ORIGINAL RESEARCH

Prevalence and Impact of Comorbid Widespread Pain in Adults with Chronic Low Back Pain: A Registry-Based Study

John C. Licciardone, DO, MS, MBA and Vishruti Pandya, MBBS, MHA

Introduction: **Widespread pain (WP) is emerging as a key comorbid condition in patients with chronic low back pain (CLBP). This study measured the prevalence of comorbid WP in adults with CLBP, WP predictors, and impact on patients.**

Methods: **Patients with CLBP were recruited from the Pain Registry for Epidemiologic, Clinical, and Interventional Studies and Innovation from 2016 through 2019. They were followed over 12 months to measure annual WP period prevalence rates using an item from the minimum dataset recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain. Patients were classified as not having WP, having nonpersistent WP, or having persistent WP. Pain intensity, back-related disability, and quality of life were measured using a numerical rating scale, the Roland-Morris Disability Questionnaire, and the PROMIS-29 instrument, respectively.**

Results: **A total of 358 patients were studied, including 56 (16%) without WP, 272 (76%) with nonpersistent WP, and 30 (8%) with persistent WP. There were no significant differences among the WP groups with regard to age, sex, or CLBP duration. However, being non-White and having moderate or high levels of pain catastrophizing remained significant predictors of nonpersistent or persistent WP after adjusting for potential confounders. Patients reported greater pain intensity and back-related disability and poorer quality of life over 12 months with increasing levels of WP persistence ($P < .001$ for each measure).**

Conclusion: **Greater efforts are needed in primary care to help close these gaps in pain intensity, back-related disability, and quality-of-life outcomes associated with WP. (J Am Board Fam Med 2020;33:541–548.)**

Keywords: **Catastrophization, Comorbidity, Low Back Pain, Prevalence, Primary Health Care, Quality of Life, Registries**

Introduction

Low back pain is a pervasive condition that affects over 600 million persons worldwide and is the leading cause of disability.[1] In the United States, about 50 million adults suffer from chronic pain.[2] This includes about 20 million adults with high-impact chronic pain, such as low back pain that interferes with work or life most days or every day. Although primary care physicians often face challenges in treating patients with low back pain that has become chronic and potentially disabling, the extent of this burden has not been well established. The National Pain Strategy called for more precise prevalence estimates of high-impact chronic pain to help develop and implement appropriate pain interventions.[3] The National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain (NIH-RTF) recommended assessing pain impact based on pain intensity, functional status, and quality of life, and considering widespread pain (WP) a key comorbid condition.[4] Chronic low back pain (CLBP) may progress to WP, with fibromyalgia manifesting as an extreme form of the

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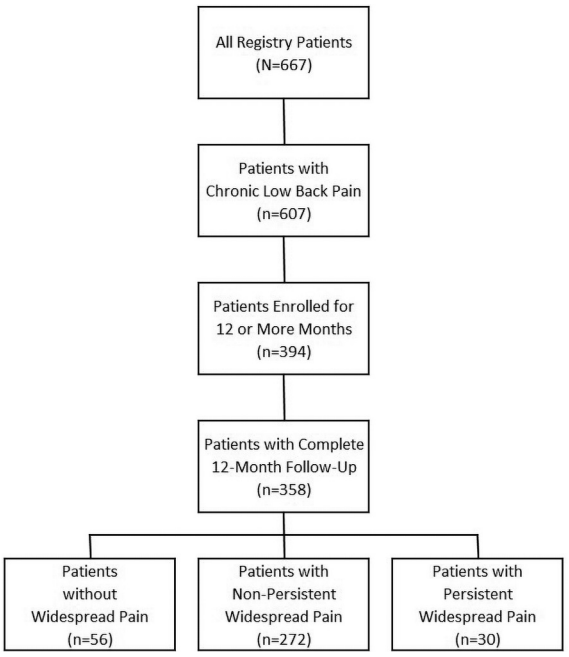
condition. Fibromyalgia was originally associated with 11 or more tender point sites identified by clinical examination.[5] However, updated fibromyalgia criteria and self-report scales have been developed to enable epidemiologic research in the absence of clinical examination.[6,7] The objectives of this study were to: measure annual period prevalence rates of nonpersistent and persistent WP among patients with CLBP using a simple patient self-report item; to identify WP predictors; and to assess the impact of WP on low back pain intensity, functional status, and quality of life.

Methods

Patients for this historical cohort study were selected from the Pain Registry for Epidemiologic, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry) within Texas from April 2016 through January 2019. A registry overview has been published.[8] Registry patients were recruited using clinic advertisements, communications with health care providers, newspaper advertisements, and social media to direct potential participants to the online screening site. Registry eligibility criteria included 1) being 21 to 79 years of age, 2) having English-language proficiency, and 3) having subacute low back pain or CLBP. However, the present study included only patients who met the NIH-RTF case definition for CLBP.[4] The latter required patients to report low back pain duration of at least 3 to 6 months, with a corresponding pain frequency of at least half of the days during the past 6 months. Registry patients are currently required to have a physician for their low back pain, as no diagnostic testing or treatment is provided by the registry. Study patients were required to attend the baseline registry encounter in person; however, follow-up encounters may have been completed in person, telephonically, or online. Regardless of the manner in which encounters were completed, all data were self-reported by patients and entered using electronic case report forms that precluded missing item responses. Thus, missing data were attributable only to missed encounters or registry attrition. Enrolled patients with complete data at each subsequent quarterly encounter over 12 months were included in the study. Pregnant or institutionalized patients were excluded. The North Texas Regional Institutional Review Board approved the study.

Figure 1. Flow of patients through the study.



The annual period prevalence of WP was assessed using the NIH-RTF minimum dataset item that measured the bothersomeness of "widespread pain or pain in most of your body" during the past 4 weeks ("not bothered at all," "bothered a little," or "bothered a lot") at each quarterly encounter.[4] Patients who consistently reported being "not bothered at all" over 12 months were considered to not have WP. Patients who consistently reported being "bothered a lot" over 12 months were considered to have persistent WP. The remaining patients were considered to have nonpersistent WP.

Baseline clinical measures included the patient-reported history of depression, Pain Catastrophizing Scale,[9] Pain Self-Efficacy Questionnaire,[10] numeric rating scale for low back pain intensity during the past 7 days, Roland-Morris Disability Questionnaire for back-related disability,[11] and Patient-Reported Outomes Measurement Information System (PROMIS-29)[12] Quality of life was measured using the SPADE cluster based on PROMIS-29 scales for sleep disturbance, pain interference with activities, anxiety, depression, and low energy/fatigue. The measures of low back pain intensity, back-related disability, and quality of life were repeated at quarterly intervals over 12 months. Contingency table methods and analysis of variance were used to

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Table 1. Baseline Sociodemographic, Clinical, and Psychological Characteristics of Patients (N = 358)

Characteristic	No.	%
Age, y		
21–49	111	31
50–59	128	36
60–79	119	33
Sex		
Male	100	28
Female	258	72
Race		
White	248	69
Non-White	110	31
Ethnicity		
Non-Hispanic	313	87
Hispanic	45	13
Highest educational level		
High school diploma or lower	91	25
Post-high school or some college	142	40
College degree or higher	125	35
Cigarette smoking status		
Never or former smoker	297	83
Current smoker	61	17
Chronic low back pain duration		
Less or equal to 5 y	128	36
Greater than 5 y	230	64
History of low back surgery		
No	301	84
Yes	57	16
Ever unemployed or unable to do usual work for one month or longer due to low back pain		
No	224	63
Yes	134	37
Ever received disability or workers' compensation benefits relating to low back pain		
No	273	76
Yes	85	24
Ever involved in a lawsuit or legal claim relating to low back pain		
No	321	90
Yes	37	10
History of comorbidities		
Herniated disc		
No	232	65
Yes	126	35
Sciatica		
No	241	67
Yes	117	33
Osteoarthritis		
No	242	68
Yes	116	32
Osteoporosis		
No	319	89
Yes	39	11
Heart disease		
No	321	90
Yes	37	10
Hypertension		
No	218	61
Yes	140	39
Diabetes		
No	283	79
Yes	75	21
Asthma		
No	256	72
Yes	102	28
Depression		
No	192	54
Yes	166	46
Pain catastrophizing (PCS score)		
Low (0–8)	112	31
Moderate (9–22)	123	34
High (23–52)	123	34
Pain self-efficacy (PSEQ score)		
Low (0–28)	117	33
Moderate (29–42)	116	32
High (43–60)	125	35
Current use of opioids for low back pain		
No	227	63
Yes	131	37

Abbreviations: PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire.

compare WP groups at baseline. Multiple logistic regression was used to identify baseline factors associated with the presence of WP (either nonpersistent or persistent) over 12 months of follow-up. Predictor variables included patient sociodemographic characteristics, cigarette smoking status, CLBP duration greater than 5 years, history of low back surgery, history of 9 spinal or medical conditions, tercile levels of pain catastrophizing and pain self-efficacy (low, moderate, or high), and current use of opioids for low back pain. Repeated measures analysis of variance was used for longitudinal comparisons of the 3 WP groups with regard to clinical measures involving low back pain intensity, back-related disability, and quality of life. Statistical analyses were performed using the IBM SPSS Statistics software package (version 25, Armonk, NY). All

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Table 2. Factors Associated with Widespread Pain (N = 358)

	Univariate Analysis			Multivariate Analysis		
Factor	OR	95% CI	*P*	OR	95% CI	*P*
Age, y						
21–49	1	…	…	1	…	…
50–59	1.6	0.8–3.3	.17	1.3	0.6–3.1	.49
60–79	1.2	0.6–2.4	.56	1.7	0.6–4.5	.30
Sex						
Male	1	…	…	1	…	…
Female	1.2	0.6–2.1	.66	1.5	0.7–3.4	.34
Race						
White	1	…	…	1	…	…
Non-White	3.6	1.6–8.3	.002	4.1	1.5–10.8	.01
Ethnicity						
Non-Hispanic	1	…	…	1	…	…
Hispanic	1.2	0.5–3.1	.65	1.8	0.6–5.5	.29
Highest educational level						
High school diploma or lower	1	…	…	1	…	…
Post-high school or some college	1.0	0.4–2.4	.92	1.8	0.6–5.2	.26
College degree or higher	0.2	0.1–0.6	.001	0.6	0.2–1.8	.38
Cigarette smoking status						
Never or former smoker	1	…	…	1	…	…
Current smoker	3.0	1.1–8.7	.04	1.3	0.4–4.5	.68
Chronic low back pain duration						
Less than or equal to 5 y	1	…	…	1	…	…
Greater than 5 y	1.6	0.9–2.8	.13	1.6	0.8–3.2	.19
History of low back surgery						
No	1	…	…	1	…	…
Yes	1.2	0.5–2.6	.72	0.7	0.3–2.1	.58
History of comorbidities						
Herniated disc						
No	1	…	…	1	…	…
Yes	1.4	0.8–2.7	.26	1.2	0.5–2.7	.67
Sciatica						
No	1	…	…	1	…	…
Yes	1.0	0.6–1.9	.93	0.9	0.4–1.9	.79
Osteoarthritis						
No	1	…	…	1	…	…
Yes	1.4	0.7–2.6	.33	1.0	0.5–2.4	.92
Osteoporosis						
No	1	…	…	1	…	…
Yes	1.3	0.5–3.5	0.61	0.8	0.2–2.9	0.77
Heart disease						
No	1	…	…	1	…	…
Yes	1.2	0.5–3.3	.71	1.7	0.5–5.7	.40
Hypertension						
No	1	…	…	1	…	…
Yes	1.3	0.7–2.4	.39	0.9	0.4–1.9	.70
Diabetes						
No	1	…	…	1	…	…
Yes	2.5	1.0–6.0	.046	1.8	0.6-5.4	.28

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Table 2. Continued

Factor	Univariate Analysis			Multivariate Analysis		
	OR	95% CI	*P*	OR	95% CI	*P*
Asthma						
No	1	…	…	1	…	…
Yes	1.0	0.5–1.9	.99	0.6	0.3–1.3	.18
Depression						
No	1	…	…	1	…	…
Yes	2.5	1.3–4.6	.004	0.8	0.4–2.0	.69
Pain catastrophizing (PCS score)						
Low (0–8)	1	…	…	1	…	…
Moderate (9–22)	4.3	2.2–8.7	<.001	4.7	2.1–11.0	<.001
High (23–52)	12.1	4.6–32.2	<.001	6.8	2.1–22.1	.002
Pain self-efficacy (PSEQ score)						
Low (0–28)	1	…	…	1	…	…
Moderate (29–42)	0.4	0.2–1.0	.052	0.7	0.2–2.1	.55
High (43–60)	0.2	0.1–0.4	<.001	0.7	0.2–2.2	.52
Currently using opioids for low back pain						
No	1	…	…	1	…	…
Yes	3.5	1.7–7.5	.001	2.1	0.8–5.4	.12

Results are for widespread pain (either non-persistent or persistent) relative to no widespread pain. Multivariate analysis included all univariate factors.
Abbreviations: PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; OR, odds ratio; CI, confidence interval.

hypotheses were assessed at the 0.05 level of statistical significance using 2-sided tests.

Results

A total of 358 (91%) of the 394 eligible patients completed the baseline encounter and each quarterly encounter over 12 months (Figure 1). There were 56 (16%) patients who did not have WP, 272 (76%) who had nonpersistent WP, and 30 (8%) who had persistent WP. The mean age of patients was 53.6 years (SD, 12.2 years), 258 (72%) were women, and 230 (64%) had CLBP for more than 5 years (Table 1). There were no significant differences among the 3 WP groups with regard to age, sex, or CLBP duration. However, race and pain catastrophizing remained significant predictors of nonpersistent or persistent WP after adjusting for potential confounders (Table 2). Non-White patients were more likely than White patients to report WP (OR, 4.1; 95% CI, 1.5 to 10.8; $P = .01$). This finding largely reflects the experience of Black patients, who comprised 97 (88%) of the 110 non-White patients. Patients with moderate (OR, 4.7; 95% CI, 2.1 to 11.0; $P < .001$) or high (OR, 6.8; 95% CI, 2.1 to 22.1; $P = .002$) pain catastrophizing were more likely to report WP than patients with low levels of pain catastrophizing.

Patients reported greater low back pain intensity and back-related disability and poorer quality of life over 12 months with increasing levels of WP persistence ($P < .001$ for each measure) (Figure 2). A significant back-related disability × time interaction effect was also observed ($P = .01$), wherein Roland-Morris Disability Questionnaire scores declined over time in patients without WP, remained stable in patients with nonpersistent WP, and increased in patients with persistent WP. All findings based on repeated measures analysis of variance remained essentially unchanged after controlling for age, sex, and CLBP duration.

Discussion

Nonpersistent or persistent WP was observed in 84% of patients with CLBP over 12 months of followup and was associated with adverse clinical consequences. These findings support the NIH-RTF stance that WP is a key comorbid condition in patients with CLBP, and suggest that WP may be

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Figure 2. Clinical measures over 12 months of followup according to widespread pain group. Abbreviations: NRS, numeric rating scale; RMDQ, Roland-Morris Disability Questionnaire; SPADE, sleep disturbance, pain interference with activities, anxiety, depression, and low energy/fatigue; WP, widespread pain. Greater scores represent worse status on each clinical measure. Error bars represent 95% CI. *P*-values were computed using repeated measures analysis of variance. All WP groups were significantly different from one another in post-hoc comparisons for all clinical measures. A significant back-related disability X time interaction effect was also observed (*P* = .01).

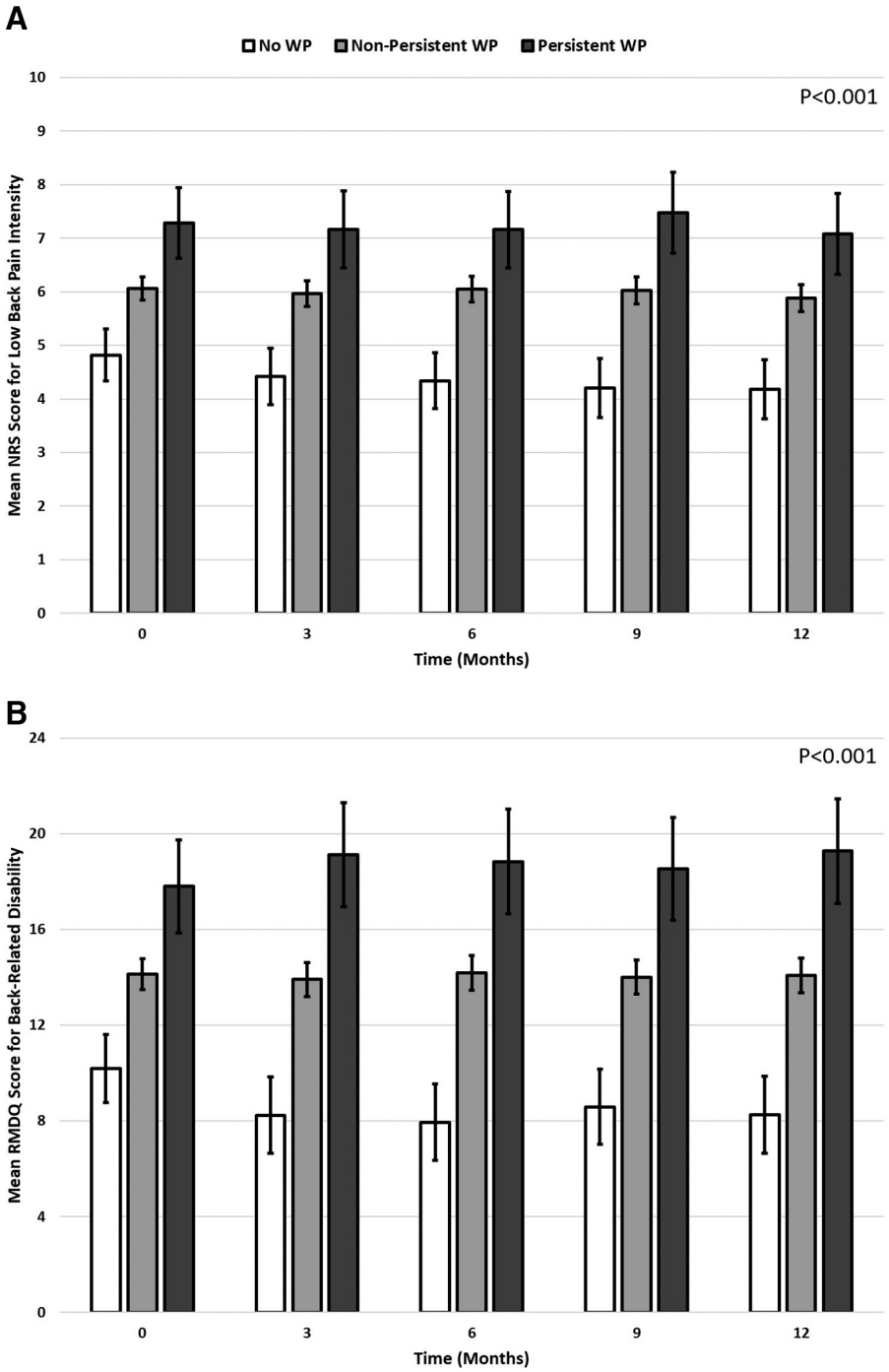

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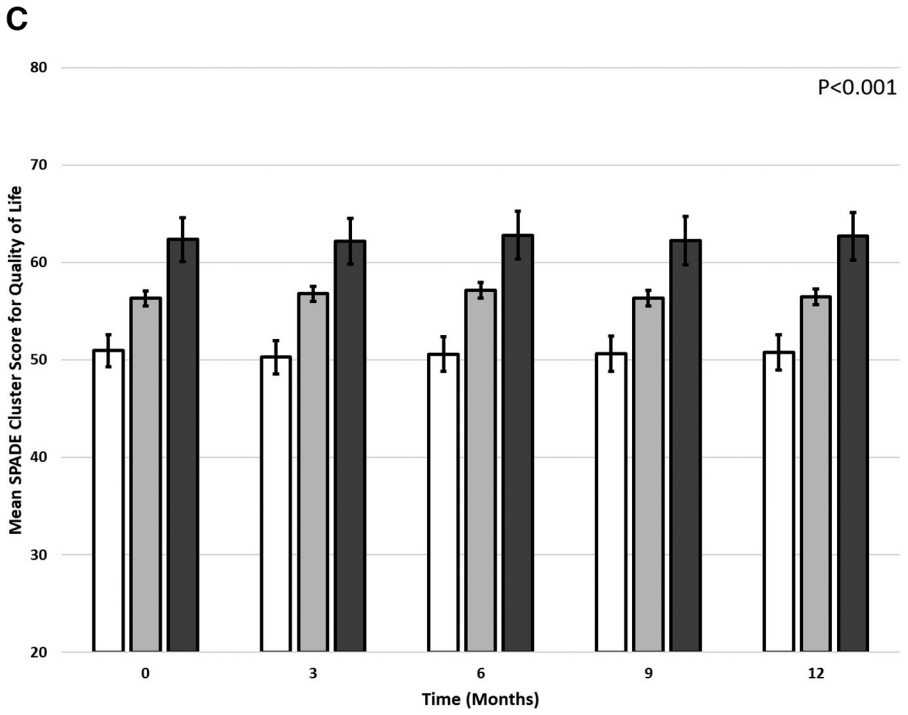
Figure 2. Continued



identified with a simple patient self-report item from the NIH-RTF minimum dataset.[4] Epidemiologic studies involving large populations have reported prevalence rates of 5% to 14% for chronic WP and 1% to 3% for fibromyalgia.[13] Among patients with CLBP, 25% met the American College of Rheumatology criteria for chronic WP.[14] Such patients with WP in the latter study were more likely to be female, have longer CLBP duration, and more often report comorbidities such as osteoarthritis and depression than patients without WP. The NIH-RTF item used in our study appears to identify patients at an earlier stage in the WP spectrum because significant associations with sex, CLBP duration, and medical comorbidities were not observed (Table 2).

The gradient in each clinical measure with increasing WP persistence generally remained constant over 12 months, despite ongoing active treatment for CLBP (Figure 2). A possible explanation for this phenomenon is that physicians may not routinely assess the presence and impact of WP when treating patients for localized pain. Consequently, pain management may not adequately address remote pain sites, physical functioning, and other quality-of-life issues relating to such factors as sleep disturbance, anxiety, and depression. However, simply providing a visual display of PROMIS symptom scores to primary care physicians in a busy clinical setting did not improve patient quality-of-life outcomes over 3 months.[15] It remains to be seen if the simpler WP bothersomeness item from the NIH-RTF minimum dataset could be more efficiently and effectively implemented in clinical practice.

Limitations of our study include self-report measures and computation of WP period prevalence rates rather than incidence rates because there were too few patients who were WP-free at baseline to assemble a suitable prospective cohort. Nevertheless, disease registries such as ours may increasingly exploit the historic (ie, retrospective) cohort design to conduct pragmatic studies that assess health care outcomes in real-world settings.[16] Low patient attrition was also a strength of our study.

In summary, annual period prevalence rates of 76% for nonpersistent WP and 8% for persistent WP were observed in patients with CLBP using the NIH-RTF minimum dataset bothersomeness item. Being non-White and having moderate or high levels of pain catastrophizing were significant independent predictors of WP. Generally stable gradients involving greater low back pain intensity

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and back-related disability and poorer quality of life were observed over 12 months in patients with increasing levels of WP persistence. Greater efforts are needed in primary care to help close these gaps in clinical measures associated with WP.

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