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# Relationship of glycemic control and diabetes duration with fibromyalgia in patients with type 2 diabetes mellitus

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## ABSTRACT

**Aim:** Fibromyalgia (FM) is a syndrome characterized by chronic widespread musculoskeletal pain, presence of specific tender points and other somatic symptoms. The objective of the present study was to identify the association of glycemic control and diabetes duration with FM based on 2016 American College of Rheumatology (ACR) criteria in patients with type 2 diabetes mellitus (T2DM).

**Methods:** A total of 275 consecutive patients with T2DM admitted to a university hospital setting were included in this cross-sectional study. FM was diagnosed based on ACR 2016 criteria in all patients. Age, gender, diabetes duration, and body mass index (BMI) were recorded and metabolic parameters were determined in all participants.

**Results:** HbA1c and fasting blood glucose were not significantly different between patients with FM and without FM. Diabetes duration was independently associated with FM in patients with T2 DM.

**Conclusions:** Development of FM in patients with T2DM was not associated with glycemic control but associated with diabetes duration. Clinicians should be aware of the possibility of concomitant FM in long term diabetes patients complaining of pain, fatigue and cognitive symptoms because of its devastating effect on quality of life.

**Keywords:** Fibromyalgia, type 2 diabetes mellitus, glycemic control.

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## Introduction

Fibromyalgia syndrome (FM) is a disease characterized by widespread pain in the skeletomuscular system and sensitivity at specific anatomic points. It is a chronic disease with unknown cause and is accompanied by symptoms involving different systems like sleep disorder, fatigue, depressive mood, cognitive function disorder and irritable colon syndrome [1,2]. In 1990 for the first time, the American College of Rheumatology (ACR) determined FM diagnostic criteria with identification of sensitivity at 11 of 18 points determined on the body [1]. FM is most frequently encountered in the 40-60 year age interval and is 9-10 times more frequent in women [3,4]. The etiopathogenesis of FM is not fully known, and it is considered that with a background of genetic tendency, this syndrome is triggered mainly by environmental factors

followed by viral infections with rheumatologic diseases progressing with chronic inflammation, immunologic, hormonal factors, sleep disorders, depression and anxiety [5-9]. In recent years, FM has been classified under the title 'central sensitivity syndromes' together with diseases like chronic fatigue syndrome, myofascial pain syndrome, restless leg syndrome, irritable bowel syndrome, tension-type headache, migraine, temporomandibular disorders and premenstrual syndrome with central sensitization playing a role in the etiology [10].

Diabetes mellitus (DM) is a disease characterized by chronic hyperglycemia and protein-lipid metabolism disorder. In the literature, musculoskeletal system diseases like osteoarthritis, adhesive capsulitis, hyperostosis, Dupuytren contracture, osteoporosis and neuropathic pain were shown to have association with DM [11-13]. Based on the fact that both DM and FM are associated with musculoskeletal symptoms, we aimed to investigate whether FM is related with glycemic control and diabetes duration in patients with T2DM. When we reviewed the literature, few studies with contradictory results were notable at this topic. We also assessed the other risk factors associated with FM and the effect of FM on quality of life in T2DM. The modified diagnostic criteria which was recommended by ACR in 2016 was used for the first time in diagnosis of FM in the present study.

## Materials and methods

Permission for the study was granted by Bolu Abant İzzet Baysal University Faculty of Medicine Non-Interventional Clinical Research Ethics Committee (Protocol number: 87, decision number: 2019/31, received date: 08.03.2019). Informed consent was obtained from all patients. The applied FM effect survey (FEA) had Turkish validation previously performed and the survey is available for free use [14].

### *Patient selection and collection of data*

Study group included 297 unselected consecutive patients with T2DM attending the outpatient Endocrinology Department of Bolu Abant İzzet Baysal University, School of Medicine. Exclusion criteria for the study were diabetes duration less than 6 months, presence of diabetic neuropathy, known renal or liver impairment, neoplasm, acute infection, psychiatric disorder, hypothyroidism, hyperthyroidism, and rheumatologic diseases. Patients using medications that interfere with FM symptoms such as antidepressants, analgesics and anticonvulsive drugs were also excluded. All patients' clinical and sociodemographic features like age, gender, BMI and exercise habits were recorded. Body mass index (BMI) was calculated for all participants [BMI: body weight (kg)/ square height ($m^2$)].

### *Fibromyalgia diagnosis*

Diagnosis of FM was based on the modified 2016 *American College of Rheumatology* (ACR) criteria; which includes all of the following three criteria: (1) pain in at least 4 of 5 regions of the right and left arm, right and left leg and axially; (2) widespread pain index (WSPI) is ≥7 and the symptom severity score (SSS) is ≥5, or the widespread pain index (WSPI) is 4-6 and the symptom severity score (SSS) is ≥9; and (3) symptoms have been present at a similar level for at least 3 months independent of the presence of any other disorder explaining the pain [15].

All patients were questioned about pain or sensitivity within the last 7 days at the 19 points stated in the widespread pain index (WSPI) criteria. For each painful point, (1) point was

given. The total for each point with positive findings was added to calculate the WSPI score. For ACR criteria, the highest point for WSPI is 19 points [15].

From the somatic symptom severity scale (SSS), 3 questions related to fatique, trouble thinking or remembering and waking up tired in the first section were asked to all patients and they were requested to state the severity of the symptoms within the last 7 days. Points were (0) for those with no symptoms, (1) for those with mild or intermittent symptoms, (2) for those with moderate severity or frequently recurring symptoms and (3) for those affected by continuous symptoms. In the second section, questions about pain or cramps in the lower abdomen, depression and headache within the last 6 months were asked. For these 3 symptoms, (1) point was given for each. The points from both sections were added and total SSS score was calculated. According to ACR criteria, highest points for the SSS are 12 [15].

Blood sampling was conducted after one night of fasting for fasting glucose, HbA1c, total cholesterol, LDL, HDL and triglycerides in all patients. HbA1c was analyzed with the HPCL method by using an Arcray Adams HA-8160 analyzer (Arcray, Inc., Kyoto, Japan), while glucose was measured with hexokinase, triglyceride was measured with glycerol oxidase, HDL with direct calorimetric methods, and cholesterol with enzymatic methods. When LDL and triglyceride levels were below 400 mg, they were calculated with the Friedewald formula. Above 400 mg, LDL was measured with the direct calorimetric method.

***Fibromyalgia impact questionnaire (FIQ)***

FIQ was performed for all participants included in the study [14]. The FIQ has a total of 10 questions. The first question relates to daily life activities, and comprises 11 subquestions. All patients were asked about how they could do 11 different activities like washing clothes and shopping. Points for each question were determined according to responses; always (0 points), mostly (1 point), sometimes (2 points) and never (3 points). Results were collected and divided by the item number of 11. For other items (questions 4-10), they were assessed in 10 units and the result was multiplied by 3.33 for normalization. The second question asked about how patients felt within the last week. For calculations of low values for quality of life with more negative change expressed, the days when the patient said they felt bad was noted. As a result, the value marked by the patient was subtracted from 7. For the other items (questions 4-10), to be assessed in 10 units, the obtained results were multiplied by 1.43 for normalization. High numbers for the third question expressed more negative change in quality of life. Questions 4 to 10 asked about how pain, fatique, morning stiffness, morning fatique, irritability, level of depression, and pain interfere with individuals' work. As each question was assessed over 10 point, the marked value was noted without changing. The value calculated for each question were added to obtain the total score. The total score ranges between 0-100. High scores show that the disease affects the person more and impairs the quality of life.

***Statistical analysis***

For statistical analysis, the SPSS 25.0 program (Armonk, NY: IBM Corp.) was used. Prevalence rates were obtained by dividing the total case number (FM) by the population at risk (DM patients). Distributions were tested for normality using the Shapiro-Wilk test. *$X^2$-kare test* and *Fisher's exact test* were used for comparison of rates. The normally distributed variables were analyzed with the Student's t test, and the variables that did not show a normal distribution were compared with Mann-

Whitney U test. For correlation analysis, Spearman correlation analysis was used. Multiple logistic regression analysis was used to identify independent risk factors for FM. P values less than 0.05 were considered statistically significant for all statistical analyses.

## Results

A total of 297 patients with diagnosis of T2DM were approached for participation, of whom 275 agreed to participate in the study. Median age was 62 (20-84) years and 56 % of the patients were female. Eighty-three patients (30 %) were diagnosed with FM, whereas the majority were female (F/M: 65/18) (Table 1). Duration of diabetes was significantly higher in patients diagnosed with FM [144 (6-400) months vs 96 (1-480) months; p=0.009]. The patients with FM were shorter [160 (148-185) cm vs 165 (141-187) cm; $p<0.001$] and body mass index was higher compared to those without FM [32.6 (23.3-52.8) vs 30.2 (18.5-54.3) kg/m$^2$; $p=0.005$] (Table 2).

There were no significant differences in terms of HbA1c, fasting blood glucose, total cholesterol, triglyceride, LDL, and HDL between patients with and without FM ($p=0.998$) (Table 2). FIQ scores, WSPI and SSS were significantly higher in the FM group than those without FM [51 (26-95) vs 29 (0-83); $p<0.001$, 9 (3-19) vs 2 (0-12); $p<0.001$, 7(5-12) vs 4(0-12); $p<0.001$, respectively] (Table 2). FIQ scores, WSPI and SSS were comparable in women and men in the fibromyalgia group [(51 (26-95) vs 52 (37-74); $p>0.05$, 7 (5-11) vs 7.5 (5-12); $p>0.05$, 10 (3-19) vs 7.5 (3-15); $p>0.05$, respectively] (Table 3).

Multivariate logistic regression analysis revealed that diabetes duration (p=0.007; OR=1.004, 95 % CI; 1.001-1.007), and gender (p=0.001; OR=3.196; 95 % CI; 1.656-6.169) were independently associated with the presence of FM (Table-4). There were no correlations between FIQ score and HbA1c, glucose, LDL, HDL, triglyceride, total cholesterol, diabetes duration, and body mass index in patients with FM (Table-5).

**Table 1**. Baseline characteristics of the patients.

| **Characteristics** | **All (n=275)** | **Female (n=156; 56%)** | **Male (n=119; 44%)** | ***p value*** |
|---|---|---|---|---|
| **Age (years)** | 62 (20-84) | 60 (21-81) | 63 (20-84) | *0.119* |
| **Diabetes duration (months)** | 120 (1-480) | 120 (3-480) | 102 (1-400) | *0.435* |
| **HbA1c (%)** | 7.6 (4.9-13.8) | 7.4 (5.1-13.8) | 8 (4.9-13.1) | *0.166* |
| **BMI (kg/m$^2$)** | 31.1 (18.5-54.3) | 32.8 (20.2-54.3) | 28.4 (18.5-42.2) | ***<0.001*** |
| **Glucose (mg/dl)** | 131 (55-522) | 127 (67-522) | 140 (55-412) | *0.064* |
| **LDL (mg/dl)** | 105 (37-234) | 110 (49-234) | 103 (37-197) | *0.131* |
| **HDL (mg/dl)** | 49 (26-100) | 52 (28-100) | 41 (26-75) | ***<0.001*** |
| **Triglycerides (mg/dl)** | 136 (48-473) | 142 (49-473) | 133 (48-436) | *0.722* |
| **Total Cholesterol** | 191 (117-321) | 195 (118-321) | 187 (117-310) | |
| **Diagnosis of fibromyalgia** | 83 (30 %) | 65 (78 %) | 18 (22 %) | ***<0.001*** |
| **FIQ score** | 38.7 (0-95) | 44 (0-95) | 33 (0-74) | ***<0.001*** |
| **WSPI** | 4 (0-19) | 6 (0-19) | 3 (0-15) | ***<0.001*** |
| **SSS** | 5 (0-12) | 6 (0-11) | 4 (0-12) | ***<0.001*** |
| **Exercise** | 100 (37 %) | 48 (48 %) | 52 (52%) | ***0.03*** |

**Table 2**. Comparison of groups with and without fibromyalgia.

| Characteristics | With Fibromyalgia (n=83) | Without fibromyalgia (n=192) | *P value* |
|---|---|---|---|
| **Sex (female %)**<br>**(male %)** | 65 (78%)<br>18 (22%) | 91 (47 %)<br>101(53%) | ***<0.001*** |
| **Age (years)** | 63 (30-77) | 61 (20-84) | *0.151* |
| **Diabetes Duration (months)** | 144 (6-400) | 96 (1-480) | ***0.009*** |
| **Height (cm)** | 160 (148-185) | 165 (141-187) | ***<0.001*** |
| **Weight (kg)** | 85 (56-127) | 84 (50-179) | *0.675* |
| **BMI (kg/m$^2$)** | 32.6 (23.3-52.8) | 30.2 (18.5-54.3) | ***0.005*** |
| **HbA1c (%)** | 7.7 (5.1-12.7) | 7.6 (4.9-13.8) | *0.998* |
| **Glucose (mg/dl)** | 127 (67-335) | 13 (55-522) | *0.176* |
| **Total Cholesterol (mg/dl)** | 192 (118-296) | 191 (117-321) | *0.998* |
| **LDL (mg/dl)** | 110 (61-175) | 104 (37-234) | *0.952* |
| **HDL (mg/dl)** | 47 (26-77) | 49 (26-100) | *0.378* |
| **Triglycerides (mg/dl)** | 153 (49-463) | 133 (48-473) | *0.444* |
| **FIQ score**<br>**(all)**<br>**(female)**<br>**(male)** | <br>51 (26-95)<br>51(26-95)<br>52 (37-74) | <br>29 (0-83)<br>32 (0-83)<br>25 (0-68) | <br>***<0.001***<br>***<0.001***<br>***<0.001*** |
| **SSS**<br>**(all)**<br>**(female)**<br>**(male)** | <br>7 (5-12)<br>7 (5-11)<br>7.5 (5-12) | <br>4 (0-12)<br>4 (0-8)<br>3 (0-12) | <br>***<0.001***<br>***<0.001***<br>***<0.001*** |
| **WSPI**<br>**(all)**<br>**(female)**<br>**(male)** | <br>9 (3-19)<br>10 (3-19)<br>7.5 (3-15) | <br>2 (0-12)<br>2 (0-10)<br>2 (0-12) | <br>***<0.001***<br>***<0.001***<br>***<0.001*** |
| **Exercise** | 23 (29%) | 77 (41%) | ***0.063*** |

**Table 3.** FIQ score, SSS and WISPI in different genders of groups with fibromyalgia.

| Characteristics | Female (n=65; 78 %) | Male (n=18; 12 %) | *p value* |
|---|---|---|---|
| **FIQ score** | 51 (26-95) | 52 (37-74) | ***0.903*** |
| **SSS** | 7 (5-11) | 7.5 (5-12) | ***0.513*** |
| **WSPI** | 10 (3-19) | 7.5 (3-15) | ***0.052*** |

**Table 4**. Multivariate logistic regression analysis for fibromyalgia.

| Variables | P value | OR | 95 % CI |
|---|---|---|---|
| **Gender** | 0.001 | 3.196 | 1.656-6.169 |
| **Diabetes Duration** | 0.007 | 1.004 | 1.001-1.007 |
| **Body mass index** | 0.106 | 1.038 | 0.992-1.085 |

*Dependent variable: fibromyalgia; independent variable; gender, diabetes duration, body mass index.*

**Table 5.** The correlation analysis of FIQ total with several parameters in patients with fibromyalgia.

| Variables | r value | *p value* |
|---|---|---|
| **HbA1c** | 0.017 | *3.125* |
| **Glucose** | 0.034 | *0.766* |
| **Diabetes duration** | 0.018 | *1.004* |
| **Body mass index** | 0.014 | *2.375* |
| **LDL** | -0.012 | *0.951* |
| **HDL** | -0.009 | *0.954* |
| **TG** | 0.301 | *0.127* |
| **Total cholesterol** | -0.025 | *0.898* |

## Discussion

The present study demonstrated that glycemic control was not associated with FM but associated with diabetes duration in patients with T2DM. The relationship of glycemic control with development of FM in diabetic patients has been a topic of studies in the literature. Tishler et al. reported an association between high HbA1c levels and FM in T2DM patients and reported a correlation between the number of sensitive points and HbA1c. They proposed that good glycemic control in diabetic patients may prevent FM development, as with other complications of diabetes [19]. Contrary to Tishler et al., Yanmaz et al. stated that fasting blood glucose and HbA1c levels were not associated with FM in diabetes patients. Additionally, they assessed the correlation between diabetes duration and FM development and did not identify a correlation [20]. In one of their study, Wolak et al. stated that the number of painful sensitive points increased with diabetic duration in diabetic individuals [21]. Similar to Yanmaz et al., we did not identify an association between fasting blood glucose levels, HbA1c and the presence of FM in the present study. However, differently, the presence of FM was significantly associated with increased diabetic duration. Apart from this, we identified that lipid profiles (total cholesterol, HDL, LDL and triglycerides) were similar in the groups with and without FM. These results of our study lead to the consideration that rather than metabolic disorder being a factor causing FM, it may develop as a result of chronic stress and mood disorders in diabetes caused by chronic disease and prolonged treatment.

It is also important to emphasize the relationship of FM with obesity. Epidemiologic studies report that the incidence of fibromyalgia is higher in obese and overweight individuals compared to individuals with normal weight [20,22-24]. In 2003, Ursini et al. stated that literature supported the view that in obese individuals, especially with reduced physical activity, the incidence of FM increased; however, they emphasized that it was not clear whether obesity was a causative factor or not. It was proposed that mechanisms like depression, sleep disorders, thyroid and growth hormone (GH) axis disorders and physical inactivity may play a role in the hidden link between FM and obesity [22]. The data related to the relationship of obesity and fibromyalgia among diabetic patients is very few. There are only two publications about this topic in the literature. A study by Patucci et al. reported a significant correlation between obesity and FM and pointed that none of the patients with a BMI below 26 $kg/m^2$ diagnosed with FM. [24]. Similarly, Yanmaz et al. emphasized that FM was associated with higher BMI in diabetic individuals [20]. In agreement with these two studies, we found that individuals with FM had higher BMI compared to individuals without FM. However, multivariate logistic regression analysis revealed that BMI was not a contributing factor for FM in the diabetic group. Supporting these finding, we did not also identify any correlation between exercise and FM.

Primary FM is observed more common in female gender. In previous studies the distribution of FM incidence coexisting with chronic diseases, was also reported to be higher in women [19,20,24]. Wolak et al. reported FM incidence was higher in diabetic women compared to healthy women (23.3 % vs. 10.6 %), with similar rates in men. They showed that diabetic women had higher widespread pain scores and similar numbers of sensitive point, while diabetic men had more sensitive points and similar widespread pain scores compared to healthy individuals [21]. In our study, similar to the literature, we found the incidence of FM in the female gender was higher compared to male gender (78 % vs 22 %) and female gender was independently associated with development of FM in patients with T2DM. FIQ scores and FIQ subscores (SSS and WSPI) were higher in the group with FM compared to the group without FM. Among FM patients, the FIQ score and FM subscores (SSS, WSPI) were similar between the genders. There were no correlations between the FIQ score of FM patients with fasting blood glucose, HbA1c, lipid profile, diabetes duration and BMI. From this aspect, it may be possible to hypothesize that FIQ score of T2 DM individuals in the presence of FM is an independent parameter for quality of life independent of metabolic parameters. As previous studies in the literature investigating the correlation of diabetes and FM were performed with ACR 1990 criteria, these studies did not investigate FIQ, SSS and WSPI. One of the limitations of this study is lack of a control group so that future research about this topic needs to be designed with healthy, age-matched controls. The novelty of this study is that we demonstrated that FM in T2DM is not related to glycemic control by the fact that it is related to diabetes duration. Concomitant FM may be an important clinical problem in T2DM patients with long term duration because of its devastating effect on quality of life. The present study takes attention to possibility of the coexistence of FM in patients with long term diabetes complaining about pain, fatigue and cognitive symptoms and is recognition is serious for the management of the disease. Our study also carries the novelty of being the first to use the 2016 ACR modified criteria for the diagnosis of FM in T2DM patients. Clinicians should be aware of the possibility of the coexistence of FM in patients with diabetes complaining about pain, fatigue and cognitive symptoms. Larger scale studies with the 2016 criteria are needed for further investigation.

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