


# Cross-sectional assessment of sleep and fatigue in middle-aged Japanese women with primary Sjogren syndrome or rheumatoid arthritis using self-reports and wrist actigraphy

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## Abstract

To investigate fatigue, health-related quality of life (HR-QOL), and sleep quality in women with primary Sjogren syndrome (pSS) or rheumatoid arthritis (RA) as compared with healthy controls using self-reports and wrist actigraphy.

In this cross-sectional observational study, we evaluated a total of 25 patients (aged 40–75 years) with pSS, 10 with RA, and 17 healthy control subjects living in Japan. The HR-QOL was assessed using the Short Form-36. Fatigue was evaluated using the Short Form-36 vitality score, visual analog scale (VAS) for fatigue, and 2 questionnaire items using scores based on a 4-point Likert scale. Sleep quality was measured using the Japanese version of the Pittsburgh Sleep Quality Index, VAS for sleep quality, and wrist actigraphy for 14 days.

Patients with pSS reported severer fatigue and lower HR-QOL than healthy controls, especially in mental health. Based on the Pittsburgh Sleep Quality Index score, 56% of the patients with pSS were poor sleepers, which was higher than healthy controls (29.4%). Furthermore, the patients with pSS scored significantly lower on the VAS for sleep quality than healthy controls (40.5 vs 63.7,  $P = .001$ ). Although subjective assessments revealed slight sleep disturbances in patients with pSS, wrist actigraphy revealed no differences when compared with healthy controls for total sleep time (421.8 minutes vs 426.5 minutes), sleep efficiency (95.2% vs 96.4%), number of awakenings (1.4 vs 0.9), and wake after sleep onset (22.4 minutes vs 16.1 minutes). Poor subjective sleep quality was associated with enhanced fatigue. However, sleep efficiency, as determined by actigraphy, was not associated with fatigue. Notably, the patients with RA and healthy controls did not differ significantly in terms of fatigue or sleep quality, although patients with RA experienced more nocturnal awakenings than healthy controls (1.7 vs 0.9,  $P = .04$ ).

Patients with pSS experience severe fatigue, poor HR-QOL, and sleep disturbances, which are associated with fatigue. However, wrist actigraphy did not reveal differences in sleep quality, suggesting that it may not be an appropriate measure of sleep in patients with pSS.

**Abbreviations:** HR-QOL = health-related quality of life, PSQI-J = Pittsburgh Sleep Quality Index – Japanese version, pSS = primary Sjogren syndrome, RA = rheumatoid arthritis, SD = standard deviation, SE = standard error, SF-36 = Short Form-36, VAS = visual analog scale.

**Keywords:** actigraphy, fatigue, rheumatic diseases, sleep, women

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## 1. Introduction

Poor sleep quality is a common symptom in patients with rheumatic diseases and is associated with fatigue, poor mental health, and increased disease activity. The majority of studies on sleep quality have focused on sleep disturbances in rheumatoid arthritis (RA), which is the most common rheumatic disease. RA patients experience more frequent nocturnal awakenings and lower sleep efficiency compared to healthy individuals.<sup>[1]</sup> Although the direct cause of sleep disturbances in RA patients is unclear, the possible causes are joint pain, sleep apnea, and depression.<sup>[2,3]</sup> Studies have also indicated an association between sleep disorders and fatigue,<sup>[4,5]</sup> which is a major concern for RA patients.<sup>[6]</sup> Although physical activity and psychosocial therapy have minimal beneficial effects on managing fatigue in RA patients, no other effective interventions have been identified.<sup>[7]</sup>

Sjogren syndrome is a chronic systemic autoimmune disorder characterized by lymphocytic infiltration of the exocrine glands. Sjogren syndrome can occur alone (primary Sjogren syndrome [pSS]) or secondary to another autoimmune disease.<sup>[8]</sup> pSS affects 0.5% to 1% of the general population, and 90% of pSS patients are women, the majority of which are postmenopausal women in their mid-50s.<sup>[8,9]</sup> The classical manifestations of pSS are dryness of the mouth and eyes; however, non-exocrine symptoms are also common. Moreover, 70% of pSS patients experience fatigue,<sup>[10–12]</sup> which is correlated with poor health-related quality of life (HR-QOL).<sup>[13]</sup> Similar to RA, fatigue is associated with impaired sleep quality in pSS patients.<sup>[14]</sup> Therefore, it is essential to identify and treat pSS patients with sleep disturbances and fatigue to improve their overall HR-QOL.

Although several studies have described sleep disturbances in pSS patients compared to those in healthy subjects,<sup>[15]</sup> most employed self-reported measures of sleep quality. However, it is necessary to include both subjective and objective measurements to obtain a comprehensive assessment of sleep. A few studies used polysomnography as an objective indicator of sleep have reported conflicting findings.<sup>[16–18]</sup> Although polysomnography is the gold standard for measuring sleep, it is expensive, may disrupt sleep, and is performed in a controlled laboratory environment for a limited time. Therefore, more detailed assessments of pSS patients' sleep that use objective measures are needed. In contrast to polysomnography, actigraphs, which are wristwatch-like instruments, support large-scale, inexpensive, and unobtrusive sleep measurements at a subject's home over an extended period of time. Actigraphs assess sleep and waking states using an accelerometer to measure wrist movements and have been reliably used in several sleep studies.<sup>[19,20]</sup>

In this cross-sectional observational study, we evaluated fatigue, HR-QOL, and sleep quality in patients with pSS and RA and compared them with those of healthy controls using both self-reporting and wrist actigraphy methods.

## 2. Materials and methods

### 2.1. Subjects

All the subjects were community-dwelling women living in Japan, aged 40 to 75 years old. The pSS patients were recruited from Japan's Sjogren's Patients Association between December 2014 and December 2016, while a local clinic referred patients with RA. Only patients who underwent regular medical checkups by their primary physicians were included in this study. Healthy

women within the target age range (40–75 years old) were publicly recruited. Patients with complications from other autoimmune diseases and healthy subjects with chronic diseases were excluded from the study; no patients included in the study had comorbidities. A portion of enrolled RA patients were on steroids; no other relevant medications were noted. The individuals who found it difficult to answer the Japanese questionnaire, did not participate in actigraphy collection, or did not provide actigraphy data were excluded.

This study was conducted in accordance with the Declaration of Helsinki (October 2013) and the Ethical Guidelines for Medical and Health Research Involving Human Subjects (revised on July 31, 2008). This study was conducted after obtaining approval from the ethics committee of the affiliated institution (Tokyo Women's Medical University: Approval No. 3290-R). Written and verbal explanations were provided to the study participants, and written informed consent was obtained.

### 2.2. Data collection

**2.2.1. Questionnaire survey.** Upon reporting to our facility, patients completed a questionnaire for demographic information including age, diagnosis, marital status, employment status, whether the subject lived alone, and whether the subject took part in social activities. Current physical symptoms, including dry mouth, dry eyes, dry skin, joint pain, and fatigue, were assessed using scores on a Likert scale, ranging from 0 (no distress) to 3 (fairly distressed).

Additionally, the questionnaire used the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J)<sup>[21,22]</sup> to subjectively measure sleep quality and disturbances over the past month. The PSQI-J has 19 measures that comprise 7 components of sleep quality (subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep medication, and daytime dysfunction). The 7 component scores (0–3) were added to calculate the total PSQI-J score (0–21). Higher scores indicate worse sleep quality and can distinguish “poor” sleepers (PSQI total score  $\geq 6$ ) from “good” sleepers (PSQI total score  $< 6$ ).<sup>[23]</sup>

The HR-QOL was assessed using the Medical Outcomes Study: Short Form-36 (SF-36).<sup>[24,25]</sup> The SF-36 is a comprehensive scale assessing the following 8 domains during the preceding 4 weeks: physical functioning, social functioning, role limitations due to physical functioning, role limitations due to emotional functioning, mental health, vitality, bodily pain, and general health. Each domain is scored 0 to 100, with 100 being the best possible functioning; therefore, a higher SF-36 score indicates a higher HR-QOL. The Sf36v2 scoring program (iHope International) was used to score the SF-36 and to calculate the summary scores reflecting the subjects' physical, mental, and social functioning.

**2.2.2. Sleep activity measurement.** The subjects wore a Motionlogger Actigraph manufactured by Ambulatory Monitoring Inc. (AMI, Ardsley, NY) for 24 hours a day over a period of 14 days to objectively measure sleep activity. Actigraph data were analyzed using specialized software (Action-W, AMI, Ardsley, NY) for the following parameters: total sleep duration, sleep efficiency (percentage of time spent sleeping), number and duration of nocturnal awakenings, and sleep latency (the time taken to fall asleep). A higher sleep efficiency indicated better sleep quality.

**2.2.3. Sleep diary.** The subjects maintained sleep diaries during the 14-day actigraphy measurement period. On each day, the

**Table 1****Demographic characteristics of patients with primary Sjogren syndrome (pSS), rheumatoid arthritis (RA), and healthy controls.**

	Controls (n=17)	pSS (n=25)	RA (n=10)	P value
Age, years, mean (SD)	51.3 (2.1)	56.8 (1.8)	59.1 (2.8)	.05*
Disease duration, years, mean (SD)	NA	9.2 (7.4)	9.3 (9.2)	.97*
Married, no. (%)	12 (70.6)	20 (80)	7 (70)	.72**
Living alone, no. (%)	4 (23.5)	3 (12)	3 (30)	.41**
Has social activity, no. (%)	7 (41.2)	13 (52)	6 (60)	.58**
Current employed, no. (%)	16 (94.1)	14 (56)	5 (50)	.01**

\* P value based on ANOVA comparison of controls vs pSS vs RA.

\*\* P value based on chi-squared comparison of controls vs pSS vs RA.

subjects rated their quality of sleep based on how they felt upon waking and rated fatigue based on how tired they felt at the end of the day. Both were scored using a 10-cm visual analog scale (VAS),<sup>[26]</sup> with 0cm indicating “not refreshed” and 10cm indicating “very refreshed”. The average daily scores were calculated for each subject.

### 2.3. Statistical analyses

The Shapiro-Wilk test was used to assess the normality of distribution for continuous variables. The age and disease duration of the subjects were compared using a one-way analysis of variance. For all other demographic data, comparisons were made using the Pearson  $\chi^2$  test. As fatigue and sleep quality differ with age,<sup>[27]</sup> the remaining data were analyzed using an analysis of covariance, with age and employment status as covariates. The employment status, which varied among the groups, was also adjusted for. Multiple comparisons between the patients with pSS and RA to healthy controls were performed using the Dunnett test. The correlation between fatigue and the sleep quality was determined using Pearson correlation. The sample size was determined based on previous studies to detect an effect size of 0.90 with 80% power to confirm a 2-sided significance level of 5%. JMP software (version 14, SAS Institute Inc.) was used for all statistical analyses and 2-tailed P values less than .05 were considered statistically significant.

## 3. Results

### 3.1. Subject characteristics and symptoms

A total of 20 healthy control subjects, 28 pSS patients, and 12 RA patients completed the questionnaire. However, 3 healthy subjects, 3 pSS patients, and 2 RA patients did not participate in the actigraphy assessment and were therefore excluded from the study. The clinical and demographic characteristics of the remaining 17 healthy subjects, 25 pSS patients, and 10 RA patients are shown in Table 1. The average ages of the RA group [59.1 (standard deviation, SD 2.8)] and pSS group [56.8 (SD 1.8)] were slightly higher than that of the healthy control group [51.3 (SD 2.1),  $P=.05$ ] but not statistically significant. There were no significant differences in the average duration of disease, whether the subjects lived alone, or had social activity among the 3 groups. However, only 56% and 50% of patients in the pSS and RA groups, respectively, were employed compared to 94.1% of subjects in the healthy control group ( $P=.01$ ).

At the time of the questionnaire, the patients with pSS, but not RA, experienced significantly more severe dry mouth, dry eye, and movement restriction than healthy controls (Table 2). Although there was a trend toward an increase in the average severity of joint pain in the pSS and RA patients compared to that in the healthy controls, this difference was not significant.

**Table 2****Current disease symptoms of patients with primary Sjogren syndrome (pSS), rheumatoid arthritis (RA), and healthy controls.**

	Controls (n=17)	pSS (n=25)	RA (n=10)	P value* ANCOVA	P value** pSS-Ctr	P value** RA-Ctr
Dry mouth symptoms						
Dry mouth	0.2 (0.2)	2.1 (0.2)	0.3 (0.3)	<.001	<.001	.85
Saliva stickiness	0.2 (0.2)	1.5 (0.1)	0.3 (0.2)	<.001	<.001	.83
Pain inside the mouth	0.1 (0.2)	1.3 (0.1)	0 (0.2)	<.001	<.001	.72
Dry eye symptoms						
Inability to tear	0.1 (0.2)	2.0 (0.2)	0.1 (0.2)	<.001	<.001	>.99
Eye fatigue	0.7 (0.2)	2.3 (0.2)	1.1 (0.2)	<.001	<.001	.32
Difficulty opening eyes when awakening	0.1 (0.2)	1.3 (0.2)	0 (0.2)	<.001	<.001	.74
Other symptoms						
Dry skin	0.8 (0.2)	1.3 (0.2)	0.7 (0.3)	.04	.09	>.99
Joint pain	0.3 (0.2)	1.1 (0.2)	1.0 (0.3)	.08	.02	.14
Movement restriction	0.2 (0.2)	1.2 (0.1)	0.6 (0.2)	<.001	<.001	.38
Nighttime incontinence	0.4 (0.2)	1.1 (0.2)	0.4 (0.3)	.01	.08	.97

Likert scale range: 0 to 3; data are represented by the mean (SE).

\* P value based on analysis of covariance (ANCOVA) comparison of all 3 groups.

\*\* P values based on Dunnett test compared to the control group.

**Table 3****Health-related quality of life (HR-QOL) as measured by the Short Form-36 (SF-36) and fatigue-related outcomes for patients with rheumatoid arthritis (RA), primary Sjogren syndrome (pSS), and healthy controls.**

	Controls (n=17)	pSS (n=25)	RA (n=10)	P value* ANCOVA	P value** pSS-Ctr	P value** RA-Ctr
<b>HR-QOL (SF-36)</b>						
Physical function	86.0 (4.3)	79.0 (3.1)	76.6 (5.0)	.08	.31	.27
Role – physical	88.6 (6.2)	60.8 (4.5)	82.8 (7.1)	.001	<.001	.76
Body pain	82.2 (6.4)	63.2 (4.7)	61.0 (7.4)	.06	.04	.06
General health	76.4 (3.8)	39.0 (2.8)	54.0 (4.3)	<.001	<.001	.001
Social function	86.3 (5.9)	65.0 (4.3)	84.7 (6.7)	.01	.01	.98
Role – emotional	86.3 (6.3)	65.1 (4.6)	84.3 (7.3)	.04	.014	.97
Mental health	77.7 (5.3)	54.9 (3.9)	69.6 (6.1)	.01	.001	.51
PCS	51.5 (2.9)	44.3 (2.1)	40.2 (3.3)	.01	.10	.03
MCS	56.6 (2.4)	41.7 (1.7)	49.1 (2.7)	<.001	<.001	.08
RCS	45.8 (3.9)	39.6 (2.8)	51.6 (4.5)	.16	.33	.51
<b>Fatigue</b>						
Vitality (SF-36)	68.9 (5.4)	37.5 (3.9)	58.7 (6.2)	<.001	<.001	.37
Fatigue (VAS)	67.9 (6.2)	39.1 (4.4)	50.8 (6.9)	.01	.001	.13
Easy to get fatigue every day (Likert)	0.6 (0.2)	1.9 (0.2)	1.2 (0.2)	<.001	<.001	.14
Difficulty doing housework (Likert)	0.2 (0.2)	1.6 (0.2)	0.7 (0.3)	<.001	<.001	.22

Likert scale range: 0 to 3; data are represented by the mean (SE).

PCS = physical component summary, MCS = mental component summary, RCS = role component summary, VAS = visual analog scale (range: 0–100)

\* P value based on analysis of covariance (ANCOVA) comparison of all 3 groups.

\*\* P values based on Dunnett test compared to the control group.

### 3.2. Quality of life and fatigue assessment

The assessment of HR-QOL by SF-36 is shown in Table 3. Compared to the healthy controls, the patients with pSS exhibited significant impairment in the HR-QOL as demonstrated by lower average SF-36 scores in role limitations due to physical functioning, role limitations due to emotional functioning, vitality, mental health, social function, body pain, general health, and the mental component summary. There were no significant differences in the physical component summary scores of patients with pSS. In contrast, the patients with RA exhibited significantly lower average general health and physical component summary scores than healthy controls. There were no significant differences in the physical function or role component summary scores among the 3 groups.

As shown in Table 3, we evaluated fatigue based on the SF-36 vitality score, whether the participants experienced tiredness at

the end of the day (using a VAS), and a 4-point Likert scale score on the questionnaire. The pSS patients had a significantly lower average SF-36 vitality score and felt more tired at the end of the day than healthy controls. They also scored higher on the fatigue-related questions of the questionnaire than healthy controls. Notably, the RA patients did not differ significantly from healthy controls in any of the fatigue-related measures. These data indicate that the patients with pSS, but not RA, experience more fatigue than healthy individuals.

### 3.3. Subjective and objective comparisons of sleep quality

We analyzed sleep quality subjectively using the PSQI-J and VAS (Table 4). The mean total PSQI-J score of the pSS patients was 6.9 (standard error, SE 0.6), and the prevalence of poor sleepers (PSQI  $\geq$  6) was 56%, which was higher than that in healthy

**Table 4****Sleep quality assessment for patients with rheumatoid arthritis (RA), primary Sjogren syndrome (pSS), and healthy controls by self-report and wrist actigraphy.**

	Controls (n=17)	pSS (n=25)	RA (n=10)	P value* ANCOVA	P value** pSS-Ctr	P value** RA-Ctr
<b>Self-report</b>						
Total PSQI-J	4.0 (0.9)	6.9 (0.6)	4.6 (1.0)	.060	.02	.87
PSQI-J $\geq$ 6, no (%)	5 (29.4)	14 (56)	3 (30)	.15 <sup>#</sup>	—	—
Sleep – VAS	63.7 (5.3)	40.5 (3.8)	46.1 (6.0)	.01	.001	.06
<b>Actigraphy</b>						
Activity (counts/min)	199.3 (6.7)	202.4 (4.8)	202.1 (7.7)	.99	.89	.95
Naps (no.)	2.2 (0.6)	3.0 (0.5)	2.7 (0.8)	.62	.52	.83
Total sleep time (min)	426.5 (17.0)	421.8 (12.3)	415.5 (19.5)	.36	.96	.88
Sleep efficiency (%)	96.4 (0.8)	95.2 (0.6)	94.1 (0.9)	.23	.33	.10
Awakenings (no.)	0.9 (0.2)	1.4 (0.2)	1.7 (0.2)	.05	.11	.04
WASO (min)	16.1 (3.6)	22.4 (2.6)	25.5 (4.1)	.25	.26	.16
Sleep latency (min)	6.0 (0.7)	5.6 (0.5)	2.9 (0.8)	.03	.85	.01

Data are represented by the mean (SE) unless otherwise stated.

PSQI-J = Pittsburgh Sleep Quality Index (range: 0–21), VAS = visual analog scale, WASO = wake after sleep onset.

\* P value based on analysis of covariance (ANCOVA) comparison of all 3 groups.

\*\* P values based on Dunnett test compared to the control group.

<sup>#</sup> P value based on chi-squared test.

**Table 5**  
**Correlation of fatigue-related outcomes with subjective and objective measures of sleep quality for patients with primary Sjogren syndrome (pSS).**

	Subjective: total PSQI-J		Objective: sleep efficiency (actigraph)	
	r	P value*	r	P value*
Fatigue outcome				
Vitality (SF-36)	-0.48	.01	-0.36	.07
Fatigue (VAS)	-0.40	.05	-0.34	.10
Easy to get fatigue every day (Likert)	0.45	.02	-0.11	.59
Difficulty doing housework (Likert)	0.52	.01	0.13	.52

PSQI-J = Pittsburgh Sleep Quality Index, r = Pearson correlation coefficient, SF-36 = Short Form-36, VAS = visual analog scale.

\* P value based on Pearson correlation.

controls [4.0% (SE 0.9) and 29.4%, respectively]. In addition, the pSS patients did not feel as refreshed on waking, as indicated by a significantly lower average score on the VAS than the healthy controls. The average total PSQI-J score, frequency of poor sleepers, and VAS score did not differ between the RA patients and healthy controls. In summary, the subjective measures of sleep quality revealed that patients with pSS, but not RA, experience inferior sleep quality compared to the healthy controls.

We used wrist actigraphy as an objective measure of sleep quality (Table 4). The subjects wore the actigraph for an average of 12.9 (SE 2.3) days. There were no differences among the 3 groups in the number of days the subjects wore the device ( $P = .46$ , data not shown). Notably, all 3 groups demonstrated high sleep efficiencies (the percentage of time in bed asleep) with average frequencies of 95.2% (SE 0.6), 94.1% (SE 0.9), and 96.4% (SE 0.8) in the pSS patients, RA patients, and healthy controls, respectively. In addition, the pSS patients did not differ in their total sleep time, number and duration of nocturnal awakenings, or sleep latency (the time it takes to fall asleep). The RA patients experienced a slight increase in the number of nocturnal awakenings, but had a lower sleep latency, although this differed by only a few minutes.

Subsequently, we analyzed the association between fatigue and subjective and objective assessments of sleep in the pSS patients (Table 5). We found moderate, yet statistically significant, correlations between the total PSQI-J score and all of the evaluated fatigue outcomes, including SF-36 vitality, the VAS for fatigue, and the Likert scales for fatigue. These data suggest a positive correlation between subjective sleep quality (as identified by a higher total PSQI-J score) and fatigue. Notably, the sleep efficiency score measured by actigraphy did not statistically correlate with any of the fatigue outcomes.

#### 4. Discussion

In this study, we evaluated HR-QOL, fatigue, and sleep quality using subjective and objective assessments in pSS and RA patients as compared to healthy controls. This is the first study to our knowledge to use wrist actigraphy to compare sleep quality between pSS patients and healthy controls. We found that pSS patients experienced more severe fatigue and poor HR-QOL compared to the healthy controls. Although subjective assessments of sleep revealed impaired sleep quality in pSS, the results from wrist actigraphy showed no differences. It is notable that the RA patients did not experience severe fatigue, lower HR-QOL, or self-reported sleep disturbances.

Consistent with other studies,<sup>[11]</sup> the pSS patients experienced more fatigue than healthy controls, as evidenced by lower SF-36 vitality, increased tiredness at the end of the day, and increased difficulty in doing housework due to fatigue. Additionally, we analyzed the HR-QOL as fatigue is associated with a poor HR-QOL in pSS patients.<sup>[13]</sup> We found that the pSS patients scored lower than healthy controls on all subdomains of the SF-36, except for physical function; statistically significant differences were not observed for RA patients. Specifically, the patients with pSS exhibited a significantly lower mental component summary score, indicating worse mental health than healthy controls.

The pSS patients reported worse sleep quality compared to healthy controls, as demonstrated by a higher total PSQI-J score. Based on the total PSQI-J score, 56% of pSS patients were classified as “poor” sleepers compared to 29.4% of healthy controls and 30% of RA patients, which is consistent with a previous study.<sup>[28]</sup> In addition, pSS patients woke up less refreshed compared to the healthy control group, indicating worse sleep. In contrast, in the objective assessment using wrist actigraphy, no significant difference was observed between pSS patients and healthy controls in terms of total sleep duration, sleep efficiency, duration and number of nocturnal awakenings, and sleep latency. This result differs from previous reports that subjectively measured the sleep profile of pSS patients and found that they frequently experience difficulty in falling back to sleep and have reduced sleep efficiency.<sup>[28,29]</sup> In addition, consistent with other studies,<sup>[14]</sup> we found statistically significant positive correlations between impaired sleep quality (as measured by the total PSQI-J score) and fatigue, although the strength of these correlations was moderate. Yet, sleep efficiency (as measured by wrist actigraphy) did not correlate with fatigue, highlighting the discrepancy between objective and subjective measures of sleep.

Wrist actigraphy data correlate with polysomnography data in healthy individuals.<sup>[30]</sup> However, some patients with chronic conditions have decreased activity and movement when awake at night, resulting in an overestimation of sleep by actigraphy.<sup>[31]</sup> In our study, the pSS patients reported more severe movement restriction when compared to healthy controls, suggesting that the discrepancy between subjective and objective sleep measures may be a result of inaccurate actigraphy results. This could result in a higher sleep efficiency and a lower number and duration of awakenings. Previous studies determined the sleep efficiency of pSS patients using actigraphy to be 86% and 89.7%, respectively.<sup>[32,33]</sup> Although the sleep efficiency of the pSS patients in our study was slightly higher (95.2%), polysomnography results determined the sleep efficiency of pSS patients to be 70%.<sup>[18]</sup> Further studies using alternative actigraphs, such as

those that utilize small pressure sensors to detect changes in muscle tone, may provide more detailed results for pSS patients.

Although actigraphy revealed a slightly higher number of nocturnal awakenings in the RA patients, consistent with the results of polysomnographic studies,<sup>[11]</sup> the RA patients did not report worse sleep quality or fatigue. This is consistent with a recent study, which found that RA was not correlated with poor sleep in male patients aged 65 years or older using a sleep health score measured by self-reporting and actigraphy.<sup>[34]</sup> Furthermore, in RA, sleep disturbances are thought to primarily stem from pain and depression.<sup>[3]</sup> Although RA patients had a significantly lower SF-36 physical component summary score than healthy controls in this study, they did not report more severe joint pain or impaired mental health, as evidenced by a similar SF-36 mental component summary score. We hypothesize that, overall, the RA patients were not experiencing sufficiently severe disease to affect their sleep patterns at the time of analysis.

The cause of fatigue in pSS patients is still unknown, and current interventions for managing fatigue are insufficient.<sup>[35]</sup> Our study and others<sup>[14]</sup> have identified associations between fatigue and sleep quality, suggesting that sleep management may be necessary for treating symptoms of fatigue. Cognitive behavioral therapy for insomnia improves sleep, fatigue, and QOL in patients with fibromyalgia,<sup>[36]</sup> suggesting that it could be effective in treating these symptoms in patients with pSS. In addition, long-term hydroxychloroquine treatment is associated with reduced sleep disturbance and higher QOL in patients with pSS.<sup>[37]</sup>

This study has a few limitations. First, our sample size was small as it was difficult for people to adapt to wearing an actigraph. Additionally, we only evaluated Japanese patients, and these findings may not be generalizable to other populations. Thus, future studies with a larger number of patients across different populations are needed to confirm our findings. Second, we could not obtain the medical data for these patients and did not determine the disease activity score as well as other parameters,<sup>[38]</sup> which could be confounding factors for poor sleep. Third, this subjective analysis of sleep relied on self-reports, which may have allowed for response bias. Finally, all of the subjects were women; however, this reflects the general pSS patient population, 90% of whom are women.<sup>[9]</sup>

This is the first study to compare sleep quality between patients with pSS and healthy controls using both self-reports and wrist actigraphy. We confirmed the presence of sleep disturbances, fatigue, and poor HR-QOL in pSS patients using subjective assessments. However, wrist actigraphy did not detect impaired sleep quality, suggesting that it is not the best measure of sleep in these patients. Of note, RA patients did not show significant differences in fatigue or sleep quality, whereas the number of awakenings and sleep latency as measured by actigraphy were different from healthy controls. Indeed, fatigue and sleep impairment have been found to be multifactorial in RA, depending on multiple aspects of the patient's mental and physical health.<sup>[39,40]</sup> Therefore, future study with larger population sizes is needed to evaluate the discrepancy between these 2 rheumatic diseases. The identification of effective tools to objectively analyze sleep quality in pSS and RA patients is crucial to treating their sleep disturbances and fatigue to improve their overall QOL.

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