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RE: Comments on Washington State Health Care Authority, HTA Program Key Questions for Spinal Injections

Ms. Santoyo, Mr. Hill, and Ms. Hole-Curry:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), the board and membership, the Executive Committee thanks Washington State Health Care Authority for providing us with an opportunity to present public comments for key questions on spinal injections. ASIPP is a not-for-profit professional organization comprised of over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 7,000 appropriately trained and qualified physicians practicing interventional pain management in the United States.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (1).

Interventional pain management techniques are minimally invasive procedures, including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (2).
It is our understanding that key questions are related to treatment of chronic back or neck pain with or without radiculopathy when more conservative care has not provided relief. Further, as per the document, spinal injections considered here included epidural injections, facet joint injections, medial branch blocks, sacroiliac joint injections, and intradiscal steroid injections. Thus, we will limit our comments to the above topics except for intradiscal steroid injections as there is no evidence for this procedure and it is not a common practice.

1. WHAT IS THE EVIDENCE OF EFFICACY AND EFFECTIVENESS OF SPINAL INJECTIONS?

1.0 Epidural Injections
Access to the epidural space is available by caudal, interlaminar, and transforaminal approaches (3-14). Substantial differences with the technique and outcomes have been described among the 3 approaches. Thus, due to the inherent variations, differences, advantages, and disadvantages applicable to each technique (including the effectiveness and outcomes), caudal epidural injections, interlaminar epidural injections (cervical, thoracic, and lumbar epidural injections), and transforaminal epidural injections (lumbosacral) are considered as separate entities.

In addition, the response to epidural injections for various pathological conditions (disc herniation and/or radiculitis, discogenic pain without disc herniation, spinal stenosis, and post surgery syndrome) is variable.

1.1 Caudal Epidural Injections
Several systematic reviews have evaluated the effectiveness of epidural steroids including caudal epidural injections (9-12,15-34). However, most of them failed to separate caudal and interlaminar techniques, arriving often at erroneous conclusions (34,35). Of importance are systematic reviews performed by Nelemans et al (15), updated by Staal et al (18,19), Koes et al (16,25), van Tulder et al (17), Armon et al (28), and Chou et al (29,30). All these reviews included essentially similar criteria as well as the same studies, uniformly arriving at inaccurate conclusions. In contrast, Abdi et al (8), Bogduk et al (13), and Manchikanti (31,32) evaluated caudal epidural steroid injections as separate procedures, reaching opposite conclusions. They concluded that the effectiveness of caudal epidural injections in managing lumbar radiculopathy was moderate.

Conn et al (9), in a systematic review evaluating the effect of caudal epidural injections with or without steroids in managing various types of chronic low back and lower extremity pain emanating as a result of disc herniation or radiculitis, post lumbar surgery syndrome, spinal stenosis, and chronic discogenic pain without disc herniation or radiculitis, has shown Level I evidence for short- and long-term relief of chronic pain secondary to disc herniation or radiculitis and discogenic pain without disc herniation or radiculitis. Further, the systematic review by Conn et al (9) also provides an indicated level of evidence II-1 or II-2 for caudal epidural injections in managing chronic pain of post lumbar surgery syndrome and spinal stenosis. The results of the systematic review were provided utilizing contemporary systematic review methodology utilizing randomized trials and observational studies, even though most of the evidence was derived from randomized trials.

In a critical review of the American Pain Society (APS) clinical practice guidelines for interventional techniques published by Chou et al (29,30), Manchikanti et al (32,34) reassessed the evidence utilizing the same criteria as Chou et al did. However, the conclusions of APS and Manchikanti et al’s assessment based on grading of good, fair, and poor, while agreeing that there was poor evidence for caudal epidural steroids for conditions other than disc herniation and radiculitis, Manchikanti et al arrived at different conclusions with fair evidence for therapeutic caudal epidural injections in disc herniation or radiculitis. However, with addition of new evidence, the evidence will be improved to fair for discogenic pain, post
lumbar laminectomy syndrome, and spinal stenosis when caudal epidurals are performed under fluoroscopic visualization.

### 1.1.1 Methodologic Quality Assessment

Methodologic quality assessment of the randomized clinical trials (35-39,41-45,47-54) evaluating the effectiveness of caudal epidural injections is illustrated in Table 1 with comparison of evaluation by Chou et al (29,30) and Manchikanti et al (32).

**Table 1. Methodological assessment of randomized clinical trials evaluating the effectiveness of caudal epidural injections.**

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Table 1 (cont). Methodological assessment of randomized clinical trials evaluating the effectiveness of caudal epidural injections.

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### Table 1 (cont). Methodological assessment of randomized clinical trials evaluating the effectiveness of caudal epidural injections.

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* Included by Chou and Huffman (29) and Conn et al (9)
+ Included by Conn et al (9), but not Chou and Huffman (29)
§ Included by Chou and Huffman (29), but not Conn (9)
∆ Not available at the time of Chou’s search

Fluoroscopy used in performing caudal epidural injections

NS = Not scored by APS-AAPM review


#### 1.1.1.1 Methodologic Quality of Randomized Controlled Trials

Based on this analysis, it appears that while most of the assessment was appropriate for the studies which were included by others in their systematic reviews, Chou and Huffman (29) included studies which did not meet inclusion criteria. This illustration shows that even though quality criteria is met, the study can be very poorly performed, and therefore not clinically relevant. Béliveau (41) had no data at 3 months. Justifiably, Chou and Huffman (29) rated this study as extremely low due to the lack of data at 3 months, along with many other deficiencies. Zahaar (42) utilized very high volumes of sterile saline with local anesthetic with or without steroid, 30 mL, injecting blindly without fluoroscopic guidance. The study was not placebo-controlled and so had low methodologic quality. Ackerman and Ahmad (52) provided inadequate descriptions and the study was poorly performed, even though it was rated by Chou and Huffman (29) as high quality; our assessment also showed high methodologic quality. However, this study was excluded from assessment and was not included by others due to the short-term follow-up of 24
weeks, along with other multiple deficiencies (9). Ackerman and Ahmad (52) was a low quality study. It also showed that there is no difference among the 3 types of treatments; but, did not show that caudal epidurals were ineffective.

Among high quality studies reporting positive results, 5 were performed under fluoroscopy (47-51,53,54), and one was performed without fluoroscopy (43). However, none of them were placebo-controlled. All the fluoroscopic studies were performed on chronic low back pain patients who had disc herniation; discogenic pain with or without disc herniation or radiculitis, post lumbar laminectomy syndrome; or spinal stenosis (47-51,53,54). The non-fluoroscopic study was performed with local anesthetic injection with or without steroid (43) in patients with disc herniation and pain duration of one month. The results were positive in this study.

1.1.1.2 Methodological Quality of Systematic Reviews

We identified multiple systematic reviews evaluating the effectiveness of caudal epidural injections (Table 2).

Quality assessment results of systematic reviews are illustrated in Table 2. The rating was judged to be inappropriate in some studies resulting in favorable or unfavorable opinions. The overall quality score was a maximum of 9; however, Chou and Huffman (29) utilized a maximum score of 7. We were unable to understand the rationale related to the modified score and analysis. Manchikanti et al (31) was not evaluated, even though it met 7 of 9 criteria. Luijsterburg et al (22) in this assessment met only 5 of 9 criteria, but APS-AAPM scored it 7/7 or (9/9 corrected) meaning it met all criteria. Abdi et al (8) was described as low quality and that it met 3 of 7 criteria. However, looking at the 9 items, even by their own (29) determination, this study met 6 of 9 criteria, with one item meeting partial criteria; our assessment showed 7 of 9 criteria were met. Vroomen et al (21) were evaluated as meeting 5 of 7 criteria, even though it should have been 8 of 9 by their own assessment; our reassessment showed only 6 of 9. Most systematic reviews except by Conn et al (9), Manchikanti et al (31), and Abdi et al (8) separated the 3 techniques, whereas DePalma et al (23) evaluated selective nerve root blocks. Luijsterburg et al (22) also utilized highly inconsistent criteria with the evaluation that findings must be consistent 80% of the time to be judged positive. Armon et al (28) received a score of 4/7 (5/9 corrected), which is higher than the reassessment score of 3/9.

The methodological quality assessment of Chou et al’s reviews (29,30) illustrated a score of 6 of 9, whereas Manchikanti et al’s reassessment (32,34) achieved a score of 8 of 9.
Table 2. Quality rating of systematic reviews of caudal epidural injections.

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*Included by Chou and Huffman (29) and Conn et al (9)
+Included by Chou and Huffman (29), but not the present reviews
* Included by Chou and Huffman (29), but not Conn (9)
§Included in Manchikanti et al (32), but not Chou and Huffman (29)
ΔNot available at the time of Chou’s search
#Fluoroscopy used in performing caudal epidural injections
NS = Not scored by APS-AAPM review


1.1.1.3 Disc Herniation and Radiculitis

Manchikanti et al (32), in a reassessment of evidence synthesis, evaluated a total of 16 studies for methodologic quality assessment, with 7 of them utilized by Chou and Huffman (29).

Eight randomized trials met criteria for inclusion for evidence synthesis (35-38,43,47,49,52,53). Ackerman and Ahmad (52) was not included in other reviews. Based on Chou and Huffman’s (29) criteria, it met the inclusion criteria. However, Zahaar (42) was not added since the methodologic criteria was low and it was not placebo-controlled, a feature misunderstood by APS guidelines (29). Bélieu...
(41) also had low methodologic quality assessment criteria. Of the 9 studies, 3 included fluoroscopy (47,49,52-54).

In the 8 studies examined, illustrated in Table 3, 7 were positive for short-term relief (less than 6 months) and 4 of 5 were positive for long-term relief (more than 6 months). Even with elimination of the 2 studies, which were not available at the time the APS guidelines were published (43,49), the results still continue to be positive, with 5 of the 6 studies positive for short-term relief (35,37,38,47,52) and 2 of the 3 studies positive for long-term relief (36,38).

1.1.3.1.1 Effectiveness

This assessment showed positive results for short-term relief in 7 of 8 studies (35,37,38,43,47,49,52). Of 5 trials reporting long-term follow-up of more than 6 months, 4 reported positive results (36,38,43,49). The results in 3 studies utilizing fluoroscopy were superior to blind epidural injections (Table 3).

Based on the present evidence, utilizing grading of good, fair, and poor, it appears that there is good evidence for the therapeutic effectiveness of caudal epidural injections, with or without steroids, in patients with disc herniation or radiculitis for short-term and long-term relief.
**Table 3. Results of randomized trials of effectiveness of caudal epidural steroid injections in managing the pain from lumbar disc herniation/radiculitis.**

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Characteristics</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ASIPP</td>
<td>APS-AAPM</td>
<td></td>
<td>3 mos.</td>
</tr>
<tr>
<td>Manchikanti et al 2008 (49)*</td>
<td>RA, DB</td>
<td>9/11</td>
<td>NS</td>
<td>LA only = 60</td>
<td>77% vs. 80%</td>
</tr>
<tr>
<td>(53)</td>
<td></td>
<td></td>
<td></td>
<td>LA with steroids = 60</td>
<td></td>
</tr>
<tr>
<td>Dashfield et al 2005 (47)*</td>
<td>RA, DB</td>
<td>8/11</td>
<td>7/11</td>
<td>Caudal = 30 Endoscopy = 30</td>
<td>SI</td>
</tr>
<tr>
<td>(53)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bush and Hillier 1991 (35)</td>
<td>RA, DB</td>
<td>7/11</td>
<td>6/11</td>
<td>23</td>
<td>SI</td>
</tr>
<tr>
<td>Hesla and Breivik 1979 (38)</td>
<td>RA, DB</td>
<td>7/11</td>
<td>NS</td>
<td>69 patients: crossover design</td>
<td>29% versus 77%</td>
</tr>
<tr>
<td>Breivik et al 1976 (37)</td>
<td>RA, DB</td>
<td>6/11</td>
<td>5/11</td>
<td>C = 19 T = 16</td>
<td>20% vs 50%</td>
</tr>
<tr>
<td>Ackerman and Ahmad 2007 (52)*</td>
<td>RA, DB</td>
<td>8/11</td>
<td>9/11</td>
<td>Caudal = 30 Interlaminar = 30 Transforaminal = 30</td>
<td>Caudal = 17 of 30 (57%) Interlaminar = 18 of 30 (60%) Transforaminal = 25 of 30 (83%)</td>
</tr>
<tr>
<td>Sayegh et al 2009 (43)*</td>
<td>RA, DB</td>
<td>11/11</td>
<td>NS</td>
<td>Steroid with LA = 93 LA only = 90</td>
<td>SI</td>
</tr>
</tbody>
</table>

*Indicates use of fluoroscopy
\(\Delta\)Not available at the time of Chou’s search
RA = randomized; DB = double blind; NS = Not scored by APS-AAPM review; C = control; T = treatment; LA = local anesthetic; NA = not available; SI = significant improvement; NSI = no significant improvement; vs = versus; P = positive; N = negative

**Short-Term and Long-Term Measures**

Manchikanti et al (49) reported significant pain relief of 50% or greater at 12 months in 70% in Group I and 77% in Group II. The overall average procedures per year were 4.3 in Group I and 3.8 \(\pm\) in Group II with an average total relief per year of 40.7 weeks in Group I and 42.7 weeks in Group II over a period of 52 weeks in the successful group.

This is only one injection without multiple or bilateral spinal injections in one setting. However, it was repeated as required with deterioration in pain relief and functional status. Dashfield et al (47) showed significant improvements for description of pain at 6 months.
Bush and Hillier (35) showed significantly better results with pain and straight leg raising in an experimental group in the short-term. However, the pain was not significantly different, but straight leg raising was significantly better for long-term relief. Mathews et al (36) showed no significant difference between experimental and control groups with short-term relief. However, after 3 months, patients in the experimental group reported significantly more pain-free status than in the control group. Hesla and Breivik (38) showed significant improvement in 59% of the patients. Breivik et al (37) showed improvement in 56% of the patients with considerable pain relief in the experimental group compared to 26% of the patients in the placebo group.

**Impact on Clinically Meaningful Physical Function and Pain**

Manchikanti et al (49,53) utilized 50% or greater pain relief whereas they utilized 50% improvement of Oswestry scores as significant improvement in function. They showed significant improvement in pain relief in 70% of patients in Group I and 77% of patients in Group II. Further, they showed reduction of Oswestry scores of at least 50% in 67% of patients in Group I and 75% of patients in Group II with steroids. They also showed a non-significant increase in return to work. Dashfield et al (47) evaluated pain and outcome instruments including SF-MPQ and HAD. They showed significant improvement in pain at 6 months and anxiety at 6 weeks, 3 months, and 6 months, whereas depression showed improvement only at 6 months.

Bush and Hillier (35) utilized as outcome measures, effect on lifestyle, back and leg pain, and angle of positive straight leg raising. The results showed significantly better results with pain and straight leg raising in the experimental group in the short-term. However, at long-term, straight leg raising was significantly improved, but not pain.

Mathews et al (36) utilized pain relief, range of movement, straight leg raising, and neurological examination as outcomes. They showed no significant difference between the experimental and control groups with short-term relief. However, after 3 months, patients in the experimental group reported significantly less pain than those in the control group.

Hesla and Breivik (38) evaluated pain relief and return to work or to be retrained for another occupation. They showed significant improvement in pain in 59% of the patients. Breivek et al (37) utilized pain relief and objective improvements as sensation, straight leg raising, and reflexes as outcome measures. They reported pain relief improvement in 56% of the patients in the experimental group compared to 26% of the patients in the placebo group.

**Impact on Quality of Life and Patient Satisfaction**

Manchikanti et al (49) and Dashfield et al (47) utilized appropriate outcome measures utilizing quality of life with significant improvement in the patients’ quality of life.

Patient satisfaction appears to have been good in all the studies, even though it was not specifically measured in all the studies.

**Opioid Use, Return to Work, and Other Measures**

Manchikanti et al (49) reported significant reduction with opioid intake from the baseline in Group I and non-significant reduction in opioid intake in Group II and no change in employment status in both groups. Dashfield et al (47) did not report opioid use and return to work.
1.1.1.4 Post Surgery Syndrome

Three studies evaluating the effectiveness of caudal epidural injections used for post surgery syndrome pain met inclusion criteria (38,39,50). Only one study (50) was performed under fluoroscopy. Of these, 2 studies (38,50) provided outcomes of longer than 6 months.

The study by Meadeb et al (40), not included in the evidence synthesis, evaluated forceful caudal epidural injections in the treatment of post laminectomy syndrome. They forcefully injected 20 mL of sodium chloride solution, with or without prednisolone acetate 120 mg; whereas in the second group, they injected 125 mg of epidural prednisolone without any mixture. They showed positive results in the forceful injection group for short-term relief. Surprisingly, in this study by Meadeb et al (40), patients receiving a forceful sodium chloride injection of 20 mL showed better results than those receiving steroids.

1.1.4.1.1 Effectiveness

All 3 randomized trials (38,39,50) studying the effectiveness of caudal epidural steroid injections for post-surgery syndrome were shown to be positive for short-term relief (38,39,50). Two studies that evaluated long-term follow-up also showed positive results (38,50) (Table 4).

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3 mos. 6 mos. 12 mos. Short-term relief &gt; 6 mos. Long-term relief &gt; 6 mos.</td>
<td></td>
</tr>
<tr>
<td>Manchikanti et al 2008 (50)*</td>
<td>RA, DB</td>
<td>LA only = 20 LA with steroids =20</td>
<td>70% vs. 65% 60% vs. 60% 65% vs. 60%</td>
</tr>
<tr>
<td>Revel et al 1996 (39)</td>
<td>RA</td>
<td>Forceful injection = 29 Regular = 31</td>
<td>NA 49% vs 19% NA</td>
</tr>
<tr>
<td>Hesla and Breivik 1979 (38)</td>
<td>RA, DB</td>
<td>69 patients: crossover design</td>
<td>77% vs 29% 59% vs 25% 59% vs 25%</td>
</tr>
</tbody>
</table>

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; NA = not available; vs = versus; P = positive; N = negative


Among the systematic reviews, only Conn et al (9) focused on post lumbar surgery syndrome. They showed moderate evidence based on 3 trials, one of which had not been published prior to the evaluation by Chou and Huffman (29).

Based on the present evidence, utilizing grading of good, fair, and poor, it appears that there is fair evidence for short-term and long-term relief in post surgery syndrome.

**Short-Term and Long-Term Measures**

Manchikanti et al (50) reported significant pain relief of 50% or more in 65% in Group I and 60% in Group II at 12 months. The average procedures per year were 3.4 with an average total relief per year of
31.7 ± 19.10 weeks in Group I and 26.2 ± 18.34 weeks in Group II over a period of 52 weeks. However, when they were separated into successful and failed groups, the improvement in the successful group was 44.1 ± 9.47 weeks in Group I, 35.0 ± 14.07 weeks in Group II with average procedures of 4.0 in Group I and 3.9 in Group II.

Revel et al (39) reported improvement in 49% of the patients in the forceful injection group compared to 19% in the control group. Hesla and Breivik (38) provided 3 epidural injections with 59% of the patients receiving caudal epidural injections of bupivacaine and depomethylprednisolone showing significant improvement.

Impact on Clinically Meaningful Physical Function and Pain
Manchikanti et al (50) showed significant improvement with at least 50% reduction in Oswestry scores in 70% of the patients in Group I and 50% of the patients in Group II. Revel et al (39) showed improvement in 49% of the patients. The only outcome measure they used was pain relief. Hesla and Breivik (38) utilized return to work or retraining as outcome.

Impact on Quality of Life and Patient Satisfaction
Quality of life appears to have improved in all patients. However, patient satisfaction was not measured in a systematic fashion in any of the studies.

Opioid Use, Return to Work, and any Other Reported Surrogate Measures
Opioid intake significantly decreased from their baseline opioid intake in both groups at 12 months. One patient in Group I returned to work at 12 months.

1.1.1.5 Spinal Stenosis
Only one randomized trial (51) evaluating the role of caudal epidural injections in spinal stenosis was published in 2008.

1.1.5.1.1 Effectiveness
The one randomized trial evaluating spinal stenosis with or without steroids with local anesthetic (51) showed positive results for short- and long-term relief.

The only systematic review discussing the effectiveness of spinal stenosis was by Conn et al (9) showing moderate evidence based on one randomized trial performed under fluoroscopy.

Based on the present evidence, utilizing grading of good, fair, and poor, it appears that there is fair evidence for short-term and long-term relief for caudal epidural injections in spinal stenosis.

Short-Term and Long-Term Measures
Manchikanti et al (51) reported significant pain relief of 50% or more in 65% in Group I and 55% in Group II at 12 months. The average procedures per year were 3.4 with an average total relief per year of 30.3 ± 19.49 weeks in Group I and 37.8 ± 14.0 weeks with 2.6 procedures per year in Group II over a period of 52 weeks. However, when they were separated into successful and failed groups, the improvement in the successful group was 42.8 ± 9.06 weeks in Group I, 37.8 ± 14.0 weeks in Group II with average procedures per year of 3.8 in Group I and 3.4 in Group II.

1.2 Interlaminar Epidural Injections
Multiple systematic reviews provided negative opinions for lumbar interlaminar epidural injections (8,10,15,17,18,25,26,28,33). Two systematic reviews were performed evaluating lumbar and cervical interlaminar epidurals (10,11). They arrived at conflicting conclusions with the systematic review of the effectiveness of the cervical epidurals in the management of chronic neck pain illustrating a
Level II-1 evidence in managing chronic neck and upper extremity pain (11); whereas, the evidence is Level II-2 for short-term relief of pain of disc herniation or radiculitis utilizing blind interlaminar epidural steroid injections with lack of evidence for long-term relief (10). Staal et al (18) updated Neleman et al’s (15) systematic review, concluding that there was insufficient evidence to support the use of injection therapy in subacute and chronic low back pain.

Finally, the reassessment of APS guidelines by Manchikanti et al (32) agreed with Chou et al (29) that the evidence was poor for lumbar interlaminar epidural injections. However, the addition of new studies performed under fluoroscopic visualization will change this evidence from poor to fair. Further, evidence for cervical interlaminar epidural injections has been shown to be fair and may be considered good based on the new studies (55,56).

1.2.1 Lumbar Interlaminar Epidural Injections
Lumbar interlaminar epidural injections were evaluated separately for disc herniation and radiculitis, spinal stenosis, and discogenic pain.

1.2.1.1 Disc Herniation and Radiculitis
Five blind lumbar interlaminar studies (57-61) and 2 fluoroscopically directed lumbar interlaminar studies (62,63) met inclusion criteria. However, most studies incorporated flawed methodology without fluoroscopy. The authors utilized a flawed process by considering local anesthetic injection as a placebo along with a small sample size, and also used poor methodology, and inadequate outcome assessments (58). Widely applauded, Carette et al’s study (57) also contained numerous deficiencies including lack of fluoroscopy, performance of the procedure in the lateral decubitus position and injection of isotonic saline as placebo into the epidural space. Arden et al (60) utilized an unrealistic outcome expectation of reduction of ODI by 75% from the baseline, performed without fluoroscopy, and repeated the injections without concern about return of the pain for a total of 3 injections. Snoek et al (59) in a study of 51 patients with lumbar root compression found no significant differences between the 2 groups. Wilson-MacDonald et al (61) also showed no significant differences.

1.2.1.1.1 Effectiveness
As shown in Table 5, of the 5 randomized trials (blind lumbar interlaminar epidurals) included in the evidence synthesis, 2 were positive for short-term and all 5 of them were negative for long-term relief of more than 6 months.
**Table 5. Results of randomized trials of effectiveness of blind and fluoroscopic lumbar interlaminar epidural steroid injections.**

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>Methodological Quality Scoring</th>
<th>Participant Size</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 mos.</td>
<td>6 mos.</td>
</tr>
<tr>
<td>RA, DB</td>
<td>72</td>
<td>LA only = 35 LA with steroids = 35</td>
<td>83% vs. 86%</td>
<td>63% vs. 89%</td>
</tr>
<tr>
<td>RA, DB</td>
<td>72</td>
<td>LA only = 35 LA with steroids = 35</td>
<td>77% vs. 86%</td>
<td>80% vs. 86%</td>
</tr>
<tr>
<td>RA</td>
<td>68</td>
<td>43</td>
<td>NSD</td>
<td>NSD</td>
</tr>
<tr>
<td>RA, DB, PC</td>
<td>86</td>
<td>228</td>
<td>NSD</td>
<td>NSD</td>
</tr>
<tr>
<td>RA, DB, PC</td>
<td>77</td>
<td>C = 80 T = 78</td>
<td>NSD</td>
<td>NSD</td>
</tr>
<tr>
<td>RA, DB</td>
<td>60</td>
<td>C = 31 T = 42</td>
<td>NSD</td>
<td>NSD</td>
</tr>
<tr>
<td>RA</td>
<td>72</td>
<td>C = 24 T = 27</td>
<td>NSD</td>
<td>NSD</td>
</tr>
</tbody>
</table>

RA = randomized; DB = double blind; PC = placebo controlled; C = control; T = treatment; SI = significant improvement; SIT = significant improvement in treatment group; NSD = no significant difference; P = positive; N = negative; * = fluoroscopy


In contrast, the only sole fluoroscopically performed study showed positive results at 6 months and one year.

Based on the grading of good, fair, and poor, it appears that the evidence is fair for lumbar interlaminar epidural injections performed under fluoroscopic visualization for disc herniation.

**Short-Term and Long-Term Measures**

Manchikanti et al (62) reported significant pain relief of 50% or more in 71% of patients in Group I and 80% in Group II at 12 months. The overall average procedures ranged from 3 to 4 with an average total relief of 35 weeks in Group I and 40 weeks in Group II over a period of 52 weeks. However, when the groups were separated into failed groups and successful groups, the results improved somewhat with average relief of 42 weeks in Group I and 41 weeks in Group II over a period of one year with an average relief of 10 to 15 weeks per procedure in the overall population. There was a significant decrease in opioid usage from the baseline in both groups. This was only after one injection; however, repeat injections were provided.
Impact on Clinically Meaningful Physical Function and Pain
Significant pain relief (≥50%) was seen in 80% of patients on functional status improvement and a 50% decrease in Oswestry scores was seen in 76% of patients by Manchikanti et al (62).

Impact on Quality of Life Patient Satisfaction
Quality of life improved; however, patient satisfaction was not measured systematically even though it was judged to be good to excellent.

Opioid Use, Return to Work, and any Other Reported Surrogate Measures
There was significant decrease in opioid usage from the baseline; however, there was no significant change in return to work.

1.2.1.2 Spinal Stenosis
Two blind lumbar interlaminar randomized trials (58,61) and one observational study (64) evaluating spinal stenosis were identified.

Cuckler et al (58) and Wilson-MacDonald et al (61) utilized flawed methodologic processes as described earlier and further, the number of patients studied was also small. The observational study by Campbell et al (64) showed significant confusion, basically demonstrating that epidural steroid injections performed blindly with an interlaminar approach in a series of 3 injections may still be effective.

Based on grading of good, fair, and poor, the evidence is poor or non-available for the role of lumbar interlaminar epidural injections in spinal stenosis due to the lack of available studies at the present time. However, based on the caudal epidural injections performed under fluoroscopy, the evidence may be positive once the randomized trials of interlaminar epidural injections performed under fluoroscopy are published.

1.2.1.3 Chronic Low Back Pain of Discogenic Origin without Radiculitis or Disc Herniation
Only one randomized trial (63) and one observational study (65) was available evaluating the effect of spinal steroid injections for degenerative disc disease under fluoroscopy, which included intradiscal injections as well as epidural injections (65). One study (64) was blind epidurals.

Both studies were performed under fluoroscopy. Manchikanti et al (63) evaluated 70 patients under fluoroscopic visualization in patients negative with facet joint pain and without disc herniation or radiculitis. Significant pain relief (≥ 50%) was demonstrated in 80% of patients in Group I and 89% in Group II at 6 months (short-term) and 74% of patients in Group I and 86% in Group II at 12 months (long-term).

In contrast, Butterman et al (65), in an observational study, reported the effects of epidural steroid injections in 93 patients with degenerative disc disease and inflammatory endplate changes and in 139 patients without inflammatory endplate changes.

Based on grading of good, fair, and poor, the evidence is fair for discogenic pain in the lumbar spine with lumbar interlaminar epidural injections with or without steroids.

Short-Term and Long-Term Measures
Manchikanti et al (63) reported significant pain relief of 50% or more in 80% of patients in Group I and Group II at 12 months. The overall average procedures ranged from 3.8 to 3.9 with an average total relief of 37.4 weeks in Group I and 33.9 weeks in Group II over a period of 52 weeks. However, when the groups were separated into failed groups and successful groups, the results improved somewhat with
average relief of 40.7 weeks in Group I and 37.7 weeks in Group II over a period of one year with an average relief of 10 to 15 weeks per procedure in the overall population. There was a significant decrease in opioid usage from the baseline in Group II. This was only after one injection; however, repeat injections were provided.

**Impact on Clinically Meaningful Physical Function and Pain**
There was significant functional status improvement with 50% reduction in Oswestry scores seen in 66% of patients by Manchikanti et al (63).

**Impact on Quality of Life Patient Satisfaction**
Quality of life improved; however, patient satisfaction was not measured systematically even though it was judged to be good to excellent.

**Opioid Use, Return to Work, and any Other Reported Surrogate Measures**
There was significant decrease in opioid usage from the baseline; however, there was no significant change in return to work.

### 1.2.1.4 Cost Effectiveness
In the evaluation of cost effectiveness, Manchikanti et al (67) and Price et al (68) concluded that lumbar interlaminar epidural steroid injections were not cost effective. There were no studies evaluating the cost effectiveness of cervical interlaminar epidural injections.

### 1.2.1.5 Safety and Complications
The common complications of lumbar interlaminar epidural injections are related to either the needle placement or the drug administration as described for caudal epidural injections (7,8,13,69-122).

In the cervical spine, additional or specific complications include spinal cord trauma, spinal cord or epidural hematoma formation, subarachnoid or subdural injections, intravascular injection, vascular injury, or vascular embolism (97-116).

### 1.2.2 Cervical Interlaminar Epidural Injections
Only 2 systematic reviews evaluated the role of cervical interlaminar epidural injections (8,11). The recent systematic review of cervical epidural injections met inclusion criteria (11). Three blind cervical epidural studies met the inclusion criteria (123-125).

Since the publication of the systematic review (11), 2 fluoroscopically directed cervical interlaminar epidural injections were published (55,56).

### 1.2.2.1 Effectiveness
Based on the systematic review of Benyamin et al (11), all 3 studies showed positive results both for short-term and long-term except that Pasqualeucci et al (125) had results not available for long-term follow-up. However, the methodologic quality scoring of these studies was low ranging from 50 to 56.

The 2 randomized trials performed showed positive results in disc herniation and discogenic pain were performed under fluoroscopic visualization.

Table 6 illustrates the results of the randomized trials of the effectiveness of cervical interlaminar epidural injections. The 2 studies performed under fluoroscopy are different from the previous ones. One study was performed in patients with cervical disc herniation. The results were preliminary comparing local anesthetic and steroids with positive results and quality rating of 72 on a scale of 0 to 100 rated as high quality. Similarly, the second study was performed in patients without disc herniation or radiculitis; also,
the patients were selected based on a negative response to facet joint pain. The study included 35 patients in each group and a one year follow-up was available similar to the first study with appropriate outcome parameters with high methodologic quality of 72 showing positive results at 6 months and one year.

Table 6. Results of randomized studies of effectiveness of cervical interlaminar epidural steroid injections.

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3 mos.</td>
<td>6 mos.</td>
</tr>
<tr>
<td>RA, DB</td>
<td>LA only = 35 LA with steroids =35</td>
<td>77% vs. 86%</td>
<td>80% vs. 86%</td>
</tr>
<tr>
<td>RA, DB</td>
<td>LA only = 35 LA with steroids =35</td>
<td>89% vs. 83%</td>
<td>77% vs. 74%</td>
</tr>
<tr>
<td>RA</td>
<td>Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10</td>
<td>79%</td>
<td>79%</td>
</tr>
<tr>
<td>RA</td>
<td>C = 17 T = 25</td>
<td>12% vs 68%</td>
<td>12% vs 68%</td>
</tr>
<tr>
<td>RA</td>
<td>Single = 20 Continuous = 20 Over 180 days</td>
<td>NA</td>
<td>58% vs 74%</td>
</tr>
</tbody>
</table>

RA = randomized; C = control; T = treatment; vs = versus; P = positive; N = negative; NA = not available

Based on 5 randomized trials with 2 of them under fluoroscopic visualization, the positive results are reported for cervical interlaminar epidural injections.

Based on grading of good, fair, and poor, the evidence is fair for at least pain of cervical disc herniation or radiculitis and discogenic pain without facet joint pain, disc herniation, or radiculitis.

The evidence for cervical spinal stenosis and post surgery syndrome is not available.

Short-Term and Long-Term Measures
Manchikanti et al (55) reported significant pain relief of 50% or more in 80 % in Group I and Group II at 12 months without disc herniation. The average procedures per year were 3.9 with an average total relief per year of 37.6 ± 16.2 weeks in Group I and 39.7 ± 13.6 weeks with 3.8 procedures per year in Group II over a period of 52 weeks. However, when they were separated into successful and failed groups, the improvement in successful group was 40.3 ± 14.1 weeks in Group I, 42.1 ± 9.9 weeks in Group II with average procedures per year of 3.9 in Group I and Group II.

Manchikanti et al (56) reported significant pain relief of 50% or more in 77 % in Group I and Group II at 12 months with disc herniation. The average procedures per year were 3.9 with an average total relief per year of 37.86 ± 13.19 weeks in Group I and 37.66 ± 15.36 weeks with 3.7 procedures per year in
Group II over a period of 52 weeks. However, when they were separated into successful and failed groups, the improvement in the successful group was 39.45 ± 11.59 weeks in Group I, 41.06 ± 11.56 weeks in Group II with average procedures per year of 3.7 in Group I and 4.0 in Group II.

**Impact on Quality of Life and Patient Satisfaction**
Quality of life appears to have improved in all the patients. However, patient satisfaction was not measured in a systematic fashion in any of the studies.

**Impact on Clinically Meaningful Physical Function and Pain**
Reduction of Neck Disability Index Scores of at least 50% was seen in 69% (Group I) and 80% (Group II) at 12-months by Manchikanti et al (55). Reduction of Neck Disability Index Scores of at least 50% was seen in 74% (Group I) and 71% (Group II) at 12-months by Manchikanti et al (56).

**Opioid Use, Return to Work, and any Other Reported Surrogate Measures**
Opioid intake significantly decreased from their baseline opioid intake in both groups at 12 months. One patient returned to work in Group I at 12 months Manchikanti et al (55, 56).

1.3 **Lumbar Transforaminal Epidural Injections**
Two systematic reviews (8,31) showed the evidence of lumbar transforaminal epidural steroid injections for lumbar nerve root pain was strong for short-term and moderate for long-term improvement. The evidence is limited for lumbar radicular pain in post surgery syndrome. DePalma et al (126) performed a critical appraisal of the evidence for selective nerve root injection in the treatment of lumbosacral radiculopathy.

The recent systematic review by Buenaventura et al (12) indicated the evidence is Level II-1 for short-term relief and Level II-2 for long-term relief in managing chronic low back and lower extremity pain. They evaluated methodologic quality assessment, relief of longer than 6 months as long-term relief, and appropriate outcomes. Thus, this systematic review met all the criteria for inclusion in the guideline synthesis. Methodologic quality rating and results are illustrated in Tables 7 and 8.

Chou and Huffman (29) in their evaluation concluded there are 3 higher quality, placebo-controlled trials evaluating the transforaminal approach reported mixed results, and concluded that for low back pain with sciatica, evidence for the efficacy of epidural steroid injections by the transforaminal approach was mixed, with 2 of 3 higher quality trials showing no benefit compared to controlled injections (129,134,150)

Vad et al (127) studied the effect of transforaminal epidural betamethasone 9 mg and lidocaine and compared it to a lumbar paraspinal muscle trigger point injection of saline. Forty-eight patients were included. Outcomes included pain score, patient satisfaction, and other measures of function. The patients were followed for an average of 1.4 years but no set short- or long-term follow-up evaluations were scheduled. Patients improved in both groups but the transforaminal group did significantly better with a much lower pain score at the end and a larger percentage of patients (84% vs. 48%) achieving a successful outcome in a shorter period of time than the trigger point group (6 weeks vs. 12 weeks).

1.3.1 **Effectiveness**
Based on grading of good, fair, and poor, the evidence is fair for lumbar transforaminal epidural injections in disc herniation or radiculitis.

1.3.2 **Cost Effectiveness**
In the management of chronic low back pain, cost per one-year improvement of QOL was $2,927 per year with transforaminal epidural steroid injections (67). Furthermore, in patients treated with transforaminal steroids, operations were avoided for contained herniations, costing $12,666 less per responder in the steroid
group (128). Cost effectiveness was also demonstrated by others by avoiding surgical intervention (129,130).

1.3.3 Safety and Complications

The most common and worrisome complications of transforaminal epidural steroid injections in the lumbar spine are related to neural trauma, vascular trauma, intravascular injection, and infection (7,8,69-71,74-92,131-147). Complications including spinal cord injury and infarction (117,136), and paraplegia (140), have been reported. Side effects related to the administration of steroids are generally attributed either to the chemistry or to the pharmacology of steroids (8,13,71,131,144-149).

Table 7. Quality rating of randomized trials of lumbar transforaminal epidural injections.

<table>
<thead>
<tr>
<th>Study</th>
<th>Randomization</th>
<th>Concealed treatment allocation</th>
<th>Baseline group similarity</th>
<th>Patient blinded</th>
<th>Care provider blinded</th>
<th>Outcome assessor blinded</th>
<th>Cointerventions avoided or similar</th>
<th>Compliance acceptable in all groups</th>
<th>Drop-out rate described and acceptable</th>
<th>Timing of outcome assessment in all groups similar</th>
<th>Intention to treat analysis</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riew et al 2000, 2006 (129*,130*)</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>11/11</td>
</tr>
<tr>
<td>Karppinen et al 2001, 2001 (134*,135*)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>10/11</td>
</tr>
<tr>
<td>Ackerman and Ahmad 2007 (52) §</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>9/11</td>
</tr>
<tr>
<td>Jeong et al 2007 (128)*</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>9/11</td>
</tr>
<tr>
<td>Ng et al 2005 (150)#</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>8/11</td>
</tr>
</tbody>
</table>

*Included by Chou and Huffman (29) and Buenaventura et al (12)
#Included by Chou and Huffman (29) and Manchikanti et al (34)
† Included by Buenaventura et al (12), but not Chou and Huffman (29)
‡ Included by Chou and Huffman (29), but not Buenaventura et al (12)
§ Included in Manchikanti et al (34), but not Chou and Huffman (29) for transforaminal, but was included for caudal and interlaminar

Table 8. Results of randomized trials of effectiveness of lumbar transforaminal epidural injections.

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3 mos.</td>
<td>6 mos.</td>
</tr>
<tr>
<td>Karppinen et al 2001/2001 (134,135)</td>
<td>RA, DB</td>
<td>C = 80 T = 80</td>
<td>SICH</td>
</tr>
<tr>
<td>Jeong et al 2007 (128)</td>
<td>RA, DB</td>
<td>239</td>
<td>PG 99 of 112 G 90 of 127</td>
</tr>
<tr>
<td>Vad et al 2002 (127)</td>
<td>RA</td>
<td>48</td>
<td>NA</td>
</tr>
</tbody>
</table>

RA = randomized; DB = double blind; P = prospective; C = control; T = treatment; PG = pre-ganglionic; G = ganglionic; SICH = significant improvement in contained disc herniation; NSI = no significant improvement; vs. = versus; NA = not available; P = positive; N = negative.


Indications and Medical Necessity

All in all, epidural injections must be recommended with 2 procedures in the diagnostic phase and 4 therapeutic interventions per region per year after the diagnostic phase is completed, if indications and medical necessity as described below are documented.

Common indications for caudal epidural injections:

♦ Chronic low back and/or lower extremity pain which has failed to respond or poorly responded to noninterventional and nonsurgical conservative management resulting from:
  - Disc herniation/lumbar radiculitis
  - Lumbar spinal stenosis
  - Post lumbar surgery syndrome
  - Epidural fibrosis
  - Degenerative disc disease/discogenic low back pain
  - Absence of facet joint pain determined by controlled local anesthetic blocks.
  - Intermittent or continuous pain causing functional disability.
  - Average pain level of ≥ 6 on a scale of 0 to 10.

Indications for lumbar interlaminar are same as for caudal epidural injections, except for post-surgery syndrome.

♦ Caudal epidural is the modality of choice for post-surgery syndrome.
Common indications for cervical interlaminar:

- Chronic neck and/or upper extremity pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:
  - Herniated, protruded, or extruded disc with or without radiculitis
  - Cervical spinal stenosis
  - Post cervical surgery syndrome
  - Degenerative disc disease
  - Absence of facet joint pain determined by controlled local anesthetic blocks.
  - Intermittent or continuous pain causing functional disability.
  - Average pain level of ≥ 6 on a scale of 0 to 10.

Common indications for thoracic interlaminar:

- Chronic mid back or upper back pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:
  - Herniated, protruded, or extruded disc with or without radiculitis
  - Thoracic spinal stenosis
  - Thoracic post-surgery syndrome
  - Degenerative disc disease
  - Absence of facet joint pain determined by controlled local anesthetic blocks.
  - Intermittent or continuous pain causing functional disability.
  - Average pain level of ≥ 6 on a scale of 0 to 10.

Common indications for therapeutic lumbar transforaminal epidurals:

- Chronic low back and/or lower extremity pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management
- Chronic low back and/or lower extremity pain resulting from:
  - Disc herniation/radiculitis
  - FBSS without extensive scar tissue and hardware
  - Spinal stenosis with radiculitis
  - Discogenic pain with radiculitis
- Average pain levels of ≥ 6 on a scale of 0 to 10
- Intermittent or continuous pain causing functional disability

Frequency of Interventions

- Guidelines of frequency of interventions apply to epidural injections caudal, interlaminar, and transforaminal.
- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks except in cancer-related pain or when a continuous administration of local anesthetic is employed for CRPS.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques should be 2 months or longer between each injection, provided that ≥ 50% relief is obtained for 8 weeks.
- If the neural blockade is applied for different regions, they may be performed at intervals of no sooner than one week and preferably 2 weeks for most types of procedures. The
therapeutic frequency may remain at intervals of at least 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures can be performed safely.

♦ In the treatment or therapeutic phase, the epidural injections should be repeated only as necessary according to medical necessity criteria, and it is suggested that these be limited to a maximum of 4 times per year.

♦ Cervical and thoracic regions are considered as one region and lumbar and sacral are considered as one region.

2.0 Percutaneous Adhesiolysis

We were not quite certain based on the questionnaire if lumbar epidural adhesiolysis is being considered or not. However, lumbar epidural adhesiolysis is considered as an epidural procedure by some (29,32). Consequently, we are providing information on lumbar epidural adhesiolysis also.

ASIPP guidelines (3) and the systematic review performed by Epter et al (162) utilizing 7 studies (163-169) 3 of which were randomized (163-165), concluded that the indicated level of evidence is I or II-1 for short- and long-term relief of percutaneous adhesiolysis in post-lumbar surgery syndrome. At the time of this systematic review no evidence was available for spinal stenosis.

A reassessment of the evidence was carried out for percutaneous adhesiolysis with inclusion of newer studies. Table 9 illustrates quality ratings of randomized trials of percutaneous adhesiolysis studies (163-165,170,171).

Table 9. Quality ratings of randomized trials of percutaneous adhesiolysis studies.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ASIPP</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>APS-AAPM</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Randomization</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Concealed treatment</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>allocation</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Baseline group similarity</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Patient blinded</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Care provider blinded</td>
<td>No</td>
<td>NS</td>
<td>No</td>
<td>Don’t know</td>
<td>No</td>
</tr>
<tr>
<td>Outcome assessor blinded</td>
<td>No</td>
<td>NS</td>
<td>No</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Compliance acceptable in all groups</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Drop-out rate described and acceptable</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Timing of outcome assessment in all groups similar</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Intention to treat analysis</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>Don’t know</td>
<td>Yes</td>
</tr>
<tr>
<td>Score</td>
<td>9/11</td>
<td>9/11</td>
<td>9/11</td>
<td>8/11</td>
<td>8/11</td>
</tr>
<tr>
<td>9/11</td>
<td>8/11</td>
<td>10/11</td>
<td>8/11</td>
<td>4/11</td>
<td></td>
</tr>
</tbody>
</table>

*Not available at the time of Chou’s search
†Included in Manchikanti et al (34), but not Chou and Huffman (29)
* Included by Chou and Huffman (29) and Manchikanti et al (34)
* Included by Chou and Huffman (29), but not Manchikanti et al (34)
NS = Not scored by APS-AAPM review

Table 10 illustrates the results of the published trials of percutaneous lysis of lumbar epidural adhesions (163-165,168,171).

**Table 10** Results of published randomized trials of percutaneous lysis of lumbar epidural adhesions.

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>Methodological Quality Scoring</th>
<th>Participants</th>
<th>Pain Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ASIPP</td>
<td>APS-AAPM</td>
<td>≤ 3 mos.</td>
<td>3 mos.</td>
</tr>
<tr>
<td>Manchikanti et al 2004 (163)</td>
<td>RA, DB</td>
<td>10/11</td>
<td>8/11</td>
<td>G1 = 25 (C)</td>
</tr>
<tr>
<td>Heavner et al 1999 (164)</td>
<td>RA, DB</td>
<td>8/11</td>
<td>2/11</td>
<td>59</td>
</tr>
<tr>
<td>Manchikanti et al 2009 (171)</td>
<td>RA, DB</td>
<td>9/11</td>
<td>NS</td>
<td>C = 60</td>
</tr>
<tr>
<td>Manchikanti et al 2009 (170)</td>
<td>RA, DB</td>
<td>9/11</td>
<td>NS</td>
<td>C = 25</td>
</tr>
</tbody>
</table>

RA = randomized; DB = double blind; NS = not scored by APS-AAPM review; G = group; C = control; T = treatment; vs = versus; SI = significant improvement; P = positive; N = negative

Table 11 illustrates the methodologic quality assessment of systematic review of percutaneous adhesiolysis (31,162,172).

Table 11. Methodologic quality assessment of systematic reviews of percutaneous adhesiolysis.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ASIPP</td>
<td>APS-AAPM</td>
<td>ASIPP</td>
</tr>
<tr>
<td>Search Method</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Bias Avoided</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Validity Criteria</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Validity Assessed</td>
<td>Yes</td>
<td>Partial</td>
<td>Yes</td>
</tr>
<tr>
<td>Methods for Combining Studies</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Appropriately Combined</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Conclusions Supported</td>
<td>Yes</td>
<td>Partial</td>
<td>Yes</td>
</tr>
<tr>
<td>Overall Quality</td>
<td>7/9</td>
<td>3/7</td>
<td>7/9</td>
</tr>
<tr>
<td>Corrected Score</td>
<td>7/9</td>
<td>6/9</td>
<td>7/9</td>
</tr>
</tbody>
</table>

*Not available at the time of Chou’s search
*Included by Chou and Huffman (29) and Manchikanti et al (34)
†Included in Manchikanti et al (34), but not Chou and Huffman (29)
**Included by Chou and Huffman (29), but not Manchikanti et al (34)
NS = Not scored by APS-AAPM review


Chou and Huffman (29) stated that the term “failed back surgery syndrome” is commonly used to refer to a heterogeneous group of conditions characterized by chronic disabling low back pain, with or without leg pain, following one or more spinal surgeries. They also described adhesiolysis. They described adhesiolysis and forceful epidural injections synonymously as they also disrupt epidural adhesions or fibrosis; however, they continue to consider sodium chloride solution injection as a placebo. They inappropriately scored systematic reviews and also provided inappropriate evidence for one study despite their consideration of the study as higher quality (163). They reported that there was a 0% response rate with epidural steroids; however, this is inaccurate as 33% of the patients in the epidural group experienced significant improvement for less than 3 months. After 3 months there was no significant improvement noted. They also misclassified the study by Heavner et al (164) as low quality.

Thus, there is fair evidence based on Chou et al’s criteria without considering the new evidence. With the consideration of multiple new randomized trials, the evidence actually appears to be good. Thus, percutaneous adhesiolysis on a one-day basis (CPT 62264) should be allowed at least 4 times per year for specific indications of post lumbar surgery syndrome and spinal stenosis. This procedure will be much more cost-effective than repeating ineffective epidurals as one has no means of monitoring if they are effective or not.

Table 11 shows the evidence synthesis for post-laminectomy syndrome and spinal stenosis. In addition to this, stronger evidence is available now with 2 randomized trials evaluating either post-surgery syndrome or spinal stenosis (170,171). In the study of post-lumbar surgery syndrome, Manchikanti et al (171) in a randomized double-blind trial evaluated 60 patients in each group showing significant improvement of
pain (≥ 50%) and function (≥ 50%) with Oswestry in 73% of patients compared to 12% in the caudal epidural group with catheter positioned at S3.

This solidifies the results of previous studies and provides better evidence.

Spinal stenosis also has been studied in a randomized, double-blind, controlled trial (90). The preliminary results of 25 patients in each group showed significant pain relief (≥ 50%) in 76% of the patients at one year follow-up in the adhesiolysis group compared to 4% of the patients in the control group. They concluded with significant pain relief in 76% of patients, percutaneous adhesiolysis utilizing local anesthetic, steroids, and hypertonic sodium chloride solution may be effective in patients with chronic function-limiting low back and lower extremity pain with spinal stenosis.

Thus percutaneous adhesiolysis on a one-day protocol may be approved when the patients meet appropriate indications and medical necessity is documented.

Indications for percutaneous adhesiolysis:

- Chronic low back and/or lower extremity pain resulting from:
  - Failed back surgery syndrome/epidural fibrosis
  - Spinal stenosis
  - Duration of pain of at least 6 months.
- Non-responsive to other modalities.
- Intermittent or continuous pain causing functional disability.
- Average pain levels of ≥ 6 on a scale of 0 to 10.
- Failure to respond or poor response to noninterventional and non-surgical conservative management and fluoroscopically-directed epidural injections
- Absence of facet joint pain determined by controlled local anesthetic blocks

Recommend frequency for percutaneous adhesiolysis is as follows:

- The number of procedures are preferably limited to:
  - 4 interventions per year, with a one-day protocol.

3.0 Facet Joint Interventions

The OIG report (173) evaluating 2006 Medicare facet joints showed to have paid over $2 billion in 2006 for interventional pain management procedures. The report also showed that Medicare payments for facet joint injections increased from $141 million in 2003 to $307 million in 2006. Further, 63% of facet joint injection services allowed by Medicare in 2006 did not meet Medicare program requirements, resulting in approximately $130 million in improper payments for physicians and facilities. This report illustrated that facet joint injection services provided in an office were more likely to contain an error than those provided in an ambulatory surgery center or hospital outpatient department. The OIG report also illustrated that 35% of Medicare facet joint injections were performed by non-interventional pain physicians; 19% by general practitioners, internists, and family practice physicians; while the remaining 16% were performed by orthopedic surgeons, neurologists, and rheumatologists.

Manchikanti et al (174) showed that overall interventional techniques increased significantly in Medicare beneficiaries. They also showed that the proportion of patients receiving interventional pain management services per 100,000 Medicare population increased by 137%, the number of visits increased by 144%, and services increased 197%. The increases for facet joint inventions were 624%.

There were significant geographic differences noted with an 11.6-fold difference (431% vs. 37% increase) between Florida and California in 2006. The differences were also significant in that patients
under 65 years of age showed an increase of 504% per 100,000 Medicare population compared to 355% for those over 65 years for facet joint injections (175). Utilization of facet joint interventions by specialties was very interesting; overall a 122% increase was seen for interventional pain management professionals (anesthesiology, pain management, neurology, neurosurgery, orthopedic surgery, physical medicine and rehabilitation, and psychiatry), the increases were 398% for nurse practitioners and CRNAs, and 1,109% for general physicians (general practice, family, and internal medicine), giving a 100% annual increase for nurse practitioners and CRNAs and 277% annual increase for general physicians. The utilization of fluoroscopy was also based on specialty with an increase seen in all specialties, but with the lowest utilization of fluoroscopy was seen by general physicians. Thus, 86% of the pain physicians utilized fluoroscopy compared to only 19% of general physicians. The overall utilization of fluoroscopy is 63% of patients (175).

3.1 Diagnostic Medial Branch Blocks
The role of controlled diagnostic blocks in the diagnosis of facet joint pain has been described in multiple publications (3,6,176-179). It has been established that the diagnosis can only be furnished appropriately with 80% pain relief with concordant duration based on the local anesthetic injected with comparative local anesthetic blocks or placebo controlled blocks with the ability to perform previously painful movements. ASIPP guidelines (3) published in July/August 2009 utilized a comprehensive review process. Based on the systematic review by Datta et al (179) utilizing 7 studies meeting inclusion criteria with 80% pain relief and ability to perform previously painful movements with controlled diagnostic blocks of lumbar facet joint nerves showed evidence of Level I or II-1 based on the United States Preventive Services Task Force (USPSTF) criteria (180). Similarly Falco et al (178) utilizing similar criterial of 80% relief with controlled diagnostic blocks with the ability to perform previously painful movements utilized 9 studies meeting inclusion criteria and showed Level I or II-1 evidence based on the USPSTF criteria. Atluri et al (177) utilizing 3 studies showed Level II-1 evidence based on USPSTF criteria.

The validity of facet joint nerve blocks in the diagnosis of facet joint pain has been established with multiple variables including with establishment of long-term follow-up (181-183), influence of sedation (184-187), psychological variables (188,189), opioid intake (190), and post-surgery (191,192).

Further, Rubinstein and van Tulder (193), experts in epidemiology and evidence-based medicine, with numerous publications, in a best-evidence review of diagnostic procedures for spinal pain concluded that there is strong evidence for the diagnostic accuracy of facet joint nerve blocks.

In summary, the 3 systematic reviews showed prevalence of lumbar facet joint pain in 21% to 40% in heterogenous population with chronic low back pain and 16% in post-lumbar surgery syndrome with an overall prevalence of 31% (179) (Table 12) (191,194-199), 36% to 67% in patients with chronic neck pain with an average prevalence of 49% (178) (Table 13) (192,194-196,200-204), and 34% to 42% in patients with chronic thoracic pain (177) (Table 14) (195,199,205). These studies also showed false-positive rates of 17% to 49% with an overall false-positive rate of 30% in the lumbar spine (179), 27% to 63% in the cervical spine with an average of 49% (178), and 42% to 55% in the thoracic spine (177).
Table 12. Data of prevalence with controlled diagnostic blocks and false-positive rates in the lumbar region.

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Prevalence</th>
<th>False-Positive Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manchikanti et al 2002 (194)</td>
<td>120</td>
<td>40% (95% CI 31%–49%)</td>
<td>30% (95% CI 20%–40%)</td>
</tr>
<tr>
<td>Manchikanti et al 2004 (195)</td>
<td>397</td>
<td>31% (95% CI 27%–36%)</td>
<td>27% (95% CI 22%–32%)</td>
</tr>
<tr>
<td>Manchukonda et al 2007 (196)</td>
<td>303</td>
<td>27% (95% CI 22%–33%)</td>
<td>45% (95% CI 36%–53%)</td>
</tr>
<tr>
<td>Schwarzer et al 1995 #(197)</td>
<td>63</td>
<td>40% (95% CI 29%–53%)</td>
<td>NA</td>
</tr>
<tr>
<td>Manchikanti et al 2001 (198)</td>
<td>120</td>
<td>40% (95% CI 31%–49%)</td>
<td>47% (95% CI 35%–59%)</td>
</tr>
<tr>
<td>Manchikanti et al 2003 (199)</td>
<td>300</td>
<td>I. 21% (95% CI 14%–27%)</td>
<td>I. 17% (95% CI 10%–24%)</td>
</tr>
<tr>
<td>Manchikanti et al 2007 (194)</td>
<td>117</td>
<td>16% (95% CI 9%–23%)</td>
<td>49% (95% CI 39%–59%)</td>
</tr>
<tr>
<td>Overall</td>
<td>1,420</td>
<td>31% (95% CI; 28%–33%)</td>
<td>30%# (95% CI; 27%–33%)</td>
</tr>
</tbody>
</table>

CI = confidence interval; NA = not available; # Schwarzer et al (93) was without evaluation of false-positive rates.


Table 13. Data of prevalence and false-positive rates of cervical diagnostic facet joint blocks.

<table>
<thead>
<tr>
<th>Study</th>
<th># of Subjects</th>
<th>Prevalence Estimates</th>
<th>False-Positive Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barnsley et al 1995 (200)</td>
<td>50</td>
<td>54% (95% CI, 40%, 68%).</td>
<td>NA</td>
</tr>
<tr>
<td>Barnsley et al 1993 (201)</td>
<td>55</td>
<td>NA</td>
<td>27% (95% CI, 15%, 38%)</td>
</tr>
<tr>
<td>Lord et al 1996 (202)</td>
<td>68</td>
<td>60% (95% CI, 46%, 73%)</td>
<td>NA</td>
</tr>
<tr>
<td>Manchikanti et al 2002 (194)</td>
<td>120</td>
<td>67% (95% CI, 58%, 75%)</td>
<td>63% (95% CI 48%, 78%)</td>
</tr>
<tr>
<td>Manchikanti et al 2004 (195)</td>
<td>255 of 500</td>
<td>55% (95% CI, 49%, 61%)</td>
<td>63% (95% CI 54%, 72%)</td>
</tr>
<tr>
<td>Manchukonda et al 2007 (196)</td>
<td>251 of 500</td>
<td>39% (95% CI, 32%, 45%)</td>
<td>45% (95% CI 37%, 52%)</td>
</tr>
<tr>
<td>Manchikanti et al 2008 (192)</td>
<td>Non-Surgery: 206 Post-Surgery: 45</td>
<td>Non-Surgery 39% (95% CI, 33%, 46%)</td>
<td>Non-Surgery 43% (95% CI 35%, 52%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post-Surgery 36% (95% CI, 22%, 51%)</td>
<td>Post-Surgery 50% (95% CI 32%, 68%)</td>
</tr>
<tr>
<td>Speldewinde et al 2001 (203)</td>
<td>97</td>
<td>36% (95% CI, 27%, 45%)</td>
<td>NA</td>
</tr>
<tr>
<td>Yin and Bogduk 2008 (204)</td>
<td>84 of 143</td>
<td>42%# (95% CI, 31%, 52%)</td>
<td>NA</td>
</tr>
<tr>
<td>OVERALL</td>
<td>980</td>
<td>49% (95% CI, 45%, 52%)</td>
<td>49% (95% CI, 44%, 54%)</td>
</tr>
</tbody>
</table>

# Authors reported adjusted prevalence as 55% (95% CI, 38%, 62%) and crude prevalence as 24%.
NA = not available or not applicable; CI = confidence interval

**Table 14. Data of prevalence with controlled diagnostic blocks and false-positive rates in thoracic region.**

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Prevalence</th>
<th>False-Positive Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manchikanti et al 2002 (205)</td>
<td>46</td>
<td>48% (95% CI 34%–62%)</td>
<td>58% (95% CI 38%–78%)</td>
</tr>
<tr>
<td>Manchikanti et al 2004 (195)</td>
<td>72</td>
<td>42% (95% CI 30%–53%)</td>
<td>55% (95% CI 39%–78%)</td>
</tr>
<tr>
<td>Manchukonda et al 2007 (196)</td>
<td>65</td>
<td>34% (95% CI 22%–47%)</td>
<td>42% (95% CI 26%–59%)</td>
</tr>
<tr>
<td><strong>COMBINED RESULTS</strong></td>
<td><strong>173</strong></td>
<td><strong>40% (95% CI 33%–48%)</strong></td>
<td><strong>42% (95% CI 33%–51%)</strong></td>
</tr>
</tbody>
</table>

CI = confidence interval


In recent days, multiple manuscripts by Chou et al (29,30,206), those published from American College of Occupational and Environmental Medicine (ACOEM) (207,208), Official Disability Guidelines (ODG) (209), and American Society of Anesthesiologists (ASA) guidelines (210), Cochrane review by Staal et al (18) have been widely utilized in demonstrating the evidence against interventional procedures. However, the deficiencies of these manuscripts have been illustrated with reanalysis of the data of ACOEM guidelines and Chou et al’s guidelines, and in other documents for Cochrane review (3,31,32,34,211,212,264,265). Consequently, we would like to illustrate the differences of the evaluation achieved after reanalysis of Chou et al’s guidelines. However, Chou et al’s analysis is limited only to low back pain. Thus, some material may be duplicated from above description.

Tables 15 to 17 illustrate methodologic quality assessment as described by Chou et al, data of prevalence with controlled diagnostic blocks and false-positive rates in lumbar spine and quality assessment of systematic reviews of diagnostic medial branch blocks (31,191,194-199,213,214).
Table 15. Quality rating of intraarticular facet joint block and medial branch blocks: diagnostic accuracy and outcome studies.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Consecutive series or random subset</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Prospective</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Evaluates patients with a spectrum of symptoms</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Adequate description of technique</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Use of current technique</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Adequate description of criteria for positive test</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Appropriate definition for positive test</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Statistical analysis of predictors for positive tests</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
<td>NS</td>
<td>Yes</td>
</tr>
<tr>
<td>Investigator not aware of clinical symptoms</td>
<td>No</td>
<td>NS</td>
<td>No</td>
<td>NS</td>
<td>No</td>
<td>NS</td>
<td>No</td>
</tr>
<tr>
<td>Score</td>
<td>8/9</td>
<td>NS</td>
<td>7/9</td>
<td>NS</td>
<td>8/9</td>
<td>NS</td>
<td>8/9</td>
</tr>
</tbody>
</table>

*Included by Datta et al (179), but not Chou and Huffman (29)
NS = not scored by APS-AAPM review

### Table 16. Data of prevalence with controlled diagnostic blocks and false-positive rates in lumbar region.

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodologic Criteria</th>
<th>Participants</th>
<th>Prevalence</th>
<th>False-Positive Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manchikanti et al 2002 (194)</td>
<td>8/9 NS</td>
<td>120</td>
<td>40% (95% CI; 31%–49%)</td>
<td>30% (95% CI; 20%–40%)</td>
</tr>
<tr>
<td>Manchikanti et al 2004 (195)</td>
<td>8/9 NS</td>
<td>397</td>
<td>31% (95% CI; 27%–36%)</td>
<td>27% (95% CI; 22%–32%)</td>
</tr>
<tr>
<td>Manchukonda et al 2007 (196)</td>
<td>7/9 NS</td>
<td>303</td>
<td>27% (95% CI; 22%–33%)</td>
<td>45% (95% CI; 36%–53%)</td>
</tr>
<tr>
<td>Schwarzer et al 1995 (197)</td>
<td>8/9 NS</td>
<td>63</td>
<td>37% (95% CI; 25%–49%)</td>
<td>NA</td>
</tr>
<tr>
<td>Manchikanti et al 2001 (198)</td>
<td>8/9 NS</td>
<td>120</td>
<td>40% (95% CI; 31%–49%)</td>
<td>47% (95% CI; 35%–59%)</td>
</tr>
<tr>
<td>Manchikanti et al 2003 (199)</td>
<td>8/9 NS</td>
<td>300</td>
<td>I. 21% (95% CI; 14%–27%) II. 41% (95% CI; 33%–49%)</td>
<td>I. 17% (95% CI; 10%–24%) II. 27% (95% CI; 18%–36%)</td>
</tr>
<tr>
<td>Manchikanti et al 2007 (191)</td>
<td>8/9 NS</td>
<td>117</td>
<td>16% (95% CI; 9%–23%)</td>
<td>49% (95% CI; 39%–59%)</td>
</tr>
<tr>
<td>Overall</td>
<td>8/9 NS</td>
<td>1,420</td>
<td>31% (95% CI; 28%–33%)</td>
<td>30%* (95% CI; 27%–33%)</td>
</tr>
</tbody>
</table>

CI = confidence interval; NA = not available; # Schwarzer et al (197) not included in false-positive rating determination

### Table 17. Quality assessment of systematic reviews of diagnostic intraarticular facet joint block and medial branch blocks.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Search Method</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>Yes</td>
<td>Yes</td>
<td>NS</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
<td>Yes</td>
<td>Yes</td>
<td>NS</td>
</tr>
<tr>
<td>Bias Avoided</td>
<td>Yes</td>
<td>Yes</td>
<td>NS</td>
</tr>
<tr>
<td>Validity Criteria</td>
<td>Yes</td>
<td>Yes</td>
<td>NS</td>
</tr>
<tr>
<td>Validity Assessed</td>
<td>Yes</td>
<td>Partial</td>
<td>Yes</td>
</tr>
<tr>
<td>Methods for Combining Studies</td>
<td>No</td>
<td>No</td>
<td>NS</td>
</tr>
<tr>
<td>Appropriately Combined</td>
<td>No</td>
<td>No</td>
<td>NS</td>
</tr>
<tr>
<td>Conclusions Supported</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Overall Quality</td>
<td>7/9</td>
<td>2/7</td>
<td>7/9</td>
</tr>
<tr>
<td>Corrected Score</td>
<td>7/9</td>
<td>(5/9)</td>
<td>7/9</td>
</tr>
</tbody>
</table>

*included by Chou and Huffman (29) and Manchikanti et al (34)
**Study published in study period, but not identified by Chou and Huffman (29).
♦Included in Manchikanti et al (34), but not Chou and Huffman (29)
NS = not scored by APS-AAPM review
( ) corrected score by their own criteria

Chou and Huffman (29) recommended against diagnostic intraarticular facet joint blocks and medial branch blocks based on European COST guidelines (215). Their search included only one study by Birkenmaier et al (216) despite the vast literature available about evaluation of diagnostic facet joint blocks. The basis was that, as in other invasive diagnostic procedures for low back pain, no reliable reference standard for facet joint pain was available to estimate the diagnostic accuracy of intraarticular facet joint blocks and medial branch blocks. Thus, they concluded that it was unknown whether the decreased positive response rate was due to fewer false-positives, fewer true-positives, or a combination. They also utilized the basic indication for diagnostic facet joint blocks as a contraindication for utilizing the lack of correlation of facet joint pain diagnosed by controlled diagnostic blocks as not correlating well with findings on imaging studies.

Chou et al excluded appropriate studies which were included by others (179), choosing to present the diagnostic accuracy of 7 studies, yet they inappropriately included Birkenmaier’s study, counting it as 2 reports (216,217). Birkenmaier’s study was of poor quality and has not met any inclusion criteria for a diagnostic accuracy study. It essentially compared 2 uncontrolled procedures. They utilized higher concentrations of bupivacaine 0.5% and higher 1 mL volumes. They also utilized cryodenervation, which has not been proven to be an effective procedure. Even so, Birkenmaier et al (216,217) showed that patients who had been selected by medial branch blocks had better pain relief than did patients who had been diagnosed using pericapsular blocks with a statistical significance noted at 6 weeks and 3 months. Birkenmaier et al concluded that the results suggest that uncontrolled medial branch blocks are superior to pericapsular blocks when selecting patients of facet joint cryodenervation. They also concluded that both blocks work and further commented that if serial controlled blocks cannot be used, lumbar facet joint pain remains a diagnostic dilemma. However, Chou et al failed to take all these issues into consideration. Further, pericapsular blocks may be misleading as the injection can be made into the joint itself and the injection might leak into the epidural or subarachnoid space, producing a false-positive result of relief.

The majority of diagnostic and therapeutic blocks issues were related to placebo injection and criterion standard. While debate continues on this issue, there are substantial differences of opinions on what constitutes a proper placebo injection. Consequently, multiple authors have focused extensively on placebo controls and continue to misinterpret the data. However, injecting high doses of sodium chloride solution into a closed space or over a nerve is not a placebo. A true placebo can only be administered by injecting the solution, which is the same amount as the active solution, in an area which is away from the epidural space or nerve root. There is general confusion regarding placebo control for almost all therapeutic trials. Further, placebo-controlled neural blockades are not viable, even though they continue to be misinterpreted (218-228). It is a common practice in interventional pain management, to focus only on methodology and to erroneously report inaccurate conclusions referring to any local anesthetic injection as a placebo. Further, the effectiveness of sodium chloride injection has been demonstrated in multiple studies (229-232).

Carette et al (57,233) showed that patients responded similarly to either an intraarticular injection or an epidural injection whether it contained a sodium chloride solution or local anesthetic with steroid. However, the response was low in both groups. Thus, their studies illustrate that sodium chloride solution injected into an intraarticular space or epidural space has similar effects as local anesthetic with steroids; the conclusion is that intraarticular steroids or epidural steroids are not an effective therapy. This may hold appropriate for intraarticular injections, but not for epidural injections. It has been shown that a small volume of local anesthetic or normal saline abolishes muscle twitch induced by a low current 0.5 (mA) during electrolocation (225-228) In addition, the literature shows different effects with injections of various solutions such as local anesthetic, normal saline, or dextrose and also with different injection site into either the disc, facet joint, or multifidus muscle (218,219,225-228).
The second issue relates to criterion standard. It appears that most methodologists and physicians not involved in techniques of interventional pain management tend to describe biopsy as the only option. However, the literature illustrates that long-term follow-up is the alternative as a criterion standard (234). Consequently, long-term follow-up has demonstrated the value of diagnostic lumbar facet joint nerve blocks (181-183). In addition, multiple studies have revealed illustrating the validity of facet joint nerve blocks in the face of confounding factors (186-192).

3.2 Therapeutic Intraarticular Injections

The evidence is poor for therapeutic intraarticular injections, thus we have chosen not to discuss this separately. They may be covered only under specific circumstances where inflammation has been demonstrated or a facet joint synovial cyst exists.

3.3 Therapeutic Medial Branch Blocks

The evidence assessment for medial branch blocks was recently published in the ASIPP guidelines with 3 systematic reviews (3,4,177-179) evaluating the effectiveness of therapeutic facet joint nerve blocks (Table 18) (235-241). The guidelines of ACOEM (207,208), Chou et al (206), and Staal et al (18) are not only outdated, but also they have failed to utilize appropriate criteria meeting inclusion. Thus, the ASIPP guidelines and the 3 systematic reviews are superior in consideration of the evidence and utilization of sound methodology. Further, additional evidence which has been available since the publication of these guidelines and systematic reviews also confirms the analysis with 2-year follow-up (235,236).

Table 18. Results of randomized trials of effectiveness of cervical, thoracic, and lumbar medial branch blocks.

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>No. of Patients</th>
<th>Long-term Relief</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3 mos.</td>
<td>6 mos.</td>
</tr>
<tr>
<td>CERVICAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RA, DB</td>
<td>Group I = 60</td>
<td>83% vs 85%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group II = 60</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RA, DB</td>
<td>Group I - no steroid=24</td>
<td>79% vs 83%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group II - steroid=24</td>
<td></td>
</tr>
<tr>
<td>THORACIC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RA, DB</td>
<td>Group I = 60</td>
<td>83% vs 85%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group II = 60</td>
<td></td>
</tr>
<tr>
<td>LUMBAR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RA, DB</td>
<td>Group I - no steroid=24</td>
<td>83% vs 82%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group II - steroid=24</td>
<td></td>
</tr>
</tbody>
</table>

RA = randomized; DB = Double-blind; O = observational; vs = versus; P = positive; N = negative

Adapted and modified from:


It is essential for the methodologists and clinicians to accurately follow the requirements of evidence-based medicine in conducting systematic reviews of diagnostic accuracy studies. The reviews by ACOEM (207,208), Chou et al (206), and Staal et al (18) were deficient in this regard. The systematic reviews and ASIPP guidelines utilized 4 randomized trials evaluating the effectiveness of facet joint nerve blocks and meeting the inclusion criteria utilizing active control design (3,177-179). These studies lack placebo. However, active control designs show the existence of effect and compare the therapies – comparative effectiveness which is promoted in the United States.

These studies also were conducted based on consolidated standards of reporting trials (CONSORT) criteria (242,243). All the studies except the earliest one (244) were double-blind, randomized, and controlled trials with inclusion of outcome assessments with numeric pain scores, Oswestry or Neck Pain Disability Index, opioid intake, and work status reported at baseline, 3 months, 6 months, and 12 months. Twenty-four month data is also under consideration for publication for cervical medial branch blocks and published for lumbar facet joint nerve blocks, however, the study on thoracic medial branch blocks has not been completed yet. In these studies, they considered significant relief as 50% or greater and significant functional status improvement as 40% or more – robust measures. The inclusion criteria involved confirmation of the existence of facet joint pain based on 80% relief with controlled local anesthetic blocks. All the studies showed positive results with 71% to 90% of the patients showing positive results on a long-term basis of one-year for thoracic facet joint blocks and 2 years for cervical and lumbar facet joint nerve blocks (235,236,239). As touted by many, the limitations of these studies include lack of placebo, non-academic setting, and single-center studies. The same authors also published prospective studies which have been mentioned before, however, results of randomized studies were shown to be superior.

The cost-effectiveness of lumbar facet joint nerve blocks was also evaluated (244) with one-year improvement of quality of life at $3,461 which was superior to multiple other treatments.

Consequently, the 3 systematic reviews concluded that the indicated level of evidence based on USPSTF criteria (180) for lumbar, thoracic, and cervical facet joint nerve blocks as Level II-1 or II-2. They also yielded based on Guyatt et al’s criteria (245) the recommendation as strong (1B or 1C) for the use of therapeutic cervical, thoracic, and lumbar facet joint nerve blocks to provide both short-term and long-term relief in the treatment of chronic facet joint pain. Finally, Chou and Huffman’s (29) analysis which is inappropriate, the reassessment leads to the same conclusions as above, but based on their evidence synthesis it is fair definitely for cervical and lumbar facet joint nerve blocks and probably for thoracic medial branch blocks.

Thus, therapeutic medial branch blocks in the cervical, thoracic, and lumbar spine must be considered for coverage with appropriate limitations of the diagnosis with 80% pain relief and ability to perform painful movements with concordant relief followed by a maximum of 4 therapeutic injections per year per region – cervical and thoracic are considered as one region and lumbar and sacral considered as a second region.

3.4 Radiofrequency Facet Denervation

The evidence by 3 systematic reviews and ASIPP guidelines (3,177-179), based on USPSTF criteria (180), showed Level II-1 to Level II-2 for cervical medial branch radiofrequency neurotomy, and Level II-2 to II-3 for lumbar radiofrequency neurotomy, with and with no evidence available for thoracic medial branch radiofrequency neurotomy (Table 19) (246-252).
Table 19. Published results of studies of cervical and lumbar facet joint nerve neurotomy.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Characteristics</th>
<th>Number of Patients</th>
<th>Pain Relief (months)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>6 mos.</td>
<td>12 mos.</td>
</tr>
<tr>
<td>Cervical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lord et al 1996 (246)</td>
<td>RA, DB</td>
<td>24-control 24-active</td>
<td>♦ 1 of sham ♦ 7 of active</td>
<td>58% in active treatment group</td>
</tr>
<tr>
<td>Sapir and Gorup 2001 (247)</td>
<td>O</td>
<td>46</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>McDonald et al 1999 (248)</td>
<td>O</td>
<td>28</td>
<td>NA</td>
<td>71%</td>
</tr>
<tr>
<td>Barnsley 2005 (249)</td>
<td>O</td>
<td>35</td>
<td>NA</td>
<td>74%</td>
</tr>
<tr>
<td>Lumbar</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nath et al 2008 (250)</td>
<td>RA, DB</td>
<td>20-control 20-active</td>
<td>SI</td>
<td>NA</td>
</tr>
<tr>
<td>Gofeld et al 2007 (251)</td>
<td>O</td>
<td>174</td>
<td>68%</td>
<td>NA</td>
</tr>
<tr>
<td>Dreyfuss et al 2000 (252)</td>
<td>O</td>
<td>15</td>
<td>87%</td>
<td>87%</td>
</tr>
</tbody>
</table>

RA = randomized; DB = double blind; O = Observational; NA = not available; SI = significant improvement; VAS = visual analog scale; P = positive; N = negative

Source:


Among the multiple studies considered and included by Chou et al evaluating the radiofrequency neurotomy, only one study by Nath et al (250) was ideal and met the inclusion criteria by other evaluators (179,253). However, Chou et al found multiple deficiencies with this study which was previously considered one of the best studies in the literature except for lack of long-term follow-up. Chou et al misinterpreted Nath et al’s data (250). Chou and Huffman reported that the final scores in both groups were identical and there was no change in low back pain; however, Nath et al showed clear and distinct differences between both groups in all aspects. The active treatment group showed statistically significant improvement, not only in back and leg pain, but also back and hip movement as well as sacroiliac joint pain. There was also significant improvement in quality of life variables, global perception of improvement, and generalized pain in the active treatment group. Further, they also used conflicting numbers in their document stating in one place that there were 40 patients and in another, 60 patients, with the actual number being 40 patients.

Chou et al also included multiple studies which failed to meet inclusion criteria by others. These were by Gallagher et al (254), van Kleef et al (255), Leclaire et al (256), van Wijk et al (257), and Tekin et al (257). Surprisingly, the authors of these studies had conflicting opinions and Leclaire et al (256) have recanted their results and recommended the study must not be used for clinical purposes (259).
Chou et al also showed multiple deficiencies in assessment of systematic reviews (32). Further information is provided in the reassessment documents (18,260-263).

The recommendation yielded 1C/strong evidence based on Guyatt et al’s criteria (245).

### 3.4.1 Effectiveness
For diagnostic facet joint nerve blocks, with medial branch blocks, there is good evidence for cervical and lumbar medial branch blocks in the diagnosis of low back and neck pain, whereas the evidence is fair in the diagnosis of thoracic facet joint pain.

For therapeutic interventions, based on the criteria of good, fair, and poor, the evidence is lacking in the cervical and lumbar facet joint injections, whereas the evidence is fair for cervical, thoracic, and lumbar medial branch blocks and cervical and lumbar radiofrequency neurotomy.

### Indications and Medical Necessity
Medical necessity must be established for each and every procedure and encounter.

General documentation requirements for spinal interventional techniques for indications and medical necessity are as follows:
1. Complete initial evaluation including history and physical examination.
2. Physiological and functional assessment, as necessary and feasible.
3. Definition of indications and medical necessity, as follows:
   - Suspected organic problem.
   - Non-responsiveness to conservative modalities of treatment.
   - Pain and disability of moderate-to-severe degree.
   - No evidence of contraindications such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain.
   - Responsiveness to prior interventions with improvement in physical and functional status for repeat blocks or other interventions.
   - Repeating interventions only upon return of pain and deterioration in functional status.

Common indications for diagnostic facet joint interventions are as follows:
- Somatic or non-radicular neck pain, headache, and upper extremity pain; mid back or upper back with or without chest wall pain; or low back and lower extremity pain.
- Duration of pain of at least 3 months.
- Average pain levels of ≥ 6 on a scale of 0 to 10.
- Intermittent or continuous pain causing functional disability.
- Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and nonsteroidal anti-inflammatory agents.
- Lack of evidence, either for discogenic or sacroiliac joint pain.
- Lack of disc herniation or evidence of radiculitis.
- No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation.
- No history of allergy to contrast administration, local anesthetics, steroids, Sarapin, or other drugs potentially utilized.
- Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs.
Common indications for therapeutic facet joint interventions are based on the above indications and positive response to controlled local anesthetic blocks (<1 mL per nerve) with a criterion standard of 80% pain relief with ability to perform prior painful movements without significant pain.

**Frequency of Interventions:**
- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks, with careful judgment of response.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 2-3 months or longer between injections, provided that ≥ 50% relief is obtained for 8 weeks.
- If the interventional procedures are applied for different regions, they may be performed at intervals of no sooner than one week or preferably 2 weeks for most types of procedures.
  - It is suggested that therapeutic frequency remain at least a minimum of 2 months for each region, it is further suggested that all the regions be treated at the same time provided that all procedures can be performed safely.
- In the treatment or therapeutic phase, the facet joint interventions (medial branch blocks, or intraarticular injections) should be repeated only as necessary according to the medical necessity criteria, and it is suggested that these be limited to a maximum of 4 times for local anesthetic and steroid blocks over a period of one year, per region.
- For medial branch neurotomy, the suggested frequency would be 6 months or longer (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 3 to 4 months.
  - The therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months per each region with multiple regions involved. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.
- Cervical and thoracic are considered as one region and lumbar and sacral are considered as one region for billing purposes.

**4.0 Sacroiliac Joint Injections**
Rupert et al (266) in a systematic review provided the latest evidence with prevalence of sacroiliac joint pain to range between 10% and 38% with a false-positive rate of 20% to 54%. The evidence was Level II-3 or limited for therapeutic interventions with a weak recommendation.

Based on the present evaluation and grading of good, fair, and poor, the evidence is fair for diagnostic sacroiliac joint injections, whereas there is no evidence for therapeutic sacroiliac joint injections or radiofrequency neurotomy.

Thus, these procedures may be approved with a frequency of limiting to a maximum of 4 therapeutic procedures per year, with appropriate documentation if they meet indications and medical necessity as described above and the following indications utilizing appropriate frequency of interventions.

**4.1 Cost Effectiveness**
No cost effectiveness evaluations were performed with radiofrequency neurotomy of sacroiliac joint innervation.
4.2 Safety and Complications
Reported complications of radiofrequency thermoneurolysis include a worsening of the usual pain, burning or dysesthesias, decreased sensation and alldynia in the skin overlying the joint, transient leg pain, persistent leg weakness, inadvertent lesioning of the spinal nerve, ventral ramus, or sciatic nerve resulting in motor deficits, sensory loss, and possible deafferentation pain. (151-161).

4.3 Indications
Indications for sacroiliac joint interventions are illustrated under intraarticular sacroiliac joint injections.

**Common indications:**
- Somatic or nonradicular low back and lower extremity pain below the level of L5 vertebra.
- Duration of pain of at least 3 months.
- Average pain levels of $\geq 6$ on a scale of 0 to 10
- Intermittent or continuous pain causing functional disability.
- Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
- Lack of obvious evidence for disc-related or facet joint pain.
- No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation.
- No history of allergy to contrast administration, local anesthetics, steroids, Sarapin, or other drugs potentially utilized.
- Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs.
- For therapeutic sacroiliac joint interventions with intraarticular injections or radiofrequency neurotomy, the joint should have been positive utilizing controlled diagnostic blocks.

**Recommendation for frequency of interventions:**
- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 2 months or longer between injections, provided that $\geq 50\%$ relief is obtained for 8 weeks.
- If the procedures are done for different joints, they should be performed at intervals of no sooner than one week or preferably 2 weeks. It is suggested that therapeutic frequency remain at 2 months for each joint. It is further suggested that both joints be treated at the same time, provided the injections can be performed safely.
- In the treatment or therapeutic phase, the sacroiliac joint interventions should be repeated only as necessary according to the medical necessity criteria, and it is suggested that they be limited to a maximum of 4 times for local anesthetic and steroid blocks over a period of one year, per region.
- For sacroiliac joint radiofrequency neurotomy, the suggested frequency is 6 months or longer between each procedure (maximum of 2 times per year), provided that $\geq 50\%$ relief is obtained for at least 3 to 4 months.

Based on the criteria of evidence of good, fair, and poor, the evidence for radiofrequency neurotomy of sacroiliac joint pain is poor.
If you have any further questions, please feel free to contact us.

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