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Negative Affect and Sleep Disturbance May Be Associated With Response to Epidural Steroid Injections for Spine-Related Pain

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Abstract

Objective—To describe whether negative affect and sleep impairment are associated with the clinical effect of epidural steroid injections (ESIs) for low back pain.

Design—Observational study; patients were evaluated before ESI and 1 and 3 months after ESI.

Setting—Spine center and related treatment sites.

Participants—Participants (N=158) seeking treatment for low back pain with or without radiculopathy.

Intervention—ESI for low back pain with or without radiculopathy.

Main Outcome Measures—We assessed the dependent (global pain severity for back and leg pain, pain behavior, pain interference) and independent variables (depression, sleep disturbance, and covariates of back pain response) with the Patient-Reported Outcome Measurement Information System (PROMIS) and legacy measures. Outcome was assessed cross-sectionally using multiple regression and longitudinally with path analysis.

Results—After 1 month, sleep disturbance was the only predictor for the global ratings of improvement in back pain ($R^2=16.8\%$) and leg pain ($R^2=11.4\%$). The proportions of variance explained by sleep disturbance and negative affect for all dependent variables were greater at 3 months than 1 month. Mediation analysis was significant for negative affect for the 3-month outcomes on PROMIS pain behavior ($\beta=.87$, $P<.01$) and pain interference ($\beta=.37$, $P<.01$). There was no evidence of mediation by sleep disturbance for any outcome.

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Conclusions—Negative affect and sleep disturbance are associated with worse outcomes after ESI. Further research is needed to determine if treatment of negative affect and sleep disturbance prior to or concurrently with ESI will improve outcomes.

Keywords

Low back pain; Rehabilitation; Sciatica; Sleep

Approximately two thirds of adults in the United States experience back pain at some time in their lives.¹ Low back pain is the second most common symptomatic reason for primary care physician visits and the fifth most common reason for all physician visits.^{2,3} Back pain is the most common cause of work-related disability in people <45 years of age, and it is the most expensive cause overall in terms of workers' compensation and medical expenses.⁴ The average cost per claim is \$8000, and estimated nationwide costs associated with back pain are between \$38 and \$50 billion.⁵

Injections of corticosteroids into the epidural space have been used to treat lumbosacral pain with and without radiculopathy since the 1950s and are widely used in the United States. Medicare Part B claims in 2001 for 40.4 million covered individuals were \$450 million for lumbosacral steroid injections.⁶ Although there are conflicting data regarding the efficacy of these injections, the best evidence suggests that compared with saline injections, there is a moderate short-term benefit (<3mo) of epidural steroid injections (ESIs) in the setting of sciatica or radiculopathy.⁷ The results of this study suggest that most patients receiving ESI for sciatica will have some short-term pain relief, often observed within a matter of weeks.

Although ESI offered transient benefits in pain symptoms at 3 weeks in patients with sciatica, benefits were not sustained in terms of pain, function, or need for surgery during the 6- to 52-week follow-up.⁷ A report from the American Academy of Neurology⁸ provides further support: when compared with control treatments, ESI may result in some improvement in radicular lumbosacral pain when assessed between 2 and 6 weeks after the injection, but there is no improvement in function or long-term pain relief beyond 3 months. Given these conflicting findings about improvement in pain and functioning, enhanced understanding of the variables associated with both pain and functioning response to ESI is clearly needed.

Negative affect and sleep disturbance have been associated with poor clinical and surgical outcomes for lumbosacral pain (with and without radiculopathy),^{9–11} supporting our focus on these variables in affecting ESI outcome. Indeed, 53% of patients presenting to a pain clinic with a chief complaint of back pain met criteria for clinically significant insomnia.¹² Another observational study of pain clinic patients observed that those with chronic pain and concurrent major depression and insomnia had the highest levels of pain-related impairment, whereas insomnia, even in the absence of major depression, was also associated with increased pain and distress.¹³ Although it logically follows that these variables might also be associated with poor outcomes after ESI, this possibility has not been adequately studied.^{7,14} Given the established association of negative affect and sleep disturbance and the treatment response of low back pain with other interventions, and the fact that negative affect and

sleep disturbance are modifiable covariates, it is important to better understand the relation between these neuropsychiatric covariates and the response to ESI.

We hypothesized that negative affect and sleep disturbance account for a significant proportion of the variance in outcome at 1 and 3 months after ESI in a sample of mixed age adults receiving ESI for low back pain with and without radiculopathy. We also hypothesized that negative affect and sleep disturbance at 1 month would mediate improvement in pain and disability 3 months after ESI.

Methods

Participants

Participants were recruited from the University of Washington Spine Center at Harborview Medical Center and related treatment sites to participate in a protocol developed by investigators from the Patient-Reported Outcome Measurement Information System (PROMIS).¹⁵ The general aim of the parent protocol was to compare the psychometric properties of PROMIS instruments with legacy instruments used in the study of pain and emotional distress. All participants were seeking treatment for a diagnosis of low back pain with or without sciatica and were scheduled for an ESI. Participants were recruited from the clinic at the time they were being evaluated and scheduled for an ESI. Data were collected at baseline prior to the ESI. In general, this was no more than 2 weeks prior to the ESI and often took place immediately before the ESI. The follow-ups were then conducted 1 and 3 months from the time they received the ESI. To refine the sample for the present analyses, we categorized the diagnoses as (1) back pain, (2) radiculitis, (3) spinal stenosis, (4) radiculopathy, and (5) herniated disk. This study sample included 158 patients. Although all subjects had back pain, they received only 1 diagnosis. Those characterized as having radiculitis or radiculopathy predominantly had leg pain. The ESI approaches included the following: (1) transforaminal (n=90), (2) caudal (n=20), and (3) interlaminar (n=48).

Patients with common psychiatric conditions (eg, depression, anxiety disorders) were included; excluding these patients would not reflect the psychological variability of those who present for ESI. All participants experienced pain for at least 6 weeks. Exclusion criteria included the following: (1) dementia or cognitive impairment interfering with completion of assessments; (2) lumbar surgery within the last year; (3) unstable neurologic symptoms (eg, bowel or bladder incontinence, numbness in the groin area, new or worsening weakness in legs or new numbness or tingling in legs, cauda equina syndrome, spinal cord injury); (4) cancer; (5) vertebral fractures; or (6) multiple sclerosis. The demographic characteristics of the sample are summarized in table 1. The participants were assessed at 3 time points: (1) baseline (pre-ESI), (2) 1 month after the ESI, and (3) 3 months after the ESI.¹⁶ Prior to participation, all patients were engaged in an informed consent process. The project was approved and monitored by the University of Washington Institutional Review Board.

Measures

The PROMIS is a National Institutes of Health Roadmap (now Common Fund) initiative devoted to developing better measurement tools for assessing constructs relevant to the clinical investigation and treatment of all diseases, for example physical functioning, pain, fatigue, emotional distress, sleep, and social participation. The PROMIS research network has created and refined a comprehensive methodology for developing item banks of health-related constructs using both qualitative and quantitative techniques and modern psychometric methods (item response theory). The PROMIS measures are described in more detail elsewhere^{17–19} and included the item banks for (1) pain and functioning (pain behavior and pain interference), (2) negative affect (anger, anxiety, and depression), and (3) sleep (sleep disturbance and sleep-related impairment during the day). All PROMIS measures were scored such that higher scores corresponded to greater impairment or severity. The PROMIS measures were administered through computerized adaptive testing (CAT). Corresponding legacy measures (ie, paper and pencil assessments with established psychometrics) were also administered to assess pain and functioning, emotional distress, and sleep, including a global assessment of back and leg pain, the Roland-Morris Low Back Pain Disability Questionnaire (RMDQ),²⁰ the Center for Epidemiologic Studies-Depression (CES-D) scale,²¹ and the Medical Outcomes Study (MOS) Sleep Scale.²² Similarly, these measures were scored such that higher scores corresponded to greater impairment or severity.

Potential predictors

To identify potential predictors of response to ESI, we selected available variables from the parent studies (part of the larger PROMIS initiative focused on depression, associated psychiatric comorbidity, and pain) with established associations with low back pain. These included the following: (1) other chronic pain problems (coded as 1 [yes] and 0 [no])²³; (2) current smoking (coded as 1 [yes] and 0 [no])²⁴; (3) current alcohol use (coded as 1 [never], 2 [monthly or less], 3 [2–4 times a mo], 4 [2–3 times a wk], and 5 [4 times a wk])²⁵; and (4) global assessment of general health (coded as 1 [excellent], 2 [very good], 3 [good], 4 [fair], and 5 [poor]).²⁶ Relevant demographic variables included age, sex (coded as 1 [man] and 2 [woman]),²⁷ education (coded as 1 [high school], 2 [college degree], and 3 [advanced degree]),²⁸ and relation status (coded as 1 [never married], 2 [married], 3 [living with partner], 4 [separated], and 5 [divorced]).²⁹ The PROMIS measures included the item banks for negative affect and sleep, and the legacy measures included the CES-D scale and MOS Sleep Scale.

Clinically relevant outcomes

We selected 5 outcome variables with high clinical relevance for pain severity and pain-related functioning. These included (1) a global rating of back pain (compared with baseline at the 2 follow-up assessments), (2) a global rating of leg pain (compared with baseline at the 2 follow-up assessments), (3) the total score from the RMDQ, (4) the score from CAT for PROMIS pain behavior, and (5) the score from CAT for PROMIS pain interference. Again, these variables were scored such that higher scores corresponded to greater impairment or severity.

Statistical analysis

Our first aim was to use a regression approach to determine whether sleep and negative affect predicted worse pain and functioning at 1- and 3-month follow-up. Using the predictor variables previously described, we used a stepwise approach to determine the order of entry of the independent variables into the regression analyses. Our approach was not hypothesis driven; we did not force variable entry into the regression model in the spirit of hypothesis generation. All previously described potential predictors were included in the regression models for each of the 5 outcomes. Using a stepwise approach, only significant predictors were retained in the final regression models. Using path analysis with these 5 outcome variables, the second aim was to examine potential mediation (by negative affect and sleep at 1mo follow-up) of pain trajectories from baseline to 3-month post-ESI. Figure 1 illustrates the paths we tested using Mplus (version 4.2).

Results

Regression analyses

Inspection of the bivariate correlations among the negative affect and sleep variables (both PROMIS and legacy measures) revealed strong relations (and potential multicollinearity). For the negative affect variables, the correlations at baseline ranged from .63 to .85; for the sleep variables, the range was .56 to .80. Therefore, we combined these 2 sets of variables to create 2 composite variables by adding the total scores of each measure. For the PROMIS measures, T scores were used in producing the composite variables. The composite score of negative affect was computed by adding the total scores of PROMIS anger, PROMIS anxiety, PROMIS depression, and the CES-D scale. The composite score of sleep disturbance was computed by adding the total scores of PROMIS sleep disturbance, PROMIS sleep-related impairment, and the MOS Sleep Scale. Significant predictors for each regression analysis and the corresponding variance explained by the aggregated predictors (R^2) are shown in table 2.

The clinical and demographic variables selected as potential predictors did, in fact, account for significant proportions of variance in 14 of the 15 regression analyses. Aggregate R^2 values ranged from 7% to 50%, with a median of 34%. Negative affect and sleep disturbance played the most prominent roles, with each of these variables making a significant contribution in 9 of the regressions. Education was included in 4 of the regression equations as the next most common predictor. At baseline, negative affect was more influential than sleep disturbance, predicting significant proportions of the variance for the RMDQ, PROMIS pain behavior, and PROMIS pain interference, whereas sleep disturbance made a contribution only to PROMIS pain behavior.

At the follow-up evaluations, the impact of negative affect remained strong, and sleep disturbance became a more important influence. At 1-month follow-up, sleep disturbance was the only significant predictor for the global ratings of improvement in back pain and leg pain. The standardized coefficients for sleep disturbance were $-.41$ and $-.34$ for back pain and leg pain, respectively. Both negative affect and sleep disturbance were significant predictors for the RMDQ (standardized coefficients were $.40$ and $.24$, respectively), whereas

negative affect was also the only significant predictor for PROMIS pain behavior and PROMIS pain interference (standardized coefficients were .56 and .62, respectively).

At 3-month follow-up, sleep disturbance was a significant predictor for all 5 pain outcome variables. Its standardized coefficients were $-.44$, $-.38$, $.31$, $.60$, and $.41$ for back pain, leg pain, RMDQ, PROMIS pain behavior, and PROMIS pain interference, respectively. Negative affect again predicted outcomes on the RMDQ (standardized coefficient $=.23$) and PROMIS pain interference (standardized coefficient $=.31$). The proportions of variance explained by sleep disturbance and negative affect (along with other significant variables) were even greater at 3-month follow-up than 1-month follow-up. See table 2 for variance explained by each predictor at each time point.

Path analyses

Prior to testing for mediation, we confirmed that there were significant changes in the 5 dependent variables (PROMIS pain behavior, PROMIS pain interference, RMDQ, back pain, and leg pain) between pre-ESI and the 3-month follow-up evaluation. For all of the variables, there were statistically significant differences ($P<.001$) between pre-ESI status and outcomes at 3 months, supporting the appropriateness of the mediational tests.

Given the strong concurrent associations between negative affect and sleep disturbance and the 5 outcome variables for pain and disability, we also examined how these predictors performed as mediators (at 1-mo follow-up) in the pain trajectories from baseline to 3 month follow-up (see fig 1). The correlations between the pain outcome variables at baseline and 3-month follow-up were $.10$, $.15$, $.47$, $.42$, and $.46$ for the global ratings of back pain, global ratings of leg pain, RMDQ, PROMIS pain behavior, and PROMIS pain interference, respectively. The correlation between negative affect and sleep disturbance at 1-month follow-up was $.70$.

When we tested the mediational paths for the global ratings of back and leg pain, none of the paths through negative affect and sleep disturbance were significant. For the RMDQ, only the path from negative affect at 1-month follow-up to outcome at 3-month follow-up was significant ($\beta=.07$, $P<.05$) (see b2 in fig 1). In addition, the mediational paths through negative affect (a_2 : $\beta=7.8$, $P<.001$; b_2 : $\beta=.11$, $P<.01$; their cross product, $a_2 \times b_2$: $\beta=.87$, $P<.01$) were significant for the 3-month outcomes on PROMIS pain behavior. The same mediational paths through negative affect (a_2 : $\beta=3.16$, $P<.001$; b_2 : $\beta=.12$, $P<.01$; their cross product, $a_2 \times b_2$: $\beta=.37$, $P<.01$) were significant for the 3-month outcomes on PROMIS pain interference. There was no evidence of mediation by sleep disturbance on these 2 outcome variables. Thus, the evidence for mediation was mixed—it varied depending on the outcome variable—but when it did appear, it was stronger for negative affect than for sleep disturbance.

Discussion

Using both cross-sectional (regression analysis) and longitudinal approaches (path analyses), we observed that both negative affect and sleep disturbance play influential roles in ESI outcome. However, these independent variables have differential effects on pain severity

and functioning. Both the cross-sectional and path analyses indicate that negative affect influences functioning 3 months after the ESI (RMDQ and PROMIS pain interference for regression analysis; PROMIS pain behavior and pain interference for path analysis). Although sleep influenced global ratings of back and leg pain and functioning in the regression analysis across the time points, it was not a significant mediator in the path analysis.

For both the regression analysis and the path analysis, negative affect was not related to global reports of either back or leg pain. Improvement in back and/or leg pain is the primary symptom target of ESI. Given the high levels of psychological distress frequently observed in patients presenting for this procedure—and evidenced by the CES-D average score of 15—it is reassuring that negative affect (depression, anxiety, and anger) may not interfere with improvement in back or leg pain. In contrast, for both of these analyses, negative affect was a significant correlate of functioning, with more severe negative affect associated with lower levels of functioning (as assessed with the RMDQ and PROMIS pain behavior and interference measures). Negative affect is an established risk factor for worse functioning after lumbar surgery,¹⁰ participation in a multidisciplinary pain program,³⁰ and physical therapy.³¹ Although hypothetical, it is possible that improving negative affect using pharmacologic or psychological interventions may result in improved functional outcomes after ESI.

Although only accounting for a small amount of the variance related to PROMIS pain interference at baseline, the influence of sleep evolved over the 1- and 3-month follow-up evaluations. In contrast with negative affect, sleep (and age) was the only independent variable associated with global back pain or global leg pain. There is rich literature describing the relation between sleep and pain. Impaired sleep has been shown to lower the pain threshold³² and increase the risk of negative affect, particularly in depression.³³ The clinical effect of sleep on pain and pain functioning increased at each follow-up. Although the regression models included sleep as the independent variable, taking the converse approach may have yielded a similar finding, given the cross-sectional nature of the study. We acknowledge that causality cannot be inferred from the cross-sectional design of these analyses. However, the results of this study suggest that with prolonged time after ESI, the link (likely bidirectional) between impaired sleep, worse back and leg pain, and functioning continues to strengthen.

We interpret the lack of a mediating effect of sleep on any of the pain or functioning outcomes as consistent with the cross-sectional regression analyses. At 1-month follow-up, sleep was only associated with global ratings of back pain and leg pain and the RMDQ, but the variance accounted for by sleep in these regression analyses was about half that attributable to negative affect for the RMDQ, PROMIS pain behavior, and PROMIS pain interference. Given the high degree of correlation (0.7) between negative affect and sleep at 1 month, we expect future studies that are initially designed and powered to test mediation might find a mediating effect of sleep on pain and functioning.

Study limitations

The strengths of this study include its being a high-quality observational study that used assessments with high internal and external validity. Indeed, all independent variables were based on established correlations with back pain natural history or treatment outcome. Focusing on both pain severity and functioning is state-of-the-science when evaluating pain treatments and correlates of outcome.³⁴ A limitation of these observations is that the parent study was not designed to formally test mediation; therefore, power may not be adequate. In addition, because this was not an efficacy study, we did not collect data on opioid and other analgesic use, pain quality (eg, burning, aching, stabbing, tingling), functional rehabilitation, such as physical therapy, and antidepressant use. Collection of these data would have added to the richness of these analyses and permitted more tests of clinically relevant covariates. These missing variables must be considered when interpreting these analyses. Because of the limited duration of this observational study (3mo), one would expect that most of the clinical response would be because of the ESI (and not other interventions). Although we were not powered for subgroup analyses, given the considerable debate about which diagnoses are most responsive to ESI treatment (with or without pain radiating into the leg), we felt that readers would want to know if patients had signs of radiculopathy/radiculitis or a low back pain diagnosis without radiation into the leg because there may have been differential results based on this distinction.

Conclusions

We observed a mediating effect of negative affect on functioning and cross-sectional effects for both negative affect and sleep on global ratings of pain and functioning. Sleep became increasingly significant in the cross-sectional analyses. Given the relevance of negative affect and sleep for other health indicators and mortality,^{35,36} the fact they are both modifiable and may be associated with less back pain and improved functioning,³⁷ and their relatively low cost of treatment compared with ESI, these data support clinical research of their stepwise treatment prior to or concurrent with ESI or other more invasive interventions.

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List of abbreviations

CAT	computerized adaptive testing
CES-D	Center for Epidemiologic Studies-Depression
ESI	epidural steroid injection
MOS	Medical Outcomes Study
PROMIS	Patient-Reported Outcome Measurement Information System
RMDQ	Roland-Morris Disability Questionnaire

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Fig 1.

Path diagram for a hypothesized model predicting pain at 3-month follow-up. This same model was used for all 5 of the dependent variables (global rating of back pain, global rating of leg pain, RMDQ, PROMIS pain behavior, and PROMIS pain interference).

Table 1

Description of participants

Characteristic	Description
Age (y)	Mean $\pm$ SD, 55 $\pm$ 13.6
	Observed range, 19e86
Sex	Male = 44%
	Female= 56%
Race and ethnicity*	Hispanic = 6%
	White = 83%
	Black = 5%
	Asian and Pacific Islander = 4%
	Native American = 4%
	Unknown = 4%
Education	<High school = 6%
	Completed high school or
	General Educational Development = 17%
	College degree = 56%
	Advanced degree = 21%
Relation status	Married = 63%
Income per annum	<\$20,000 = 14%
	\$20,000e\$49,000 = 23%
	\$50,000e\$99,000 = 36%
	>\$100,000 = 24%
	Unknown = 3%
CES-D (score)	Mean $\pm$ SD, 15 $\pm$ 10.2
	Theoretical range, 0e60 [†]
RMDQ (score)	Mean $\pm$ SD, 13 $\pm$ 5.6
	Theoretical range, 0e24 [‡]
Diagnosis supporting ESI	Back pain = 13%
	Radiculitis = 33%
	Spinal stenosis = 27%
	Radiculopathy = 21%
	Herniated disk = 6%

* Participants were allowed to choose more than one race category.

[†] Score 16 on the CES-D is consistent with clinically significant depressive symptoms.²¹

[‡] To put these scores into perspective, the average score for low back pain patients referred for physical therapy was 11.8,³⁸ and the average score for patients seen at the hospital clinic for treatment of radiculopathy was 14.2.³⁹

Table 2

Regression analysis summary using aggregated predictor variables

Time Point	Dependent Variable	Significant Independent Variable(s)	β	Individual R^2 (%)	Total R^2 (%)
1	Back pain	NA	NA	NA	NA
	Leg pain	NA	NA	NA	NA
	RMDQ	Negative affect	.572	34.9	39.2
		Relation status	.207	4.3	
	PROMIS pain behavior	Negative affect	.404	33.8	45.2
		Education	-.200	6.2	
		Sleep	.212	2.6	
2		Relation status	.165	2.6	
	PROMIS pain interference	Negative affect	.601	37.1	42.3
		Education	-.182	2.8	
		Sex	-.159	2.5	
	Back pain improvement	Sleep	-.410	16.8	16.8
	Leg pain improvement	Sleep	-.338	11.4	11.4
	RMDQ	Negative affect	.396	30.6	33.8
3		Sleep	.239	3.3	
	PROMIS pain behavior	Negative affect	.562	37.0	39.9
		Relation status	.175	2.8	
	PROMIS pain interference	Negative affect	.615	37.8	37.8
	Back pain improvement	Sleep	-.439	16.4	19.7
		Age	-.184	3.3	
	Leg pain improvement	Sleep	-.376	14.1	14.1
	RMDQ	Negative affect	.233	31.0	40.4
		Sleep	.313	3.6	
		Global health	.214	3.4	
		Age	.158	2.4	
	PROMIS pain behavior	Sleep	.596	45.4	48.7
		Global health	.198	3.3	

Time Point	Dependent Variable	Significant Independent Variable(s)	β	Individual R^2 (%)	Total R^2 (%)
	PROMIS pain interference	Sleep	.413	41.5	46.1
		Negative affect	.314	4.5	

Abbreviation: NA, not applicable.