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Research Article

Diabetes Mellitus Patients with Fibromyalgia have a Higher Risk of Cardiovascular Disease

Fibromyaljisi Olan Diabetes Mellitus Hastaları Yüksek Kardiovasküler Hastalık Riskine Sahipler

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Abstract

Aim: The primary aim of this study is to investigate the effect of the presence of Fibromyalgia(FM) on cardiovascular risk and cardiopulmonary capacity in diabetes mellitus (DM) patients. In addition, the prevalence of FM in DM patients was investigated according to the American College of Rheumatology (ACR) 2016 criteria.

Material and Methods: The study included 188 premenopausal female patients with Type 2 DM. The physical activity level of the study participants was assessed with the International Physical Activity Questionnaire - short form. The cardiopulmonary capacity was evaluated with the 6-minute Walk Test. The cardiovascular risks were evaluated with the Framingham risk score. Participants were examined for the presence of FM according to the ACR 2016 criteria.

Results: 63 (33.5%) participants met the ACR 2016 FM diagnostic criteria. DM patients with FM have significantly lower physical activity levels (p=0.004) and cardiopulmonary capacity (p=0.009), and they also have significantly higher cardiovascular risks (p=0.02) than DM patients without FM.

Conclusion: FM is seen in approximately one-third of DM patients, and the presence of FM reduces cardiopulmonary capacity and increases cardiovascular risk. In the management of patients diagnosed with DM, the presence of FM should be investigated, and treatment should be applied with pharmacological and non-pharmacological methods to reduce the contribution to cardiovascular risk.

Keywords: Cardiovascular risk, fibromyalgia, physical activity

Öz

Amaç: Bu çalışmanın birincil amacı, diabetes mellitus (DM) tanılı hastalarda Fibromiyalji (FM) varlığının kardiyovasküler risk ve kardiyopulmoner kapasite üzerindeki etkisini araştırmaktır. Ayrıca DM hastalarında FM prevalansını Amerikan Romatoloji Cemiyeti (ACR) 2016 kriterlerine göre araştırmaktır.

Materyal ve Metot: Çalışmaya Tip 2 DM tanılı 188 premenopozal kadın hasta dahil edildi. Katılımcıların fiziksel aktivite düzeyleri Uluslararası Fiziksel Aktivite Anketi kısa formu ile değerlendirildi. Kardiyopulmoner kapasiteleri 6 Dakika Yürüme Testi ile değerlendirildi. FM varlığı ACR 2016 FM tanı kriterlerine göre incelendi. Kardiyovasküler risk Framingham risk skoru ile hesaplandı.

Bulgular: ACR 2016 FM tanı kriterlerine göre 63 (%33.5) katılımcının FM'si vardı. FM'li DM hastalarının FM'siz DM hastalarına göre fiziksel aktivite düzeyleri ve kardiyopulmoner kapasiteleri daha düşük (sırasıyla, p=0.004, p=0.009), kardiyovasküler riskleri daha yüksekti (p=0.02).

Sonuç: FM, DM hastalarının yaklaşık üçte birinde görülür. FM varlığı kardiyopulmoner kapasiteyi azaltır ve kardiyovasküler riski artırır. DM tanılı hastaların yönetiminde FM varlığı araştırılmalı, FM'nin kardiyovasküler riske katkısını azaltmak için farmakolojik ve nonfarmakolojik tedavi yöntemleri uygulanmalıdır.

Anahtar Kelimeler: Fibromiyalji, fiziksel aktivite, kardiyovasküler risk

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INTRODUCTION

The group of diseases affecting the blood vessels and heart such as cerebrovascular disease, coronary artery disease, and peripheral vascular disease are defined as cardiovascular diseases and are a leading cause of mortality (1). Determination and modification of the risk factors of cardiovascular disease are one of the basic functions of preventative healthcare services.

The increasing incidence of Diabetes mellitus (DM), which is characterized by glucose metabolism disorder causing mortality and morbidity, presents a significant threat to societal health. DM is an independent cardiovascular disease risk factor, and the primary reason for mortality and morbidity in patients with DM is cardiovascular disease (2). There is a highly complex, multi-directional relationship between DM and cardiovascular diseases. Glyco-oxidation end-products which lead to oxidative stress, endothelial dysfunction, hypercoagulability, autonomous neuropathy, and inflammation are factors directly associated with the pathogenesis of cardiovascular disease in DM (3). Factors such as hypertension, dyslipidemia, and obesity, which often indirectly accompany DM, also increase the risk of cardiovascular disease (4).

The etiology and pathogenesis of Fibromyalgia Syndrome (FM) are not yet fully understood, but in the pathophysiology, there are known to be various neuroendocrine dysfunctions and changes in central pain mechanisms and clinical findings include chronic widespread bodily pain, fatigue, sleep disorders, and multiple somatic and cognitive disorders (5-7). Cardiovascular risk factors such as heavy smoking, low physical activity, and cardiopulmonary vitality have been reported at higher rates in FM patients than in control subjects (8,9). In a population-based cohort study by Tsai et al, the risk of coronary artery disease was shown to be 2-fold higher in FM patients compared to individuals without FM (10). Patients with FM are also known to be predisposed to atrial fibrillation, which is a rhythm disorder associated with morbidity and mortality (11). Patients with coronary pathology have also been reported to have more FM symptoms (12).

When FM is determined together with other diseases, the management of these patients is more difficult, and clinical findings are more complex. According to the American College of Rheumatology (ACR) 1990 and ACR 2010 criteria, FM is known to accompany 17-21% of DM patients (13-15). However, the clinical reflections of FM co-existing in DM patients have not yet been investigated. Therefore, the primary aim of this study was to investigate the effect of the presence of FM on cardiovascular risk and cardiopulmonary capacity in DM patients. In addition, the prevalence of FM in DM patients was investigated according to the ACR 2016 criteria, which are the current FM diagnostic criteria.

MATERIAL AND METHOD

The cross-sectional study included 188 premenopausal female patients followed up for a diagnosis of Type 2 DM in a tertiary level university hospital. The sample size of the study was calculated according to DM prevalence of 14.2% in Turkish females, d=0.05, and a 95% confidence interval (16). According to the patients' medical records or medical history, patients were excluded from the study if they had peripheral vascular disease, heart failure, coronary artery disease, cerebrovascular disease, hyperlipidemia, were using antihypertensive drugs, had any orthopedic disability, irregular menstrual cycles, myofascial pain syndrome, Vitamin D or Vitamin B12 deficiency, any metabolic disease other than DM, respiratory system disease, any psychiatric disease such as schizophrenia, inflammatory rheumatological disease, or any acute or malignant disease.

Written and verbal informed consent was obtained from all the study participants. The study was conducted with the decision of the local ethics center of Sivas Cumhuriyet University Non-Interventıonal Research Ethics Commıttee dated 10.03.2021 and decision number 2021-03/27. All procedures were applied in compliance with the Good Clinical Practice guidelines and the Helsinki Declaration.

A record was made for each participant of socio-demographic data, including age and educational level, anthropometric measurements of body mass index and abdominal circumference, DM-related microvascular complications such as retinopathy, nephropathy, and neuropathy from medical records or mediacal history, smoking status, the time since DM diagnosis, and laboratory findings of HbA1c and fasting glucose level.

The physical activity level of the study participants was assessed with the International Physical Activity Questionnaire -short form, which has been shown to have validity and reliability in Turkish (17,18). In this questionnaire formed of 7 items, the periods of sitting, walking, and physical activity in the last 7 days are evaluated and thus the level of physical activity can be calculated with the MET-minute score.

The cardiopulmonary capacity of the study participants was evaluated with the 6-minute Walk Test (6MWT). After resting, the participants were requested to walk at as fast a tempo as possible for 6 mins in a corridor 30 m in length. Before starting the test, it was explained that the patients could rest if they experienced dyspnea or excessive tiredness, but the resting time would be included in the test time. During the test, the time remaining was given at one-minute intervals. At the end of 6 minutes, the distance walked was recorded in meters (19).

The cardiovascular risks of the participants were evaluated with the Framingham risk score using a web-based calculation tool (20), by evaluating gender, age, systolic blood pressure, total and HDL cholesterol levels, antihypertensive drug use, the presence of diabetes, history of vascular disease, and smoking habits. The Framingham risk score calculates the 10-year risk of experiencing a

cardiovascular event and is a reliable method widely used for this purpose (21). The presence and level of components of the scoring system are scored on a points scale, the points are totaled, and the risk percentage equivalent to the total points is determined on a separate scale. A risk percentage of <10% indicates a low risk of cardiovascular disease, 10%-20% a moderate risk, and >20% a high risk (21).

Following these evaluations, the study participants were examined on the same day by a physiatrist for the presence of FM according to the ACR 2016 criteria. The ACR 2016 FM diagnostic criteria are the most up-to-date criteria providing a diagnosis of FM by questioning the presence, severity, and duration of symptoms such as fatigue, waking unrested and how many pains are felt from 11 common pain regions and 5 body regions defined from the extremities and axial body regions (5). According to these criteria, FM is diagnosed with symptoms of similar severity for at least 3 months, symptom severity scale score of ≥5, and general pain index score of ≥7, or symptom severity scale score of ≥9, and general pain index score of 4-6, and pain in at least 4 of the 5 common pain regions (5).

Statistical Analysis

Data were analyzed using SPSS v. 22 software (SPSS Inc., Chicago, IL, USA). Conformity of the data to normal distribution was examined using visual methods such as histogram and probability graphs, and analytical methods such as the Kolmogorov-Smirnov test and Shapiro-Wilk test. Categorical data were stated as number (n) and percentage (%) and as numerical data did not show normal distribution they were stated as median, minimum and maximum values. In the comparisons of DM patients with and without FM, the Chi-square test or the Fisher's Exact test for categorical variable, and the Mann-Whitney U-test was used for numerical variables. Type-1 error level was set as 0.05.

RESULTS

This cross-sectional study included 188 patients with Type 2 DM, of which 63 (33.5%) met the ACR 2016 FM diagnostic criteria.

The sociodemographic data, clinical findings, and laboratory test results of the DM patients with and without FM are shown in Table 1. The mean age, duration of DM, and HbA1c level were determined to be similar in both groups. The physical activity levels of the DM patients with FM were determined to be significantly lower (p=0.004).

The 6MWT results and the Framingham risk scores of the groups are shown in Table 2. The 6MWT results of the DM patients with FM were determined to be significantly lower than those of the DM patients without FM (p=0.009). The Framingham risk scores of the DM patients with FM were determined to be significantly higher than those of the DM patients without FM (p=0.02). The statistically significant difference in the Framingham risk scores was due to the difference in the groups with low and moderate Framingham risk scores (p=0.08). No statistically significant difference was determined between the groups with low and high Framingham risk scores (p=0.24) or between those with moderate and high scores (p=0.27).

Table 1. Sociodemographic data and clinical findings of the study participants

	DM patients with FM (n=63)	DM patients without FM (n=125)	p
Age (years)	51 (39-55)	51.6 (39-56)	
Duration of education (years)	9 (7-16)	9 (7-16)	0.68
Body Mass Index kg/m²	30.6 (25.8-40.3)	29.9 (24.9-39.4)	0.69
Abdominal circumference, cm	140 (129-150)	138 (125-147)	0.96
DM-related microvascular complications			0.98
Retinopathy n(%)	7 (11.1)	14 (11.2)	
Nephropathy n(%)	4 (6.3)	8 (6.4)	
Neuropathy n(%)	25 (39.7)	40 (32)	
Smoker, yes, n(%)	38 (60.3)	70 (56)	0.57
DM duration, years	8 (5-12)	9 (5-13)	0.48
HbA1c	7.6 (5.9-8.8)	7.5 (5.6-8.9)	0.81
Fasting blood glucose, mg/dl	157 (109-202)	154 (115-197)	0.11
Resting heart rate atım/dk	73 (65-78)	74 (60-77)	0.77
Physical activity level, MET-min	550 (502-2100)	749 (621-2298)	**0.04**

Table 2. Comparisons of the cardiopulmonary capacity cardiovascular risks of the groups

		DM patients with FM (n=63)	DM patients without FM (n=125)	p
6-Minute Walk Test		406 (342-490)	430 (312-584)	**0.009**
Framingham Risk Score				**0.02**
	Low	16 (25.4)	54 (43.2)	
	Moderate	34 (54)	44 (35.2)	
	High	13 (20.6)	27 (21.6)	

DISCUSSION

Previous research has shown that FM increased the cardiovascular risk compared to healthy control subjects (8,10,22). In the current study, for the first time in literature, the effect on cardiovascular risk and cardiopulmonary capacity was examined of the presence of FM in DM patients, which is a major risk for cardiovascular disease, and the results showed that cardiopulmonary capacity was lower and the cardiovascular risk was higher in DM patients with FM. The study results also showed a prevalence of 33.5% of FM in DM patients according to the ACR 2016 FM diagnostic criteria.

FM may accompany several systemic, rheumatological, infectious, and metabolic diseases (13,23,24). When determined together with other diseases, the clinical findings in particular of the patients may become more complex and patient management can be more difficult (23). For example, in cases with FM accompanying rheumatoid arthritis, which is the most common inflammatory rheumatological disease, the number of sensitive joints increases because of impaired pain perception, and the general health condition of the patient is worsened (23). Therefore, the disease activity score is affected and real difficulties are experienced in planning patient treatment. It is known that FM is present in approximately a quarter of DM patients (13-15), but how this affects DM patients has not been previously investigated. As DM is a significant risk factor for cardiovascular disease, the focus of this research was on the effect of FM on this risk.

Cardiovascular reasons are the leading cause of death in DM patients, and the results of the current study demonstrated that the risk of cardiovascular disease was higher in DM patients with FM. Many humoral, cellular, neuroendocrine, and biopsychosocial factors could be the reason for this result. One of these reasons is that inflammation plays a key factor in the development of atherosclerosis. Although FM is accepted as a non-inflammatory rheumatismal disease, recent studies have indicated that there are various cytokines, chemokines, lipid mediators, oxidative stress, and plasma-origin factors in the immunological background of FM (25). Another reason is mitochondrial dysfunction, which is a cellular factor with a common line in the pathogenesis of FM and cardiovascular diseases (26-28). Another is that mood disorders are seen in FM patients, and it has been previously shown that depression and anxiety increase the risk of myocardial infarct and adverse events related to coronary artery disease (29, 30). There is a close relationship between FM and chronic stress, and the fact that chronic stress causes impairments in the sympathetic nervous system and the hypothalamus-hypophysis-adrenal gland axis may be another reason. Changes in heart rate associated with this autonomous dysfunction have been shown to increase cardiovascular risk (9). Yet another reason is the cardiovascular side-effect profile of NSAIDs used to control the symptoms of general body pain experienced by DM patients with FM (31). Finally, it can also be considered that there are more lifestyle effects in FM patients such as smoking, sedentary lifestyle, and low levels of physical fitness, which are independent cardiovascular risk factors (8). The methodology of this research was not sufficient to assess all these factors, but of the factors focussed on, the physical activity level and cardiopulmonary fitness level were determined to be lower in the DM patients with FM.

Both the level of physical activity and the level of cardiopulmonary fitness are consociated with the risk of cardiovascular disease (32,33). Just as regular exercise is the first step in the prevention of cardiovascular diseases, it is one of the keystones in the management of DM patients and the first step in treatment (34). It is protective against cardiovascular disease through mechanisms such as reducing inflammation, improving the lipid profile, regulating blood pressure, and reducing insulin resistance (35). As in the current study, previous research has reported that females with FM have a low level of physical activity and cardiopulmonary capacity (8, 36, 37). This can cause an increase in the cardiovascular risk of DM patients with FM.

The prevalence of FM in DM patients has been investigated in a limited number of studies, and these studies have used the ACR 1990 diagnostic criteria and the ACR 2010 FM classification criteria (13-15). The ACR 1990 FM criteria only focus on the pain and sensitive points of the patient and do not question other biopsychosocial effects related to FM (38). The ACR 2010 FM criteria have the positive aspect of a holistic approach to the patient but also negative aspects of including the mistaken diagnosis of several regional pain syndromes and psychological disorders and preventing FM diagnosis in individuals

with other diseases (39). With the revision of the negative aspects of the ACR 2010 FM criteria, the ACR 2016 FM criteria were formed and are currently used. These ACR 2016 criteria have gained validity with the most important feature of the use of the concept of secondary FM when it accompanies other diseases (5). As the patient groups covered by these criteria are different, the prevalence of FM may vary according to the diagnostic criteria used (40). This could explain the higher prevalence obtained in the current study compared to previous research. In similar research of patients with rheumatoid arthritis, a higher prevalence value was also obtained using the 2016 diagnostic criteria (23).

There were some limitations to this cross-sectional study. As the duration of FM was not known in the DM patients with FM, and the FM severity was not evaluated with the FM impact scale, the findings could not be analyzed according to symptom duration and severity. In addition, the physical activity levels were evaluated according to the patients' statements, and quantitative methods to determine the actual physical activity levels were not used. Moreover, the study focussed on determining the cardiovascular risk of the presence of FM in DM patients, and all the factors which could play a role in forming this result were not investigated in detail.

CONCLUSION

In conclusion, the results of this study demonstrated that FM is seen in approximately one-third of DM patients, and the presence of FM reduces cardiopulmonary capacity and increases cardiovascular risk. In the management of patients diagnosed with DM, the presence of FM should be investigated, and treatment should be applied with pharmacological and non-pharmacological methods to reduce the contribution to cardiovascular risk. There is a need for further studies to investigate in more detail why the presence of FM increases cardiovascular risk.

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