

Prevalence of fibromyalgia syndrome in diabetics with chronic pain at the Kenyatta National Hospital

Umar JIN¹, Oyoo GO^{1,2}, Otieno CF^{1,2}, Maritim M^{1,2}, Ngugi N²

¹Department of Clinical Medicine and Therapeutics, University of Nairobi, Nairobi Kenya
²Kenyatta National Hospital, Nairobi, Kenya

Corresponding author:
 Dr. JIN Umar, Department of Clinical Medicine and Therapeutics, University of Nairobi, Kenya. Email: documar84@yahoo.com

Abstract

Background: Fibromyalgia Syndrome (FMS), an increasingly recognized disorder with heightened response to pressure, characterized by Chronic Widespread Pain (CWP), for which no other cause can be identified. Diabetes Mellitus (DM) is the most common metabolic endocrinopathy. It is estimated that more than 50% of diabetic patients will suffer from chronic disability. Musculoskeletal complications of diabetes may be as a consequence of DM complications or direct associations e.g. FMS.

Objectives: To determine the prevalence of FMS in diabetics with chronic pain and to determine the severity of FMS related symptoms using the revised FMS questionnaire (FIQR) tool.

Design: Descriptive cross-sectional study.

Setting: The Diabetic Out-patient Clinic (DOPC), Kenyatta National Hospital (KNH).

Subjects: Two hundred and nineteen patients with chronic musculoskeletal pain.

Results: The prevalence of fibromyalgia in this group of patients was 61 (27.9%) (95% CI 21.9-34.2). Mean age for patients with FMS was 59.9 years, significantly older than patients without FMS (55.6%) (P=0.034). There was a higher female preponderance at 49 (80%). Majority of our study population were on follow-up for Type 2 DM (94.1%). The mean tender-point count for patients with FMS was estimated at 13.7 (SD 2.1). The mean FIQR score was 51.9 (SD 18.4) (moderate disease). Patients with FMS had a higher HbA1c value compared to those without (9.6% vs. 9.3%) (P=0.565). Other factors such as marital status, nature of employment, activities of daily living and type of medications used were not found to be statistically significant. (P>0.05).

Conclusion: FMS is a prevalent disease in the diabetic population. There is increased need of awareness by the clinicians of

this disease entity and a multidisciplinary approach required to manage patients presenting with CWP in DM.

Introduction

FMS is a common disorder with cardinal symptoms of diffuse chronic pain associated with muscle stiffness and tenderness of specific points on examination. This disease has strong biologic underpinnings and the aetiopathogenesis is variable. Trigger factors may be environmental or psychosocial. This condition affects mainly women, and its estimated prevalence in various populations varies between 0.2% and 4.4%. The American College of Rheumatology Criteria (ACR) 1990 requires CWP for at least 3 months and presence of >11/18 pre-specified Tender Points (TP) on examination¹.

A newer diagnostic criteria published in 2010-2011, no longer requires performing a tender point count to make the diagnoses and instead entails asking about the constellation of non-pain somatic symptoms that are typically present in addition to the widespread pain². DM affects connective tissue in multiple ways and this may be as a result of micro or macrovascular complications, a consequence of metabolic derangements inherent to DM, and notable associations, FMS being a key presentation³. Over the past few years, the most important predictor that predisposed to development of musculoskeletal complications is blood glucose control. The HUNT study⁴ outlined the association between DM and chronic musculoskeletal complaints in 64,785 patients and noted a high prevalence of FMS and a positive correlation with HbA1c levels. Attar⁵, revealed that up to 17.9% of diabetics suffer from chronic musculoskeletal manifestations, fibromyalgia being one of them. Yunus⁶, in his review article, in 2011, noted that Central Sensitization Syndromes (CSS) have an increased prevalence in patients with diabetes mellitus. Of particular interest, a study

done by Tishler *et al*⁷, the prevalence of FMS in diabetes mellitus was at 17% and this was associated with elevated levels of HbA1c in patients with FMS than those without ($9.2 \pm 1.1\%$) vs. ($6.4 \pm 1.5\%$). Current prevalence of DM in Kenya is estimated at 3.3% and is projected to rise to 4.5% by 2025⁸, according to the Kenya National Diabetes Strategy. The ageing cohort and better health care facilities for all does not improve the prevalence of chronic musculoskeletal complaints, as age is a common predisposing factor for development of pain related disorders in the diabetic subset. This is the first study on the continent aiming to evaluate the prevalence of FMS in DM. The study aimed to sensitize the clinicians on the disease condition and create awareness regarding the CSS related conditions.

Materials and Methods

Our research question was to study the magnitude of FMS in DM with chronic musculoskeletal pain at the DOPC, KNH. The broad objective was to determine the burden of FMS in DM with chronic pain at the DOPC, KNH. Our specific objective was to determine the prevalence of FMS in diabetics with chronic pain and to determine the severity of FMS related symptoms using the FIQR tool. The secondary objective was to correlate FMS with sociodemographic characteristics and metabolic control of patients attending the DOPC presenting with chronic musculoskeletal pain.

This was a cross sectional descriptive study carried out at the DOPC, KNH. The DOPC, KNH is arguably the busiest clinic facility with more than 6000 registered patients attending⁹. It serves as a point of care for referral from minor facilities around the nation. It runs on a daily basis, with a major clinic every Friday where up to 120 patients are reviewed on a day. Consultant physicians/endocrinologists, senior house officers and DM educators run this facility. This study included all patients with a file diagnoses of DM ≥ 18 years with chronic pain lasting more than 3 months. Patients were requested to give an informed written consent prior to participation. This study excluded all patients with significant neurologic impairments who were unable to give a proper description of symptoms. Consecutive sampling was used.

Sample size: The minimum study sample population using the Fischers 1998 formula was calculated at $n=217$ patients. The margin of error was set at 5%. Patient confidentiality was maintained throughout the process. Duplication was avoided by using serial numbers on the questionnaires.

Data collection tools and methods: Consecutive sampling was used for recruitment of study population. This was followed by interviewer administered study proforma. All patients were subjected to an HbA1c test to check

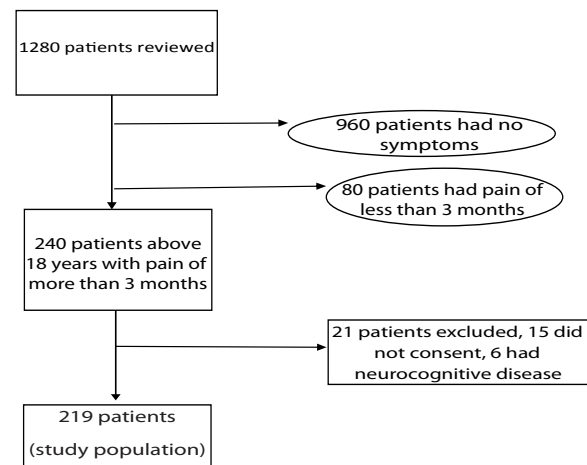
on glucose control. A clinical examination to check for tender points was performed and patients who satisfied the ACR 1990¹ criteria for FMS (i.e. pain >3 months and $\geq 11/18$ TP) were subjected to the FIQR. Data was collected and recorded on the study proforma by the PI and research assistants. SPSS version 21.0 was used to process the available information.

Study variables: The independent variable included demographic, clinical characteristics and the HbA1c level. Levels of pain, energy, stiffness, quality of sleep, anxiety or depression, memory, balance and increased sensitivity to environment (cold, noise, odors), each scored out of ten, were all listed as independent variables. The 10 point scoring was on the basis of the FIQR. The prevalence of FMS was listed as a dependent variable and calculated with a 95% CI.

Results

A total of 1280 patients were interviewed between April 2016 and June 2016. Of these 960 reported to having no pain symptoms and a further 80 patients had pain less than 3 months. Twenty one patients were further excluded (fifteen did not consent and 6 patients had neurocognitive disease) and the study population reached to 219 patients. This information is presented on Table 1.

Table 1: Patient flow chart



Demographic and clinical characteristics of study population: The mean age was at 56.8 years (SD13.6). Females predominated at 70.8% giving a male to female ratio of 1:2.4. About 114 (52.1%) patients reported to be involved in non-manual form of ADL. A vast majority were on follow up for Type 2 DM ($n=206$, 94.1%). One hundred eighty two patients (82.6%) were on Oral Glucose Lowering Agents (OGLA) either as monotherapy or in combination with insulin. Biguanides therapy with metformin and sulfonylureas were drugs of choice. Mixtard insulin 30/70 was used by 17.4% of all the study population. This is shown on Table 2.

Table 2: Sociodemographic and clinical characteristics of study population

Variable	Frequency (%)	Variable	Frequency (%)
Mean age (SD)	56.8 (13.6)	Type of diabetes	
		Type I	13 (5.9)
		Type II	206 (94.1)
Gender		Medications used	
Male	64 (29.2)	Insulin based	
Female	155 (70.8)	regime	38 (17.4)
		OGLA	104 (47.0)
Marital status		Combination	78 (35.6)
Single	13 (5.9)	OGLA (n=182)	
Married	148 (67.6)	Sulfonylureas	99 (45.2)
Separated	13 (5.9)	Biguanides	146 (80.2)
Widowed	45 (20.5)	DPP 4 inhibitors	7 (3.8)
Daily activities		Glitazones	2 (1.1)
Manual labour	64 (29.2)	Insulin	38 (100.0)
Office job	41 (18.7)	Pre mixed	
Non manual	114 (52.1)		
Occupation			
Employed	77 (35.2)		
Unemployed	90 (41.1)		
Retired	52 (23.7)		

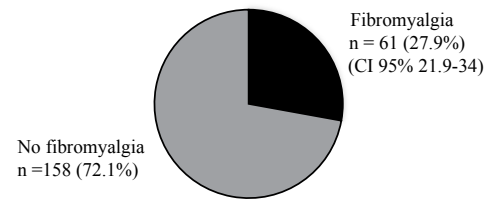
The mean HBA1c levels for the study population was at 9.4% (SD 2.6). Very good control was only seen in 16.6% (n=37). Conversely, 35.2% had an HBA1c level of $\geq 10\%$ (Table 3).

Table 3: Mean HBA1c levels for study population

Variable	Frequency
Mean HBA1c (SD)	9.4% (2.6)
Range of HBA1c	n (%)
≤ 7	37(16.9)
7.0-7.99	39(17.8)
8.0-8.99	35(16.0)
9.0-9.99	28(12.8)
≥ 10	77(35.2)
Missing	3(1.4)

Prevalence of FMS in DM with chronic pain: Of the 219 patients, 61 patients satisfied the ACR 1990¹ criteria for FMS. This gives a prevalence of 27.9% (95% CI 21.9-34.2) (Figure 1).

Figure 1: Prevalence of FMS



Frequency and severity of FMS related symptoms: The 3rd domain of the revised FM questionnaire was used to assess this information. Each patient was asked to rate the degree of impact the disease had on their symptoms. One hundred percent had pain over the past 7 days, 100% reported reduced levels of energy, 100% had stiffness experienced, 98% reported disturbances in sleep patterns, depression was present in 95%, memory problems in 93%, anxiety was reported in 91%. One hundred percent reported to have tenderness to touch, balance problems were present in 98% and increased sensitivity to loud noises was reported in 98%. This is depicted on Table 4.

Table 4: Frequency and severity of FMS related symptoms

Symptoms	Severity of symptoms (n=61)			
	0(%)	1-3 (%)	4-6 (%)	7-10 (%)
Pain	0	13 (21.3)	18 (29.5)	30 (49.2)
Energy	0	12 (19.7)	21 (34.4)	28 (45.9)
Stiffness	0	10 (16.4)	21 (34.4)	30 (49.2)
Sleep quality	1 (1.6)	8 (13.1)	12 (19.7)	40 (65.6)
Depression	3 (4.9)	16 (26.2)	28 (45.9)	14 (23.0)
Memory	4 (6.6)	17 (27.9)	29 (47.5)	11 (18.0)
Anxiety	5 (8.2)	19 (31.1)	26 (42.6)	11 (18.0)
Tenderness	0	15 (24.6)	29 (47.5)	17 (27.9)
Balance	1 (1.6)	23 (37.7)	21 (34.4)	16 (26.2)
Sensitivity	1 (1.6)	9 (14.8)	17 (27.9)	34 (55.7)

FIQR domain scores: The FIQR scores were rated as follows: 0-39, 40-59 and more than 60, classified as having mild, moderate and severe disease respectively. The mean FIQR score for the study population, (n = 61) was 51.9 (SD 18.4). This denotes them as having moderate disease. From our study, 24.6% had mild disease, 42.6% moderate disease and 32.8% had severe disease (Table 5).

Table 5: The FIQR domain scores

Variable	Frequency(%) (SD)	95% CI
FMS n(%)		
Yes	61(27.9)	21.9-34.2
No	158(72.1)	65.8-78.2
FIQR Score (n=61)		
Mean (SD)	51.9(18.4)	
Severity		
Mild	15(24.6)	13.1-36.1
Moderate	26(42.6)	29.5-54.1
Severe	20(32.8)	21.3-45.9

Discussion

Fibromyalgia Syndrome is a clinical syndrome having a common group of symptoms. No single aetiological factor is present though environmental and psychosocial factors do play an important role in the trigger. Certain non-rheumatic conditions such as depression and hypothyroidism closely mimic FMS¹¹. Although FMS and DM are very common, no association had been reported in this region. The factors associated include gender and age. Gender though not statistically significant (P=0.053), showed a trend in which female preponderance was present. The OR was calculated at 2.0(95% CI 1.0-4.1) Tishler *et al*⁷, Malombe *et al*¹², Dokwe *et al*¹³ and Yanmaz *et al*¹⁴ in their studies previously showed that the female gender was more prone to developing CWP. From the findings, the study also concluded that DM patients with FMS were significantly older than their counterparts without FMS (P=0.034). The study did not find statistically significant association between FMS and medication use, type of diabetes, ADL or the marital status (P>0.05).

In this study, FMS was detected in 61 (27.9%) of the DM patients presenting with chronic pain (total n=219). The detection of FMS in patients with DM is important since muscle aches and stiffness are inadvertently managed as cases of diabetic polyneuropathy by physicians. Nevertheless, clinical findings of specific TP on examination and symptom evaluation using the revised FIQR noted without doubt that FMS is an independent disease entity in this group of DM patients. Pain, sleep disturbances, anxiety, depressive illness, heightened sensitivity to environmental stimuli all support the diagnoses of FMS in our study. These patients are subjected to a poor quality of life, warranting frequent visits to the health facilities for frequent analgesics or sedatives.

Pain is central to the diagnoses of FMS and the FIQR. We noted that 100% of patients presented with pain over the past seven days. The concept of hyperalgesia and allodynia is worth a mention as entities present in central sensitization syndromes, FMS being one of them. Other components of the revised FM questionnaire (FIQR) noted loss of balance, mood disorders and sleep disturbances being highly prevalent. This negatively impacts on the quality of life of patients having both diseases i.e FMS and DM.

Conclusion

FMS in DM is a pertinent and prevalent disease and worth looking for in all diabetic patients presenting with chronic pain. The intransigent nature of FMS makes it very difficult for the patients as well as the healthcare professionals to take care of. It is our hope that from this study, part of diabetes care will be to look for chronic pain

syndromes in diabetics. Timely diagnoses and appropriate referral to specialized care would greatly improve the quality of life of patients already condemned to a chronic debilitating disease such as diabetes.

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