ORIGINAL RESEARCH

Quality of Life Among Hospitalized Fibromyalgia Older Adults: a Case-Control Study

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ABSTRACT

Background

Only few studies addressed the topic of Fibromyalgia Syndrome (FMS) effects on geriatric population quality of life and drug usage. The objective of this study was to demonstrate the significant impact of FMS in terms of quality of life (QOL) in geriatric aged patients.

Methods

80 patients were studied, 40 with FMS according to FMS 2016 classification criteria, and 40 non-FMS controls. The patients were all above the age of 65 years. The FMS and control group completed Widespread Pain Index (WPI) and Symptom Severity Score (SSS). Three questionnaires, Fibromyalgia Impact Questionnaire (FIQ), Short Form (SF-36) Questionnaire, and Health Assessment Questionnaire Disability Index (HAQ-DI) were completed. These with additional medical records were used to classify symptoms and severity in both groups.

Results

Fibromyalgia patients demonstrated significant higher disability scores, (FIQ of 79.5 vs. 33.9, $p<.01$, and HAQ-DI of 2.00 vs. 1.00, $p<.01$ for FMS vs. non-FMS, respectively), and lower social functioning in comparison to non-FMS controls (SF-36 of social functioning 0.31 vs. 0.92, $p<.01$ for FMS vs. non-FMS, respectively). The FMS group had a higher use of pain management medications (opioid use of 12 patients vs. 0, $p<.01$, use of non-steroidal anti-inflammatory drugs by 11 FMS patients vs. 4 non-FMS controls, $p<.01$).

Conclusions

Patients with FMS older than 65 years of age demonstrate poorer outcomes and worse symptoms in comparison to matched-aged non-FMS control group. An association was found between FMS and the effect on the quality of life in this population.

Key words: fibromyalgia, quality of life, pain

INTRODUCTION

Fibromyalgia syndrome (FMS) is a syndrome characterized by chronic widespread musculoskeletal pain. It is frequently accompanied by additional symptoms including, headaches, fatigue, sleep disturbances, irritable bowel syndrome, paresthesia, and worsening of symptoms in response to weather changes and stress. Such symptoms cause significant functional impairment to the patient's day-to-day life.[1] The prevalence of FMS worldwide is approximately 5%, with some variability between countries.[2] It is more frequent among female population with peak onset of disease between the ages of 30 and 50 years.[3] The frequency of FMS has been shown to increase with age, with data demonstrating higher frequencies of 7% between the ages of 60 and 79 years.[4] Moreover, other diseases may mimic the presentation of FMS. This has been especially seen in psychological conditions, where symptoms overlapping is frequent, which makes the diagnosis rather challenging.[1]

There are several studies exploring fibromyalgia prevalence and clinical features in the Middle East region.[5–9] The prevalence tends to be high compared to previous literature and can reach 12.6% (as an example shown among students in Egypt[7]). FMS syndrome presents clinically as diffuse chronic muscular pain. This pain is especially felt along the torso and in the upper and lower extremities. Additionally, patients typically suffer from sleep disorders, difficulty falling asleep, multiple awakenings, and unrefreshing sleep resulting in marked fatigue.[1] The combination of sleep disturbances and diffuse muscular pain results in patients reporting a decrease in their quality of life (QoL).[10] In addition, patients may experience systemic symptoms including irritable bladder and\or bowel, as well as memory and concentration

difficulties. Patients in this population tend to suffer from depression, anxiety, and psychiatric conditions in comparison to healthy patients.

According to the United Nations definitions, an older person is defined as 60 years of age or older. Fibromyalgia clinical features among old, hospitalized patients was yet to be studied.[11] Our study hypothesis was that there is a direct relationship between FMS syndrome and its' influence on the quality of life in the geriatric population. The aim of the study was to explore whether older adult population suffering from FMS experience a significant impairment in their quality of life in comparison to individuals of the same age not affected by FMS.

METHODS & MATERIALS

This study is a cross sectional prospective study. The initial stage of the study retrieved patients from the Internal Medicine and Rheumatology Departments at Ha'Emek Medical Center, Afula, Israel. Subsequently, a compatibility check with inclusion and exclusion criteria was performed for each patient. A written informed consent was obtained from all patients. After obtaining consent, a complete medical history and physical examination were performed by the physician to determine if the patient met the criteria for FMS syndrome based on 2016 classification criteria.[12] Patients who had other inflammatory rheumatological conditions, oncological conditions, or neurological conditions that may cause chronic pain were excluded from the study. Patients who were defined as end-of-life care, acute medical condition at the time of study, or pregnant were excluded from the study. The control group consisted of patients who were 65 years and older, without a history of FMS (history is not enough) to match the study group.

The relevant questionnaires were filled out by the researchers. Both groups were required to complete the following four questionnaires: Health Assessment Questionnaire Disability Index (HAQ-DI),[13] Visual Analog Scale for Pain (VAS),[14] Short form (SF-36) questionnaire,[15] and FMS Impact Questionnaire (FIQ).[16] (See cited references for questionnaire information and validation in FMS.) The SF-36 was previously assessed among older patients in Israel, yet not for FMS population.[17,18] Additional information was retrieved from the patients' electronic medical files including demographic and clinical data, laboratory results, and necessary imaging for each patient included in the study.

The study took place in Ha'Emek Medical Hospital located in northern Israel, and data were collected over the period of six months.

Statistical Analysis

Analysis of the data was performed by the SPSS program (version 18, Armonk, NY: IBM Corp.). The data collected was summarized in frequency tables, summary statistics, safety coefficients and normal *p* values. All the statistical tests were performed at a significance level of α=0.05 bilateral unless noted otherwise. All *p* values were rounded out to 3 digits after the decimal point.

Size of the sample was calculated according to the comparison of the levels of continuous variables; the main outcome measure was the SF-36 quality-of-life questionnaire. According to the power calculation we needed to recruit 40 patients in each group.

To compare scalar variables, we used the Student's *t*-test. Pearson's correlation coefficient was used to estimate the relationship between specific scalar variables and, in the case of abnormal distribution of the variables, we used the Mann Whitney test. To compare categorical variables, we used the chi-square test or, in the case of unequal conditions, the Fisher test. To evaluate prognostic score, the single or multi-year regression tests was used. To isolate independent data that influence the results, *p* values were used. The statistical significance was determined by $p<.05$. If the preliminary methods described above yielded significant data, we applied complex statistical analysis to analyze the correlation between the relevant variables.

Ethical Considerations

The study was performed according to the International Conference on Harmonization (ICH) and the Harmonized Tripartite Guideline for Good Clinical Practice (GCP), and according to the procedures of the Ministry of Health for conducting medical research. The study was approved by the Ethics Committee of Emek-Medical Center.

RESULTS

Our study sample consisted of 40 FMS patients (mean age of 80 years, range 65–93 years, 31 females, 9 males) and 40 controls (mean age 77 years, range 65–96 years, 16 females, 24 males). Table 1 presents the baseline characteristics by group. There was a statistically significant difference in sex distribution between the two groups (31 females vs. 16, $p<.001$, for FMS vs. non-FMS groups, respectively). Additionally, the FMS group demonstrated a trend towards older population in comparison to the control groups (mean of 80.1 years of age vs. 76.9, $p=.07$, for FMS vs. non-FMS groups, respectively). There was no statistically significant difference in comorbidities except for chronic kidney disease (12 patients among FMS vs. none among non-FMS group, $p<.001$). Within the FMS group, there was a statistically significant higher use of pain management medications (Opioids use among 30% of patients vs. none, SSRI use of 62.5% vs. 12.5%; duloxetine use of 60% vs. 12.5%; pregabalin use of 25% vs. 7.5%; paracetamol use of 45% vs. 20%; and NSAIDS use of 27.5% vs. 10%; all for FMS vs. non-FMS groups, all significantly different for $p<.05$, Table 1). Dipyrone use, a frequently used over-the-counter medication available in Israel, was not different between groups, except for higher CRP levels among control group (1.2 mg/dl vs. 2.7 mg/dl, for FMS vs. Control group).

The study compared SSS, WPI, VAS, SF-36, HAQ-DI and FIQ for the two groups (see Tables 2 and 3). The FMS group demonstrates a higher VAS score of 6.45 points in comparison to the control group (8.75 vs. 2.3 for FMS vs Control, $p<.01$). An increase in SSS of 1 increased VAS by .153 (over all groups). There was no interaction demonstrated between groups for SSS or WPI for the Visual Analogue Scale (VAS). HAQ-DI was higher among FMS group (2.00 vs. 1.00, for FMS Vs Control, $p<.01$). All SF-36 components were lower among FMS compared to controls (see Table 3 and Figure 1). FIQ was higher among FMS group (79.5 vs. 33.9, for FMS vs Control, $p<.01$). After correcting for CKD, opioids, SSRI, duloxetine, and SSS, there was still a statistically significant difference in VAS between the groups. After correcting for CKD, opioids, SSRI, and duloxetine use, the main effect of group and its interaction with SSS became borderline statistically significant (data not shown).

Table 4 demonstrates a medium association between SSRI and duloxetine use and FIQ, HAQ-DI, VAS, and SF36. There was a medium association between opioid use and FIQ, HAQ-DI, VAS, and the SF36 components: physical functioning, limits due to emotional problems, emotional well-being, and general health subscales. There was no association between the diabetes mellitus, hypertension, and ischemic heart disease comorbidities; however, there was a weak-to-medium association with CKD. Also, there was a weak association between pregabalin and paracetamol use and the outcome variables and weak association between NSAID use and SF36.

Overall patients FIQ, HAQ-DI, and VAS were positively correlated with WPI, SSS, and length of pain and negatively correlated with CRP. SF-36 scales were negatively correlated with WPI, SSS, and length of pain, and positively correlated with CRP. Within the control group, only VAS was positively correlated with length of pain. Within the FMS group, FIQ and HAQ-DI was positively correlated with SSS. In addition, HAQ-DI and VAS were positively correlated with length of pain.

TABLE 1.
Baseline characteristics[a]

	Fibromyalgia (n=*40*)	*Control* (n=*40*)	χ^b	*P*
Age[c]	80.1±7.3 (65-93)	76.9±8.2 (65-96)	1.84	.07
Sex			11.60	<.001
Male	9 (22.5)	24 (60.0)		
Female	31 (77.5)	16 (40.0)		
Comorbidities				
Diabetes Mellitus	23 (57.5)	19 (47.5)	0.80	.37
Ischemic Heart Disease	34 (85.0)	35 (87.5)	0.10	.74
Hypertension	38 (95.0)	37 (92.5)	0.21	>.99
Chronic Kidney Disease	12 (30.0)	0 (0.0)	14.12	<.001
Immunodeficiency	0 (0.0)	0 (0.0)	---	---
Pain Medications				
Opioids	12 (30.0)	0 (0.0)	14.12	<.001
SSRI	25 (62.5)	5 (12.5)	21.33	<.001
Duloxetine	24 (60.0)	5 (12.5)	19.53	<.001
Pregabalin	10 (25.0)	3 (7.5)	4.50	.03
Dipyrone	15 (37.5)	10 (25.0)	1.46	.23
Paracetamol	18 (45.0)	8 (20.0)	5.70	.02
NSAIDS	11 (27.5)	4 (10.0)	4.02	.045

[a]Data is N (%) unless otherwise indicated.
[b]Independent sample *t*-test.
[c]Data are mean±SD (range).
SSRI = selective Serotonin reuptake inhibitor; NSAIDS = non steroidal anti inflammatory drugs.

TABLE 2.
Symptom Severity Score (SSS) and Widespread Pain Index (WPI) comparison between groups[a]

	Fibromyalgia	*Control*	t/Z	*P*
WPI	8.2±1.0 (6-10)	1.8±0.7 (1-3)	33.06	<.001
SSS	7.4±1.0 (6-9)	1.8±0.7 (1-3)	28.41	<.001
Pain, weeks	32.0±34.0 (12-260)	2.4±4.0 (0-8)	7.74	<.001

[a]Continuous data is mean±SD (range).

TABLE 3.
Outcome variables comparison between groups

	Fibromyalgia Score: mean±SD (range)	*Control Score: mean±SD (range)*	*P*	*Effect Size*
FIQ	79.5±5.3 (70-92)	33.9±3.8 (28-40)	<.001	.96
HAQ-DI (median±IQR)	2.00±0.28	1.00±0.14	<.001	.92
VAS	8.75±0.59 (8-10)	2.30±0.56 (1-4)	<.001	.97
SF36			<.001	.99
Physical functioning	0.29±0.04 (0.20-0.35)	0.94±0.04 (0.20-0.35	<.001	.98
Limits due to physical health	0.17±0.11 (0.00-0.30)	0.95±0.04 (0.85-1.00)	<.001	.96
Limits due to emotional problems	0.30±0.14 (0.00-0.66)	0.94±0.06 (0.70-1.00)	<.001	.90
Energy/Fatigue	0.35±0.05 (0.25-0.40)	0.91±0.08 (0.65-1.00)	<.001	.95
Emotional well-being	0.33±0.05 (0.28-0.44)	0.91±0.08 (0.68-1.00)	<.001	.95
Social functioning	0.31±0.05 (0.25-0.40)	0.92±0.06 (0.80-1.00)	<.001	.97
Pain	0.34±0.09 (0.20-0.55)	0.92±0.06 (0.81-1.00)	<.001	.94
General Health	0.24±0.03 (0.15-0.25)	0.92±0.06 (0.80-1.00)	<.001	.98

FIQ = FMS Impact Questionnaire, HAQ-DI = Health Assessment Questionnaire Disability Index; VAS = Visual Analog Scale for Pain; SF-36 = Short Form questionnaire.

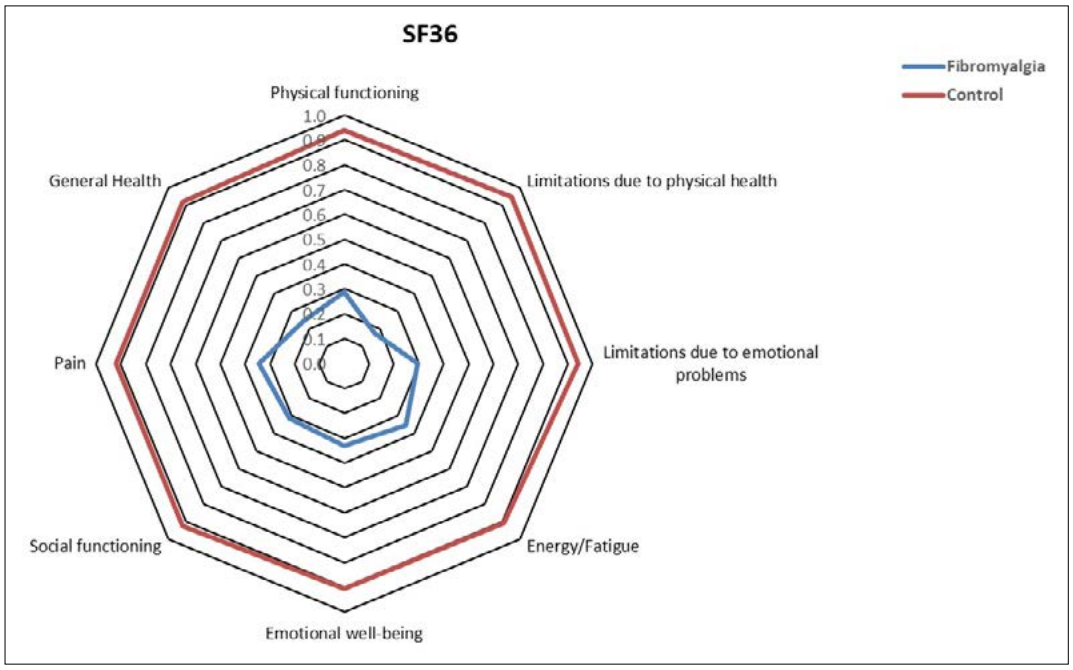

FIGURE 1. SF-36 components

DISCUSSION

The study aim was to explore the effect of FMS on quality-of-life measures among geriatric population. We found that HAQ-DI was higher among FMS group (2.00 vs. 1.00, for FMS vs. Control, $p<.01$). All SF-36 components were lower among FMS compared to controls (see Table 3 and Figure 1), and FIQ was higher among FMS group (79.5 vs. 33.9, for FMS vs. Control, $p<.01$).

Regarding the patient's characteristics, we found high frequency of females among FMS compared to controls (31 females vs. 16, $p<.001$, for FMS vs. non-FMS groups, respectively). This finding is relatively expected as FMS is more prevalent among females compared to males. Yet this hasn't been demonstrated specifically among geriatric population so far.[19] In our study all patients were above 65 years of age by inclusion definition, while the FMS group was 3.2 years older ($p=.07$), which is considered as a comparable age. We explain this by the consecutive method of patient collection, as age matching was not done. In a previous study, age has been demonstrated to be a significant variable that affects presentation of FMS. We found statistically significant difference in sex and CKD distribution between the two groups. Other than this, the two groups were comparable for all other measures (see Table 1).

Health-related quality of life was assessed in the present study using Questionnaire SF-36. The results showed that FMS patients in general demonstrated lower levels in all the parameters examined, further indicating impairment in their quality of life (see Table 4 and Figure 1). In comparison to the control group, FMS patients show impairment in each of the parameters of quality of life, except social functioning. In a study by Martinez *et al*.,[20] the average social functioning of the healthy controls was about two-thirds higher than that of FMS patients. Pagano *et al*.[21] found about half higher as stated. In the present study, no difference was found in terms of social functioning between the groups. This might be explained by the different age groups (> 65 years) and by sample size, which is relatively small.

Also, social function is affected by multiple factors such as cultural and socio-economic, which hasn't been evaluated specifically at this study. The overall perception of health (termed "general health" in Table 3) in the control population was higher (0.24 vs. 0.92, $p<.001$, FMS vs. non-FMS, respectively). A similar picture can be seen in the studies of Pagano and Martinez stated earlier, yet with a lesser difference (0.46 vs. 0.81, $p<.001$ for Pagano trial). The main difference between studies is that ours was done to explore the difference among older adults. The mean age in the Pagano study was 49 years of age, 31 years younger than our study population.[21] Quality-of-life assessment of FMS patients in Israel according to the present study was higher than patients from other countries. An Israeli study in 2001 demonstrated similar findings, where patients were matched by age, the quality of life was perceived to be poorer by the FMS group.[22]

TABLE 4.
Association of comorbidities and pain relief with the outcome variables

	DM	*HTN*	*IHD*	*CKD*	*Opioid*	*SSRI*	*Duloxetine*	*Pregabalin*	*Dypirone*	*Paracetamol*	*NSAIDS*
FIQ	.108	.072	.022	.419	.446	.505	.506	.240	.138	.244	.195
HAQ-DI	.121	.049	.062	.424	.487	.478	.526	.256	.123	.237	.175
VAS	.099	.089	.036	.446	.456	.499	.514	.219	.155	.296	.187
SF36											
Physical Functioning	.099	.056	.026	.406	.424	.519	.519	.243	.107	.235	.222
Limits due to physical health	.073	.013	.034	.404	.360	.483	.471	.228	.134	.283	.226
Limits due to Emotional Problems	.148	.062	.077	.426	.468	.477	.454	.197	.146	.198	.207
Energy/Fatigue	.105	.038	.055	.395	.373	.503	.480	.246	.168	.290	.183
Emotional Well-being	.114	.058	.018	.421	.406	.495	.502	.240	.162	.285	.225
Social Functioning	.096	.052	.000	.396	.368	.504	.483	.243	.137	.308	.232
Pain	.088	.051	.000	.379	.334	.501	.501	.247	.121	.272	.213
General Health	.102	.054	.020	.411	.409	.496	.501	.235	.144	.279	.205

DM = Diabetes Mellitus; HTN = Hypertension; IHD = Ischemic Heart Disease; CKD = Chronic Kidney Disease; FIQ = FMS Impact Questionnaire; HAQ-DI = Health Assessment Questionnaire Disability Index; VAS = Visual Analog Scale for Pain; SF-36 = Short Form questionnaire.

Both FIQ and HAQ-DI were different between the groups, (FIQ 79.5 vs. 33.9, $p<.01$, HAQ-DI 2 vs. 1, $p<.01$, for FMS vs. non-FMS, respectively). Previous studies examining FIQ among older adults are scarce. One study by Jacobson *et al*.[23] examined FMS severity among older adults. FIQ was assessed and found to be 90, SD 8; also there was no correlation between age and FIQ. In addition, there was no comparison regarding FIQ with a control group in their study.

We found higher WPI, SSS, and VAS scores among FMS group compared to non-FMS (data shown in Tables 1 and 2). This result is understandable according to FMS classification criteria and patient selection methods. Nevertheless, is it worth mentioning that a VAS of 8.75 as an average of the FMS group is considered relatively high. This might be explained by the fact that our patients were interviewed during hospitalization, which might have influenced their assessment of pain.

Regarding HAQ-DI score, an interesting study by Wolfe *et al*. demonstrated that the strongest predictor for social security disability definition of FMS patients was functional status as measured by HAQ-DI.[24] Yet this study mean age was 52 years old. The absolute score was 1.2 for all patients, with 1.6 for the disabled FMS patients which is lower than our FMS cohort. We believe the difference might also be explained by those age differences between studies. We found a significantly higher use of analgesics, especially Opioids and NSAIDS, among FMS group vs. Controls. The impact of analgesic in older adults' population suffering higher frequencies of comorbidities is important. NSAIDS, for example, might raise risk for adverse cardiovascular events, while opioids and tramadol might increase risk of falls and frailty in older adultspopulation.[25,26] The use of duloxetine and pregabalin in FMS was mainly investigated among younger populations; hence the relatively high frequency of use of these drugs for this indication in older adults warrants further investigation.[27] In the Jacobson *et al*. study, about 11% of FMS patients used opioids compared to 30% of patient in our study. Although the studies are not comparable regarding time frame, hospitalization status, and cultural differences, both studies show a relatively high proportion of FMS patients using opioids which are strongly recommended against by most of rheumatological consensus statements and guidelines.[1,23]

There are several limitations to our research. First, this is a single-center study, with only 40 FMS patients recruited, most of who are older adults with multiple underlying diseases. We tried to overcome this limitation by comparing it to similar age group population under same circumstances (in-hospital setting), yet as the nature of the study is a cross-sectional one, we could not control for all confounders which might affect our outcomes. Also, the number of subjects in the sample was within the required minimum, but a larger number would have contributed to greater validity of conclusions concerning the general population. All the questionnaires conducted in the study were completed via self-reporting through an interview done by our investigators. At the time of the interview, our investigators knew whether the patient had or had not a diagnosis of FMS, which might affect the way of interviewing and interpretation of the patients' answers. In addition, this study took place within a time frame of six months, and therefore limits representation of FMS population across a longer period. Nonetheless, our research has several strengths being a study conducted on a single data system. The data were collected by a physician from the hospital who is proficient in the data system and its form of documentation.

SUMMARY & CONCLUSIONS

The health-related quality of life and functioning ability of older adults with FMS as assessed by SF-36, FIQ, and HAQ-DI is lower compared to older adults without FMS. The impact of FMS over older adult populations' quality of life is important to assess and address. Further research is required to investigate special aspect among older adults with FMS.

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CONFLICT OF INTEREST DISCLOSURES

We have read and understood the *Canadian Geriatrics Journal*'s policy on conflicts of interest disclosure and declare there are none.

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