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HEALTH LITERACY AND MEDICATION ADHERENCE IN FIBROMYALGIA

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ABSTRACT

Aim: Patients with fibromyalgia syndrome (FMS) are reported to be 3 times more likely to use health care servic es compared to the general population, 4 times more likely to go to the doctor, have 4 times more drug use and 2.5 times more pain-related expenditures. In this study, we firstly aimed to investigate the relationship between health literacy (HL) and medication adherence (MA) in FMS patients who were treated for at least six months. Secondly, we planned to investigate the association of HL with disease activity.

Methods: This study had a cross-sectional analytical design. Patients diagnosed with FMS according to the 2014 ACR diagnostic criteria for at least six months were included in the study. Visual Analog Scale (VAS), fibromyalgia impact questionnaire (FIQ), The European Health Literacy Survey Questionnaire (HLS-EU-Q47) and the Morisky 8-Item MA scale forms were filled out in face-to-face interviews with the patients.

Results: The study was completed with a total of 142 FMS patients. There was a statistically significant difference between the Morisky 8-Item MA groups according to the HLS-EU-Q47 scale and sub-scale scores ($p<0.05$). There was also a difference between the Morisky 8-Item MA groups according to the health service score. There was a negative significant correlation between the Morisky 8-Item MA scale score and VAS measurements.

Conclusions: We believe that educational programs for patients about FMS and increasing their MA and HL will positively affect their treatment outcomes.

Keywords: Health literacy, HLS-EU-Q47, fibromyalgia syndrome, medication adherence, VAS

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Introduction

Fibromyalgia Syndrome (FMS) is a chronic disease characterized by widespread pain of unknown origin, fatigue, sleep disturbances, cognitive dysfunction and generalized tenderness in the body [1]. The prevalence of illness among patients, the majority of whom are female, is reported to be 0.66-1.5% in the general population [2]. The prevalence in women between 20 and 74 years of age has been found to be 3.6% in Turkey [3]. Although the etiology of FMS is still uncertain, it is suggested that the main mechanism is central sensitization and that genetic, immunological and hormonal factors also play an important role [4]. According to EULAR recommendations, non-pharmacological and pharmacological treatments are applied in a multidisciplinary manner in FMS treatment [5]. Pharmacological agents with proven efficacy in FMS are tricyclic antidepressants (TSA), tramadol, serotonin-norepinephrine reuptake inhibitors (SNRI), selective serotonin reuptake inhibitors (SSRI) and anticonvulsants (pregabalin and gabapentin) [5,6]. Patients with FMS are reported to be 3 times more likely to use health care services compared to the general population, 4 times more likely to go to the doctor, have 4 times more drug use and 2.5 times more pain-related expenditures [7].

Health literacy (HL) can be defined as the ability of a patient to understand, interpret and behave accordingly when medical information is presented to the patient [8]. It has been shown that HL is related to a health seeking behavior [9]. It has been stated that patients with insufficient HL seek a solution in coming to the emergency services while patients with sufficient HL present to the relevant specialists [10]. Chronic diseases such as FMS are an extra burden for both governments and health care professionals [11,12]. It is argued that societies with better HL use health care services more efficiently [13].

The most important factor that plays a role in the efficacy of treatment is patient medication adherence. Medication adherence (MA) is the extent to which the behavior of the patient coincides with clinical advice, such as using medications, following a diet, exercising or performing other lifestyle changes. Non-adherence may start with not adhering to the drug treatment, not having the prescription written, or not following the recommended program [14]. Medication adherence reduces relapses. HL affects medication adherence positively [15]. Although there are a limited number of studies with rheumatologic diseases, HL affects the success of treatment in chronic diseases [16-20]. It has been shown that HL is associated with insulin doses used in DM patients [21]. Similarly, there is a positive correlation between the type and dose of drugs used in COPD patients. Adequate HL affects both drug costs and patient quality of life positively [22].

In this study, we firstly aimed to investigate the relationship between HL and medication adherence in FMS patients who were treated for at least six months. Secondly, we planned to investigate the association of HL with disease activity.

METHOD

Study Design

This study had a cross-sectional analytical design. Data of 200 patients were evaluated. The patients were diagnosed with FMS according to the 2014 ACR diagnostic criteria for at least six months in the Physical Therapy and Rehabilitation and Rheumatology Clinics of the University of Health Sciences Bursa Training and Research Hospital and were using medication between April 2017 and September 2017. Detailed information was given to

the patients before the study, and their written informed consent was obtained afterwards. Our work was carried out in accordance with the World Declaration of Helsinki. The local ethics committee of the hospital approved the study.

Participants

Patients who were older than 18 years of age and who were able to read and write were included in the study. Patients who did not want to participate in the questionnaire or who were illiterate were not included in the study. Demographic data of the patients were recorded. Of the 200 patients, 43 patients were excluded because they responded to the questionnaire inadequately, and 15 patients were excluded from the study because they did not agree to participate in the study.

Interventions

Visual Analog Scale (VAS): VAS was used to determine the severity of pain and fatigue of the patients. Numbers from 0 to 10 on a 10-cm line in the VAS were described to the patients [23].

Fibromyalgia Impact Questionnaire (FIQ): This form was developed by Burchardt et al. [24] to measure functional status in FMS patients and adapted in terms of validity and reliability specific to Turkey by Sarmer et al. [25].

The European Health Literacy Survey Questionnaire (HLS-EU-Q47): The scale was developed in 2011 [8] and the Turkish validity and reliability of the scale was determined by Tanrıover et al. [26].

The Morisky 8- Item Medication Adherence Scale: The Morisky 8-Item Medication Adherence Scale was used for medication adherence [27]. It was translated into Turkish and validated by Asilar et al. [28, 29].

Statistical analysis

A post hoc power analysis was conducted using a moderate effect size, based upon findings of the present study. A moderate effect size was obtained by comparing overall health literacy scale points between medical adherence groups. Using this effect size (r=0.49) with a sample size of 142 participants, the power was estimated to be 0.81 at a significance level of α= 0.05. The normal distribution of variables was examined by Shapiro Wilk test. Continuous variables are expressed as median (minimum: maximum) values. Categorical variables are expressed as percentage n (%). Kruskal Wallis test was used in the comparison between normative test results, between groups determined according to the HLS-EU scale and subscale scores, and comparison between related scores and medication groups. The Fisher-Freeman-Halton test was used in comparisons between drug groups according to drug compliance. Scores of the HLS-EU scale and subscales and scores of the Morisky 8 Item MA scale were examined by correlation analysis between FIQ total and VAS measures and reported by Spearman correlation coefficient. The internal consistency of the HLS-EU scale was examined by Cronbach alpha coefficient. Data analysis was performed with SPSS (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.). Values of $p < 0.05$ were accepted as significant

RESULTS

The study was completed with a total of 142 FMS patients. The mean age of the patients was calculated as 46.62±11.50. The socio-demographic characteristics of the participants are given in Table 1.

Table1. The socio-demographic characteristics and evaluation parameters of the participants

Gender*(Female/Male)*	138(%97) / 4(%3)
Age (year)	46.62±11.50(22:86)
Age Groups	
20-29	7(%4.90)
30-39	33(%23.20)
40-49	53(%37.30)
50-59	31(%21.80)
>60	18(%12.70)
Marital status	
single	10(%7.04)
married	114(%80.30)
widow	18(%12.66)
Employment status	
Not working	10(%7.04)
housewife	80(%56.33)
worker	15(%10.56)
retired	15(%10.56)
Professional occupation	22(%15.49)
Educational level	
No school education	17(%11.97)
Primary school	75(%52.80)
High school	19(%13.40)
University	24(%16.90)
HLS-EU-total	27.47±7.34 (7.20-48.23)
HLS-EU-Health Care	29.62±7.29 (5.21-48.96)
HLS-EU-Disease Prevention	26.67±8.44 (3.85-50.00)
HLS-EU-Health Promotion	29.03±8.07 (7.29-50.00)
The Morisky 8- Item Medication Adherence Scale	4.86±2.38(0-8)
VAS	6.7±2.0(1-9)
FIQ-Total)	56.94±17.34 (20.24-91.68)

HLS-EU: The European Health Literacy Survey Questionnaire FIQ: Fibromyalgia Impact

Questionnaire VAS: Visual Analog Scale mean ± standard deviation (min-max) and percentages are given

relationship between the obtained data and HLS-EU-Q47 is given in Table 2. There was a statistically significant difference between the Morisky 8 Item MA groups according to the HLS-EU-Q47 scale and sub-scale scores ($p<0.05$).

Table2. Comparison of HLS-EU scores among Morisky 8-Item Medication Adherence Score

HLS-EU Score	The Morisky 8- Item Medication Adherence Scale Score			p-value
	Low adherence (n=79)	Moderate adherence (n=40)	High adherence (n=23)	
Health Care (Q1-16)	29.17(5.21:46.88)	31.25(17.71:43.33)	31.25(21.88:48.96)	**0.005[a]**
Disease Prevention (Q17-31)	26.67(3.75:50)	31.11(14.44:42.86)	28.89(12.22:42.22)	**0.034[a]**
Health Promotion (Q32-47)	23.95(7.29:50)	29.17(7.78:43.75)	29.17(14.58:42.71)	**0.040[a]**
Total (Q1-47)	26.95(7.20:48.23)	30.67(15.91:43.33)	29.43(16.31:42.55)	**0.009[a]**

The values were given as median (minimum:maximum); a: Kruskal Wallis testi, HLS-EU: The European Health Literacy Survey Questionnaire

There was a difference between the Morisky 8 Item MA groups according to the health service score. In the analysis of subgroups, it was determined that the scale scores in the groups with high and moderate MA were higher than those with low MA ($p<0.05$).

There was a statistically significant difference between the MA groups according to the disease prevention score. When the subgroups were analyzed, it was determined that the scale scores in the group with moderate MA was higher than those with low MA ($p=0.018$).

There was a difference between the MA groups according to the health promotion score. In the analysis of subgroups, it was determined that the scale scores in the group with moderate MA were higher than those with low MA ($p=0.025$).

There was a difference between the MA groups according to the overall scale score. In the subgroup analyses, it was determined that the scale scores in the groups with high and moderate MA were higher than those with low MA ($p=0.050$ and $p=0.005$, respectively).

62% of the participants (n=88) used only duloxetine, 15.5% (n=22) used only pregabalin, 9.2% (n=13) used both duloxetine and pregabalin, and 13.3% (n=19) of the patients used other treatments. The distribution of the scale scores according to the drugs used by the patients is given in Table 3. There was no difference between the drug groups according to the HLS-EU sub-scales and overall scale scores.

There was no difference according to the MA level among the drug groups. There was no difference between the drug groups according to the FIQ total and VAS measurements.

Table3. Relationship between FIQ total score, VAS measures and Health literacy and Morisky 8 Item medication adherence scores

		FIQ Total	**VAS**
HLS-EU Health Care	r	-0.21	-0.25
	p	**0.016**	**0.003**
HLS-EU Disease Prevention	r	-0.16	-0.24
	p	0.073	**0.004**
HLS-EU Health Promotion	r	-0.26	-0.27
	p	**0.003**	**0.001**
HLS-EU Total	r	-0.22	-0.27
	p	**0.012**	**0.001**
Morisky 8-Item medication adherence	r	-0.17	-0.25
	p	0.051	**0.003**

HLS-EU: The European Health Literacy Survey Questionnaire FIQ: Fibromyalgia Impact Questionnaire VAS: Visual Analog Scale r: Spearman correlation coefficient

The relationships between the HLS-EU-Q47 and FIQ are shown in Table 4. There was a negative correlation between the health service score and the FIQ Total and VAS pain score. The increases observed in the FIQ Total and VAS measurements led to a decrease in health service scores. There was a negative correlation between the disease prevention score and VAS measurements. The increases observed in the VAS measurements led to a decrease in the disease prevention score. There was a negative correlation between the health promotion score and the FIQ Total and VAS measurements. The increases observed in the FIQ Total and VAS measurements led to a decrease in the health promotion score. There was a negative correlation between the overall scale score and the FIQ Total and VAS measurements. The increases observed in the FIQ Total and VAS measurements led to a decrease in the overall scale score. There was no relationship between the HLS-EU-Q47 sub-scale and overall scale scores. There was a negative significant correlation between the Morisky 8 Item MA scale score and the VAS measurements. The increases observed in the VAS measurements led to a decrease in the Morisky 8 Item MA scale score. There was no relationship between the Morisky 8 Item MA scale score and the FIQ Total.

Table4. Comparison of HLS-EU scores, Morisky 8 Item medication adherences scores and treatment related measures between drug groups

	Medication groups				**p-value**
	Duloksetin	**Pregabalin**	**Duloksetin & Pregabalin**	**Other medication**	
HLS-EU-Health Care	30,21 (5.21:43.75)	30,73 (7.78:48.96)	28,13 (21.88:43.33)	29,17 (18.75:46.88)	0.471[a]
HLS-EU Disease Prevention	27,78 (6.77:44.44)	27,23 (3.85:50)	26,67 (17.78:42.86)	28,89 (13.33:50)	0.865[a]
HLS-EU Health Promotion	27,95 (7.29:41.67)	24,20 (7.78:50)	23,96 (15.63:43.75)	28,13 (10.42:45.83)	0.912[a]
HLS-EU Total	28,37 (9.57:39.01)	26,06 (7.20:48.23)	28,13 (10.42:45.83)	29,71 (15.60:47.52)	0.902[a]
Morisky scale					
Low adherence	48(%54.50)	9(%40.90)	7(%53.80)	15(%78.90)	0.326[b]
Moderate adherence	25(%28.40)	9(%40.90)	3(%23.10)	3(%15.80)	
High Adherence	15(%17)	4(%18.20)	3(%23.10)	1(%5.30)	
FIQ Total	58,16 (24,27:91.52)	56,12 (22.06:91.68)	51,23 (32.49:82.14)	54,82 (20.24:90.77)	0.726[a]
VAS	23,75 (2:50)	20,75 (9:41.50)	22,50 (14:34)	23 (9:43)	0.919[a]

Values given as median(minimum-maximum), n(%) percentage; a: Kruskal Wallis test, b: Fisher-Freeman-Halton test HLS-EU: The European Health Literacy Survey Questionnaire, Morisky Scale: The Morisky 8- Item Medication Adherence Scale, FIQ: Fibromyalgia Impact Questionnaire, VAS:Visual Analog Scale.

Internal reliability coefficients of the HLS-EU-Q47 and Morisky 8 Item MA scale score are given in Table 5. The internal reliability coefficients were found to be sufficient for both scales. Reliability coefficients of the HLS-EU-Q47 scale and subscales: α = 0.885 for health care, α = 0.911 for disease prevention, α = 0.911 for health reduction and α = 0.965 for general health. The internal consistency of the Morisky 8 Item MA scale compliance score was calculated using the Kuder-Richardson 20 Test (KR-20) coefficient and the reliability coefficient was calculated as KR20 = 0.767.

Table5. General Health Literacy and Sub Indexes and Morisky 8-Item Medication Adherence Internal Reliability Coefficients

	Cronbach's alfa or KR=20
HLS-EU Health Care	α=0.965
HLS-EU Disease Prevention	α=0.885
HLS-EU Health Promotion	α=0.915
HLE-EU Total	α=0.911
Morisky 8-Item medication adherence	KR_{20}=0.767

HLS-EU: The European Health Literacy Survey Questionnaire

Figure 1 shows the relationship between medication adherence to fibromyalgia drugs and health literacy.

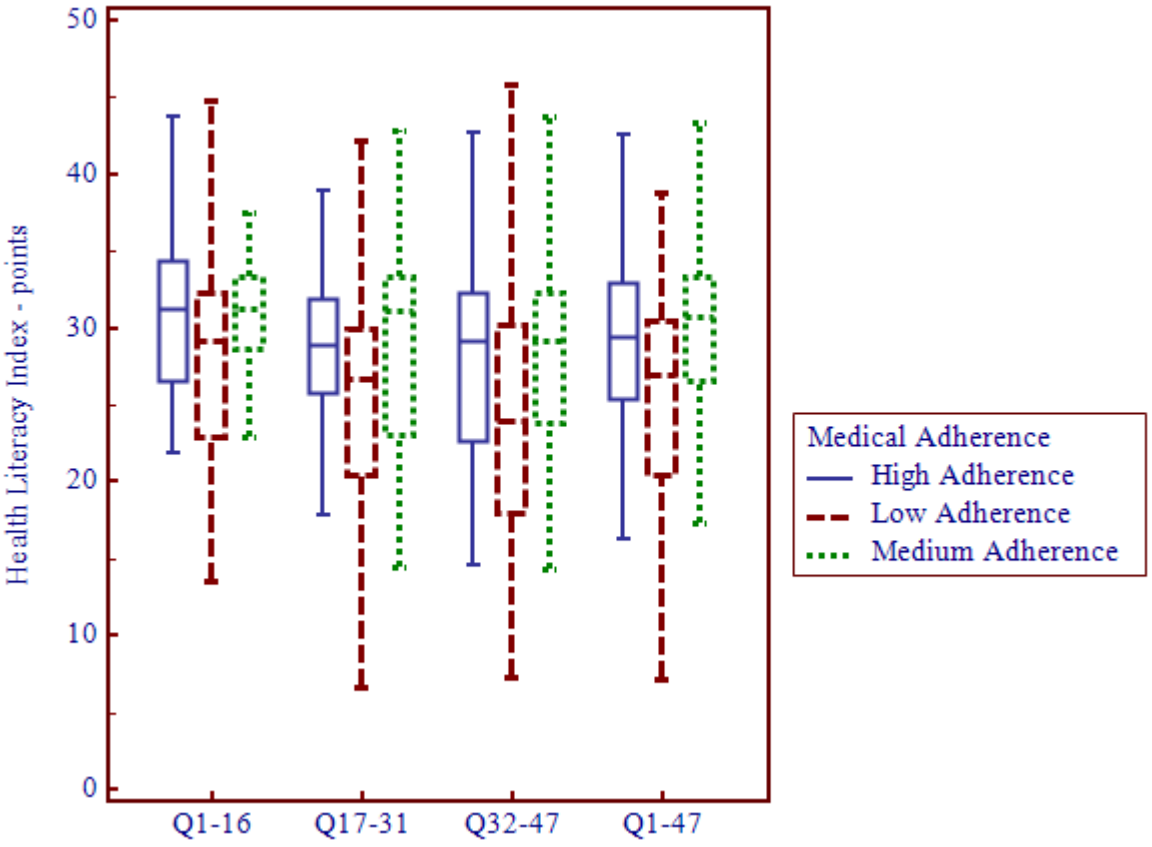

Figure1. Medication adherence to fibromyalgia drugs and health literacy

DISCUSSION

Based on the results of our study, as HL increased among FMS patients, the MA of the patients also increased. The patients' FIQ results were significantly negatively associated with their HL. There was also a negative relationship between the MA and the VAS pain status. There was no relationship between the distribution of drugs used in the treatment and health literacy.

Previous studies have reported that the Morisky 8-Item MA scale is reliable in chronic diseases such as hypertension, diabetes mellitus and COPD [30-33]. As a result of our study, we found that the scale was also reliable for FMS patients, another common chronic disease. In a study of hypertension patients, it has been reported that there is a relationship between Morisky 8-Item MA scores and blood pressure control [34]. Similarly, the Morisky 8-Item MA scale showed a negative correlation with the VAS scale that assessed the current pain status in the FMS patients.

The importance of HL is more and more understood each passing day [35]. HL is an important guide for survival and health expenditures. In the present study,

it was seen both that the HLS-EU-Q47 scale was reliable in FMS patients and that HL was associated with MA. The patients with high HL scores were cases that used their medicines more regularly and therefore responded better to treatment. Buchbinder et al. [36] investigated HL in rheumatoid arthritis patients and concluded that low HL, which is considerable in patients with rheumatoid arthritis, may lead to difficulties for patients to understand the treatment or prescription-related instructions. Likewise, HL was investigated in patients with chronic pain, and it was found that pain severity was lower in people with high HL, which led to the idea that it may be easier for patients with HL to cope with pain [37].

It is known that there is a negative correlation between pain and education level [37]. In the present study, we found a correlation between HL and the FIQ and VAS scores. Accordingly, as the patients' pain scores increased, HL decreased. The theory that pain is a primitive complaint is confirmed [38]. We are convinced that educating patients about their illnesses will have a positive impact on reducing their pain or on their efforts in this area.

The most commonly used treatments for the patients within the scope of the study were duloxetine and pregabalin. Combined uses were also the case. In the literature, there is information that a combined treatment with these drugs will provide a positive contribution, in addition to their individual use. Separate or combined uses are also recommended in the guidelines. In this sampling, no relationship was found between the drugs used by patients and HL or MA. There is literature suggesting that as HL increases, gravitating towards specific treatments increases [16,39], but there was no correlation between the drugs used in this sample and the HL status.

Limitations: The most important limitation in this study was the fact that it was a single-centered study and that it had a low number of cases. However, the sample size was found to be sufficient in the power analysis that was conducted. However, due to the above limitations, we think that no generalizations can be made about the subject. Another limitation is that we included patients who had been taking medication for at least six months. It can be considered that the HL status and the MA of the patients who stopped or who were not using the medicine immediately after the diagnosis were low, but this was not evaluated in the present study.

In conclusion, the Morisky 8 Item MA scale is reliable in patients with FMS and is negatively correlated with

the present pain sensation. The HLS-EU-Q47 scale is also reliable in fibromyalgia patients, and its results correlate in the same direction as the Morisky 8 Item MA scale results. We believe that educational programs for patients about FMS and increasing their MA and HL will positively affect their treatment outcomes.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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