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ORIGINAL ARTICLE

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.

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.

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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

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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 Neurology[8] 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

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**