Making Sense of the Accuracy of Diagnostic Lumbar Facet Joint Nerve Blocks: An Assessment of the Implications of 50% Relief, 80% Relief, Single Block, or Controlled Diagnostic Blocks

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Background: The presence of lumbar facet joint pain has been overwhelmingly supported and the accuracy of controlled diagnostic blocks has been demonstrated in multiple studies and confirmed in systematic reviews. However, controversy surrounds the following related issues: placebo control, the amount of relief (50% versus 80%), single block versus double block, and placebo or comparative control.

Study Design: An observational report of an outcome study to establish the diagnostic accuracy of controlled lumbar facet joint nerve blocks.

Setting: An interventional pain management practice setting in the United States.

Objective: To determine the accuracy of controlled diagnostic blocks in managing lumbar facet joint pain at the end of 2 years, with 2 different criteria (50% or 80% relief) and single block versus double block.

Methods: A previous study of 152 patients showed an 89.5% of sustained diagnosis of lumbar facet joint pain at the end of a 2-year follow-up period when the diagnosis was made with double blocks and at least 80% relief. The present evaluation includes comparison of the above results with a study of 110 patients undergoing lumbar facet joint nerve blocks with positive criteria of at least 50% relief and follow-up of 2 years. The inclusion criteria in both studies was based on a positive response to diagnostic controlled comparative local anesthetic lumbar facet joint blocks, with either 50% or 80% relief and the ability to perform previously painful movements. The treatment in both groups included therapeutic lumbar facet joint interventions either with facet joint nerve blocks or radiofrequency neurotomy.

Outcome Measures: The sustained diagnosis of lumbar facet joint pain at the end of one year and 2 years based on pain relief and functional status improvement.

Results: At the end of one year, the diagnosis was confirmed in 75% of the group with 50% relief, whereas it was 93% in the group with 80% relief. At the end of the 2-year follow-up, the diagnosis of lumbar facet joint pain was sustained in 51% of the patients in the group with 50% relief, whereas it was sustained in 89.5% of the patients with 80% relief.

The results differed between 50% relief and 80% relief with prevalence of 61% facet joint pain with dual blocks with 50% relief, and 31% with dual blocks with 80% relief; whereas with only a single block, the prevalence was 73% with 50% relief and 53% in the 80% relief group.

Limitations: The study is limited by its observational nature.

Conclusion: Controlled diagnostic lumbar facet joint nerve blocks are valid utilizing the criteria of 80% pain relief and the ability to perform previously painful movements, with a sustained diagnosis of lumbar facet joint pain in at least 89.5% of the patients at the end of a 2-year follow-up. In contrast, the diagnosis was sustained in 51% of the patients with 50% relief at the end of 2 years. Thus, inappropriate diagnostic criteria will increase the prevalence of facet joint pain substantially, leading to inappropriate and unnecessary treatment.

Key words: Chronic low back pain, lumbar facet or zygapophysial joint pain, facet joint nerve or medial branch blocks, controlled local anesthetic blocks, construct validity, diagnostic studies, diagnostic accuracy

Pain Physician 2010; 13:133-143
Significant controversy has been erupting in recent years about the accuracy of diagnosing facet joint pain. Hancock et al (1), in a systematic review of tests to identify the disc, sacroiliac joint, and facet joint as the source of low back pain, found that none of the tests for facet joint pain were found to be informative. Consequently, controlled local anesthetic blocks of the facet joint or its nerve supply are routinely employed to diagnose facet joint pain. The rationale for these blocks is that anesthetic blockade of a painful joint will abolish pain arising from that joint for the duration of the anesthetic effect, while anesthetic blocks of a non-painful joint will not alter the pain report (2). To ensure accuracy and validity, facet joint nerve blocks must be controlled and verified for placebo response. Multiple studies and systematic reviews have evaluated the reliability of diagnostic facet joint nerve blocks (2-10). Datta et al (6), Falco et al (7), and Atluri et al (8) recently performed a systematic assessment of the diagnostic accuracy of facet joint nerve blocks and concluded that controlled diagnostic blocks, utilizing at least 80% pain relief from baseline pain and the ability to perform previously painful movements, provide strong evidence in the diagnosis of facet joint pain. Rubinstein and van Tulder (11) also provided a best-evidence review of diagnostic procedures for neck and low back pain. They commented that it is quite remarkable that while many named orthopedic tests of neck and low back are often illustrated in orthopedic textbooks, there is little evidence to support the diagnostic accuracy, and therefore their use in clinical practice. However, they concluded that there is strong evidence for the diagnostic accuracy of facet joint blocks in evaluating spinal pain.

The reliability of controlled comparative blocks has been criticized and their validity as precision diagnostic techniques has been questioned (12-22). Further, the magnitude and quality of pain relief have become issues of controversy among the proponents of facet joint pain (19-22). Other issues related to the accuracy itself include the reference standard, prior exposure to opioids, sedation, systemic local anesthetic effect, and non-specific effect resulting in positive results (19,23-31).

The validity of controlled lumbar facet joint nerve blocks as a gold or reference standard in the diagnosis of lumbar facet joint pain has been established (2-10). Reference standard is established in surgical situations by biopsy or autopsy. However, these are difficult to apply in the diagnosis of chronic low back pain of facet joint origin. Thus, the long-term or dedicated clinical follow-up of the subjects appears to be the only solution in establishing a reference standard with controlled facet joint nerve blocks (18,32). Two different studies demonstrated the accuracy of diagnostic lumbar facet joint nerve blocks at 2-years (33,34). Manchikanti et al (33) established an 85% accuracy for the diagnosis at 2-year follow-up in 44 patients. Pampati et al (34) evaluated 152 patients diagnosed with controlled diagnostic blocks and concluded that controlled diagnostic lumbar facet joint nerve blocks were valid utilizing the criteria of 80% pain relief and the ability to perform previously painful movements, with sustained diagnosis of lumbar facet joint pain in at least 89.5% of the patients at the end of 2-year follow-up. Other variables related to prior opioid exposure (26), influence of sedation (27-30), influence of previous surgery (35,36), age (37), and psychological factors (38,39) have been studied. Consequently, recent systematic reviews and guidelines (6-10) have concluded in favor of 80% pain relief with controlled diagnostic blocks.

In a series of retrospective multi-center analyses, Cohen et al (20-22) evaluated the issues related to 50% or 80% relief and single block versus dual blocks. Cohen et al (20) evaluated lumbar facet joint radiofrequency denervation success as a function of pain relief during diagnostic medial branch blocks. They showed that the success rate following radiofrequency neurotomy was 52% in the group with greater than 50% relief, whereas in the group with greater than 80% relief from diagnostic blocks, 56% obtained 50% or greater pain relief. Based on this retrospective evaluation they concluded that using more stringent pain relief criteria when selecting patients for lumbar zygopophysial joint radiofrequency denervation is unlikely to improve success rates and may lead to misdiagnosis and withholding a potentially valuable treatment from good candidates. These conclusions, however, have been questioned (40,41).

Facet joint interventions are one of the most commonly performed interventions in the United States (42-45). The exponential growth in expenses for interventional techniques is partly attributed to facet joint interventions (46). Manchikanti et al (42) showed an overall increase of interventional techniques per 100,000 Medicare beneficiaries of 197% from 1997 to 2006. In contrast, facet joint interventions increased 543% during the same period. Multiple proposals of health care reform and regulations to reduce growth, overuse, abuse, and fraud have been proposed (46),
and it is clear that proper diagnosis reduces health care costs, overuse, abuse, and fraud (47).

A diagnostic test is useful only to the extent that it distinguishes between conditions or disorders that might otherwise be confused (32,48,49). Almost any test can differentiate healthy persons from severely affected ones, but this ability tells us nothing about the clinical utility of a test. The true pragmatic value of a test is therefore established only in a study that closely resembles clinical practice. Datta et al (6), utilizing at least 80% pain relief with controlled diagnostic blocks with concordant relief and ability to perform previously painful movements as the inclusion criteria, were able to include only 7 studies (36,50-55) and concluded that the overall prevalence was 31% with an overall false-positive rate of 30% with a single block. The reference standard also has been confirmed for lumbar diagnostic facet joint nerve blocks with long-term follow-up, but only utilizing 80% pain relief with controlled diagnostic blocks (33,34). Consequently, there has not been a reference standard established with long-term follow-up with 50% or greater pain relief for a single block.

This evaluation was undertaken to establish the accuracy of lumbar facet joint nerve blocks in diagnosing lumbar facet joint pain utilizing a dedicated long-term follow-up of 2 years in 2 groups of patients either with 50% or greater relief or 80% or greater pain relief with controlled comparative local anesthetic blocks. To compare the results of 50% or greater relief to 80% or greater relief, the data from a previous study was utilized (34). However, this is not a report of detailed outcomes of lumbar facet joint interventions. These outcomes have been reported elsewhere (56-60).

**Methods**

**Participants**

After Institutional Review Board (IRB) approval, this observational study was undertaken by evaluating consecutive patients diagnosed with lumbar facet joint pain from January 1999 to December 2000 for a period of 2 years for patients with ≥ 50% pain relief with controlled comparative local anesthetic blocks. For participants with 80% or greater relief, the data from the previous publication (34) was utilized. The patients with suspected lumbar facet joint pain received controlled comparative local anesthetic blocks and if they tested positive, they were followed with therapeutic facet joint interventions with either medial branch blocks or radiofrequency neurotomy.

**Setting**

An interventional pain management setting in a non-university private practice in the United States. The procedures were performed in an ambulatory surgery center in a sterile operating room under fluoroscopy.

**Inclusion Criteria**

The chart review was performed by 3 investigators who were not involved in performing the procedures. Inclusion criteria for diagnosis and therapy have been described elsewhere in detail (50-52,54,55,61,62).

**Diagnostic Facet Joint Nerve Blocks**

Lumbar facet joint pain was investigated in all patients starting with diagnostic blocks using 1% lidocaine. Patients with lidocaine-positive results were further studied using 0.25% bupivacaine on a separate occasion, usually 3 to 4 weeks after the first injection. Following each block, the patient was examined and asked to perform previously painful movements. A positive response was defined as at least 50% or 80% reduction of pain and the ability to perform previously painful movements, as assessed using a verbal numeric pain rating scale. To be considered positive, pain relief from a block had to last at least 2 hours when lidocaine was used and at least 3 hours or longer than the duration of relief with lidocaine when bupivacaine was used. All patients judged to have a positive response with lidocaine blocks underwent subsequent bupivacaine blocks.

**Therapeutic Facet Joint Interventions**

Therapeutic facet joint interventions with medial branch blocks or radiofrequency neurotomy have been described elsewhere (34,56,57).

**Co-Interventions**

The same co-interventions as needed with opioid and non-opioid analgesics, adjuvant analgesics, and previously directed exercise programs before enrollment, were continued in all patients. Medical therapy was also adjusted based on response and physical and functional needs (34,56,57).

**Outcomes**

Patients were evaluated with multiple outcome measures including numeric rating scale (NRS), Oswestry Disability Index (ODI), work status, and opioid intake (56) in the study evaluating 80% pain relief. However, in patients with ≥ 50% relief, only significant pain relief with NRS and functional status improvement were identified.
Sample Size
A sample size of 80 patients was chosen for the group with ≥ 50% relief. The previous study utilized a sample size of 150 patients (34). The estimated sample size was based on previous studies of lumbar and cervical facet joint interventions which included less than 20 patients in each group (63,64); other literature of interventional techniques identifying 50 patients as acceptable in randomized trials (65); and randomized evaluations of medial branch blocks (56,58), epidural injections (66-74), and adhesiolysis (75-77) with inclusion of 60 patients in each group.

Statistical Analysis
Data was recorded in a database using Microsoft Access by a person not participating in the study. The SPSS version 9.0 statistical package was used to generate the frequency tables. Students’ t-test was used to test mean significant differences between groups. Categorical data were compared using a chi-squared test. Fisher’s exact test was used wherever the expected value was less than 5. Results were considered statistically significant if the $P$-value was less than 0.05.

Intent-to-Treat Analysis
An intent-to-treat analysis was performed. Either the last follow-up data or initial data were utilized in the patients who dropped out of the study and no other data were available.

Results
Participant Flow
The number of patients suspected of facet joint pain and undergoing screening diagnostic lumbar facet joint blocks with 1% lidocaine were 491 in the 80% or greater pain relief group and the number of patients in the greater than 50% pain relief was 181. Of these, 152 or 31% tested positive with double blocks utilizing greater than 80% relief and 61% or 110 tested positive in the group with relief of 50% or more.

Demographic Variables
Table 1 illustrates demographic characteristics of patients included in both groups, either with ≥ 50% relief or ≥ 80% relief. There were no significant differences noted in the baseline demographic characteristics.

Table 1. Baseline demographic characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Group with ≥ 50% relief</th>
<th>Group with ≥ 80% relief</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>110</td>
<td>152</td>
<td>0.900</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>44% (48)</td>
<td>45% (68)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>56% (62)</td>
<td>55% (84)</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>48 ± 13.3</td>
<td>47 ± 15.0</td>
<td>0.610</td>
</tr>
<tr>
<td><strong>Height (inches)</strong></td>
<td>67 ± 3.8</td>
<td>67 ± 3.9</td>
<td>0.759</td>
</tr>
<tr>
<td><strong>Weight (lbs)</strong></td>
<td>180 ± 46.2</td>
<td>185 ± 47.7</td>
<td>0.454</td>
</tr>
<tr>
<td><strong>Duration of Pain (months)</strong></td>
<td>116 ± 109.2</td>
<td>115 ± 116.8</td>
<td>0.956</td>
</tr>
<tr>
<td><strong>Mode of Onset of pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-traumatic</td>
<td>64% (70)</td>
<td>65% (99)</td>
<td>0.896</td>
</tr>
<tr>
<td>Traumatic</td>
<td>36% (40)</td>
<td>36% (53)</td>
<td></td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working</td>
<td>19% (21)</td>
<td>22% (33)</td>
<td>0.987</td>
</tr>
<tr>
<td>Unemployed</td>
<td>11% (12)</td>
<td>11% (16)</td>
<td></td>
</tr>
<tr>
<td>Housewife</td>
<td>9% (10)</td>
<td>9% (14)</td>
<td></td>
</tr>
<tr>
<td>Disabled</td>
<td>46% (50)</td>
<td>45% (68)</td>
<td></td>
</tr>
<tr>
<td>Over 65</td>
<td>15% (17)</td>
<td>14% (21)</td>
<td></td>
</tr>
</tbody>
</table>
**Diagnosis of Lumbar Facet Joint Pain**

Table 2 illustrates the results of lumbar facet joint nerve blocks with a prevalence of 61% (95% CI, 53%, 68%) in ≥ 50% group versus 31% (95% CI, 26%, 35%) in ≥ 80% group. The table also illustrates the false-positive rate of 17% (95% CI, 10%, 24%) versus 42% (95% CI, 35%, 50%) in ≥ 50% relief versus ≥ 80% relief groups. There were significant differences between ≥ 50% relief and ≥ 80% relief groups with prevalence ($P = 0.001$) as well as false-positive rated with a single block ($P = 0.001$).

**Duration of Pain Relief with Diagnostic Blocks as A Variable**

Table 3 illustrates the differences between the duration of initial pain relief or subsequent pain relief in weeks among both groups, with longer relief with confirmatory block in the group with ≥ 80% relief ($P = 0.031$).

**Follow-Up Evaluation Results**

At one year follow-up, in patients with ≥ 50% relief, 75% of the patients continued to have a diagnosis of facet joint pain, whereas in the group of ≥ 80% relief, 93% sustained a diagnosis of facet joint pain. However, at 2-year follow-up, the differences were much more significant, with only 51% of the patients with ≥ 50% relief showing the continued diagnosis of facet joint pain, whereas it was 89.5% in the group with ≥ 80% relief (Table 4).
**Discussion**

This observational report of diagnostic evaluation with long-term follow-up utilizing 2 diagnostic criteria with controlled diagnostic blocks with ≥ 50% or ≥ 80% pain relief illustrated superiority of 80% pain relief with 89.5% of patients continuing to have a diagnosis of facet joint pain at 2 year follow-up; compared to 51% of the patients in those with the diagnosis of facet joint pain based on ≥ 50% pain relief, a significant difference. Thus, in the ≥ 80% pain relief group, the accuracy of diagnosis was ≥ 90% at one and 2 years with only 9 of 152 patients at one-year follow-up and 16 of 152 patients at 2-year follow-up either changed to a different diagnosis or failed to respond to therapeutic facet joint interventions. In contrast, in the group with ≥ 50% pain relief (some of whom are expected to have ≥ 80% relief), 27 patients at the end of one year and 54 patients at the end of 2 years (from a total of 110 patients) were judged to be negative for facet joint pain due to either a changed diagnosis or failure to respond to therapeutic facet joint interventions.

Thus, with application of a single block with ≥ 50% relief, in the present evaluation, approximately 73% of the patients suspected of facet joint pain will undergo radiofrequency neurotomy in contrast to 31% in patients with 80% relief and dual blocks. If the patients who have been judged to be negative for facet joint pain undergo caudal epidural injections, which are less expensive, the treatment will result in cost savings and also provide appropriate treatment. This is preferred to subjecting the patient to unnecessary expensive and inappropriate interventions (10,66,70,74). Further, the studies utilizing ≥ 80% relief with double blocks have shown relief in a greater proportion of patients (78,79). The direct comparison of cost effectiveness has not been performed. Further, even utilizing double blocks, the prevalence has been shown to be 61% in similar population groups in the same practice setting indicating an additional prevalence of 30% (a 97% increase). Obviously, in the ≥ 50% group also, approximately 50% would have experienced ≥ 80% relief since there were no cutoffs of 80% or higher and it was only evaluated as ≥ 50%. The sustained diagnosis of lumbar facet joint pain at the end of 2 years in 65% of the population indicates that the majority of the patients who have received good pain relief, rather than low levels, probably have sustained the diagnosis at the end of 2 years.

Cohen et al (20) contended that the false-positive rate is low (25% to 40%) and it is not necessary to perform double blocks on the basis of busy practices, low level of complications with radiofrequency neurotomy, and radiofrequency neurotomy as a definitive treatment for facet joint pain. Thus, they believe that it is not cost-effective either to do double blocks or use 80% or near total relief as the standard prior to therapeutic interventions. It has also been stated that patients may be deprived of a treatment because of a misdiagnosis leading to increased disability, unnecessary interventions, and amplified costs. However, the same argument can be applied for unnecessary treatment with radiofrequency neurotomy. Patients not suffering with facet joint pain are better off being treated with another modality of treatment, namely, epidural injections with or without steroids, with at least 80% of patients having a positive response (10,66,70,74). By the same token, patients receiving radiofrequency neurotomy responded with 52% and 56% of the patients with ≥ 50% or ≥ 80% relief respectively.

Overall, this evaluation clearly illustrates double blocks with 80% relief are superior to a single block with 80% relief, single block with 50% relief, or double blocks with ≥ 50% relief.

The results of this study will also function in providing reliability and validity to facet joint diagnosis with diagnostic blocks. In general, the validity of a diagnostic test is demonstrated by comparing it to a gold or criterion standard. A criterion standard is a well accepted and commonly applied method of identifying the disease or clinical entity of interest. Sensitivity of a test is the proportion of people with a disease who will have a positive result, whereas specificity is the proportion of people without the disease who will have a negative test result (80). Thus, it is interpreted that a valid diagnostic test has the ability to correctly identify people with a condition (positive for the condition or at risk for that condition) or absence of the condition (negative for the condition or not at risk for the condition). Validity incorporates content validity, face validity, and construct validity. However, of the 3 components, construct validity is considered the most critical of all subtypes of establishing if the test actually achieves what it is supposed to achieve by not only measuring the extent to which a test correctly distinguishes the presence, but also the absence of the condition that the test is supposed to detect. Consequently, construct validity measures the capacity of the test and shows the clinician if the test actually works (81). Thus, for each test, a criterion standard must be established.

Construct validity, which is the crucial and most argued part of the diagnostic evaluation, is avoiding false-positives and proving the accuracy of the test on a long-
term basis. The construct validity essentially establishes that the test actually achieves what it is supposed to achieve by measuring the extent to which a test correctly distinguishes the presence, and also the absence, of the condition that the test is supposed to detect – namely false-positive results. This evaluation confirms that over a long period of time, controlled comparative diagnostic lumbar facet joint nerve blocks have been shown to be accurate in at least 90% of the population with a strict criterion of 80% relief and the ability to perform previously painful movements. In contrast, utilizing loose criteria of 50% relief fails to achieve significant construct validity, and thus may not be utilized as a reference standard.

A criterion standard may be obtained in many ways, including laboratory tests, imaging tests, function tests, and pathology, but also by dedicated clinical follow-up of the participants. However, if no single reference standard is available, the most likely state of the patients can be derived from careful clinical follow-up (82). Further, the criterion, reference, or gold standard has been described as a proxy for the target condition and often imperfect, a factor which is not well appreciated (83). This evaluation establishes once again the appropriateness of utilizing the results of controlled comparative local anesthetic blocks with 80% pain relief as the criterion standard in the diagnosis of lumbar facet joint pain, rather than a single block with 50% or 80% pain relief, or a double block with 50% pain relief. Pearl (84) described a hierarchal outcomes approach to test assessments using a description of 6 criteria, which included technical aspects, diagnostic accuracy and validity, diagnostic thinking, therapeutic effectiveness, the ability to improve patient outcomes, or at least provide diagnosis and societal outcomes. In our previous report (34), we have illustrated how these criteria have been met with controlled comparative local anesthetic blocks with 80% pain relief. Further, the results also have been shown to be similar in cervical and thoracic spine (2-11).

The importance of ≥ 80% relief has been illustrated by Datta et al (6) and Falco et al (7) with exclusion of multiple studies which failed to meet the criteria of controlled or dual blocks with 80% pain relief (20-22,60,61,85-99). Some of these studies consistently showed overall higher prevalence compared to the studies meeting inclusion criteria. Further, these studies also showed poorer therapeutic response.

Limitations of this study include the lack of placebo-controlled diagnostic blocks, and a 2-year follow-up which may be considered by some as short-term and the retrospective nature of the data collection.

Placebo-controlled neural blockades are not realistic even though it has been misinterpreted (100, 101). Some have mistakenly reported that any local anesthetic injection which yields similar results as steroids is considered a placebo. However, these interpretations are inaccurate. Further, the difference between injections of sodium chloride solution and dextrose have been shown (102). The experimental and clinical findings from investigation of the electrophysiological effects of 0.9% sodium chloride solution and dextrose 5% in water solution have added new knowledge and controversy to multiple aspects of neural stimulation used in regional anesthesia. The potential inaccuracy created by 0.9% sodium chloride solution versus 5% dextrose has been described (102,103).

The 2-year follow-up is appropriate for interventional procedures. However, longer term relief would be more appropriate. The observational nature of the study also adds to some of the limitations; however, diagnostic studies are always observational and non-randomized, though not retrospective.

Overall, evidence in this report demonstrates that lumbar facet joint pain diagnosed by controlled, comparative local anesthetic blocks with a criteria of 80% pain relief, which is sustained after prior painful movements for the appropriate duration of action of local anesthetics, and treated appropriately with lumbar facet joint interventions, provides validity to the diagnosis of facet joint pain by controlled comparative diagnostic blocks at 2-year follow-up with sustained diagnosis. In comparison, ≥ 50% relief with 2 diagnostic blocks has been shown to be unreliable with inferior outcomes and lack of sustained diagnosis at the end of 2-year follow-up.

CONCLUSION

The results of this observational evaluation of the accuracy of diagnosis of lumbar facet joint pain by controlled comparative local anesthetic blocks utilizing either 50% or 80% pain relief as the criteria, have demonstrated the validity of 80% pain relief with controlled diagnostic blocks rather than ≥ 50% pain relief.

ACKNOWLEDGMENTS

We would like to thank Kim Damron, RN, Carla McManus, RN, BSN, and Renee Barnhill, RN, BSN clinical coordinators; and Tonie M. Hatton and Diane E. Neihoff, transcriptionists; for their assistance in preparation of this manuscript. We also would like to thank the editorial board of Pain Physician for review and criticism in improving the manuscript.
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