

# Predictors of a favourable outcome in patients with fibromyalgia: results of 1-year follow-up

J.-E. Kim<sup>1</sup>, D.-J. Park<sup>1</sup>, S.-E. Choi<sup>1</sup>, J.-H. Kang<sup>1</sup>, Y.-R. Yim<sup>1</sup>, J.-W. Lee<sup>1</sup>, K.-E. Lee<sup>1</sup>,  
L. Wen<sup>1</sup>, S.-K. Kim<sup>2</sup>, J.-Y. Choe<sup>2</sup>, S.-S. Lee<sup>1</sup>

<sup>1</sup>Division of Rheumatology, Department of Internal Medicine, Chonnam National University Medical School & Hospital, Gwangju, Republic of Korea; <sup>2</sup>Department of Internal Medicine, Catholic University of Daegu School of Medicine, Daegu, Republic of Korea.

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## Abstract

### Objective

To determine the outcomes of Korean patients with fibromyalgia (FM) and to identify prognostic factors associated with improvement at 1-year follow-up.

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### Methods

Forty-eight patients with FM were enrolled and examined every 3 months for 1 year. At the time of enrollment, we interviewed all patients using a structured questionnaire that recorded sociodemographic data, current or past FM symptoms, and current use of relevant medications. Tender point counts and scores were assessed by thumb palpation. Patients were asked to complete the Korean versions of the Fibromyalgia Impact Questionnaire (FIQ), the Brief Fatigue Inventory, the SF-36, the Beck Depression Inventory, the State-Trait Anxiety Inventory (STAI), the Self-Efficacy Scale, and the Social Support Scale. Tender points, FIQ scores, and the use of relevant medications were recorded during one year of follow-up.

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### Results

Of the 48 patients, 32 (66.7%) had improved FIQ scores 1 year after enrollment. Improved patients had higher baseline FIQ scores ( $68.4 \pm 13.9$  vs.  $48.4 \pm 20.8$ ,  $p=0.001$ ) and STAI-II scores ( $55.8 \pm 10.9$  vs.  $11.5 \pm 11.5$ ,  $p=0.022$ ). Patients treated with pregabalin were more likely to improve after 1 year, based on the FIQ scores (71.9% vs. 37.5%,  $p=0.031$ ). On multivariate logistic regression analysis, a higher STAI-II score at the time of enrollment and pregabalin treatment during one year of follow-up were the predictors of improvement.

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### Conclusion

Two-thirds of our Korean FM patients experienced some clinical improvement by 1-year follow-up. A high baseline STAI-II score and treatment with pregabalin were the important predictor of improved FM.

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### Key words

fibromyalgia, outcome, treatment

Ji-Eun Kim, MD  
Dong-Jin Park, MD, PhD  
Sung-Eun Choi, MD  
Ji-Hyoun Kang, MD  
Yi-Rang Yim, MD  
Jeong-Won Lee, MD  
Kyung-Eun Lee, MD  
Lihui Wen, MD  
Seong-Kyu Kim, MD, PhD  
Jung-Yoon Choe, MD, PhD  
Shin-Seok Lee, MD, PhD

Please address correspondence to:  
Professor Shin-Seok Lee,  
Division of Rheumatology,  
Department of Internal Medicine,  
Chonnam National University  
Medical School & Hospital,  
42 Jebong-ro, Dong-gu,  
Gwangju 61469, Republic of Korea.  
E-mail: shinseok@chonnam.ac.kr

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## Introduction

Fibromyalgia (FM) is a common chronic pain disorder characterized by widespread musculoskeletal pain and tenderness; the prevalence ranges from 0.5 to 5.4% (1). FM is associated with various symptoms such as fatigue, sleep disturbance, and physical and psychological impairment; the clinical manifestations differ among affected individuals (2, 3). As FM is a complex and heterogeneous condition, different treatment strategies are required to optimally manage the disease. The response to treatment tends to vary among individuals.

Unfortunately, very few studies have sought to identify predictors of a response to FM treatment. One previous work found that selected sociodemographic and psychological variables, such as higher-level education, a longer duration of symptoms, a lower perceived ability to cope and function, a Multidimensional Pain Inventory (MPI) classification, and the types of intervention, were all significant, but not strong, predictors of improvement after treatment (4). Another study found that a brief (1.5-day) FM treatment program (FTP) was effective in improving symptoms and quality-of-life; the improvements were maintained for 6-12 months (5). Among the study participants, several characteristics were associated with a positive response to a brief interdisciplinary FTP. Younger age, a higher level of education, a higher baseline FM Impact Questionnaire (FIQ) depression score (but not a higher total FIQ score), a lower tender point count, and the absence of an abuse history at baseline, were predictors of remarkable benefits afforded by the FTP (6). However, the cited work explored treatment outcomes after the FTP with a focus on Cognitive-behavioural therapy (CBT) and did not evaluate the effects of medications such as gabapentin, pregabalin, and serotonin-norepinephrine reuptake inhibitors (SNRIs). Thus, the data cannot be generalized to predict the outcomes of other types of interventions. Also, depression and abuse history, important predictors of the treatment response, were not assessed using a validated questionnaire.

The aim of our study was to identify FM patient characteristics associated with favourable outcomes during 1 year of follow-up in longitudinal, prospective follow-up of a cohort of patients with FM.

## Patients and methods

### *Study design and population*

We assessed the participants in the cohort of FM patients to evaluate prognostic factors of treatment outcome in FM among the Korean population. Among the cohort, we selected 132 patients with FM at Chonnam National University Hospital, Gwangju, Korea and Catholic University of Daegu Hospital, Daegu, Korea. All patients fulfilled the 1990 American College of Rheumatology criteria for the classification of FM (7). All subjects were followed up every 3 months for 1 year; we evaluated clinical outcomes including responsiveness to medication. Tender point counts and scores, FIQ scores, and current medications, were recorded on each visit. Total of 48 FM patients who had completed 1 year of follow-up were included in the analysis. The Institutional Review Board/Ethics Committee of each center approved the study. All patients provided written informed consent prior to participation.

### *Clinical measures and medications*

The patients were interviewed to determine their demographic and clinical characteristics, including age, gender, body mass index (BMI), symptom duration, level of education, employment status, annual income, and alcohol use and smoking status at the time of enrollment. Information on co-morbidities (diabetes mellitus, hypertension, hepatitis, thyroid disease, or an affective disorder) and past and current medications were also obtained via interview and review of medical records. Tender point counts and scores were assessed using the standardized manual tender point evaluation (8). Direct thumb palpation was applied at 18 specific sites, and the number of tender points (0-18) counted. The tender point scores were as follows: 0, no tenderness; 1, light tenderness (confirmed when asked); 2, moderate tenderness

(spontaneous verbal response); and 3, severe tenderness (withdrawal of the affected region). Each total score ranged from 0 to 54.

We asked all subjects to complete several structured questionnaires at the time of enrolment, and at the end of the study. The Korean version of the FIQ was used to assess functional disability (9) and the Brief Fatigue Inventory (BFI) to evaluate the severity of fatigue and disturbance to daily life (10). Physical and mental health were explored using the 36-item Medical Outcomes Study Short-Form Health Survey (SF-36) (11), which yields physical and mental component summary scores (PCS and MCS). The severity of depression was measured using the Beck Depression Inventory (BDI) (12), and that of anxiety using the State-Trait Anxiety Inventory (STAI)-I and STAI-II; 20 items in STAI-I assess state anxiety and 20 items in STAI-II measure trait anxiety (13). Finally, a 20-item psychometric scale exploring self-efficacy was used to explore whether patients were optimistic that they could cope with the variety of difficult demands imposed by the condition (14).

All subjects were prescribed medications by a rheumatologist during the 1 year of follow-up. The medications were selective serotonin re-uptake inhibitors (SSRIs), serotonin-norepinephrine re-uptake inhibitors (SNRIs), pregabalin, gabapentin, tricyclic antidepressants, nonsteroidal anti-inflammatory drugs (NSAIDs), tramadol, acetaminophen, benzodiazepine, and muscle relaxants.

#### Definition of improvement

The FIQ is an instrument developed to measure FM patient status, progress, and outcomes, and assesses all problems associated with FM and responses to therapy (15). Thus, a fall in the FIQ score (compared to baseline) at the time of the 1-year follow-up was regarded as an indicator of disease improvement. We explored the associations between such improvement and the variables mentioned above.

#### Statistical analysis

All data are described as means (with SDs) or as percentages (%). Continu-

ous demographic and clinical variables including age, height, BMI, symptom duration, time since diagnosis, level of education, annual income, tender point counts and scores, and scores on the structured questionnaires, were compared between improved and non-improved patients using the nonparametric Mann-Whitney U-test. Categorical variables such as gender, employment status, alcohol and smoking status, comorbidities, and current relevant medications were compared between the two groups employing the Chi-square test. A  $p$ -value  $<0.05$  was considered to reflect statistical significance. Uni- and multi-variate logistic regression analyses were used to identify independent predictors of a favourable outcome. Variables with  $p$ -values  $<0.05$  were entered into both models. The results are reported as odds ratios (ORs) with 95% confidence intervals (95% CIs). All analyses were performed with the aid of SPSS v. 20.0 (SPSS-PC Inc., Chicago, Illinois, USA).

## Results

### Clinical characteristics of study patients

Of 132 participants recruited at baseline, a total of 48 FM patients who completed 1 year of follow-up were included in the analyses. Reasons for discontinuing with the study were as follows; patients felt the treatment would not help, could not be reached or refused to visit the clinic. The mean age was  $49.8 \pm 12.9$  years, and 75% were female (females=36; males=12). The mean duration of disease was  $2.4 \pm 2.7$  years. Of all participants, 32 (66.7%) improved over 1 year but 16 did not (71.9% vs. 37.5%,  $p=0.031$ ).

We also had performed the analysis for the all of the baseline variables to determine if any significant differences were present between the dropouts ( $n=84$ ) and completers ( $n=48$ ). The two groups differed significantly in terms of symptom duration ( $p=0.046$ ), time since diagnosis ( $p=0.000$ ), and baseline MCS score ( $p=0.048$ ). Those with shorter symptom and disease durations, a higher MCS, and who had been prescribed pregabalin, were more likely to dropout (data not shown).

The demographic and baseline characteristics of all subjects are shown in Table I. We found no significant between-group difference in any of age, gender, height, weight, or BMI. The two groups did not differ in terms of symptom duration, time since diagnosis, level of education, employment status, annual income, or the prevalence of co-morbidities (diabetes mellitus, hypertension, hepatitis, thyroid disease, or an affective disorder).

The mean scores on structured questionnaires were compared in Table II. The mean baseline FIQ score of improved patients was higher than that of the non-improved ( $68.4 \pm 13.9$  vs.  $48.4 \pm 20.8$ ,  $p=0.001$ ). Notably, improved patients had higher STAI-II scores ( $55.8 \pm 10.9$  vs.  $11.5 \pm 11.5$ ,  $p=0.022$ ), but the STAI-I scores did not differ between the groups ( $11.3 \pm 11.3$  vs.  $14.4 \pm 14.4$ ,  $p=0.325$ ). The tender point numbers and counts were similar between the two groups. No other between-group difference was evident. All participants were taking relevant medications, such as SSRIs, SNRIs, pregabalin, gabapentin, TCA, and/or muscle relaxants. We compared the prescription rates of major treatment options at the time of enrolment and during the 1 year of follow-up (Table III). Interestingly, patients treated with pregabalin were more likely to improve over the 1 year of follow-up (71.9% vs. 37.5%,  $p=0.031$ ), but baseline pregabalin-positive status did not affect disease outcome (40.6% vs. 37.5%,  $p=0.835$ ). Additionally, the percentages of patients treated with SSRIs, SNRIs, and TCA did not differ significantly between groups at the time of enrollment (15.6% vs. 6.3%,  $p=0.648$ ; 21.9% vs. 43.8%,  $p=0.178$ ; and 31.3% vs. 26.7%,  $p=1.000$ , respectively) or after 1 year of follow-up (3.1% vs. 6.3%,  $p=1.000$ ; 37.1% vs. 38.9%,  $p=1.000$ ; and 6.3% vs. 18.8%,  $p=1.000$ , respectively).

The outcomes of uni- and multi-variate logistic regression of factors associated with favourable FM outcomes during follow-up are presented in Table IV. In the univariate analysis, the STAI-II score (OR=1.061, 95% CI 1.002–1.125,  $p=0.043$ ) and pregabalin treatment during the 1 year of follow-up (OR=4.259,

**Table I.** Demographic and baseline characteristics at enrollment in 48 patients with fibromyalgia.

	All patients (n=48)	Improved group (n=32)	Non-improved group (n=16)	p value
Age, years	49.8 ± 12.9	51.2 ± 14.0	47.1 ± 10.1	0.347
Female (%)	36/48 (75)	23/32 (71.9)	13/16 (81.3)	0.725
Height, cm	159.5 ± 8.6	159.1 ± 9.4	160.5 ± 6.9	0.352
Weight, kg	59.2 ± 10.6	59.7 ± 11.6	58.0 ± 8.2	0.936
Body mass index, kg/m <sup>2</sup>	23.3 ± 3.4	23.7 ± 3.5	22.6 ± 3.1	0.432
Symptom duration, years	10.6 ± 9.0	11.23 ± 9.7	9.39 ± 7.5	0.660
Disease duration, years	2.4 ± 2.7	2.78 ± 2.99	1.69 ± 2.06	0.377
Education, years	9.5 ± 5.0	10.4 ± 4.89	9.60 ± 3.62	0.584
Employment status (%)	14/48 (29.2)	8/32 (25.0)	6/16 (37.5)	0.503
Annual income, x10 <sup>3</sup> Won	20,379 ± 2,234	28,046 ± 2,321	24,900 ± 1,910	0.670
Alcohol use (%)	17/48 (35.4)	10/32 (31.3)	7/16 (43.8)	0.393
Smoking status (%)	8/48 (16.7)	4/32 (12.5)	4/16 (25.0)	0.273
Diabetes mellitus (%)	3/48 (6.3)	3/32 (9.4)	0/16 (0.0)	0.540
Hypertension (%)	12/47 (25.5)	9/32 (29.0)	3/16 (18.8)	0.505
Hepatitis B or C (%)	2/48 (4.2)	1/32 (3.1)	1/16 (6.3)	1.000
Thyroid disease (%)	4/48 (8.3)	2/32 (6.3)	2/16 (12.5)	0.592
Affective disorder (%)	15/48 (31.3)	11/32 (34.4)	4/16 (25.0)	0.742

**Table II.** Comparison of structured questionnaires between improved and non-improved groups of fibromyalgia patients.

	All patients (n=48)	Improved group (n=32)	Non-improved group (n=16)	p value
Tender point number (0-18)	13.7 ± 5.7	14.1 ± 4.1	15.4 ± 5.5	0.146
Tender point count (0-54)	30.0 ± 17.5	30.2 ± 16.8	35.1 ± 15.2	0.324
FIQ	61.7 ± 18.9	68.4 ± 13.9	48.4 ± 20.8	0.001
BFI	8.1 ± 8.5	8.00 ± 7.3	8.24 ± 10.9	0.284
PCS	35.4 ± 8.2	34.2 ± 8.1	37.7 ± 8.1	0.113
MCS	29.2 ± 11.1	27.5 ± 8.7	32.6 ± 14.2	0.229
BDI	20.6 ± 9.7	22.2 ± 8.3	17.4 ± 11.6	0.168
STAI I	51.1 ± 12.4	11.3 ± 11.3	14.4 ± 14.4	0.325
STAI II	53.3 ± 11.6	55.8 ± 10.9	11.5 ± 11.5	0.022
Self-efficacy	682.1 ± 264.4	279.0 ± 279.0	236.0 ± 235.9	0.577

FIQ: Fibromyalgia Impact Questionnaire; BFI: Brief Fatigue Inventory; PCS: Physical component summary; MCS: Mental component summary; BDI: Beck Depression Inventory; STAI: State-Trait Anxiety Inventory. Data are shown as mean ± SD.

95% CI 1.194–15.198,  $p=0.026$ ) were independently associated with a favourable outcome. After adjustment for age, gender, and disease duration, the STAI-II score (OR=1.068, 95% CI 1.004–1.137,  $p=0.037$ ) and pregabalin prescription (OR=5.845, 95% CI 1.382–24.713,  $p=0.016$ ) were also significant. Patients with high baseline STAI-II scores, and who were treated with pregabalin during the 1 year of follow-up, enjoyed more favourable outcomes.

**Discussion**

We defined several characteristics of Korean FM patients associated with favourable outcomes upon standard medical care. The predictors of a better outcome were a higher STAI-II score

at baseline and prescription of pregabalin during 1 year of follow-up. None of age, educational level, employment status, or tender point count previously reported to contribute to FM outcomes was significantly associated with improvement.

In this study, we found that a higher baseline STAI-II score which measures trait anxiety was associated with a better response to treatment. It is well known that emotional and interpersonal problems are associated with poorer treatment outcomes (16). Earlier studies found that depression was predictive of poor outcomes in terms of all of pain, physical functioning, any global treatment effect, and quality-of-life (17, 18). Although a strong positive correlation between depres-

sion and trait anxiety was reported in a previous study (19), it may seem counterintuitive that high-level trait anxiety is associated with a favourable outcome. One possible explanation is that depression is associated with chronic pain (20), whereas anxiety predicts the response to acute pain (21). The fear-avoidance model of pain maintains that when patients perceive non-threatening acute pain, they usually maintain normal activities and achieve functional recovery (22). However, when pain is interpreted as threatening, pain-related fear evolves, triggering avoidance behaviors and hypervigilance to bodily sensations, followed by disability, disuse, and depression. Pain-related fear may be adaptive in the acute stage, but may aggravate the course of disease if persistent (23). Therefore, it is possible that anxiety associated with acute pain may mediate favourable FM outcomes, whereas depression associated with chronic pain causes poorer outcomes. To the best of our knowledge, this is the first study to report that higher baseline anxiety levels are associated with favourable treatment outcomes in FM patients.

We also found that patients who were prescribed pregabalin during the 1-year follow up responded better than did those taking other medicines. According to a prior systemic review/meta-analysis to explore the efficacy and safety of pregabalin given to treat FM, pregabalin at doses of 300, 450, and 600 mg/day effectively reduced mean pain severity scores measured using an 11-point Numeric Rating Scale, and improved the Medical Outcome Study-Sleep Problems Index scores, as compared to placebo (24). A recent post-hoc analysis of four placebo-controlled trials revealed that pregabalin significantly (and rapidly) relieved pain, and improved sleep quality, as compared to placebo (25). Thus, pregabalin effectively manages both pain and the sleep disturbances, which are key symptoms of FM. However, all previous studies were randomised clinical trials of a maximum duration of 6 months, and pregabalin was prescribed to only carefully selected FM patients. Here, we explored whether pregabalin clinically

**Table III.** Medications at the time of enrollment and during follow-up in patients with fibromyalgia.

	All patients (n=48, %)	Improved group (n=32, %)	Non-improved group (n=16, %)	p value
<i>Baseline medication</i>				
SSRI	6/48 (12.5)	5/32 (15.6)	1/16 (6.3)	0.648
SNRI	14/48 (29.2)	7/32 (21.9)	7/16 (43.8)	0.178
Pregabalin	19/48 (39.6)	13/32 (40.6)	6/16 (37.5)	0.835
Gabapentin	2/48 (4.2)	2/32 (6.3)	0/16 (0)	0.546
TCA	14/48 (29.2)	10/32 (31.3)	4/16 (26.7)	1.000
Muscle relaxant	16/48 (33.3)	13/32 (41.9)	3/16 (18.8)	0.112
<i>Medication during the 1 year of follow-up</i>				
SSRI	2/48 (4.2)	1/32 (3.1)	1/16 (6.3)	1.000
SNRI	25/48 (52.1)	17/32 (37.1)	8/16 (38.9)	1.000
Pregabalin	29/48 (60.4)	23/32 (71.9)	6/16 (37.5)	0.031
Gabapentin	0/48 (0)	0/32 (0)	0/16 (0)	1.000
TCA	5/48 (10.4)	2/32 (6.3)	3/16 (18.8)	1.000
Muscle relaxant	9/48 (18.8)	5/32 (15.6)	4/16 (25.0)	1.000

SSRI: Selective serotonin re-uptake inhibitor; SNRI: Serotonin norepinephrine re-uptake inhibitor; TCA: Tricyclic antidepressant.

**Table IV.** Univariate and multivariate logistic regression analyses identifying predictors of a favourable outcome in fibromyalgia patients.

Variable	Univariate analysis		Multivariate analysis*	
	OR (95% CI)	p value	OR (95% CI)	p value
STAI-II score	1.061 (1.002-1.125)	0.043	1.068 (1.004-1.137)	0.037
Pregabalin during the 1-year follow-up	4.259 (1.194-15.198)	0.026	5.845 (1.382-24.713)	0.016

STAI: State-Trait Anxiety Inventory. \*Adjusted by age, gender, disease duration.

improved FM treatment outcomes during 1 year of follow-up. In addition, we investigated predictors in a setting of real clinical practice. The value of this study is that we confirmed the efficacy of pregabalin during 1 year of follow-up in routine clinical practice, supporting the evidence found in randomized controlled trials. One thing to be noted is that the average daily dose of pregabalin was 134, 138, 138, and 137 mg at 3, 6, 9, and 12 months, respectively, much lower than the recommended doses. In practice, we prescribe such doses to avoid adverse events such as dizziness and somnolence. Our lower doses of pregabalin may be related in part to the lower body mass index of our patients compared to Western patients. Our study is not without limitation. First of all, only a small number of patients completed the 1-year follow-up. A bias may be in play; perhaps subjects completing follow-up were particularly

compliant with treatment. Second, we assessed outcomes after pharmacological treatment; our data may not be readily generalisable to other treatment interventions or to the natural outcomes of disease when intervention is absent. Third, we used the difference in the FIQ score between baseline and the 1-year follow-up as an indicator of disease improvement. Admittedly, composite measures such as the OMERACT-10 response criteria are better at assessing improvement than a single-outcome measure like the FIQ (26). However, most studies on FM patients have not adopted the OMERACT-10 response criteria, and it is easier to use the FIQ to assess responses in routine clinical practice. In addition, the FIQ has been reported to be superior to other measures in its capacity to discriminate between patients who improve and those who do not (15). Therefore, we believe that our results based on the FIQ are

more relevant clinically and are acceptable to physicians managing FM patients. Fourth, results obtained in this study are specific to the variables where the research is performed.

In summary, a higher STAI-II score at baseline and prescription of pregabalin during the 1 year of follow-up predicted favourable FM outcomes, as compared to standard medical treatment. The results suggest that a subgroup of patients with high trait anxiety respond well to medical treatment, and our results can help clinicians in choosing medication for the effective management of FM patients.

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