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ORIGINAL RESEARCH

Pain Phenotyping Indicators in Older Adults with Chronic Low Back Pain: A Secondary Analysis of a Randomized Controlled Trial

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Purpose: A multimodal approach to clinical care is often recommended for chronic low back pain (cLBP); however, treatment responses are highly variable. Phenotyping could help determine subgroups of patients, allowing for targeted and tailored interventional approaches.

Patients and Methods: 263 (Mage=69.8 (7.2); 64.6% female) individuals with cLBP participated in the parent study, a 3-arm, randomized clinical trial examining auricular point acupressure treatment outcomes. Parent study participants were randomized (1:1:1) to APA ear points targeted to cLBP (T-APA, n=92), non-targeted to cLBP (NT-APA, n=91), or education control (n=89). The current study used latent class analysis to identify clustering for pain severity (intensity, neuropathic pain) and pain impact (anxiety, depression, pain catastrophizing, fatigue, sleep disturbance) and determine if these classes were related to treatment outcomes (pain and disability reduction). Bayesian Information Criterion (BIC) was used for model selection. Post-LCA, ANOVA and Fisher's exact tests examined potential subgroup differences.

Results: The three-class model emerged as the best fit due to relatively low BIC (−12105.46) and good patient distribution per class; class 1 n=79, class 2 n=109, class 3 n=75. Latent class 1 had moderate pain severity and pain impact, class 2 had high pain severity and pain impact, and class 3 had low pain severity and pain impact. No significant differences between classes were seen for age, sex, or BMI (p-value>0.05); however, latent class 3 had the highest physical functioning, lowest fear of physical activity, and disability, and significantly lower unemployment rate. There were no significant differences in treatment outcomes among the three classes.

Conclusion: Three distinct clusters of factors related to pain and psychological function for individuals with cLBP were found. These clusters align with previous work and add to the literature by providing important associations with demographic and clinical factors that have not been previously examined.

Keywords: pain phenotyping, chronic low back pain, pain impact, pain severity, latent class analysis

Introduction

Chronic low back pain (cLBP), pain affecting the lower region of the spine, is one of the most commonly reported locations for chronic pain, with prevalence estimates as high as 577 million individuals globally.[1,2] It has been estimated that up to 20% of adults have back pain within a single year and up to 80% of people experience at least one episode of back pain at some points in their lifetime.[3] It has been a leading cause of disability and one of the major reasons for missing workdays worldwide.[4] Recent analyses have demonstrated that individuals with cLBP have a high number of years lived with disability that peak in midlife (45–49 years of age) and are higher for females with cLBP.[1] The impact of cLBP on individuals, healthcare systems, and the economy is significant.

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Previous studies have shown that treatment for low back pain depends on the underlying cause and the severity of symptoms. It often involves a combination of self-care measures, over-the-counter pain medications, physical therapy, chiropractic care, prescription medications, injections, or surgery.[5] However, patients with cLBP respond very differently to these treatment methods in clinical practice.[6,7] Stratified care for acute and cLBP, which involves dividing patients into subgroups based on their specific factors to develop targeted treatment, has been proposed as an effective method to maximize treatment responses.[8,9] However, the subgroup factors most predictive of cLBP treatment outcomes have not been well established.

Therefore, the current study focused on statistically identifying subgroups of individuals who are clustered together based on their baseline pain profiles or related factors that may influence treatment outcomes. Specifically, the primary aims of this secondary analysis were to 1) examine baseline characteristics with latent class analysis to identify phenotypic subgroups of individuals with cLBP and 2) explore whether auricular point acupressure (APA) treatment responses differed between the pain phenotyping groups identified. Latent class analysis may be particularly useful for identifying clinical phenotypes that can build toward a precision medicine approach.[10] In the current study, we focused on groupings of factors that may be modifiable; and how these groupings (ie, classes) were related to treatment outcomes.

Materials and Methods

Study Design and Sample

A total of 272 individuals with chronic low back pain were recruited for the parent study, 9 patients were excluded from the pain phenotyping analyses because of missing baseline pain profile data. The parent study, "Management of chronic low back pain (cLBP) in older adults using auricular point acupressure (APA)" (NIH/NIA R01AG056587; Clinicaltrails.gov Trial ID: NCT03589703), was a 3-arm, randomized clinical trial (RCT). The study protocol was approved by the Institutional Review Board of the Johns Hopkins School of Medicine and this study complies with the Declaration of Helsinki. All participants provided informed consent before participation; full protocol details were previously published.[11–13] See Supplementary Figure 1 for the CONSORT Diagram of Study Participation in the Parent Study. Adults, 60 years or older with cLBP for at least 3 months or caused pain for at least half of the days over the previous 6 months, were recruited. To be included, individuals were required to have average pain intensity over the past week of ≥4 on an 11-point scale, intact cognition, the ability to apply the APA study materials to their ears, and be willing to commit to the study procedures and timeline. Individuals were excluded if they had malignant or autoimmune disease, acute compression fractures, or hearing aid use that would obstruct application of study materials to the ear. Prior to recruitment initiation, the study statistician used a random-number generator to create group assignment lists. Participants were randomized (1:1:1) in blocks of 3 or 6 to APA ear points targeted to cLBP (T-APA, n = 92), APA ear points non-targeted to cLBP (NT-APA, n = 91), or education control (n = 89). Given evidence of APA as a safe and non-invasive treatment option, education control group participants were rerandomized to T-APA or NT-APA at 1 month follow-up. Participants were followed up to 6 months; and parent study outcomes were assessed at baseline, immediately post-intervention, and 1, 3, and 6 month follow-ups. Participants in the APA groups received 4 weekly APA sessions and were instructed to self-stimulate ear points at home; the education control group received 4 weekly educational sessions. The current analyses focus on baseline data for identifying latent classes. The primary treatment outcomes for the parent study included changes in pain (Numerical Rating Scale) and function (Roland and Morris Disability Questionnaire). Pain-related secondary outcomes were included. Data collection took place at 9 time points.

Indicators for Latent Class Model

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations on patient phenotyping of chronic pain treatments[6] were used to select the following indicators used to build the model:

1. Neuropathic pain was assessed from the painDETECT questionnaire,[14] which includes seven items to identify the neuropathic components in patients with lower back pain.

2. Pain intensity was measured by a numeric scale. Participants were asked to rate their usual pain in the past week from 0 (no pain) to 10 (worst pain imaginable).
3. Sleep quality was assessed from PROMIS Sleep Disturbance – Short Form 4a.[15] Participants were asked to answer four sleep-related questions based on their sleep quality in the past week. Lower scores indicate better sleep.
4. Depression and anxiety were measured with the PROMIS Depression and Anxiety – Short Form 4a.[16] Each short version of the questionnaires contains four items evaluating depression and anxiety symptoms. All questions have 5-point scales and were scored 1 to 5, with higher scores indicating higher frequency of symptoms in the past seven days.
5. Fatigue was assessed from the 4-item PROMIS Fatigue – Short Form 4a.[17] Participants scaled their fatigue levels from 1 to 5, where higher score represents higher fatigue level in the past one week.
6. Pain catastrophizing was measured with the Pain Catastrophizing Scale (PCS).[18] The 13-item PCS instrument asked participants to measure their catastrophizing when experiencing pain on a numeric scale from 0 (not at all) to 4 (all the time). Higher total scores indicate worse pain catastrophizing.

Covariates – Baseline Characteristics

In addition to sociodemographic characteristics (sex, age, body mass index (BMI), and work status), the following baseline characteristics were included as covariates:

1. Comorbidity was measured by the Charlson Comorbidity index,[19] which is a valid method to estimate the mortality risk of comorbid diseases.
2. Self-reported functional limitation for low-back pain was assessed by the 24-item Roland Morris Disability Questionnaire (RMDQ).[20] Patients were asked to check a statement if it was applicable for them. The RMDQ score is the total number of the checked items, with the range from 0 (no disability) to 24 (maximum disability).
3. Physical function was measured with PROMIS Physical Function – Short Form 4a.[21] Participants answered this 4-item questionnaire by scoring numerically from 1 (without any difficulty) to 5 (unable to do).
4. Fear of physical activity was evaluated by the first 5 items in the Fear-Avoidance Beliefs Questionnaire (FABQ).[22] Patients answered each question by scoring from 0 (completely disagree) to 6 (completely agree).

Raw scores were standardized to PROMIS T-scores for all PROMIS instruments.[23]

Treatment Outcome Measures

For the current analyses, two variables, pain and disability reduction, were created to examine possible treatment latent class outcomes. The pain reduction variable refers to the change of worst pain from baseline to 1-month post-intervention. Disability reduction was calculated by the difference of the RMDQ score from baseline to 1-month post-intervention.

Statistical Analyses

Latent class analysis (LCA) is a statistical modeling method that is used to find clusters or subgroups of cases in multivariate data. These subgroups are called "latent classes".[24] It is a widely used tool to investigate if there are unobserved or unmeasured subgroups within a population. To better understand cLBP, latent class analysis (LCA) was performed to cluster individuals into different classes based on their pain severity and pain impact at baseline (first visit). The IMMPACT recommendations[6] were used to explore the pain phenotypes and select the indicators for the LCA model. The Bayesian Information Criterion (BIC) was used for model selection. A lower BIC indicates better model fit. Additionally, following prior recommendations, a restriction criterion was established that deemed classes <5% of the sample size as inadequate.[25] R package mclust5[26] was used to perform LCA. According to package documents, model-based clustering were based on parameterized finite Gaussian mixture models. Models are estimated by EM algorithm initialized by hierarchical model-based agglomerative clustering. The optimal model is then selected according to BIC. The LCA modeling approach allowed covariates to emerge during the classification process, they were then treated as predictors within the LCA regression framework. R^2 between each pair of indicators was calculated and no significant collinearity was found. After identifying participants into different latent classes, ANOVA and Fisher's exact tests were conducted on continuous and categorical covariates, respectively, to see if there are any differences between the subgroups.

The parent study found that APA treatments significantly improved pain and functioning relative to the control group, with improvements lasting to the 6-month follow-up time period.[13] The current study expanded on these analyses by incorporating phenotyping indicators from the LCA models. To assess the treatment effect, we calculated the difference of the worst pain and the RMDQ score between baseline and 1-month post-intervention. Patients without worst pain or RMDQ records were excluded, 199 patients with complete pain intensity and RMDQ data were included in the treatment effect evaluation. Two-way ANOVA was performed to examine the influence of treatment groups and latent classes.

Results

Patient Demographics and Baseline Characteristics

Of the 263 participants that had complete data for inclusion in the latent class analyses, 88 (33.46%) were in the T-APA treatment group, 88 (33.46%) in the NT-APA group, and 87 (33.08%) in the control group. See Table 1 for full demographic and clinical information.

Table 1 Demographic and Clinical Characteristics of the Sample (N = 263)

Characteristic	M or n (SD or %)
Age (years)	69.79 (7.17)
BMI	31.03 (7.74)
Sex	
Female	170 (64.64%)
Male	93 (35.36%)
Race	
White	95 (36.12%)
Black or African American	157 (59.70%)
Other	11 (4.18%)
Education Level[a]	
No High School Diploma or GED	25 (9.54%)
High School Graduate/GED, Some College, or Associates	143 (54.37%)
Degree	
Bachelor's Degree or higher	86 (32.70%)
Unknown	9 (3.42%)
Work Status	
Employed	31 (11.79%)
Other	8 (3.04%)
Retired	158 (60.08%)
Unemployed	66 (25.10%)
Smoking Status	
Never Smoked	99 (37.64%)
Current Smoker	47 (17.87%)
Former Smoker	117 (44.49%)
Opioid Use	
Yes	116 (44.11%)
No	135 (51.33%)
Not Sure	12 (4.56%)
Physical Function	37.61 (6.70)
Fear of Physical Activity	37.61 (6.70)
Disability	12.38 (5.70)
Comorbidity via Charlson Comorbidity index	1.11 (2.27)

Note: [a]Highest level obtained.

Clustering Results Based on the Latent Class Analysis (LCA)

Model Selection

Using the mclust5 package in R, all possible LCA models (a total of 126 different LCA models) were evaluated. The top three models with the lowest BIC, indicating better model fit, are provided in Table 2. Table 2 also gives an overview of the number of participants in each latent class for these models. Of these models, the VEI-7 and VEI-8 models (with 7 and 8 latent clusters respectively) contain small clusters with less than 5% of total subjects), which are not good for downstream analysis and interpretation. Thus, we consider the 3-class ellipsoidal and equal shape model (VEV-3) as the best due to relatively low BIC, good participant distributions across the latent classes, and model interpretation.

Identification of Latent Classes

Based on the best model (VEV-3), seven baseline characteristics emerged: anxiety, depression, fatigue, pain intensity, neuropathic pain, sleep, and pain catastrophizing. A breakdown of the pain severity and pain impact characteristics for each latent class are provided in Table 3. Results indicated that Latent class 2 had high pain severity (intensity, neuropathic pain) and high pain impact (anxiety, depression, pain catastrophizing, fatigue, sleep disturbance), Latent class 1 had moderate pain severity and pain impact, and Latent class 3 had low pain severity and pain impact. Based on the identified latent classes, demographic and clinical characteristics were subsequently examined (Table 4). Of the total participants (N = 263), Latent class 1 had 79 (30.04%), Latent class 2 had 109 (41.44%), and Latent class 3 had 75 (28.52%) subjects. No significant differences between these three latent classes were seen for age, BMI, or sex. However,

Table 2 BIC for the Three Best Fitted Models and Number of Participants in Each Class for Each Model (N = 263)

Model Type, Number of Classes	**VEV-3**	**VEI-7**	**VEI-8**
BIC	−12105.46	−12117.11	−12129.23
N in each Latent Class	**VEV, 3**	**VEI, 7**	**VEI, 8**
Latent Class 1	79	87	74
Latent Class 2	109	17	35
Latent Class 3	75	37	38
Latent Class 4		69	54
Latent Class 5		26	26
Latent Class 6		11	11
Latent Class 7		16	15
Latent Class 8			10

Note: "VEV" indicates ellipsoidal and equal shape. "VEI" indicates diagonal, varying volume, equal shape.

Table 3 Indicator Characteristics at Baseline in Each Latent Class for the Best Model (VEV-3)

Indicator	**Latent Class 1 n = 79**	**Latent Class 2 n = 109**	**Latent Class 3 n = 75**
		Mean (SD)	
Anxiety	55.11 (6.38)	56.94 (9.72)	41.43 (2.94)
Depression	51.36 (8.28)	58.26 (6.01)	41.00 (0.00)
Fatigue	54.69 (9.95)	56.34 (8.30)	45.74 (8.11)
Average Pain Intensity	5.75 (1.55)	6.72 (1.87)	5.61 (1.65)
Neuropathic Pain	15.92 (5.13)	20.13 (9.40)	13.69 (5.06)
Sleep Disturbance	54.71 (5.36)	56.51 (8.95)	49.80 (8.45)
Pain Catastrophizing	16.51 (11.30)	23.16 (14.11)	8.04 (6.67)

Table 4 Demographic and Clinical Characteristics at Baseline in Each Latent Class for the Best Model (VEV-3)

Indicator	Latent Class 1 n = 79	Latent Class 2 n = 109	Latent Class 3 n = 75	p-value
	Mean (SD) or N (Percentage)			
Age	69.23 (6.89)	69.40 (7.46)	70.95 (7.02)	0.2540
BMI	30.78 (7.60)	31.18 (7.83)	31.07 (7.88)	0.9396
Sex				0.1644
Female	52 (19.77%)	76 (28.90%)	42 (15.97%)	
Male	27 (10.27%)	33 (12.55%)	33 (12.55%)	
Work Status				**0.0356**
Employed	13 (4.94%)	6 (2.28%)	12 (4.56%)	
Retired	41 (15.59%)	67 (25.48%)	50 (19.01%)	
Unemployed	22 (8.37%)	32 (12.17%)	12 (4.56%)	
Other	3 (1.14%)	4 (1.52%)	1 (0.38%)	
Physical Function	37.74 (7.12)	35.23 (4.66)	40.95 (7.37)	**<0.0001**
Fear of Physical Activity	15.28 (8.50)	18.58 (7.84)	13.35 (8.09)	**0.0001**
Disability	11.76 (5.36)	14.96 (4.99)	9.28 (5.35)	**<0.0001**
Comorbidity	1.30 (2.94)	1.36 (2.35)	0.53 (0.76)	**0.0340**

Note: Significant p-values are bolded.

significant differences by latent class were observed for baseline physical function, fear of physical activity, disability, comorbidity, and work status. Specifically, latent class 3 had the highest physical functioning, lowest fear of physical activity, and disability, and significantly lower unemployment rate compared to the other two classes.

APA Treatment Responses for the Three Identified Latent Classes

Note that 64 subjects without worst pain score and/or RMDQ records were excluded for APA treatment response analysis, resulting in n = 199 subjects for APA treatment response analysis for different latent phenotyping classes. Results from the two-way ANOVA allowed us to examine how the three latent classes mapped to differences in pain reduction and disability reduction by treatment group. As seen in Table 5, the APA treatment was significant in pain reduction, but not significant in disability (RMDQ) reduction; however, pain phenotyping latent class was not significant in both pain reduction and disability reduction. For each of the latent classes, we further examined the APA treatment effects by one-way ANOVA and the results are reported in Table 6. Interestingly, the APA treatment effect in pain intensity reduction and disability reduction was not significant for Latent Class 1, however, in Latent Class 2, the APA treatment effect in disability reduction was significant, while the APA treatment effect in pain intensity reduction was significant in Latent Class 3.

Table 5 Reduction in Pain and Disability by Treatment Group and Latent Class Based on Two-Way ANOVA (N =199)

	Degree of Freedom	F Statistics	p-value
Pain Reduction			
Treatment Group	2	4.610	**0.011**
Latent Class	2	0.989	0.163
RMDQ Reduction			
Treatment Group	2	2.060	0.130
Latent Class	2	2.194	0.114

Note: Significant p-values are bolded.

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Table 6 Reduction in Pain and Disability by Group in Each Latent Class for the Best Model (VEV-3) (N=199)

	T-APA	NT-APA	Control	p-value
	Mean (SD)			
	Latent Class 1			
Pain Intensity Reduction	1.35 (1.97)	0.79 (2.69)	1.10 (1.75)	0.731
Disability Reduction	0.04 (4.64)	−0.58 (7.28)	2.10 (4.39)	0.292
	Latent Class 2			
Pain Intensity Reduction	1.97 (2.37)	1.57 (2.94)	0.59 (1.72)	0.100
Disability Reduction	2.66 (6.15)	4.07 (5.04)	0.63 (3.47)	**0.041**
	Latent Class 3			
Pain Intensity Reduction	2.15 (1.95)	2.73 (3.06)	0.53 (1.83)	**0.012**
Disability Reduction	3.30 (5.97)	3.60 (5.97)	0.29 (3.87)	0.106

Note: Significant p-values are bolded.

Discussion

The current study used latent class analysis to identify phenotypic indicators within individuals with chronic low back pain and explored whether these subgroups were related to auricular point acupressure (APA) treatment outcomes. Three clusters were identified, where latent class 1 had moderate pain severity (intensity, neuropathic pain) and moderate pain impact (anxiety, depression, pain catastrophizing, fatigue, sleep disturbance), latent class 2 had high pain severity and pain impact, and latent class 3 had low pain severity and pain impact. When baseline demographic and clinical characteristics were examined, no significant differences were seen between the three classes for age, sex, or BMI. However, those with low pain severity and impact (latent class 3) had the highest physical functioning, lowest fear of physical activity, and disability, and significantly lower unemployment compared to the other two classes. Although follow-up analyses failed to detect significant differences in APA treatment responses among the three latent classes in general, the APA treatment effect in pain intensity reduction and disability reduction was different in different latent classes. The APA treatment effect in both pain intensity reduction and disability reduction was not significant for those with moderate pain severity and impact (latent class 1); however, the APA treatment effect in disability reduction was significant for those with high pain severity and impact (latent class 2); and the APA treatment effect in pain intensity reduction was significant for those with low pain severity and impact (latent class 3).

Latent class analysis is a specialized statistical approach that allows us to look at factor clustering that are indicative of phenotypic characteristics, and in the context of this study, factors that group together for individuals with chronic low back pain. Latent class analysis may be particularly useful for identifying clinical phenotypes that can build toward a precision medicine approach.[10] In the context of chronic pain, there is hope that these phenotypes may be connected to treatment outcomes and lead to improved treatment efficacy.[27] These phenotypic analyses provide an important and novel opportunity to look at how pain and emotional factors may overlap and could indicate how these modifiable factors can be approached.

The variables examined in the current study represent potentially modifiable factors, including pain intensity, neuropathic pain, catastrophizing, anxiety, depression, fatigue, and sleep difficulty. In our exploratory analyses, we expected the three latent classes related to low, moderate, and high pain severity and pain impact to map onto APA treatment outcomes. However, these groupings (ie, classes) were not related to treatment outcomes in general, but the APA treatment effect is different in different latent classes. Although we only found a weak relationship between the latent classes and the treatment groups in the current APA study, we do propose that these classes may be related to other treatment types or indicate clinical characteristics that are especially important for physicians to consider.[28] It may seem intuitive that the factors that represented pain severity and pain impact clustered together, as these factors often co-occur and can exacerbate each other. For example, those with pain and sleep difficulties tend to have higher depression symptoms, pain catastrophizing, and anxiety.[29,30] This co-occurrence and potential amplification between the variables identified as clustering factors in the current analyses is especially relevant, as it provides further support for the interrelationship between these variables for people with chronic low back pain.

The potential compounding effect of the overlapping pain and pain impact variables highlighted in these clusters may be important in the clinical context, as they could be used to indicate those who may be in greater need of intervention or it may indicate alternative interventions that may be useful. For example, if an individual with high pain intensity seeks care and their pain is the sole focus of care, leaving their depression, anxiety, and catastrophizing untreated, they are unlikely to meaningfully improve. This lends support that a biopsychosocial treatment approach may have greater efficacy for this patient population.[31,32]

The current findings are similar to previous studies,[7,33] as our pain phenotyping latent class analysis successfully clustered patients into classes presenting different pain profiles and emotional burden. Like previous studies, we can also see the relationship between physical and mental health among classes: the higher pain severity, the higher pain impact, which provides us a comprehensive understanding of the chronic low back pain population. Additionally, in line with previous work,[7] we also found a significant difference of comorbidity among pain profiling groups. The current study expanded on these findings by demonstrating for the first time that the three pain profiling groups differed in physical function, fear of physical activity, disability, and work status. Lastly, related previous work that established similar pain and pain impact clustering did not explore the relationship between pain profiling classes and the treatment effect. Although we failed to find this association, these analyses were an important addition to the chronic low back pain phenotyping literature.

The current work sheds light on modifiable factors that appear to be phenotypic clusters in chronic low back pain; however, the limitations of the current study must be taken into account. Although the current study was powered to allow identification of latent classes, the parent study had higher than expected attrition due to halt of in-person assessments caused by COVID-19. The primary study endpoint of 1 month follow-up may have limited the ability to see therapeutic changes over time and may indicate a need for longer follow-up assessment. This study was conducted in the Baltimore area at an academic medical center which may limit generalizability to other regions. In the parent study, although most participants indicated that they believed they were in the T-APA group, it should be noted that the interventionist were not blinded to APA group assignment. Latent class analysis provides a unique opportunity to examine pain phenotypes; however, it should be noted that this type of analysis is based on probabilities and may underestimate or misestimate the number of individuals in each class.[34] Moreover, the majority of the pain severity and pain impact variables included in the current study were assessed over a brief period of time (eg, pain intensity over the past 7 days). This represents a relatively short window of time and is likely not reflective of longer-term pain and psychological burden. Future work should consider variables that reflect a greater time span (eg, chronic pain stage)[35] and are therefore more indicative of the patient experience.

Conclusion

Although the classes identified in the current analyses did not map onto APA treatment responses, they may still be useful for other interventions and should be explored in other clinical trials. The overlap in the clusters identified in the current analysis with previous work highlights the importance of co-occurring pain and pain impact factors. The relationship between those with the lowest pain and psychological distress with high physical functioning and higher employment status is a novel addition to the literature. It may be that the identified classes could be used in a clinical context to highlight those most in need of critical pain care and the importance of a personalized approach to pain management. They may also indicate the type of intervention that may be most useful, as a multidisciplinary approach to lessen pain with a focus on psychological distress may be warranted most for those in the high pain severity and pain impact class.

Data Sharing Statement

The deidentified datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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Disclosure

The authors report no conflicts of interest in this work.

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