rheumatic symptoms in kidney patients. Rheumatologic diseases are major complications of CKD and approximately 60% of hemodialysis patients develop musculoskeletal disease. However, few studies have investigated the frequency of FM in individuals with CKD.<sup>9,10</sup>

This study aimed to evaluate the incidence of FM in hemodialysis (HD) patients and the effect of FM on quality of life in these patients. A further aim of the study was to examine the relationship between FM and routine laboratory results and Kt/V values, which are indicators of dialysis adequacy in CKD patients.

## Methods

This was a cross-sectional study. It was approved by Cumhuriyet University Ethics Committee (Project Number 2016-01/22). The study protocol was prepared in accordance with the Helsinki Declaration. Participation in the study was voluntary. Written, informed consent was obtained from all patients before their participation. No, a priori sample size calculation was conducted. The sample size was based on the available population of patients.

## Participants

In this study, 383 patients over 18 years of age receiving hemodialysis treatment were interviewed between April 2016 and July 2016 from five centers: 1) Cumhuriyet University Medical Faculty Hospital, Nephrology Clinic Hemodialysis Unit; 2) Sivas Numune Hospital Hemodialysis Unit; 3) Private Sivas Dialysis Center, 4) Sivas Diaverum Central Anatolian Special Dialysis Center; and 5) Sivas Medicana Hospital Hemodialysis Unit.

The inclusion criteria were as follows: 1) Routine hemodialysis treatment for at least three months, three times a week for CKD; 2) aged >18 years old; and 3) giving fully informed, competent consent for the study. The exclusion criteria were as follows: 1) Hemodialysis treatment for less

than three months and less than three sessions per week due to CKD; 2) any malignancy; 3) rheumatological disease including rheumatoid arthritis, systemic lupus erythematosus, ankylosing spondylitis, familial Mediterranean fever; and 4) orthopedic problems, sequelae of cerebrovascular disease or neuromuscular disease that limit mobilization.

Volunteers who agreed to take part in the study underwent an interview and physical and clinical evaluation, and completed the questionnaires at the same session.

All individuals included in the study were evaluated in detail in terms of FM diagnosis according to ACR 2010 diagnostic criteria, which occurred when the widespread pain index (WPI) was  $\geq 7$  and the symptom severity (SS) scale score was  $\geq 5$ , or when the WPI was between 3 and 6 and the SS scale score was  $\geq 9$ . In addition, the patients' symptoms needed to have been of this severity for at least three months, and there was no other disorder that could have caused the pain.<sup>11</sup> Thirty-three patients (33 females) met the 2010 ACR criteria for FM Syndrome. The control group consisted of 215 patients (100 females, 115 males) who also had CKD but were not diagnosed with FM, based on ACR criteria.

Kidney Disease Quality of Life-36 (KDQOL-36) and Short Form-36 (SF-36) questionnaires were completed by all subjects to evaluate their QOL. In addition, the Fibromyalgia Impact Questionnaire (FIQ), which is specific for FM patients, was administered to individuals diagnosed with FM to assess their current health status. Questionnaires were administered to all subjects by the same researcher through face-to-face interviews. In addition, the results of the routine clinical and laboratory examinations performed in the previous month were recorded. These parameters included body mass index (BMI), hemoglobin, blood urea nitrogen (BUN), creatinine, albumin, alkaline phosphatase (ALP), Calcium and Phosphate (Ca, P), parathyroid hormone (PTH) and Kt/V values.

Statistical analyses were performed using the SPSS for Windows version 22.0 software program (IBM Inc., Chicago, IL, USA). The Kolmogorov-Smirnov Z test was used in order to test whether parametric test assumptions were fulfilled or not. When parametric test assumptions were not fulfilled, Mann Whitney-U test was used for two-category variables and Kruskal Wallis H test was used for variables with more than two categories. When parametric test assumptions were fulfilled, the Independent Sample t-Test was used for two categorical variables and the F Test was used for more than two categorical variables. In addition, the Chi-Square test was used to compare if both variables were categorized. A  $p < 0.05$  was considered to be statistically significant.

## Results

Of the 383 patients initially interviewed, 135 were excluded for the following reasons: 45 declined consent; 23 had been receiving hemodialysis treatment for less than three months and less than three sessions per week; 32 had rheumatologic disease; and 12 were elderly and suffering from age-related poor health and cooperation disorder. In addition 10 had mobilization/orthopedic problem including severe osteoarthritis (n=5), amputation (n=2), use of crutches (n=2) and confined to a wheelchair (n=1), seven had cerebrovascular disease sequelae, four were suffering from mental retardation, and two more hearing problems making participation unfeasible. As a result, 248 of the original 383

patients interviewed were included in the study. The demographic data for all 248 patients are shown in Table 1.

**Table 1.** Demographic characteristics of HD patients

HD Patients		
Characteristic	FMS group	Control group
n (%)	33 (13.3)	215 (86.7)
Age, mean ± SD	65.06±8.92	60.29±12.20**
Gender, men/women	0/33	115/100
BMI	27.05±5.14	25.80±5.18*
Hemodialysis duration (months), mean ± SD	85.54±74.4	69.38±63.20*
Education level, no. (%)	9	
No schooling	25 (75.79)	71 (33) ***
Primary school	8 (24.2)	91 (42.33) ***
Junior or senior high school	0	41 (19.07) ***
College	0	12 (5.6) ***
WPI	11.82±3.37	0.71±1.38***
SSS	8.39±1.47	4.24±2.07***

FMS: Fibromyalgia Syndrome, SD: Standard Deviation, WPI: Widespread Pain Index, SSS: Symptom Severity Scale. \*:  $p>0.05$ , \*\*:  $p<0.05$ , \*\*\*:  $p<0.001$

The major etiology of kidney failure was diabetes mellitus (32.7%) followed by hypertension (31.0%), although polycystic kidney disease (10.9%) was also responsible for a notable proportion of kidney failure. Additionally, various other causes accounted for 10.5% of kidney failure, while in 14.9% of the patients, the cause remained unknown. FM was identified in 33 (13.3%) patients and all of these patients with FM were female. The mean age was higher in the group with FM. In the FIQ evaluation of FM patients in CKD patients, the mean±standard deviation (range) FIQ score was 72.48±14.41 (31.33-89.67). The WPI and SS scores were higher in the FMS group, as expected ( $p<0.001$ ).

There was no statistically significant relationship between FM and BMI or dialysis duration in patients ( $p>0.05$ ). However, the level of education was lower in the patients diagnosed with FMS ( $p<0.05$ ). Frequency of FM decreased as education level increased.

Table 2 shows the comparison of laboratory parameters of patients with and without FM. The difference between the laboratory parameter results of the groups was not statistically significant.

**Table 2.** The laboratory results of HD patients in the FM and control groups (Mean±SD)

	FM Group (n=33)	Control Group (n=215)
Hemoglobin, g/dL	11.49±1.48	11.47±1.48*
Albumin, g/dL	3.93±0.55	3.98±0.41*
Bun	64.24±17.93	65.09±16.73*
Creatinin	7.28±1.46	7.96±2.45*
CaxP (mg/dL)	42.23±11.02	40.56±10.15*
Kt/V	1.59±0.23	1.50±0.33*
Parathyroid hormone, pg/mL	418.88±582.88	345.86±355.42*
Alkaline phosphatase, IU/L	156.75±174.43	123.90±84.41*

SD: Standart Deviation. CaxP: CalsiumxPhosphorus, Kt/V=index of dialysis adequacy, FM: Fibromiyaljiya Syndrome. \*:  $p>0.05$

When compared to patients without FM, all parameters from the SF-36 quality of life and KDQOL-36 score scale sub-parameter results were found to be lower in the patients with FM diagnosis ( $p<0.05$ ) (Table 3).

**Table 3.** Comparison of SF-36 Quality of Life and KDQOL-36 Score Scale Sub-Parameter Results of HD patients in the FM and control groups (Mean±SD)

	FM Group (n=33)	Control Group (n=215)
Physical functioning	24.39±27.12	60.20±30.54**
Role-physical	0.00±0.00	17.60±37.02*
Role-emotional	29.29±35.12	55.50±43.59*
Energy/fatigue	25.30±18.19	47.76±20.20**
Emotional well-being	57.93±20.69	68.72±18.27*
Social functioning	36.74±29.80	69.53±32.57**
Pain	30.37±20.73	85.43±21.25**
General health	16.21±16.53	36.13±19.99**
SF-12 PCS	25.24±5.66	37.96±9.03**
SF-12 MCS	37.62±10.78	45.62±11.46**
Burden of kidney disease	20.07±20.89	37.40±25.73**
Symptom/problem list	69.69±8.76	83.96±9.50**
Effects of kidney disease	63.07±14.64	75.96±16.66**

SD: Standart Deviation. SF-36: Short Fom-36, KDQOL-36: Kidney Disease Quality of Life-36, SF-12 PCS: Short Form-12 Physical component summary score, SF-12 MKS: Short Form-12 Mental component summary score, FM: Fibromyalgia Syndrome. \*:  $p<0.05$ , \*\*:  $p<0.001$

## Discussion

Musculoskeletal system disorders are relatively common in patients with CKD. These disorders, having a wide spectrum which includes FM, are observed in about 60% of hemodialysis patients.<sup>9,10</sup> However, there are some studies in the literature examining the frequency of FM in individuals with CKD.

FM frequency has been evaluated in hemodialysis patients and the results are contentious. A study conducted in Turkey by Yuceturk et al. reported the frequency of FM to be 7.4% in hemodialysis patients, whereas Couto et al. found the FM prevalence to be 3.9%.<sup>12,13</sup> Samimaghani et al. investigated a cohort of Iranian hemodialysis patients and reported an FM frequency of 12.2%.<sup>14</sup> Leblebici et al. studying another Turkish cohort of 221 hemodialysis patients to be 9%.<sup>15</sup> In the USA, Wolfe et al. investigating 3006 individuals from the general population found the FM prevalence to be 2%; 3.4% in females, and 0.5% in males.<sup>16</sup> In the present cohort the FM frequency was 13.3%, higher than the normal population.

Although FM is observed in all ethnic groups, and across the age groups and genders, it is most prevalent in the female 40-60 age group.<sup>7</sup> While previous studies<sup>12-14</sup> of hemodialysis patients have reported a female preponderance, Leblebici et al. did not find any relationship between gender and FM in their study on hemodialysis patients.<sup>15</sup> In our study, 100% of the 33 patients with a diagnosis of FM were women. FM was not observed in male patients, which is in contrast to the findings reported by Wolfe et al where 0.5% of cases of FM in the general population were identified in males.

FM frequency has been reported to increase with age, and the frequency of relapse decreases at more advanced ages.<sup>6,16</sup> Nevertheless, in earlier studies of the prevalence of FM in hemodialysis patients, no statistically significant

correlation was found between age and FM.<sup>12,15</sup> Our findings are in keeping with this.

In line with the literature, the main etiology for CKD in our cohort was Diabetes Mellitus and Hypertension.<sup>13,14,17,18</sup> Community studies have shown that FM develops more frequently in those with a low level of education.<sup>6,16,19</sup> In the studies conducted on hemodialysis patients, while no statistically significant relationship between education level and FM frequency was found in the study of Couto *et al.*, FM was reported to be more frequent in patients with a low level of education by Leblebici *et al.*<sup>13,15</sup> We have also found that FM frequency increased in those with a low level of education.

Many studies have investigated the relationship between obesity and FM, and in most, patients with a diagnosis of FM had higher BMI.<sup>20,21</sup> However, in the study conducted by Couto *et al.*, no significant association between BMI and a diagnosis of FM was identified.<sup>13</sup> In our study, BMI was also similar across the groups compared. The lack of an association between BMI and FM in this and the Couto *et al* study might be due to dietary restriction in hemodialysis patients and long-term complications of CKD.

When the relationship between FM and either systemic disease or hepatitis B and C infection were examined in the literature, FM prevalence was found to be higher both patients with diabetes mellitus and those with hepatitis B and C infections.<sup>22,23</sup> Furthermore, systemic diseases such as coronary artery disease, thyroid dysfunction, and osteoporosis were more prevalent in patients diagnosed with FM compared to the general population.<sup>24-27</sup> In our cohort FM frequency increased in patients diagnosed with systemic diseases, other than CKD.

No relationship was found between hemodialysis duration and dialysis adequacy index (Kt/V) and FM in our study and our results are compatible with the literature.<sup>12,15</sup> Moreover, we found that serum albumin, BUN, creatinine, hemoglobin, CaxP, and ALP levels were similar in the groups with and without FM diagnosis in the month prior to the study and these results are compatible with the literature.<sup>12,13,15</sup> It can be inferred from these findings that chronic inflammatory conditions, bone and mineral metabolism, and malnutrition do not correlate with FM in hemodialysis patients. Previous studies have reported differing findings concerning the concentration of PTH in FM patients. Whilst Yüçetürk *et al.*, Couto *et al.* and Leblebici *et al.* found similar plasma PTH values in patients diagnosed with FM and in their respective control groups, Samimaghani *et al.* reported significantly higher PTH levels in patients diagnosed with FM compared to the control group.<sup>12,15</sup> In our study, plasma PTH values tended to be higher in patients diagnosed with FM compared to controls, but the difference was not statistically significant.

Couto *et al.* compared to hemodialysis patients with and without a diagnosis of FM using the SF-36 and all sub-parameter scores, with the exception of the pain sub-parameter were found to be lower in those with a diagnosis of FM.<sup>13</sup> In our study, a decrease in all sub-parameter scores of the SF-36 in hemodialysis patients with FM diagnosis was identified, implying that the QOL in this subgroup of hemodialysis patients is poorer. The presence of FM in hemodialysis patients and the finding that these patients reported poorer QOL by SF-36, with the exception of the pain sub-parameter, compared to the general population in Turkey, imposes an additional negative burden on these patients in terms of QOL.<sup>28</sup>

When the KDQOL-36 questionnaire was completed by our participants a decrease in all sub-parameter scores in hemodialysis patients with a diagnosis of FM was found when compared to hemodialysis patients without FM.

### Conclusion

In the present study the FM prevalence in hemodialysis patients (13.3%) was higher than the general population and more frequent in female patients. No relationship was identified between laboratory parameters, BMI, hemodialysis duration, and Kt/V values of the patients and FM. However, FM was reported to negatively affect the QOL by hemodialysis patients. To counter this decrease in QOL, measurement of laboratory parameters is not sufficient, it we believe that is also important to evaluate FM, which is increased in frequency in these patients, particularly in women when compared to the general population. In conclusion, we believe that FM, which reduced both SF-36 and KDQOL-36 scores across all sub-parameters, should be an important element of diagnosis that should be investigated in hemodialysis patients routinely during follow up.

### Conflict of Interest

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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