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Original article

Effect of fibromyalgia syndrome on the health-related quality of life and economic burden in Korea

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Abstract

Objective. To investigate the health-related quality of life (HRQOL) and economic burden of patients with FM syndrome (FMS) and compare the changes in these parameters 3 months before and after FMS diagnosis.

Methods. A total of 2098 patients with FMS (1818 previously diagnosed with FMS and 280 newly diagnosed with FMS) were enrolled in this study. The newly diagnosed patients with FMS participated in a 3-month prospective observational study to assess HRQOL and economic burden in terms of direct health-care costs, direct non-health-care costs and indirect costs. HRQOL was estimated using the Short Form 36 Health Survey.

Results. Mean (S.D.) scores obtained on the physical component summary (PCS) and mental component summary (MCS) scales by patients with FMS were 34.01 (7.28) and 37.29 (11.17), respectively. The total expenditure for the 3 months before enrolment was $1481 (S.D. $2206). Indirect costs [$1126 (S.D. $2016)] were about three times higher than direct costs [$355 (S.D. $534)]. The PCS and MCS scores increased to 4.03 (S.D. 6.79) and 4.06 (S.D. 10.57), respectively, 3 months after the initial FMS diagnosis ($P < 0.001$, both). Total expenditure after FMS diagnosis was reduced by $1025 (S.D. $1347) as compared with costs before FMS diagnosis ($P < 0.001$).

Conclusion. Patients with FMS experience a decline in their HRQOL and constitute a significant economic burden on health-service utilization. The improvement in health-related costs and HRQOL after a diagnosis of FMS demonstrates a need for early diagnosis and treatment of FMS to reduce costs and enhance HRQOL.

Key words: fibromyalgia, health-care costs, quality of life.

Introduction

FM syndrome (FMS) is a common chronic pain disorder characterized by widespread musculoskeletal pain with multiple tender points over the entire body and a wide range of related symptoms [1]. Data from an Internet survey performed by the National Fibromyalgia Association showed that patients with FMS complained of various neurological, psychological and constitutional symptoms/disturbances, including sleep disturbance, fatigue, morning stiffness, tingling sensation, headache, memory disturbance, depression and anxiety, in addition to widespread pain [2]. Long-term pain and emotional and physical disabilities related to FMS may lead to poor health-related quality of life (HRQOL) and a substantial economic burden.

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CLINICAL SCIENCE

In a comparative analysis of quality of life (QOL), Burckhardt *et al*. [3] demonstrated that the QOL of women with FMS was markedly worse than that of women with other painful disorders, including OA, RA and chronic obstructive pulmonary disease. Additional studies using various common QOL-related measures, such as the Fibromyalgia Impact Questionnaire (FIQ), the Quality of Well-being Scale and the Short Form 36 Health Survey (SF-36), have confirmed greater impairment in the QOL of patients with FMS compared with the general population or those without chronic disease conditions [4–9]. They have also demonstrated that some characteristics such as gender, disease duration, educational level, work status and self-rated health may influence QOL as assessed by the FIQ and SF-36 [9–11].

The substantial economic burden of FMS is a major issue that arises from chronic pain and emotional and physical disabilities [12–17]. A long-term prospective FMS outcome study has shown high levels of utilization of a number of medical services by patients with FMS [17], which is thought to be related to a greater incidence of symptoms and related morbidities in this group compared with patients with other rheumatic diseases. Although studies on health-care costs have been characterized by differences in methods of analysis and research design, the economic burden of patients with FMS in terms of health-care costs was 2- to 3-fold greater than that of control groups [12, 16]. Patients with FMS also reported far greater use of health-care resources, including office visits, prescriptions and diagnostic testing for the disease before than after the initial FMS diagnosis [13]. In addition to direct health-care costs, indirect costs related to the transient or permanent loss of productivity and the need for sick leave to treat FMS were clearly elevated in FMS patients [14, 15]. These data imply that FMS itself may contribute to increasing the economic burden secondary to high rates of health-service utilization, such as direct and indirect costs.

Although it is recognized that patients with FMS experience significantly impaired QOL and higher rates of service utilization related to FMS, there are limited data assessing the QOL and economic costs of newly diagnosed FMS patients and the changes of these parameters after the diagnosis of FMS as compared with established patients. The aims of this study were to assess the economic burden, work-related disability and HRQOL of newly diagnosed and established patients with FMS, and to compare these parameters before and after FMS diagnosis in newly diagnosed patients. We also sought to identify demographic and clinical risk factors associated with economic costs and work-related disability due to illness.

Patients and methods

Study design and population

This study enrolled 2098 patients with FMS recruited from outpatient clinics at 44 medical centres across the Republic of Korea. The study subjects were evaluated using the 1990 ACR classification criteria for a diagnosis of FMS [18]. Patients who had previously been diagnosed with FMS ($n = 1818$) were consecutively recruited from the rheumatology outpatient clinic at each medical centre. Additionally, subjects who were diagnosed as having FMS for the first time and who met the ACR criteria for FMS were regarded as newly diagnosed cases ($n = 280$). The institutional review board/ethics committee at each medical centre approved the study (Chonnam National University Institutional Review Board, Catholic University of Daegu Hospital Institutional Review Board, Inje University Haeundae Paik Hospital Institutional Review Board, Asan Medical Center Institutional Review Board, Guri Hospital Institutional Review Board, Konkuk University Hospital Institutional Review Board and Severance Hospital Institutional Review Board). All study patients provided informed consent before participation.

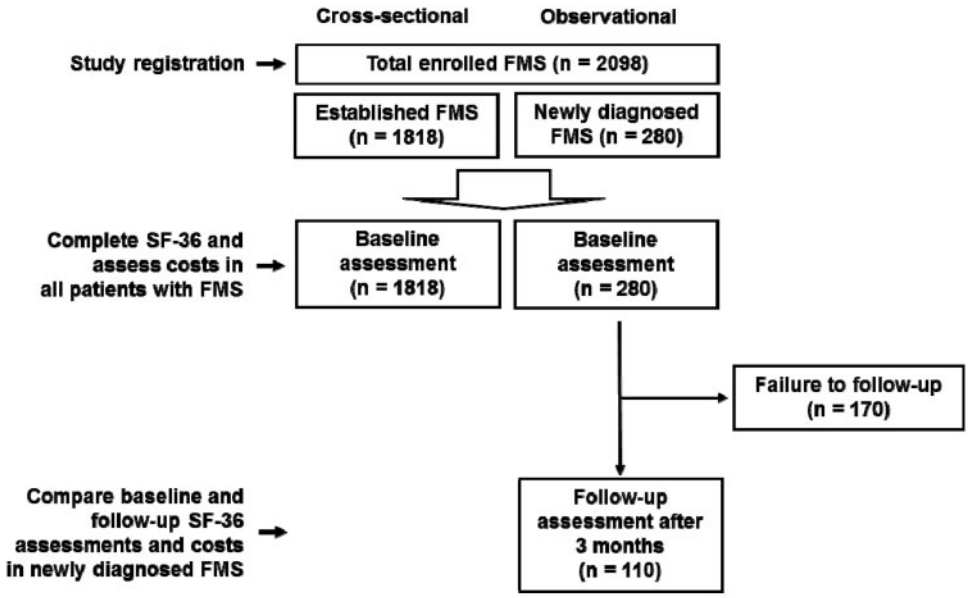
When patients who were newly diagnosed or were already diagnosed as FMS visited the outpatient clinic in each participating centre, they were invited to join the study. After obtaining the informed consent from patients, we proceeded to the next step. Our study consisted of two parts, as shown in Fig. 1. For the first part we conducted a cross-sectional study using baseline data on all 2098 patients with FMS, irrespective of time of diagnosis, to estimate the economic burden associated with this disorder, such as health-care and non-health-care costs, indirect costs related to loss of productivity and HRQOL. To this end the subjects completed the SF-36 questionnaire at the time of enrolment. For the second part we conducted a prospective observational study targeting the 280 patients who were newly diagnosed with FMS to compare changes in costs and HRQOL 3 months before and after FMS diagnosis. Among the 280 newly diagnosed patients with FMS, 110 finished our study, but 170 failed to follow up 3 months after diagnosis.

Demographic characteristics such as age, gender, educational level, occupational status, type of health insurance (including medical insurance and medicaid), income level and smoking status were assessed via interviews during the study period (Table 1). The time since diagnosis and presence of rheumatic/non-rheumatic diseases were assessed via interviews and a review of medical records. Tender points at 18 specific sites in each patient were counted according to the standardized manual tender point survey [19]. We also measured the intensity of each tender point as described in our previous study [20] and the sum of these points served as the score for tender points. The patients were asked to complete the Korean version of the FIQ [21] and SF-36 [22] to assess the function and QOL in all patients at baseline, and the newly diagnosed patients were reassessed 3 months later.

Estimation of health-care and non-health-care costs

The economic burden associated with FMS consists of direct and indirect costs [23, 24]. Direct costs were divided into two subgroups: direct health-care costs (i.e. outpatient and inpatient medical expenditure) and non-health-care costs (i.e. travel expenses, nursing costs and complementary/alternative treatment). Indirect costs (loss of productivity) were defined as the costs

FIG. 1 Summary of study design and population.



incurred as a result of lost workdays due to inpatient and outpatient visits to treat the disease and were estimated on the basis of the number of days ill or spent experiencing discomfort and the number of absences and early departures from work due to illness or discomfort. The analysis of direct health-care costs, direct non-health-care costs and indirect costs was based on expenditure for the treatment of FMS during the past 3 months; these data were collected via patient interviews. Direct health-care costs should include both co-pays, which were addressed on the patient questionnaire, and expenditure by National Health Insurance (NHI). Therefore co-pay rates for each service were verified to calculate expenditure by the NHI (Survey on the Benefit Coverage Rate of the NHI in 2008 issued by the NHI) before estimating the direct health-care costs attributable to illness. Indirect costs were calculated as follows: employment rate per age (Annual Report on the Economically Active Population Survey issued by the National Statistical Office in 2009) $\times$ average daily wage (fixed hourly wage: Survey on Wage Structure issued by the Ministry of Labor in 2009). Data on the conversion of housework into wages provided by the Korean Women's Development Institute were used for housewives.

Statistical analysis

The data are described as means (S.D.s) or percentage (%) of cases. Comparisons between established and newly diagnosed patients with FMS in terms of socio-demographic and clinical characteristics, such as age, number of tender points, scores for tender points, FIQ scores and SF-36 scores, were measured by independent *t*-tests. Comparisons of the frequencies of categorical data, including gender, educational level, type of insurance, income level, occupational status, smoking status, non-pain symptoms and co-morbidities, were analysed with the χ^2-test. Additionally, a paired *t*-test was used to compare changes in the SF-36 and some parameters related to economic burden, including direct health-care, direct non-health-care and indirect costs pre- and post-initial FMS diagnosis. We confirmed that the data were normally distributed by plotting cumulative frequency against observed frequency and by performing tests for skewness and kurtosis and the Kolmogorov–Smirnov test. Determination of the risk factors for economic burden and HRQOL was performed by multiple linear regression analysis using socio-demographic and clinical characteristics as independent parameters and HRQOL and costs as dependent parameters. $P < 0.05$ was considered statistically significant. Statistical analyses were performed with SAS version 9.1 (SAS Institute, Cary, NC, USA).

Results

Baseline demographic and clinical characteristics and FMS-related outcomes

The baseline characteristics of study participants are described in Table 1. The majority of enrolled subjects were female (92.71%) and the mean (S.D.) age of the sample was 49.93 (10.42) years. The established patients with FMS were significantly older than the newly diagnosed patients ($P = 0.018$). The values for tender points differed significantly between established and newly diagnosed patients. The mean (S.D.) FIQ score in all patients with FMS was 61.45 (19.01) and the newly diagnosed patients with FMS obtained much higher scores than the established patients ($P < 0.001$). The FIQ scores of patients with FMS with rheumatic and non-rheumatic diseases did not differ ($P = 0.441$). Established and newly

Table 1 Baseline socio-demographic and clinical characteristics of study patients with FM

Clinical parameters	Total FMS (*n* = 2098)	Established FMS (*n* = 1818)	Newly diagnosed FMS (*n* = 280)	*P*
Female, *n* (%)	1945 (92.71)	1683 (92.57)	262 (93.57)	0.550
Age, mean (S.D.), years	49.93 (10.42)	50.14 (10.41)	48.56 (10.41)	0.018
Time since diagnosis, *n* (%), years				
<1		783 (43.96)		
1–3		577 (32.40)		
>3		421 (23.64)		
Tender point				
Number of tender points, mean (S.D.), 0–18	12.81 (4.20)	12.62 (4.35)	14.01 (2.85)	<0.001
Scores of tender points, mean (S.D.), 0–54	22.54 (12.01)	22.23 (12.27)	24.51 (10.01)	<0.001
FIQ, mean (S.D.)	61.45 (19.01)	60.90 (19.19)	64.96 (17.43)	<0.001
Educational level, *n* (%)				
⩽Elementary school	363 (17.30)	317 (17.44)	46 (16.43)	0.801
⩽Middle school	360 (17.16)	312 (17.16)	48 (17.14)	
⩽High school	803 (38.27)	700 (38.50)	103 (36.79)	
⩾University	572 (27.26)	489 (26.90)	83 (29.64)	
Type of health insurance, *n* (%)				
Medical insurance	1791 (85.37)	1549 (85.20)	242 (86.43)	0.589
Medicaid	307 (14.63)	269 (14.80)	38 (13.57)	
Income level/month, *n* (%)[a]				
<865	643 (30.75)	567 (31.31)	76 (27.14)	0.320
874–1730	421 (20.13)	364 (20.10)	57 (20.36)	
1739–2595	395 (18.89)	348 (19.22)	47 (16.79)	
2604–3460	259 (12.39)	216 (11.93)	43 (15.36)	
3469–4325	159 (7.60)	133 (7.34)	26 (9.29)	
>4334	214 (10.23)	183 (10.10)	31 (11.07)	
Occupational status, *n* (%)				
Employed	658 (31.36)	565 (31.08)	93 (33.21)	0.473
Not employed	1440 (68.64)	1253 (68.92)	187 (66.79)	
Smoking status, *n* (%)				
Smoker	196 (9.34)	164 (9.02)	32 (11.43)	0.198
Non-smoker	1902 (90.66)	1654 (90.98)	248 (88.57)	
Non-pain symptoms, *n* (%)				
Fatigue	1919 (91.47)	1662 (91.42)	257 (91.79)	0.838
Anxiety	1259 (60.01)	1093 (60.12)	166 (59.29)	0.791
Depression	1335 (63.63)	1152 (63.37)	183 (65.36)	0.519
Sleep disturbance	1447 (68.97)	1246 (68.54)	201 (71.79)	0.274
Memory disturbance	1564 (74.55)	1358 (74.70)	206 (73.57)	0.687
Other[b]	130 (6.20)	112 (6.16)	18 (6.43)	0.863
Co-morbidities, *n* (%)				
Rheumatic diseases	920 (43.85)	813 (44.72)	107 (38.21)	0.041
RA	307 (14.63)	269 (14.80)	38 (13.57)	0.589
SLE	66 (3.15)	61 (3.36)	5 (1.79)	0.161
SS	52 (2.48)	47 (2.59)	5 (1.79)	0.423
OA	290 (13.82)	251 (13.81)	39 (13.93)	0.956
AS	15 (0.71)	11 (0.61)	4 (1.43)	0.129
SSc	6 (0.29)	5 (0.28)	1 (0.36)	0.577
Inflammatory muscle disease	9 (0.43)	9 (0.50)	0 (0.00)	0.618
Behçet's disease	113 (5.39)	105 (5.78)	8 (2.86)	0.044
Osteoporosis	129 (6.15)	118 (6.49)	11 (3.93)	0.097
Non-rheumatic diseases				
Hypothyroidism	63 (3.00)	56 (3.08)	7 (2.50)	0.596
Headache	417 (19.88)	355 (19.53)	62 (22.14)	0.307
Irritable bowel syndrome	175 (8.34)	155 (8.53)	20 (7.14)	0.436
Irritable bladder syndrome	122 (5.82)	94 (5.17)	28 (10.00)	0.001

The response rate was not 100% for all questions. [a]Cost presented in US dollars. [b]Other includes constipation, dizziness, dyspepsia, anorexia, tinnitus and palpitation.

diagnosed groups did not differ significantly with respect to educational level, type of health insurance, income level, occupational status, smoking status and non-pain symptoms. Approximately 43.8% of the patients with FMS had co-morbid rheumatic diseases. Additionally, rheumatic diseases were more prevalent in established than in newly diagnosed patients ($P = 0.041$). In terms of non-rheumatic diseases, the prevalence of irritable bladder syndrome differed significantly between the two groups ($P = 0.001$).

The mean (S.D.) PCS and MCS scores in all patients with FMS were 34.01 (7.28) and 37.29 (11.17), respectively (Fig. 2). The mean PCS scores of the established and newly diagnosed patients with FMS were similar, whereas the newly diagnosed patients had lower MCS scores on the SF-36 than did the established patients ($P = 0.030$). As for individual SF-36 items, the two groups differed significantly with respect to bodily pain, vitality and role limitation due to emotional health ($P < 0.001$, $P = 0.004$ and $P = 0.039$, respectively). Those with FMS and non-rheumatic diseases reported better physical functioning on the SF-36 subscales ($P = 0.007$), whereas the results of the two groups on the other subscales were similar. Additionally, patients with FMS with both rheumatic and non-rheumatic diseases obtained similar scores on the PCS and MCS ($P > 0.05$).

One hundred and ten of the 280 newly diagnosed patients with FMS completed this study. We found no significant differences in baseline characteristics between patients with FMS who did and did not complete the study (data not shown).

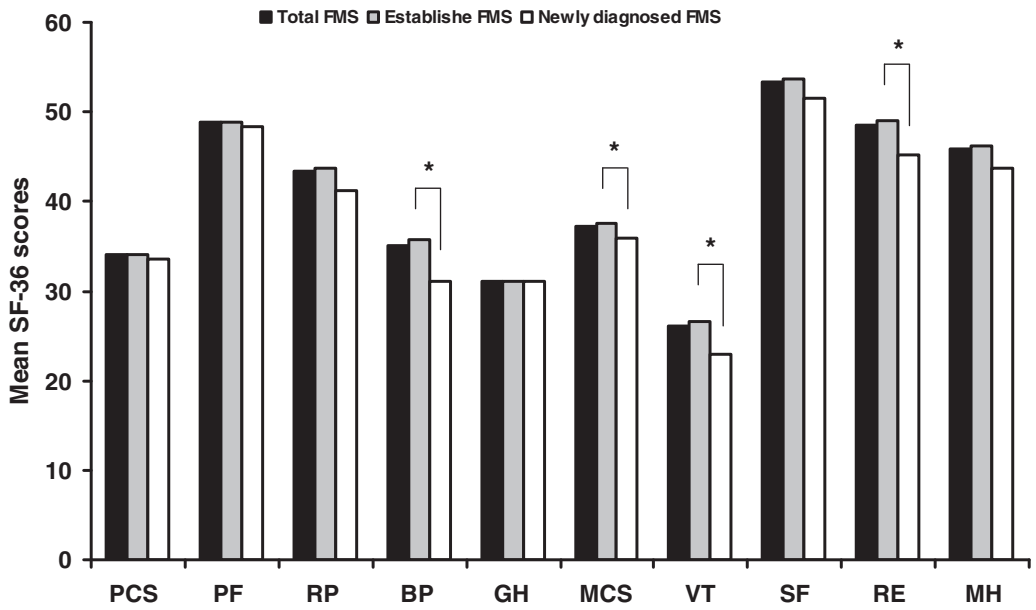
Analysis of health-related costs during the 3 months preceding diagnosis

Costs for the utilization of medical services are presented in Table 2. Direct health-care costs for the treatment of FMS for the 3 months before initial diagnosis were estimated at $257 (S.D. $615); these were chiefly attributable to costs related to outpatient rather than inpatient services. We found significant differences between the two groups in direct health-care costs ($P = 0.002$). Costs for newly diagnosed patients with FMS were nearly twice as high as for those with established FMS. Clinic visits among those newly diagnosed with FMS were more frequent than among those previously diagnosed with FMS ($P = 0.003$), whereas no differences in the frequencies and costs for hospital admissions were observed between the two groups ($P > 0.05$).

In contrast, direct non-health-care costs, including travel expenses, costs for nursing and costs for complementary/alternative therapies were estimated at $74 (S.D. $330). We found no significant differences between the two groups in direct non-health-care costs. Costs for complementary or alternative treatments used to manage FMS accounted for a greater proportion of non-health-care costs.

Indirect costs related to loss of productivity were estimated at $1126 (S.D. $2016). However, the indirect costs of the two groups were similar. Although total direct costs differed significantly between the two groups and were 1.7 times higher in the newly diagnosed than in the established patients with FMS ($P = 0.001$), the total expenditure was not different between the two groups ($1412 *vs* $1679, $P = 0.086$).

Fig. 2 Mean scores of individual components of the SF-36 questionnaire in patients with FM.



Asterisk indicates statistical significance at the 0.05 level between the established and newly diagnosed FMS patients. PF: physical functioning; RP: role limitation due to physical health; BP: bodily pain; GH: general health perception; VT: vitality; SF: social functioning; RE: role limitation due to emotional health; MH: mental health.

Table 2 Analysis of health-related costs and productivity loss during the 3 months preceding diagnosis

Individual costs	Total FMS ($n = 2098$)	Established FMS ($n = 1818$)	Newly diagnosed FMS ($n = 280$)	*P*
Health-related costs				
Direct costs[a]	355 (534)	217 (433)	366 (756)	0.001
Direct health-care costs[a]	257 (615)	227 (524)	417 (966)	0.002
Number of outpatient clinic visits	3.60 (6.95)	3.32 (5.92)	5.39 (11.43)	0.003
Total cost for outpatient clinics[a]	217 (489)	190 (165)	392 (769)	<0.001
Number of admissions	0.06 (0.34)	0.06 (0.34)	0.07 (0.36)	0.624
Total cost for admissions[a]	40 (275)	40 (274)	35 (283)	0.788
Direct non-health-care costs[a]	74 (330)	67 (239)	80 (264)	0.438
Travel expenses[a]	9 (16)	9 (16)	9 (17)	0.893
Cost of nursing[a]	6 (122)	4 (107)	16 (193)	0.310
Use of complementary/alternative medicine, *n* (%)	635 (30.27)	547 (30.09)	88 (31.43)	0.650
Cost of complementary/alternative medicine[a]	84 (306)	85 (317)	75 (222)	0.500
Indirect costs (productivity loss)[a]	1126 (2016)	1118 (2001)	1182 (2107)	0.618
Total expenditure[a,b]	1481 (2206)	1412 (2134)	1679 (2450)	0.086
Productivity loss				
Experience of work loss, *n* (%)	338 (24.51)	299 (24.96)	39 (21.55)	0.320
Days ill	44.04 (39.82)	43.22 (39.54)	49.34 (41.24)	0.017
Days absent due to illness	15.55 (26.99)	15.44 (26.84)	16.24 (27.99)	0.647
Days left early due to illness	20.34 (30.39)	19.87 (29.90)	23.45 (33.30)	0.090
Reduced efficiency while working or studying, *n* (%)	1241 (59.15)	1079 (59.35)	162 (57.86)	0.636

The response rate was not 100% for all questions. Unless otherwise indicated, data are shown as mean (S.D.). [a]Cost presented in US dollars. [b]Total expenditure: the sum of direct health-care costs, direct non-health-care costs and indirect costs.

About 24% of the patients with FMS experienced loss of work due to illness (Table 2). Approximately 44 days were spent suffering from FMS-related symptoms and signs. Additionally, newly diagnosed patients with FMS reported a greater number of sick days than did established patients with FMS ($P = 0.017$). Our data showed that more than half the patients with FMS felt less efficient at work or during the period of the study, although no significant difference was observed between the two groups in this regard.

Determination of risk factors for costs for medical services during the 3 months preceding diagnosis

Direct outpatient and inpatient health-care costs were significantly related to a new diagnosis of FMS, the presence of non-rheumatic diseases and higher levels of income ($P < 0.001$, $P = 0.001$ and $P = 0.021$, respectively) (Table 3). Additionally, income level and fatigue were risk factors for direct non-health-care costs ($P = 0.024$ and $P = 0.043$, respectively). Parameters related to indirect costs included younger age, being female, medicaid, work loss, anxiety and sleep disturbance. Overall, greater total expenditure was found in younger females with non-rheumatic diseases, medicaid, unemployed status and non-pain symptoms including anxiety and sleep disturbance.

Comparison of economic burden and SF-36 scores 3 months before and after diagnosis

Scores on both the PCS and MCS significantly increased at the 3-month follow-up after FMS diagnosis compared with their baseline values ($P < 0.001$, both) (Table 4). Similarly, both direct and indirect health-care costs were markedly lower 3 months after diagnosis than at baseline ($P < 0.001$, both), whereas direct non-health-care costs did not change during this period. Overall, total expenditures were statistically reduced from $2139 (S.D. $1839) during the 3 months before diagnosis to $1114 (S.D. $1995) during the 3 months after diagnosis ($P < 0.001$).

Discussion

This study demonstrated that FMS patients experience significantly impaired HRQOL and higher health-service costs. In particular, newly diagnosed patients had higher mental disability and higher direct health-care costs than did the established patients. A significant reduction in the economic burden and an improvement in HRQOL were demonstrated after FMS diagnosis.

The mean (S.D.) PCS and MCS scores of the patients in this study were 34.01 (7.28) and 37.29 (11.17), respectively, which are similar to those reported by previous studies [4, 6, 8–10]. When the SF-36 scores of our patients were compared with those in the healthy Korean population [25, 26], the FMS patients reported markedly lower scores on all subscales of the SF-36, indicating significantly impaired QOL. Additionally, we found no differences between established and newly diagnosed patients with FMS with respect to PCS scores on the SF-36, whereas newly diagnosed patients with FMS had lower MCS scores, which indicates increased susceptibility to psychosomatic distress.

Table 3 Regression coefficients for health-related costs by socio-demographic and clinical parameters

Clinical parameters	Direct costs						Indirect costs		Total expenditure	
	Health-care costs		Non-health-care costs		Health-care and non-health-care costs					
	β	*P*	β	*P*	β	*P*	β	*P*	β	*P*
Age, years	1	0.707	0	0.882	1	0.691	−16	< 0.001	−16	0.002
Sex (ref: male)										
Female	−57	0.288	22	0.321	−35	0.548	759	< 0.001	724	<0.001
Time since diagnosis	−1	0.140	0	0.889	−1	0.196	0	0.860	−1	0.558
New patient (ref: established patient)										
Newly diagnosed patient	161	<0.001	10	0.561	171	<0.001	52	0.669	223	0.096
Co-morbidity (ref: non-rheumatic diseases)										
Rheumatic diseases	−88	0.001	−8	0.468	−96	0.001	−109	0.183	−205	0.023
Education level (ref: < high school)										
⩾High school	12	0.711	24	0.082	36	0.325	−129	0.200	−93	0.403
Insurance (ref: medicaid)										
Medical insurance	57	0.157	13	0.449	70	0.116	−710	<0.001	−640	<0.001
Income level/month	22	0.021	9	0.024	31	0.003	−17	0.564	14	0.654
Occupational status (ref: unemployed)										
Employed	−19	0.540	14	0.243	−4	0.900	−1515	<0.001	−1519	<0.001
Smoking status (ref: smoker)										
Non-smoker	−15	0.752	−18	0.350	−33	0.525	−67	0.641	−100	0.527
Non-painful symptoms										
Fatigue (ref: no)										
Yes	−69	0.162	−41	0.043	−110	0.043	129	0.390	18	0.912
Anxiety (ref: no)										
Yes	55	0.103	14	0.300	70	0.061	378	< 0.001	448	< 0.001
Depression (ref: no)										
Yes	34	0.316	−2	0.911	33	0.384	146	0.160	179	0.119
Sleep disturbance (ref: no)										
Yes	59	0.056	15	0.250	74	0.030	217	0.020	291	0.005
Memory disturbance (ref: no)										
Yes	−4	0.908	7	0.596	3	0.927	23	0.818	26	0.811

Table 4 Comparison of SF-36 and costs 3 months before and after diagnosis of FM

Variable	Baseline ($n = 110$)	Follow-up ($n = 110$)	*P*
SF-36			
PCS	32.44 (6.24)	36.47 (7.43)	<0.001
MCS	35.26 (10.81)	39.32 (10.33)	<0.001
Costs[a]			
Direct health-care costs	337 (338)	135 (191)	<0.001
Direct non-health-care costs	98 (257)	43 (189)	0.095
Direct health-care + non-health-care costs	419 (507)	176 (287)	0.001
Indirect costs	1722 (1691)	824 (1635)	<0.001
Total expenditure[b]	2139 (1839)	1114 (1995)	<0.001

Data are shown as mean (S.D.). [a]Cost presented in US dollars. [b]Total expenditure: the sum of direct health-care costs, direct non-health-care costs and indirect costs.

In addition to the increased risk of lower QOL in FMS, economic consequences related to FMS should also be a focus. It has been agreed that FMS is associated with significantly high health-care costs [12–17], although studies have differed in terms of health-care systems, study populations, analytical methods and study design. In our study the average baseline total economic costs during the 3 months before the initial diagnosis were $1481 (S.D. $2206) in 2098 patients with FMS. A recent study of 1338 Korean patients with diabetes mellitus (DM) and peripheral neuropathy showed that the direct and indirect costs during the 3 months preceding diagnosis were $356 (S.D. $893) [27]. The total costs during the 3 months before initial diagnosis in FMS patients were four times higher than those in patients with DM and peripheral neuropathy. Similarly Berger *et al*. [12] demonstrated that the total health-care costs over 12 months in 33 176 patients with FMS were approximately three times higher than those in the comparison group [$9573 (S.D. $20 135) *vs* $3291 (S.D. $13 643)]. This suggests that patients with FMS may be considered to have higher health-service costs compared with patients with other chronic diseases.

It is suggested that indirect costs should be included in actual estimations of the economic impact of FMS. Wolfe *et al*. [17] reported that the average yearly cost for the high utilization of medical services was $2274, adjusted for 1996 costs, in a 7-year prospective and longitudinal study among 538 patients with FMS. They assessed only direct medical costs such as hospitalization, drugs and outpatient visits. Among their cost sources, hospitalization was identified as a main contributor to direct medical costs. Several studies evaluating both direct and indirect costs have shown that indirect costs overwhelmingly exceeded direct costs [14, 15]. Mean (S.D.) direct costs were estimated at Can$2298 (Can$2303) in an assessment of the 6-month costs for 180 Canadian women with primary FMS, whereas the indirect costs were twice as high, at Can$5035 (S.D. Can$7439) [14]. The predominance of indirect costs in the economic burden of FMS was also confirmed by data from a multicentre FMS study in Spain [15]. These findings are in accordance with our results that 75% of the total costs for FMS were attributable to indirect costs.

Interest in the determinants of the economic burden of FMS has been increasing. Several investigators have tried to identify causal factors related to health-related costs. Measures of FMS disability (FIQ and health assessment questionnaire scores) and the number of co-morbidities have been significantly associated with the direct costs incurred by patients with FMS [14, 17]. Furthermore, it has recently been reported that the increased economic burden is primarily attributable to functional ability, depression, co-morbidities and younger age [15]. The evidence suggests that the severity of FMS, including the ability to work and co-morbid disorders, may influence the economic burden associated with this disorder. In the current study, the risk factors for FMS-related costs were younger age, being female, co-morbid disorders, insurance type, being employed and non-painful symptoms. The risk factors identified in our study are consistent with those identified in earlier studies [14, 15, 17].

In this study we prospectively investigated changes in two summary scores of the SF-36 questionnaire and the health-related costs (direct and indirect) 3 months before and after the initial diagnosis of FMS. The results showed significantly improved PCS and MCS scores and reduced health-service utilization costs, including direct and indirect costs. Hughes *et al.* [13] demonstrated that the high number of clinic visits, diagnostic tests and prescriptions before FMS diagnosis were significantly reduced after diagnosis, although these rates increased within 2–3 years. This finding is in line with our data, suggesting that the actual FMS diagnosis should result in alleviating FMS-related symptoms. In contrast, Boehm *et al*. [10] showed that longer disease duration rather than actual diagnosis of FMS was closely related to QOL and functioning. Unfortunately, sufficient data on health-related costs before and after FMS diagnosis were not available in the above-mentioned study. A UK study was conducted to calculate the number of clinic visits, prescriptions and diagnostic tests at 6-month intervals from 10 years before to 4 years after FMS diagnosis [13]. These rates were markedly reduced after diagnosis. Despite only

3 months of follow-up, our study suggests that early diagnosis of FMS may contribute to reducing the economic burden associated with this disorder. Based on the UK study and our data, we suggest that actual diagnosis can help reduce FMS-related costs. Considering that the average time taken for FMS diagnosis is >2 years and patients report seeing between two and four physicians before a diagnosis is made [28], it is recommended that efforts to facilitate FMS diagnosis and start medication earlier are needed to decrease the economic burden and improve HRQOL.

Our study has some limitations. First, 43.9% of total patients had co-morbid rheumatic diseases because this study was conducted in the rheumatology outpatient clinic. Although we asked patients to answer the costs directly related to FM during the interview and it was emphasized that the costs should be related to FM in the questionnaire questions, costs may be overestimated because of costs related to accompanying rheumatic diseases. Secondly, we were able to obtain follow-up on only 39% of the newly diagnosed patients. This study is a nationwide survey conducted in 44 medical centres across the country. The centres joined the study voluntarily and it was impossible to collect the Case Record Forms fully. Although there were no significant differences in baseline characteristics between patients who did and did not complete the study, improved patients were more likely to be followed up than unimproved patients. Thirdly, the estimation of costs was largely based on patient's recall. Like other studies of this kind, our study could be subject to recall bias to a certain degree.

In conclusion, we found a greater economic burden and a decreased HRQOL among Korean patients with FMS, particularly in newly diagnosed patients. This 3-month follow-up observational study demonstrated a significant reduction in the economic burden and an improvement in the HRQOL after FMS diagnosis compared with before FMS diagnosis, implying the need for early diagnosis. The impact of actual FMS diagnosis on the HRQOL and health-related costs should be confirmed by longer-term studies with larger samples.

Rheumatology key messages

- Patients with FM have significantly impaired HRQOL and have higher health-service costs in Korea.
- Early diagnosis of FM can improve the HRQOL and reduce the economic burden.

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