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Psychometric properties of a single-item scale to assess sleep quality among individuals with fibromyalgia

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Abstract

Background: Sleep disturbances are a common and bothersome symptom of fibromyalgia (FM). This study reports psychometric properties of a single-item scale to assess sleep quality among individuals with FM.

Methods: Analyses were based on data from two randomized, double-blind, placebo-controlled trials of pregabalin (studies 1056 and 1077). In a daily diary, patients reported the quality of their sleep on a numeric rating scale ranging from 0 ("best possible sleep") to 10 ("worst possible sleep"). Test re-test reliability of the Sleep Quality Scale was evaluated by computing intraclass correlation coefficients. Pearson correlation coefficients were computed between baseline Sleep Quality scores and baseline pain diary and Medical Outcomes Study (MOS) Sleep scores. Responsiveness to treatment was evaluated by standardized effect sizes computed as the difference between least squares mean changes in Sleep Quality scores in the pregabalin and placebo groups divided by the standard deviation of Sleep Quality scores across all patients at baseline.

Results: Studies 1056 and 1077 included 748 and 745 patients, respectively. Most patients were female (study 1056: 94.4%; study 1077: 94.5%) and white (study 1056: 90.2%; study 1077: 91.0%). Mean ages were 48.8 years (study 1056) and 50.1 years (study 1077). Test re-test reliability coefficients of the Sleep Quality Scale were 0.91 and 0.90 in the 1056 and 1077 studies, respectively. Pearson correlation coefficients between baseline Sleep Quality scores and baseline pain diary scores were 0.64 ($p < 0.001$) and 0.58 ($p < 0.001$) in the 1056 and 1077 studies, respectively. Correlations between the Sleep Quality Scale and the MOS Sleep subscales were statistically significant ($p < 0.01$), except for the MOS Snoring subscale. Across both studies, standardized effect sizes were generally moderate (0.46 to 0.52) for the 300 mg group and moderate (0.59) or moderate-to-large (0.70) for the 450 mg group. In study 1056, the effect size for the 600 mg group was moderate-to-large (0.73). In study 1077, the effect size for the 600 mg group was large (0.82).

Conclusion: These results provide evidence of the reproducibility, convergent validity, and responsiveness to treatment of the Sleep Quality Scale and provide a foundation for its further use and evaluation in FM patients.

Background

The American College of Rheumatology (ACR) defines fibromyalgia syndrome (FM) using two criteria: (1) chronic widespread pain and (2) pain upon digital palpation in at least 11 of 18 defined tender point sites [1,2]. Common co-morbid symptoms associated with FM include sleep disturbances, fatigue, morning stiffness, affective disorders, chronic daily headache, dyscognition, irritable bowel syndrome, and irritable bladder [3]. In a series of focus group and ranking exercises, clinical experts and patients agreed that while pain is the cardinal symptom of FM, it is important to also assess fatigue, impact on sleep, health-related quality of life, depression, and cognitive difficulties [4]. Assessing the effectiveness of new therapies therefore requires accurate assessment of a multidimensional array of symptoms and problems.

This paper focuses on the measurement of sleep problems in patients with FM. Disturbed sleep is consistently ranked by patients as a highly bothersome symptom of the disease [5,6]. While FM patients report that pain interferes with their sleep, recent studies also suggest a reciprocal relationship. Specifically, sleep quality is predictive of pain as well as broader areas of functioning and emotional well-being such as fatigue, social functioning, and depression [7,8].

While multiple-item, patient-reported surveys are available to measure specific sleep problems, single-item assessments of overall sleep quality provide a useful summary measure and are frequently included in research on FM [9]. Single-item sleep quality assessments allow patients to implicitly weight the various components of sleep that are important to them and assign an overall rating based on their individual rankings and experiences. While rankings and experiences will vary, it is likely that there is a common set of key components that constitute overall sleep quality. A recent study of the subjective meaning of sleep quality among individuals with insomnia and normal sleepers found that both groups similarly defined sleep quality as tiredness on waking and throughout the day, feeling rested and restored on waking, and the number of awakenings experienced in the night [10].

Single-item sleep quality assessments are practical when measurements are taken at frequent intervals, such as in patient diaries that are completed every day. Sleep diaries are reliable and valid assessments for capturing such patient-reported outcomes and reduce recall bias since they are collected on a daily basis [11]. This study reports psychometric properties of a single-item Sleep Quality numeric rating scale completed by FM patients daily in two clinical trials.

Methods

Study design and subjects

This paper reports the psychometric properties of the daily diary Sleep Quality Scale using data from two randomized, double-blind, placebo-controlled clinical trials of pregabalin conducted in the United States (US), referred to here as studies 1056 [12] and 1077 [13]. The study designs for these trials have been described elsewhere [12,13]. The studies were randomized, double-blind, and placebo-controlled clinical trials of three doses of pregabalin (300 mg/day, 450 mg/day, and 600 mg/day). Patients were 18 years of age or older with FM as defined by the ACR criteria [1,2].

During the baseline phase, study patients had to have an average daily diary pain score of at least 4 (within the last 7 days) on a numeric rating scale ranging from 0 ("no pain") to 10 ("worst possible pain"). Further, study patients had to have a score of at least 40 mm on the 100 mm visual analogue scale (VAS) of the Short-Form McGill Pain Questionnaire [14] at the screening and baseline (randomization) study visits. In study 1077, patients with a 30% or greater reduction in the VAS from the screening to the randomization study visits (a single-blind placebo run-in period) were discontinued; this criterion in study 1077 was intended to exclude potential placebo responders. In both studies, the primary efficacy measure was endpoint mean pain score defined as the mean of the last 7 pain diary entries while the patient was on study medication.

The Sleep Quality Scale

In the daily diary assessment, patients reported the quality of their sleep over the past 24 hours on an 11-point numeric rating scale ranging from 0 ("best possible sleep") to 10 ("worst possible sleep"). Patients were instructed to complete the scale in the morning upon awakening. The baseline scores were computed as the average rating over the 7 days prior to taking study medication. The end of treatment score was computed as the average rating over the last 7 days during which the patient was receiving study medication. Since higher scores indicate poorer sleep, negative change scores (end of treatment score minus baseline score) indicate improvement.

The MOS Sleep Scale

The studies also included a validated sleep survey, the MOS Sleep Scale [15-17]. The MOS Sleep Scale provided 6 subscale scores (Sleep Disturbance, Snoring, Awakening Short of Breath or with a Headache, Quantity of Sleep, Sleep Adequacy, and Somnolence) and an overall Sleep Problems Index score [15]. The Quantity of Sleep subscale score documented the number of hours of sleep per night (possible range from 0 to 24 hours). The remaining scale

scores ranged from 0 to 100 where higher scores indicated greater sleep dysfunction, except for the Sleep Adequacy subscale where higher scores reflected more adequate sleep.

Statistical methods

Test re-test reliability and convergent validity analyses of the Sleep Quality Scale were obtained from all available study patients across all treatment groups. Test re-test reliability of the Sleep Quality scores were evaluated using pre-treatment data. Intraclass correlation coefficients (ICC) based on the daily assessments were computed and the Spearman-Brown Prophecy formula was used to calculate the reliability of the Sleep Quality score (average of 7 daily assessments) [18,19]. Reliability coefficients less than or equal to 0.70 were considered unacceptable; coefficients between 0.70 and 0.90 were considered acceptable; and coefficients of 0.90 or higher were considered excellent levels of test re-test reliability [20].

Convergent validity analyses were evaluated using baseline data. Baseline Sleep Quality scores were correlated with baseline pain diary and baseline MOS Sleep scores using Pearson correlation coefficients.

Treatment effects on the Sleep Quality Scale have been reported previously [12,13]. Treatment effects were based on analysis of covariance (ANCOVA) models of end-of-treatment Sleep Quality scores with treatment and center as factors and corresponding baseline Sleep Quality scores as covariates. The model-estimated least square mean change scores by treatment group were used in these analyses to compute effect sizes. Specifically, standardized effect sizes were computed as the difference between least squares mean changes in Sleep Quality scores in the pregabalin and placebo groups divided by the standard deviation of Sleep Quality scores across all patients at baseline. These effect sizes were interpreted (in absolute value) as follows: trivial (less than or equal to 0.20), small (0.20), moderate (0.50) and large (0.80) [21].

Results

Studies 1056 and 1077 included 748 and 745 patients, respectively. Most patients were female (94.4% in study 1056 and 94.5% in study 1077) and white (90.2% in study 1056 and 91.0% in study 1077) (Table 1). In study 1056, the mean age of patients was 48.8 years and the average duration of FM was 9 years. In study 1077, the mean age of patients was 50.1 years and the average dura-

Table 1: Baseline patient characteristics and sleep scores

Characteristics	Study 1056 (N = 748)		Study 1077 (N = 745)	
	n	%	n	%
Gender				
Male	42	5.6	41	5.5
Female	706	94.4	704	94.5
Race				
White	675	90.2	678	91.0
Black	35	4.7	33	4.4
Other	38	5.1	34	4.6
	N	**Mean ± SD**	**N**	**Mean ± SD**
Age (years)	748	48.8 ± 10.9	745	50.1 ± 11.4
Duration of FM Prior to Study Start (months)	747	111.7 ± 95.0	745	120.2 ± 96.2
Number of Painful Tender Points[a]	719	17.1 ± 1.6	723	16.9 ± 1.8
Baseline Mean Pain Score[b]	748	7.1 ± 1.3	745	6.7 ± 1.3
Sleep Quality Scale[b]	748	6.7 (1.7)	745	6.2 (1.6)
MOS Sleep Scales				
Sleep Disturbance	744	67.8 ± 23.4	740	60.0 ± 24.9
Snoring	726	40.6 ± 35.9	717	36.7 ± 34.6
Awaken Short of Breath or with Headache	744	37.6 ± 31.1	743	32.3 ± 32.0
Quantity of Sleep	747	5.4 ± 1.6	744	5.6 ± 1.6
Sleep Adequacy	745	20.6 ± 22.0	744	23.7 ± 23.2
Somnolence	743	50.3 ± 24.1	740	42.1 ± 23.1
Sleep Problems Index (9-item)	741	65.0 ± 16.3	736	58.3 ± 17.7

SD = Standard Deviation

[a] Total number of tender points with value >0 at randomization; the number is missing if any of 18 tender points is missing.

[b] Baseline = Last 7 available pain scores before taking study medication up to and including Day1. If fewer than 7 scores are available then baseline consists of all scores that are available.

tion of FM was 10 years. In both studies, baseline mean pain scores were approximately 7 on a scale from 0 ("no pain") to 10 ("worst possible pain").

Test re-test reliability coefficients of the pre-treatment Sleep Quality scores, averaged over seven daily measurements prior to study medication, were 0.91 and 0.90 in the 1056 and 1077 studies, respectively (Table 2). Reliability coefficients of this magnitude suggested excellent reproducibility [20].

Pearson correlation coefficients between baseline Sleep Quality scores and baseline average daily diary pain scores were 0.64 ($p < 0.001$) and 0.58 ($p < 0.001$) in the 1056 and 1077 studies, respectively (Table 3). Correlations between the Sleep Quality and the MOS Sleep Scale subscales were statistically significant ($p < 0.01$), except for the MOS Snoring subscale where no correlation was expected (Table 3). Correlations were largest for the MOS Sleep Disturbance subscale: 0.45 ($p < 0.001$) and 0.42 ($p < 0.001$) in studies 1056 and 1077, respectively (Table 3).

As reported previously, all three doses of pregabalin were associated with statistically significantly greater improvements in sleep quality relative to placebo in both the 1056 [12] and 1077 [13] studies. Our current analysis facilitates the interpretation of the magnitude of those treatment differences by reporting effect sizes that were evaluated relative to accepted benchmarks. Across both studies, standardized effect sizes were generally moderate (0.46 to 0.52) for the 300 mg group and moderate (0.59) or moderate-to-large (0.70) for the 450 mg group (Table 4). In study 1056, the effect size for the 600 mg group was moderate-to-large (0.73). In study 1077, the effect size for the 600 mg group was large (0.82).

Discussion

These results suggest that the Sleep Quality Scale has favorable measurement properties. Consistent with the clinical profile of FM, patients' baseline MOS Sleep scores were substantially poorer than the general population values on MOS Sleep scores for Sleep Disturbance (24.5), Snoring (28.3), Awaken Short of Breath or with Headache (9.5), Quantity of Sleep (6.8 hours), Somnolence (21.9), and Sleep Problems Index II (25.8) [16,17]. Test re-test reliability of pre-treatment scores was excellent in both trials. The Sleep Quality Scale was correlated with pain and with relevant aspects of another sleep assessment, the MOS Sleep Scale. Further, the Sleep Quality scale was responsive to treatment effects.

The observed correlations between Sleep Quality scores and pain (0.58 to 0.64) were large and larger than those reported in previous FM studies (0.32 to 0.33) [7,8]. The earlier studies used multi-item sleep quality and pain scales, specifically the Pittsburgh Sleep Quality Index (PSQI) to assess sleep quality and the McGill Pain Questionnaire [8] and SF-36 Bodily Pain scale [7] to assess pain. In the current study, sleep quality and pain were based on single-item, 11-point, numeric rating scales reported by patients in daily diaries.

While these findings support continued applications of the Sleep Quality Scale in FM, we note three areas for further research. First, this study does not address how FM patients define sleep quality. While the p-values for the Pearson correlation coefficient are restricted to the null hypothesis of zero correlation, not to the strength of the correlation, the magnitude of the correlations between the Sleep Quality Scale and the MOS Sleep Scale provides some insights into the specific components of sleep that these patients considered when evaluating the overall quality of their sleep. Specifically, Sleep Quality showed a moderate correlation with MOS Sleep Disturbance, which includes questions about trouble falling asleep, the amount of time to fall asleep, restlessness, and awakening during sleep; a moderate correlation with MOS Quantity of Sleep; a modest correlation with MOS Sleep Adequacy; a small correlation with MOS Somnolence and MOS Awaken Short of Breath or with Headache; and no correlation with MOS Snoring. Qualitative research among FM patients is underway to confirm these findings and to further understand how FM patients evaluate sleep quality.

Second, these clinical trial patients were experiencing fairly high levels of pain and may not be necessarily representative of all FM patient populations; although the patients studied here embody many patients with FM. Consistent with FM being more common in women (3.4%) compared with men (0.5%) [22], the vast majority

Table 2: Test re-test reliability of pre-treatment Sleep Quality Scale scores

Study	Between-Subjects Error Variance	Within-Subject Error Variance	ICC of a Single Daily Score	ICC for the Average of Seven Daily Scores
1056	2.40	1.68	0.59	0.91
1077	2.23	1.69	0.57	0.90

ICC = Intraclass Correlation Coefficient = (Between-Subjects Error Variance)/(Between-Subjects Error Variance + Within-Subject Error Variance)
ICC for the Average of Seven Daily Scores = 7(ICC for single score)/[1 + 6(ICC for a single score)]

Table 3: Baseline correlations of the Sleep Quality Scale with pain and the MOS Sleep Scale

	Pearson Correlation (r) with Sleep Quality Scale (-)			
	Study 1056		Study 1077	
	r	p-value	r	p-value
Average Daily Diary Pain Numeric Rating Scale (-)	0.64	<0.001	0.58	<0.001
MOS Sleep Scales				
Sleep Disturbance (-)	0.45	<0.001	0.42	<0.001
Snoring (-)	0.01	0.884	0.00	0.993
Awaken Short of Breath or with Headache (-)	0.21	<0.001	0.14	<0.001
Quantity of Sleep (+)	-0.31	<0.001	-0.34	<0.001
Sleep Adequacy (+)	-0.21	<0.001	-0.32	<0.001
Somnolence (-)	0.11	0.004	0.15	<0.001

(-) Higher scale scores indicate poorer outcome. (+) Higher scale scores indicate better outcome.

Table 4: Treatment differences and effect sizes for the Sleep Quality Scale

Pregabalin Dose Group	Treatment Comparison (Pregabalin – Placebo)[a]			Effect Size[a]
	Difference	95% CI	p-value	
Study 1056				
300 mg	-0.86	-1.30, -0.43	0.0001	-0.521
450 mg	-0.97	-1.40, -0.53	<0.0001	-0.587
600 mg	-1.21	-1.64, -0.77	<0.0001	-0.732
Study 1077				
300 mg	-0.73	-1.14, -0.31	0.0007	-0.458
450 mg	-1.12	-1.54, -0.71	<0.0001	-0.703
600 mg	-1.31	-1.73, -0.90	<0.0001	-0.822

CI = Confidence Interval

[a]Higher Sleep Quality scores indicate poorer sleep quality. Therefore a negative difference between pregabalin and placebo and negative effect size indicates a greater improvement in sleep quality for patients receiving pregabalin relative to those receiving placebo.

of patients in this sample were women. Study patients also had a long history of FM, averaging 9 to 10 years. Therefore the clinical and demographic profiles of these samples reflect those mainly of women with about a decade of experience with FM. Applications in real-world settings and within subpopulations of patients, such as children with FM [23], menopausal women with FM [24], and those with newly diagnosed FM [25], would provide additional insight into the impact of FM on sleep quality.

Finally, exploration of frequent comorbid conditions, such as obstructive sleep apnea, and the co-variation of sleep quality and pain merit further study [22,26,27].

Conclusion

This investigation is a psychometric analysis of a single-item, overall rating of sleep quality for patients with FM. Single-item scales reduce patient burden, particularly when repeated assessments are necessary, such as for ratings recorded in a daily diary. The results of this investigation suggest that the single-item Sleep Quality Scale has favorable measurement properties; namely, these results provide evidence of its reproducibility, convergent validity, and responsiveness to treatment as an overall rating of sleep in two clinical trials. To assess specific areas of sleep, the trials included a multi-item sleep assessment, the MOS Sleep Scale, which also demonstrated favorable psychometric properties in this setting [17]. This paper provides the foundation for further use and evaluation of the Sleep Quality Scale in FM patients, for which sleep disturbances are a key complaint.

Competing interests

The research reported in this paper was funded by Pfizer Inc. Drs. Cappelleri and Petrie and Mr. Bushmakin are full-time employees of Pfizer Global Research and Development, New London, CT. Dr. Sadosky is a full-time employee of Pfizer Global Pharmaceuticals, Outcomes Research, New York, NY. Ms. Martin, currently at RTI Health Solutions, was a full-time employee of Pfizer Global Research and Development, Outcomes Research, Ann Arbor, MI, when this work was performed. Dr. McDermott was a paid consultant to Pfizer in connection with the development of this manuscript.

Authors' contributions

JCC and AGB made substantive contributions to the statistical analysis, interpretation of results, and drafting of the manuscript. AM and ABS made substantive contributions in interpreting the analysis and helped to draft the manuscript. SM and CDP made substantive contributions to study design, conduct, and interpretation of results. All authors read and approved the final manuscript.

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