

Evidence-Based Medicine



Comprehensive Review of Therapeutic Interventions in Managing Chronic Spinal Pain

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Background: Available evidence documents a wide degree of variance in the definition and practice of interventional pain management.

Objective: To provide evidence-based clinical practice guidelines for interventional techniques in the treatment of chronic spinal pain.

Design: Best evidence synthesis.

Methods: Strength of evidence was assessed by the U.S. Preventive Services Task Force (USPSTF) criteria utilizing 5 levels of evidence ranging from Level I to III with 3 subcategories in Level II.

Outcomes: Short-term pain relief was defined as relief lasting 6 months or less and long-term relief as longer than 6 months, except \leq one year and $>$ one year for intradiscal therapies, mechanical disc decompression, spinal cord stimulation, and intrathecal infusion systems.

Results: The indicated evidence for therapeutic interventions is Level I for caudal epidural steroid injections in managing disc herniation or radiculitis, and discogenic pain without disc herniation or radiculitis. The evidence is Level I to II-1 for percutaneous adhesiolysis in management of pain secondary to post-lumbar surgery syndrome. The evidence is Level II-1 or II-2 for therapeutic cervical, thoracic, and lumbar facet joint nerve blocks; for caudal epidural injections in managing pain of post-lumbar surgery syndrome, and lumbar spinal stenosis, for cervical interlaminar epidural injections in managing cervical pain (Level II-1); for lumbar transforaminal epidural injections; and spinal cord stimulation for post-lumbar surgery syndrome.

Limitations: The limitations of this guideline preparation included a paucity of literature, lack of updates, and lack of conflicts in preparation of systematic reviews and guidelines by various organizations.

Conclusion: The indicated evidence for therapeutic interventions is variable from Level I to III. This comprehensive review includes the evaluation of evidence for therapeutic procedures in managing chronic spinal pain and recommendations. However, this review and recommendations do not constitute inflexible treatment recommendations or **"standard of care."**

Key words: Interventional techniques, chronic spinal pain, therapeutic interventions, facet joint interventions, epidural procedures, epidural adhesiolysis, radiofrequency, mechanical disc decompression, spinal cord stimulation, intrathecal implantable systems

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Available evidence in managing chronic spinal pain documents a wide degree of variance in the definition and practice of interventional pain management (1-16). Application of interventional techniques by multiple specialties is highly variable for even the most commonly performed procedures and treated conditions (9-13).

Evidence-based therapeutic interventional techniques in the management of chronic spinal pain include various types of neural blockade and minimally invasive surgical procedures. These include epidural and facet joint interventions, intradiscal therapies, percutaneous disc decompression, and implantables.

1.0 METHODOLOGY

The methodology of guideline development and evidence synthesis has been well described (1-8,17-28). Thus, the guidelines for therapeutic interventional techniques are based on the hierarchy of evidence described by Guyatt and Drummond (29).

Level of evidence described by the U.S. Preventive Services Task Force (USPSTF) (30) as shown in Table 1; methodologic quality assessment of individual articles described by West et al (31) and Cochrane review criteria (32,33); and grading of recommendations by Guyatt et al (34) as illustrated in Table 2 are utilized.

1.1 Sequential Process

The sequential process as described by Atkins et al (35) includes establishing the process, systematic review and preparation of an evidence profile for important outcomes, and grading quality of evidence and strength of recommendations.

2.0 RATIONALE

- ◆ Chronic spinal pain is a complex problem (36-44).
 - Chronic pain is defined as, "pain that persists 6 months after an injury and beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathologies; may not be amenable to routine pain control methods; and healing may never occur" (2).
- ◆ Cardinal source(s) of chronic spinal pain, particularly discs and joints, are accessible to neural blockade (1-6,45-79).
 - Extensive literature has been published on

diagnostic and therapeutic interventions. The diagnostic interventions have shown significant evidence in appropriate diagnosis of spinal pain originating from intervertebral discs, facet joints, and sacroiliac joints.

- ◆ Removal or correction of structural abnormalities of the spine may fail to cure and may worsen painful spinal conditions (1-5,58,62,69,76-115).
 - The evidence for surgical interventions and cost-effectiveness is neither strong nor conclusive. Further, increasing surgery without proof of effectiveness has been questioned (113).
- ◆ Degenerative processes of the spine and the origin of spinal pain is complex without correlation of radiographic changes to clinical picture and prognosis (1-5,47-76,80-82,113,116-118).
 - Multiple structural abnormalities are seen in asymptomatic patients (119-131).
- ◆ The effectiveness of a large variety of therapeutic interventions used to manage chronic spinal pain has not been demonstrated conclusively (1-5,47-76,113).
- ◆ There is increasing evidence supporting the use of interventional techniques in managing spinal pain (1-5,47-76,113).

3.0 FACET JOINT INTERVENTIONS

A preponderance of the evidence supports the existence of facet joint pain (52,53,63-65,116,117,132-146), although there are a few detractors (147-156). Based on a detailed review of the literature, the general consensus appears to be that facet joint pain can be diagnosed with reasonable certainty only on the basis of controlled diagnostic local anesthetic blocks (52,53,63-65,116,117,135-146). Therefore, assessment of the efficacy of interventional procedures for the treatment of facet joint pain requires that studies only employ controlled diagnostic medial branch blocks or intraarticular injections as selection criteria for such studies.

Facet joint pain may be managed by intraarticular injections, medial branch blocks, or neurolysis of the medial branches (1-5,53,57,63-65,144-146).

Relief was considered as short-term if documented for less than 6 months and long-term if documented for 6 months or longer.

3.1 Intraarticular Injections

Therapeutic benefit has been reported with the injection of corticosteroids, local anesthetics, or normal saline into the facet joints.

Table 1. *Quality of evidence developed by USPSTF.*

I	Evidence obtained from at least one properly randomized controlled trial
II-1	Evidence obtained from well-designed controlled trials without randomization
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
III	Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees

Adapted from the U.S. Preventive Services Task Force (USPSTF) (30).

Table 2. *Grading recommendations.*

Grade of Recommendation/ Description	Benefit vs Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
1A/strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B/strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C/strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A/weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B/weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C/weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Adapted from Guyatt G et al. Grading strength of recommendations and quality of evidence in clinical guidelines. Report from an American College of Chest Physicians task force. *Chest* 2006; 129:174-181 (34).

3.1.1 Effectiveness Assessment

The comprehensive search identified 9 systematic reviews evaluating the therapeutic role of intraarticular facet joint injections (32,53,57,63-65,157-159). There were multiple guidelines and other reviews (1-5,160-162). Nelemans et al (32) was updated by Staal et al (157). Boswell et al's systematic review of 2005 (57) was updated in 2007 (53). Thoracic facet joint interventions, cervical facet joint interventions, and lumbar facet joint interventions were systematically reviewed recently (63-65).

Following the comprehensive review of all the systematic reviews, 4 systematic reviews (63-65,157) met the inclusion criteria. Staal et al (157) utilized 6 weeks of relief as short-term and longer than 6 weeks as long-term, whereas Atluri et al (64), Falco et al (63), and Datta et al (65) utilized 6 months of relief as short-term and over 6 months as long-term. Further, 2 systematic reviews (63,65) utilized 80% pain relief with controlled diagnostic blocks as the inclusion criteria, whereas one systematic review (64) utilized 50% relief with controlled diagnostic blocks. In contrast, Staal et al (157) had no inclusion criteria based on the validity of diagnosis. In addition, there were 6 studies (163-168) either considered or included in one or more systematic reviews.

Staal et al (157) included the studies by Carette et al (163) and Lilius et al (166) in their analysis and qualified them as one high quality (163) and one low quality study (166) comparing the effects of facet joint injections with corticosteroids to placebo injections. They concluded that there was moderate evidence with 2 trials including 210 patients that facet joint injections with corticosteroids are not significantly different from placebo injections for short-term pain relief and improvement of disability. They also concluded that there was conflicting evidence whether facet joint injections with corticosteroids are more effective for intermediate term pain reduction and improvement of disability than placebo injections.

Datta et al (65) considered 5 randomized trials and 15 observational studies for inclusion and concluded that none of them met inclusion criteria with appropriate diagnosis and duration of follow-up. Atluri et al (64) showed there were no studies available for consideration. Falco et al (63) also concluded that there were no studies meeting the criteria for inclusion.

3.1.2 Studies Not Meeting Inclusion Criteria

The effectiveness of intraarticular corticosteroid

lumbar facet joint injections (163-167) and cervical facet joint injections (168) were studied comparing the results to those of a similar group not receiving intraarticular steroids. Of these, 3 randomized trials, one by Carette et al (163) involving lumbar facet joint injections, a second study by Fuchs et al (167), and the third one by Barnsley et al (168) involving cervical facet joint injections have been described as well conducted studies.

Carette et al (163) was rated as a high quality study by Staal et al (157) which compared the effects of facet joint injections with corticosteroids to placebo injections. In this study, they selected the patients who responded positively to a facet joint injection with lidocaine with more than a 50% reduction in pain score. However, they failed to exclude placebo responders, which may account for the relatively high incidence of patients in their study with presumed facet joint pain of 58%, which may have diluted the results, making detection of differences between the study and control groups more difficult. They randomly treated these patients with either corticosteroids or placebo injections. No significant differences for self-rated improvement, pain, or functional status were found between the groups at one and 3 months. At 6 months, significant differences were found with regard to self-rated improvement, pain, and functional status in favor of the corticosteroid group. Further, at the present time we do not know the role of a placebo (sodium chloride solution expected to be an inert substance) when injected into a closed joint space. The resultant effect could be a therapeutic effect rather than placebo or nocebo effect.

The second study by Lilius et al (166) included in the Cochrane review by Staal et al (157) compared corticosteroids injected intraarticularly with corticosteroids injected peri-capsularly to placebo injections. No significant differences between the groups were reported for pain, disability, and work attendance at one hour, 2 weeks, 6 weeks, and 3 months. This study also used overly broad criteria for inclusion without confirming the diagnosis by controlled diagnostic blocks and injected excessive volumes of 3 mL to 8 mL of active agents.

Staal et al (157) also used Fuchs et al (167) and concluded that there was limited evidence that facet joint injections with sodium hyaluronidase are not more effective than similar injections with corticosteroids in providing short- and long-term pain relief. However, this was not a placebo controlled trial; rather, it was an equivalence or non-inferiority trial. They (167) in-

investigated the efficacy and safety of intraarticular sodium hyaluronate compared with intraarticular glucocorticoids (triamcinolone acetonide) in the treatment of chronic nonradicular lumbar pain. They included 60 patients in this randomized, controlled, blind-observer clinical study and randomly assigned to the 2 groups to receive 10 mg of sodium hyaluronate or 10 mg triamcinolone acetonide per facet joint. The facet joints on both sides at level L3/4, L4/5, and L5/S1 were treated once per week under computed tomographic (CT) guidance. The results showed significant pain relief, improved function, and quality of life (QOL) with both treatments. The follow-up was carried out at 3 and 6 months after completion of treatment. This study showed intraarticular hyaluronic acid was not inferior to intraarticular glucocorticoid injections. The drawbacks of this study include the lack of diagnosis of facet joint pain by controlled local anesthetic blocks which may have increased the probability of inclusion of patients without facet joint pain.

3.1.3 Cost Effectiveness

No studies were performed evaluating cost effectiveness of therapeutic intraarticular facet joint injections.

3.1.4 Safety and Complications

Complications of intraarticular injections are rare but can be serious. Complications include infection, intraarterial or intravenous injection, spinal anesthesia, chemical meningitis, neural trauma, spinal cord injury, dural puncture, pneumothorax, radiation exposure, facet capsule rupture, hematoma formation, and steroid side effects (53,57,63-65,169-180).

3.1.5 Indications

Due to the lack of effectiveness and no significant evidence, there are no specific indications identified for therapeutic intraarticular injections.

3.1.6 Level of Evidence

The evidence for lumbar intraarticular injections is Level III. The evidence for cervical intraarticular injections is lacking. There was no evidence available for thoracic intraarticular facet joint injections.

3.1.7 Recommendations

Based on the available evidence, therapeutic intraarticular facet joint injections are not recommended.

3.2 Medial Branch Blocks

Therapeutic benefit has been reported with medial branch blocks with local anesthetics with or without steroids. The literature describing the effectiveness of medial branch blocks as a therapeutic intervention is scarce.

3.2.1 Effectiveness Assessment

The therapeutic role of medial branch blocks was evaluated in 6 systematic reviews (53,57,63-65,157). The effectiveness was also evaluated in multiple guidelines (2-4). The systematic reviews evaluating the effectiveness of therapeutic medial branch injection included one update (53) of an original publication (57), and 3 publications (63-65) that were current with application of strict methodologic inclusion criteria, with controlled diagnostic blocks as a prerequisite, along with assessment of 6 months of relief as short-term and longer than 6 months as long-term. In addition, 6 randomized clinical trials (181-186) and 2 observational studies (187,188) evaluating the effectiveness of therapeutic role of medial branch blocks were considered.

Following the comprehensive review of all the available systematic reviews, 4 systematic reviews (63-65,157) met the inclusion criteria (31). Staal et al (157) utilized more than 6 weeks of relief as long-term, whereas others (63-65) utilized over 6 months of relief as long-term. Further, 3 systematic reviews utilized strict diagnostic criteria. Staal et al (157) included one study by Manchikanti et al (181). Staal et al (157) concluded that there was no difference between local anesthetic only and local anesthetic with steroids; however, they failed to take into consideration the design of the study – non-inferiority or equivalence trial versus efficacy trial (26).

Among the studies evaluating effectiveness, the 3 systematic reviews (63-65) included 6 studies after exclusion of the preliminary publications which were considered as duplicates (185,186).

3.2.2 Descriptive Characteristics

3.2.2.1 Randomized Trials

All of the 4 randomized trials evaluating the effectiveness of facet joint nerve blocks and meeting the inclusion criteria were performed by Manchikanti et al (181-184) utilizing an active control design. These studies are referred to as non-inferiority or equivalence trials. Consequently, they lack placebo. Active control designs show the existence of effect

and compare therapies. These studies also were conducted based on Consolidated Standards of Reporting Trials (CONSORT criteria) (189). All the studies except the earliest one (181) 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. They considered significant relief as 50% or greater and significant functional status improvement as 40% or more. Their inclusion criteria were patients with a confirmed existence of facet joint pain based on 80% relief with controlled local anesthetic blocks. The limitations of these studies include lack of placebo, non-academic setting, and single center studies.

For the first trial of lumbar facet joint nerve blocks, Manchikanti et al (181) selected 73 patients positive for lumbar facet joint pain by means of controlled, comparative local anesthetic blocks. They randomly allocated patients into 2 groups, either receiving therapeutic medial branch blocks with a local anesthetic and Sarapin or with a mixture of local anesthetic, Sarapin, and methylprednisolone. Significant improvement was documented in both groups on various parameters of pain relief, functional status, opioid intake, return to work, and psychological status. Significant pain relief was seen with one to 3 injections in 100% of the patients for up to one to 3 months, 82% of the patients for 4 to 6 months, and 21% for 7 to 12 months. The mean relief was 6.5 ± 0.76 months.

In the second study, Manchikanti et al (184) in a randomized, double blind controlled trial design evaluated the role of lumbar facet joint nerve blocks in managing chronic facet joint pain. The study included 60 patients in Group I with local anesthetic and 60 patients in Group II with local anesthetic and steroid. The inclusion criteria were based on the positive response to the diagnostic controlled comparative local anesthetic lumbar facet joint blocks. The results showed significant improvement with significant pain relief ($\geq 50\%$) and functional improvement ($\geq 40\%$) observed in 82% and 85% in Group I, with significant pain relief in over 82% of the patients and improvement in functional status in 78% of the patients in Group II. Based on the results of the present study, it appears that patients may experience significant pain relief 44 to 45 weeks of one year, requiring approximately 3 to 4 treatments with an average relief of 15 weeks per episode of treatment.

The only published study of therapeutic cervical facet joints nerve blocks was by Manchikanti et al (182) in a double blind, randomized, controlled trial which included 120 patients meeting the diagnostic criteria of cervical facet joint pain by means of comparative, controlled diagnostic blocks with 80% pain relief. Group I consisted of medial branch blocks with bupivacaine, whereas Group II consisted of cervical medial branch blocks with bupivacaine and steroids. The average number of treatments for one year was 3.5 ± 1.0 in the non-steroid group and 3.4 ± 0.9 in the steroid group. Duration of average pain relief with each procedure was 14 ± 6.9 weeks in the non-steroid group and it was 16 ± 7.9 weeks in the steroid group. Significant relief and functional improvement was reported for 46 to 48 weeks in a one year period. The authors concluded that therapeutic cervical medial branch nerve blocks, with or without steroids, might provide an effective management strategy for chronic neck pain of facet joint origin.

Finally, Manchikanti et al (183) reported preliminary results of the effectiveness of thoracic medial branch blocks in managing chronic pain, in a randomized, double-blind controlled trial, illustrating the results of 48 patients with 24 patients in each group receiving either local anesthetic or steroid. The inclusion criteria was diagnosis of thoracic facet joint pain by means of comparative, controlled diagnostic blocks. The results showed the majority of the patients with significant improvement in pain relief ($\geq 50\%$) and functional status improvement ($\geq 40\%$). Patients receiving only local anesthetic in Group I showed significant pain relief and functional improvement of 79% at 3, 6, and 12 months. In Group II, patients receiving bupivacaine with steroids for medial branch blocks showed improvement of 83%, 81%, and 79% at 3, 6, and 12 months. Based on the results of this study, it appears that patients may experience significant pain relief of 46 to 50 weeks of a year, requiring approximately 3 to 4 treatments with an average relief of 16 weeks per episode of treatment.

3.2.2.2 Observational Studies

Manchikanti et al (187) evaluated the therapeutic effectiveness of cervical facet joint nerve blocks in chronic neck pain in a prospective outcome study. They evaluated 100 consecutive patients meeting the diagnostic criteria of facet joint pain by means of comparative, controlled diagnostic blocks. There

were significant differences in numeric pain scores and pain relief (> 50%) at 3 months (92%), 6 months (82%), and 12 months (56%) compared to baseline measurements. There was significant improvement in functional status, psychological status, and employment among patients eligible for employment (employed and unemployed) from baseline to 12 months.

Manchikanti et al (188) in a prospective outcome study with a minimum of one year follow-up, evaluated the therapeutic role of thoracic medial branch blocks in managing chronic thoracic pain. Fifty-five consecutive patients meeting the diagnostic criteria of thoracic facet joint pain by means of comparative, controlled diagnostic blocks were included. Medial branch blocks were performed with local anesthetic with or without steroids. The results showed significant differences in numeric pain scores and significant pain relief (> 50%) in 71% of the patients at 3 months and 6 months, 76% at 12 months, 71% at 24 months, and 69% at 36 months, compared to baseline measurements. Functional improvement was demonstrated at one year, 2 years, and 3 years from baseline. There was significant improvement with increase in employment among the patients eligible for employment from baseline to one year, 2 years, and 3 years in conjunction with improved psychological function.

3.2.3 Cost Effectiveness

The cost effectiveness of lumbar facet joint nerve blocks was evaluated by Manchikanti et al (181) with a one year improvement of QOL at a cost of \$3,461. The cost of one year improvement was similar to various investigations with neural blockade, but also was significantly better than the cost effectiveness with intrathecal morphine delivery or lumbar laminectomy, with or without instrumented fusion.

3.2.4 Safety and Complications

Complications with medial branch blocks are rare; however, the most common and worrisome complications of spinal facet joint nerve blocks are related to needle placement and drug administration (169-180).

These complications include infection, intraarterial or intravenous injection, spinal anesthesia, chemical meningitis, dural puncture, neural trauma, spinal cord trauma, pneumothorax, radiation exposure, hematoma formation, and steroid side effects.

3.2.5 Indications

Common indications for therapeutic facet joint interventions are:

- 1) Somatic or nonradicular low back and/or lower extremity pain; mid back, upper back, or chest wall pain; and neck pain, suspected cervicogenic headache, and/or upper extremity pain.
- 2) Duration of pain of at least 3 months with average pain levels of 6 or greater on a scale of 0 – 10.
- 3) Intermittent or continuous pain causing functional disability.
- 4) Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and nonsteroidal antiinflammatory agents.
- 5) Lack of evidence, either for discogenic or sacroiliac joint pain, lack of disc herniation or evidence of radiculitis.
- 6) No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation.
- 7) No history of allergy to contrast administration, local anesthetics, steroids, or other drugs potentially utilized.
- 8) Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs.
- 9) Positive response to controlled, comparative local anesthetic blocks with at least 80% relief with < 1 mL of anesthetic per level.

3.2.6 Level of Evidence

Table 3 illustrates the results of published reports of effectiveness of cervical, thoracic, and lumbar medial branch blocks.

Based on the quality of evidence using the USPSTF criteria (30), the indicated level of evidence for cervical, thoracic, and lumbar facet joint nerve blocks is Level II-1 or II-2.

3.2.7 Recommendations

Based on Guyatt et al's criteria (34), the recommendation is 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.

Table 3. Results of published reports of effectiveness of cervical, thoracic, and lumbar medial branch blocks.

Study	Study Characteristics	Methodological Quality Score(s)	No. of Patients	Initial Relief	Long-term Relief		Results	
				< 6 weeks	3 mos.	6 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
CERVICAL								
Manchikanti et al 2008 (182)	RA, DB	76	76	83% vs 85%	87% vs 95%	85% vs 92%	P	P
Manchikanti et al 2004 (187)	O	69	100	92%	82%	56%	P	P
THORACIC								
Manchikanti et al 2008 (183)	RA, DB	60	Group I-no steroid = 24 Group II-steroid = 24	79% vs 83%	79% vs 81%	79% vs 79%	P	P
Manchikanti et al 2006 (188)	O	69	55	71%	71%	76%	P	P
LUMBAR								
Manchikanti et al 2008 (184)	RA, DB	73	Group I-no steroid = 60 Group II-steroid = 60	83% vs 82%	83% vs 93%	82% vs 85%	P	P
Manchikanti et al 2001 (181)	RA	59	73	100%	82%	21%	P	P

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

Adapted and modified from:

Falco FJE et al. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician* 2009; 12:323-344 (63).

Atluri S et al. Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions. *Pain Physician* 2008; 11:611-629 (64).

Datta S et al. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. *Pain Physician* 2009; 12:437-460 (65).

3.3 Medial Branch Neurotomy

Percutaneous neurotomy of medial branches is a procedure that offers pain relief by denervation of the nerves that innervate a painful joint. The denervation may be performed by radiofrequency thermoneuroly-

sis utilizing a thermal or pulsed mode, cryoneurolysis, or laser denervation. However, in these guidelines, due to the paucity of literature and the emerging nature of multiple modalities of treatments, we have considered only thermal radiofrequency neurotomy.

3.3.1 Effectiveness Assessment

There have been 9 systematic reviews of medial branch radiofrequency neurotomy (53,57,63-65,159,190-192), multiple guidelines (2-4,160), and numerous clinical evaluations (193-222).

Among the 9 systematic reviews of medial branch radiofrequency neurotomy available, several were either updates or duplicates (53,57,158). Consequently, only 3 systematic reviews (63-65) which included inclusion criteria of controlled local anesthetic blocks and appropriate outcome parameters were included in this review. The description of multiple systematic reviews is provided briefly to illustrate the deficiencies.

Geurts et al (190) concluded that there was moderate evidence that radiofrequency lumbar facet denervation was more effective for chronic low back pain than placebo, and there was only limited evidence existent for the effectiveness of radiofrequency neurotomy for chronic cervical zygapophysial joint pain after flexion/extension injury. Niemesto et al (192), within the framework of the Cochrane Collaboration Back Review Group, concluded that there was limited evidence that radiofrequency denervation had a positive short-term effect on chronic cervical zygapophysial joint pain, and a conflicting short-term effect on chronic low back pain. Slipman et al (159) concluded that the evidence for radiofrequency denervation was Level 3 or moderate. The systematic reviews by Manchikanti et al (191) and Boswell et al (53,57) concluded that the evidence for pain relief with radiofrequency neurotomy of medial branch nerves was moderate to strong in the cervical and lumbar spine.

3.3.2 Descriptive Characteristics

The therapeutic role of medial branch neurotomy was evaluated in 9 randomized trials (193-201), and in 21 observational studies (202-222).

For cervical and lumbar medial branch neurotomy, 2 randomized trials (193,201) and 5 observational studies (202,208,209,212,221) met inclusion criteria with methodologic quality assessment for evidence synthesis. Two studies (210,216) were identified which showed thoracic percutaneous facet denervation of medial branches; however, both of them failed to meet inclusion criteria, with low methodologic quality. The manuscripts meeting the diagnostic criteria of 80% relief, with low volume local anesthetic injection and with the ability to perform previously pain-

ful maneuvers were included in the methodologic quality assessment. Thus, multiple studies not meeting inclusion criteria were excluded with the details illustrated in the systematic reviews (63-65).

3.3.2.1 Randomized Trials

Nath et al (201), in a randomized control trial (RCT) of 40 patients with chronic low back pain (20 active and 20 controls), found that the active treatment group showed improvement accompanied by significantly greater improvements in paravertebral tenderness, various movements, QOL, and use of analgesics. The pain relief was, however, only monitored for 6 months, as it was felt that patients who received placebo treatment could not be left untreated for longer than 6 months. Bogduk (223) provided a favorable opinion and highlighted the selection criteria, generalizability, and relief of index pain.

In 1996, Lord et al (193) evaluated the effectiveness of percutaneous radiofrequency neurotomy for chronic cervical zygapophysial joint pain in 24 patients. This randomized, double blind clinical trial with strict diagnostic selection criteria compared percutaneous radiofrequency neurotomy to a sham treatment wherein the procedural technique was the same including local anesthetic injection, but radiofrequency was not applied in the control group. At 3 months all patients were interviewed by completing the visual analog scale (VAS), the McGill Pain Questionnaire (MPQ), side effects, complications, and any sensation of numbness. At 27 weeks, one patient in the control group and 7 in the active treatment group remained free of pain. The median time for return of pain to at least 50% of the pre-operative level was 263 days in the active group and 8 days in the placebo group. This study found that radiofrequency neurotomy can provide pain relief for a moderate proportion of patients lasting from months to over a year.

3.3.2.2 Observational Studies

Sapir and Gorup (208) in 2001 examined the efficacy of radiofrequency medial branch neurotomy to treat cervical zygapophysial joint pain from whiplash meeting diagnostic selection criteria in an observational study comparing the results of litigants and non-litigants. Pain was evaluated prior to treatment based on the VAS as well as other outcome measures such as self-report of improvement and change in medication usage. Fifty patients were included in the

study meeting the criterion of at least 80% pain relief from comparative diagnostic blocks and underwent radiofrequency neurotomy. Forty-six patients completed the study consisting of 29 (63%) litigants and 17 (37%) non-litigants. Twenty-one patients (14 litigants and 7 non-litigants) reported a recurrence of pain within one year and 25 patients (15 litigants and 10 non-litigants) remained asymptomatic at one year. Time to pain recurrence defined as 50% return of pain was approximately 8.3 ± 2.3 months in the 21 patients whose pain returned within one year. There was an overall VAS pain reduction of 4.6 ± 1.8 from radiofrequency neurotomy at one year with a small but statistically significant difference with litigants having a slightly greater reduction in pain.

Barnsley (202) assessed outcomes in a series of consecutive patients with percutaneous radiofrequency neurotomy for chronic neck pain utilizing Lord et al's technique (193). Eligibility criteria included definite or complete relief of pain with both anesthetic agents and no response to placebo under double blind conditions. The objective of the treatment was to provide complete relief of pain and the primary outcome was the duration of pain relief. The endpoint adapted was the return of any patient's usual neck pain; secondary outcomes were the duration of any postoperative pain and any other adverse effects. Outcomes were determined by an independent assessor who had no prior knowledge of the patient and no involvement in the treatment or routine follow-up of patients. Forty-seven procedures were performed on 35 patients, 2 patients were lost to follow-up, 12 patients had 2 procedures, and 36 of 45 assessable procedures (80%) produced significant pain relief. These 36 procedures achieved a mean duration of pain relief of 35 weeks, with a median of 35 weeks. Repeat procedures usually achieved reproducible pain relief. Most patients had significant post-procedure pain for about one week. Limitations of this study include the lack of generalizability due to utilization of placebo-controlled treatments and the radiofrequency neurotomy technique described by Lord et al (193) which is not universal practice, specifically in the United States, and the small number of patients.

A study was conducted in 1999 by McDonald et al (209) to determine the long-term efficacy of percutaneous radiofrequency medial branch neurotomy in the treatment of chronic neck pain. This study was created in response to the report by The

Quebec Task Force on Whiplash-Associated Disorders (224) that reported there are no valid diagnostic techniques for chronic neck pain and no proven therapy. Radiofrequency neurotomy was performed between 1991 and 1996 in 28 patients diagnosed with cervical facet joint neck pain by controlled diagnostic blocks. The patients' pain was recorded using a VAS and the MPQ. Patients also described 4 activities of daily living that were eliminated or impeded by their pain and that they would want restored if they could be relieved of their pain. A successful result was defined as complete pain relief for a minimum of 90 days. Initially, 18 of the 28 patients had greater than 3 months of complete pain relief with 421.5 days of median pain relief. The median duration of pain relief for all 28 patients was 218.5 days. Repeat radiofrequency neurotomy was performed in 6 of the 10 patients who obtained no relief from the initial treatment and 2 of the patients had greater than 3 months of complete pain relief. Therefore, 20 of the 28 patients (71%) obtained complete relief after one or more attempts from radiofrequency neurotomy. Eleven of the 20 subjects underwent repeat neurotomy after pain reoccurrence. This study found that patients can expect between 223 and 730 days of complete relief after an initial procedure and between 144 and 478 days of relief after repeat procedures, but not permanent relief.

Dreyfuss et al (212) reported that 87% of 15 patients obtained at least 60% pain relief 12 months status post radiofrequency denervation, with 60% of the patients achieving at least 90% relief. In addition to stringent inclusion criteria, the authors used 16 gauge electrodes and assessed the efficacy of radiofrequency denervation by performing electromyography of the multifidus muscle.

Gofeld et al (221) evaluated, in a large clinical audit, extending from 1991 to 2000, 209 patients, with 174 completing the study. They included only the patients with an appropriate response to comparative double diagnostic blocks. Of the 174 patients with complete data, 55 (31.6%) experienced no benefit from the procedure and 119 patients (68.4%) had good to excellent pain relief lasting from 6 to 24 months. They concluded that proper patient selection and anatomically correct radiofrequency denervation of the lumbar zygapophysial joints provides long-term pain relief in a routine clinical setting.

Table 4. Published results of studies of cervical and lumbar facet joint nerve neurotomy.

Study	Study Characteristics	Methodological Quality Score(s)	Number of Patients	Pain Relief (months)		Results	
				6 mos.	12 mos.	Short-term relief ≤ 6 months	Long-term relief > 6 months
CERVICAL							
Lord et al 1996 (193)	RA,DB	67.	24	1 of sham 7 of active	58% in active treatment group	P	P
Sapir and Gorup 2001 (208)	O	87	46	NA	Mean VAS change 4.6 ± 1.8	P	P
McDonald et al 1999 (209)	O	65	28	NA	71%	P	P
Barnsley 2005 (202)	O	54	35	NA	74%	P	P
LUMBAR							
Nath et al 2008 (201)	RA,DB	50	20-control 20-active	SI	NA	P	NA
Gofeld et al 2007 (221)	O	63	174	68%	NA	P	P
Dreyfuss et al 2000 (212)	O	73	15	87%	87%	P	P

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

Adapted and modified from:

Falco FJE et al. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician* 2009; 12:323-344 (63).

Datta S et al. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. *Pain Physician* 2009; 12:437-460 (65).

3.3.3 Cost Effectiveness

No cost effectiveness evaluations were performed with medial branch neurotomy.

3.3.4 Safety and Complications

The common complications of radiofrequency neurotomy include dural puncture, spinal cord trauma, infection, intraarterial or intravenous injection, spinal anesthesia, chemical meningitis, neural trauma, pneumothorax, radiation exposure, hematoma formation, painful cutaneous dysesthesias, increased pain due to neuritis or neurogenic inflammation, anesthesia dolorosa, cutaneous hyperesthesia, and deafferentation pain (169-176,225-229).

3.3.5 Indications

The indications for all therapeutic facet joint interventions are described in Section 3.2.5.

3.3.6 Level of Evidence

Table 4 illustrates the results of published studies of cervical and lumbar facet nerve neurotomy. There were no studies meeting inclusion criteria in the thoracic spine.

Based on USPSTF criteria (30), the indicated evidence for cervical medial branch radiofrequency neurotomy is Level II-1 to Level II-2, Level II-2 to II-3 for lumbar radiofrequency neurotomy, with no evidence available for thoracic medial branch radiofrequency neurotomy.

3.3.7 Recommendations

Based on Guyatt et al's (34) criteria for cervical and lumbar radiofrequency neurotomy, the recommendation is 1C/strong recommendation.

4.0 EPIDURAL INJECTIONS

Substantial differences with the technique and outcomes have been described between the 3 available approaches to access the lumbar epidural space: caudal, interlaminar, and transforaminal (2-6,60,69-74,230-237) approaches. The interlaminar entry is directed more closely to the assumed site of pathology, requiring less volume than the caudal route. The caudal entry is relatively easily achieved, with minimal risk of inadvertent dural puncture. The transforaminal approach is target specific with the smallest volume, fulfilling the aim of reaching the primary site of pathology, the ventrolateral epidural space.

Thus far, the literature has been more favorable to lumbar transforaminal epidurals, followed by caudal epidural and cervical interlaminar epidural injections, with limited evidence for blind lumbar interlaminar epidural injections and no evidence available either for thoracic interlaminar or for thoracic and cervical transforaminal epidural injections (230-237).

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 (cervical, thoracic, and lumbosacral) must be considered as separate entities.

In addition, multiple factors must be taken into consideration including the pathology. The response to epidural injections is different for various pathological conditions. The most commonly utilized indications are disc herniation and/or radiculitis, discogenic pain without disc herniation, spinal stenosis, and post surgery syndrome.

4.1 Effectiveness Assessment

There have been multiple systematic reviews (32,33,60,69-71,74,157,158,231,232-237). Abdi et al (60,231) and Boswell et al (236) followed a similar methodology. These systematic reviews are updates of each other. Recent publications include 4 systematic reviews describing caudal epidural, lumbar interlaminar epidural, cervical interlaminar epidural, and lumbar transforaminal epidural injections (69-71,74). These systematic reviews (69-71,74) utilized the appropriate methodologic quality assessment criteria, 6 months

of relief as short-term and greater than 6 months as long-term, and evaluated multiple pathologies when the literature was available. However, Staal et al (157) in an updated Cochrane review and Armon et al (232) combined caudal and interlaminar approaches in managing chronic low back pain, considering more than 6 weeks of relief as long-term.

Staal et al (157) detailed epidural corticosteroids versus placebo injections, epidural corticosteroid injections versus other treatments, and epidural injections with local anesthetic versus other treatments. They concluded that there was limited evidence that epidural corticosteroid injections were not significantly different from placebo injections for general improvement in the short-term and that the effect of epidural corticosteroid injections is not significantly different from non-steroidal anti-inflammatory agents, benzodiazepines, and morphine combined with corticosteroids. They also concluded that while there is insufficient evidence to support the use of injection therapy in subacute and chronic low back pain, it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy.

Armon et al (232) in a report of the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology assessed the use of epidural steroid injections to treat radicular lumbosacral pain. In this evaluation their search yielded 37 articles, 4 of which met the predetermined inclusion criteria (238-241). While they claimed strict assessment, they failed to separate various types of epidural injections, thus combining lumbar and caudal procedures. Further, none of them were performed under fluoroscopy. This systematic review faced substantial criticism (242). In addition, they also attempted to include transforaminal epidural injections; however, they felt that the studies did not meet the inclusion criteria even though they were graded as high quality studies by others (243,244). Consequently, this flawed analysis showed a lack of evidence when assessed between 2 and 6 weeks following the injection, compared to controlled treatments, either placebo or active control.

Abdi et al (60,231) and Boswell et al (236) separated caudal, interlaminar, and transforaminal epidural injections and arrived at conclusions that were different from other systematic reviews. Further, in a reassessment of the evidence synthesis by ACOEM guidelines, Manchikanti et al (158) showed results similar to those of Abdi et al (60,231) with significant

evidence for caudal, cervical interlaminar, and lumbar transforaminal epidural injections. Manchikanti et al (245,246) also described evidence synthesis methodology and pointed out the deficiencies in evidence synthesis, which may have deleterious implications on patient care.

Consequently, based on the best evidence synthesis, the 4 latest systematic reviews met criteria for inclusion (69-71,74).

4.2 Caudal Epidural Injections

Several systematic reviews have evaluated the effectiveness of epidural steroids including caudal epidural injections (32,33,69,157,232-235,237). However, they failed to separate caudal and interlaminar techniques, arriving at erroneous conclusions. Of importance are systematic reviews performed by Nelemans et al (32), updated by Staal et al (157), Koes et al (33), van Tulder et al (237), and Armon et al (232). All these reviews included essentially similar criteria as well as the same studies, uniformly arriving at inaccurate conclusions. In contrast, Abdi et al (60,231), Boswell et al (236), Manchikanti et al (158), and Bogduk et al (230) evaluated caudal epidural steroid injections as separate procedures, reaching opposite conclusions from the aforementioned reviews. They concluded that the effectiveness of caudal epidural injections in managing lumbar radiculopathy was moderate.

4.2.1 Effectiveness Assessment

Conn et al (69) in a recent 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 laminectomy 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 (69) also indicated evidence of Level II-1 or II-2 for caudal epidural injections in managing chronic pain of post lumbar laminectomy 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.

4.2.2 Descriptive Characteristics

4.2.2.1 Disc Herniation and Radiculitis

Of all the available studies, 6 randomized trials (238,247-251) met the inclusion criteria under this category.

4.2.2.1.1 Study Characteristics

Of the 2 studies utilizing fluoroscopy, Dashfield et al (248) compared the effectiveness of caudal steroid epidural with targeted steroid placement during spinal endoscopy for chronic sciatica in a prospective, randomized, double-blind trial, in 60 patients with symptom duration of 18 months. Patients in the caudal group underwent caudal epidural corticosteroid injections with a total of 10 mL of lidocaine 1% with 40 mg of triamcinolone being injected into the epidural space. Patients in the epiduroscopy group underwent epiduroscopy performed by an experienced epiduroscopist with placement of steroid over the nerve root, which included 10 mL of lidocaine 1% with triamcinolone 40 mg. The epiduroscopy group also received an infusion of 50 to 150 mg mL of sodium chloride solution. If adhesions were encountered around the painful nerve root, an attempt was made to break the adhesions down using saline boluses or by manipulating the endoscope. However, very little scar tissue was encountered in their patient population, as they had never had surgery. No significant differences were found between the groups for any of the measures at any time. There were significant differences within both groups compared with pretreatment values. For the caudal group, significant improvements were found for descriptive pain at 6 months; VAS at 6 weeks, 3 months, and 6 months; present pain intensity at 3 months and 6 months; anxiety at 6 weeks, 3 months, and 6 months; and depression at 6 months only.

Manchikanti et al (247) in a preliminary report of a randomized, double-blind, equivalence trial, published results in 84 patients with 42 patients in each group of local anesthetic with or without steroid. The study consists of 60 patients in each group with Group I patients receiving caudal epidural injections with local anesthetic of lidocaine 0.5% preservative free, whereas Group II patients received caudal epidural injections with 0.5% lidocaine, 9 mL, mixed with 1 mL of steroid. Repeat caudal epidural injections were provided based on the response to prior caudal epidural injections evaluated by improvement in physical and functional status. Multiple outcome

Table 5. Results of randomized trials of effectiveness of caudal epidural steroid injections in managing pain of lumbar disc herniation/radiculitis.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (247)*	RA, DB	72	84	81%	86%	79% to 81%	P	P
Dashfield et al 2005 (248)*	RA, DB	50	Caudal = 30 Endoscopy = 30	SI	SI	NA	P	NA
Bush and Hillier 1991 (238)	RA, DB	55	23	SI	NSI	NSI	P	N
Mathews et al 1987 (249)	RA, DB	62	C = 34 T = 23	SI	SI	SI	N	P
Hesla and Breivik 1979 (251)	RA, DB	58	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P
Breivik et al 1976 (250)	RA, DB	68	C = 19 T = 16	20% vs 50%	20% vs 50%	NA	P	NA

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; C = control; T = treatment; NA = not available; SI = significant improvement; NSI = no significant improvement; vs = versus; P = positive; N = negative

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (69).

measures were utilized with measurements of pain outcomes, employment status, and opioid intake assessed at 3 months, 6 months, and 12 months post-treatment. Significant pain relief was established as 50% or more reduction in numeric rating scale (NRS) from baseline, whereas significant improvement in function was described as at least a 40% reduction in Oswestry Disability Index (ODI). Sample size justification was provided for preliminary analysis and intent-to-treat analysis was performed. This report showed significant pain relief ($\geq 50\%$) in 79% to 81% of the patients with significant improvement in functional status (40% or greater reduction in Oswestry scores) in 83% to 91% of the patients at the end of one year follow-up with no significant differences noted with or without steroids. The overall average procedures per year were 3 to 4 with an average total relief per year of 35 to 36 weeks over a period of 52 weeks. Opioid intake and employment also showed significant improvement. The importance of this study lies in the fact that it was performed under fluoroscopy in a private practice setting with a randomized double-blind design as an equivalence trial. The results of this study

are generalizable to interventional pain management settings in the United States.

4.2.2.1.2 Effectiveness

Of the 6 randomized trials, 5 were judged to be positive for short-term relief (238,247-250). Only 4 trials (238,247,249,251) reported positive results with long-term follow-up of more than 6 months. The results in 2 studies utilizing fluoroscopy (247,248) were superior to blind epidural injections. Table 5 illustrates the results of the effectiveness of randomized trials in disc herniation and radiculitis.

4.2.2.2 Post Surgery Syndrome

Three studies were identified evaluating the effectiveness of caudal epidural injections in post surgery syndrome (251-253). Only one study by Manchikanti et al (252) was performed under fluoroscopy. Of these, 2 studies (251,253) provided outcomes of longer than 6 months. Revel et al (253) and Manchikanti et al (252) studied exclusively post lumbar laminectomy syndrome patients, whereas, Hesla and Breivik (251) studied 36

of 69 patients previously operated on for herniated disc. There were no observational studies available in this category for inclusion.

4.2.2.2.1 Study Characteristics

The only fluoroscopic study, that of Manchikanti et al (252), evaluated 40 patients in a randomized, double-blind equivalence trial with the objective of evaluating the effectiveness of caudal epidural injections in patients with chronic low back and lower extremity pain after surgical intervention with post lumbar surgery syndrome. The results were preliminary from an expected study of 120 patients including 40 patients completing one year follow-up with justification of sample size in the subgroup analysis. They assigned patients into one of 2 groups with Group I patients receiving caudal epidural injections of local anesthetic (lidocaine 0.5% preservative free), and Group II patients receiving caudal epidural injections with 0.5% lidocaine, 9 mL, mixed with 1 mL of non-particulate Celestone, 6 mg, under fluoroscopy. Multiple outcome measures were utilized including measurement of pain and disability, employment status, and opioid intake. Significant pain relief was described as a 50% or more reduction in NRS from baseline, whereas significant improvement and function was described as at least a 40% reduction in the ODI. In this study utilizing contemporary practice with fluoroscopy and in a private practice setting in a double-blind equivalence

trial, preliminary results of one year showed significant pain relief ($\geq 50\%$) in 60% to 65% of the patients and functional improvement (greater than 40% reduction in ODI) in 55% to 70% of the patients with no significant differences between the groups at one year follow-up. Patients in the study received overall 3 to 4 procedures in a year with an average total relief of 26 to 32 weeks of 52 weeks. There were significant withdrawals due to failure to improve. Thus, separation into successful and failed groups showed results different from overall results. In the successful group, the total relief per year ranged from 35 to 44 weeks with poor response in the failed subjects. Average relief per procedure was 10 to 14 weeks. Opioid intake was also reduced significantly at one year follow-up. The advantages of this study include the fact that it is an equivalence trial performed in a private practice setting with the results generalizable to the interventional pain patient population across the country when performed fluoroscopically.

4.2.2.2.2 Effectiveness

Of the 3 randomized trials studying the effectiveness of caudal epidural steroid injections in post-surgery syndrome, all of them were shown to be positive for short and long-term relief (251-253). Table 6 illustrates the results of randomized trials in managing chronic pain of post surgery syndrome with caudal epidural injections.

Table 6. Results of randomized trials in managing low back pain of post-surgery syndrome with caudal epidural injections.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief \leq 6 mos.	Long-term relief $>$ 6 mos.
Manchikanti et al 2008 (252)*	RA, DB	70	40	65% to 70%	60%	60% to 65%	P	P
Revel et al 1996 (253)	RA	62	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (251)	RA, DB	58	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P

*Indicates use of fluoroscopy

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

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (69).

4.2.2.3 Spinal Stenosis

There was one randomized trial evaluating the role of caudal epidural injections in spinal stenosis (254). This study met inclusion criteria and was performed under fluoroscopy with one year follow-up. There were 4 observational studies (255-258) available with 2 studies (255,258) meeting inclusion criteria.

4.2.2.3.1 Study Characteristics

Manchikanti et al (254) published preliminary results of a randomized equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain secondary to spinal stenosis. The study included 40 patients with 20 patients in each group with justification of sample size. They utilized multiple outcome measures, included NRS, ODI, employment status, and opioid intake with assessment at 3 months, 6 months, and 12 months post-treatment. They defined significant pain relief as 50% or more, whereas significant improvement in disability score was defined as reduction of 40% or more. Patients were assigned randomly into 2 groups, with Group I patients receiving caudal epidural injections of local anesthetic (lidocaine 0.5%) Group II patients receiving caudal epidural injections with 0.5% lidocaine, 9 mL, mixed with 1 mL of non-particulate Celestone.

Significant pain relief ($\geq 50\%$) was demonstrated in 55% to 65% of patients with functional status improvement with at least a 40% reduction in the ODI scores in 55% to 80% of the patients. The overall average procedures ranged from 3 to 4 with an average total relief of 23 to 30 weeks 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 ranging from 38 to 43 weeks over a period of one year with an average relief of 10 to 15 weeks per procedure in the overall population. There was also a reduction of opioid intake. Even though this is a small study, it was performed utilizing contemporary interventional pain management techniques under fluoroscopic evaluation with appropriate outcome parameters in a private practice setting, yet utilizing a randomization and double-blind design in an equivalence trial comparing local anesthetic and steroid. Thus, these results can be applied to populations across the United States. Further, this is the first randomized trial evaluating the role of caudal epidural injections in spinal stenosis.

Of the 4 observational studies (255-258), 2 met inclusion criteria (255,258). Botwin et al (258) in a pro-

spective evaluation evaluated 34 patients with bilateral radicular pain from lumbar spinal stenosis with fluoroscopically guided caudal epidural injections after failure of conservative care. They administered on average 2.2 injections per patient, all within 6 weeks of evaluation; 65% of the patients at 6 weeks, 62% at 6 months, and 54% at 12 months had a successful outcome, reporting at least a greater than 50% reduction between pre-injection and post-injection VAS. They also reported significant improvement in multiple other scores including sitting, standing, and satisfaction.

Ciocon et al (255), in a prospective evaluation, determined the effectiveness of caudal epidural blocks in 30 elderly patients suffering from degenerative lumbar canal stenosis. They received a total of 3 doses of 0.5% Xylocaine with 80 mg DepoMedrol at weekly intervals. Significant relief of pain ranging from 4 to 10 months was reported.

4.2.2.3.2 Effectiveness

The one randomized trial evaluating spinal stenosis with or without steroids with local anesthetic (254) and 2 observational studies (255,258) showed positive results for short- and long-term relief (Table 7). Huntoon and Burgher (259) concluded in an editorial that the results of caudal epidurals were similar to surgery.

4.2.2.4 Discogenic Pain

One randomized trial (260) and 2 observational studies (261,262) met inclusion criteria based on methodologic quality assessment.

4.2.2.4.1 Study Characteristics

Manchikanti et al (260) in a randomized, double-blind, equivalence trial evaluated the effectiveness of caudal epidural injections with or without steroids in managing chronic low back pain without disc herniation or radiculitis in providing effective and long-lasting pain relief and evaluated the differences between local anesthetic with or without steroids. Inclusion criteria consisted of lack of disc herniation and symptoms of radiculitis, negative response to controlled diagnostic facet joint nerve blocks and sacroiliac joint blocks, and failure of conservative management. Patients were randomly assigned to one of 2 groups, Group I patients received caudal epidural injections with local anesthetic (lidocaine 0.5%), and Group II patients receiving caudal epidural injections with 0.5% lidocaine

Table 7. Results of effectiveness in evaluation in managing spinal stenosis.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (254)*	RA, DB	70	40	50% to 65%	60% to 65%	55% to 65%	P	P
Ciocon et al 1994 (255)	O	57	30	SI	SI	NA	P	NA
Botwin et al 2007 (258)*	O	61	34	65%	62%	54%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; O = observational; NA = not available; SI = significant improvement; vs = versus; P = positive; N = negative

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (69).

9 mL mixed with 1 mL of steroid. Randomization was performed by computer-generated random allocation sequence by simple randomization. Multiple outcome measures were utilized which included the NRS, the ODI 2.0, employment status, and opioid intake with assessment at 3 months, 6 months, and 12 months post-treatment. Significant pain relief was defined as 50% or more, whereas significant improvement in disability score was defined as reduction of 40% or more. Significant pain relief ($\geq 50\%$) was demonstrated in 72% to 81% of patients and functional status improvement was demonstrated by a reduction of 40% or more in the ODI scores in 81% of the patients. The overall average procedures per year were 3.6 ± 1.05 in Group I and 3.9 ± 1.33 in Group II with an average total relief per year of 32.3 ± 16.93 weeks in Group I and 30.7 ± 17.94 weeks in Group II over a period of 52 weeks. Limitations of the study were lack of a placebo group and a preliminary report of 36 patients in each group. They concluded that caudal epidural injections with or without steroids may be effective in patients with chronic function-limiting low back pain without facet joint pain, disc herniation, and/or radiculitis in over 70% of the patients.

Manchikanti et al (262) in a randomized trial evaluated the effectiveness of caudal epidural steroid injections with Sarapin or steroids for chronic low back pain. The study included 65 patients who underwent diagnostic facet joint nerve blocks utilizing comparative local anesthetic blocks and were shown to be negative

for facet joint pain and other problems such as sacroiliac joint pain before enrollment into the study. They were randomly selected from 105 patients negative for facet joint pain allocated into 3 groups, with Group I consisting of 15 patients comprising a convenience control sample treated conservatively; Group II, consisting of 22 patients treated with caudal epidural with local anesthetic and Sarapin; and Group III, consisting of 33 patients treated with caudal epidural with a mixture of local anesthetic and betamethasone. The study period lasted for 3 years. Results showed that there was significant improvement in patients receiving caudal epidural injections, with a decrease in pain associated with improved physical, functional, and mental status; and decreased narcotic intake combined with return to work. The study showed that at one month 96% of the patients evaluated showed significant improvement, which declined to 56% at 3 months and 16% at 6 months, with administration of one to 3 injections. The study also showed cost effectiveness of this treatment, with a cost of \$2,550 for one year improvement of QOL. They concluded that the treatment is not only effective clinically, but also is cost effective.

Manchikanti et al (261) in a prospective evaluation of the effectiveness of caudal epidural injections in discogram positive and negative chronic low back pain evaluated 100 consecutive patients, without evidence of disc herniation or radiculitis, who had failed to respond to conservative management with physical therapy, chiropractic, and/or medical therapy, under-

went discography utilizing strict criteria of concordant pain and negative adjacent discs, after being judged to be negative for facet joint and/or sacroiliac joint pain utilizing comparative local anesthetic blocks. Any other type of response was considered negative. This study included 62 patients, who underwent caudal epidural steroid injections with Sarapin. They included Group I, comprised of 45 of 55 patients negative on provocative discography and Group II, with 17 of 45 patients with positive provocative discography. Results showed that there was significant improvement in patients receiving caudal epidural injections, with a decrease in pain associated with improved physical, functional, and mental status; decreased narcotic intake; and increased return to work. The study showed that at one month, 100% of the patients evaluated showed significant improvement in both groups; this declined to 86% at 3 months in Group I, but remained at 100% in Group II, declining to 60% and 64% at 6 months in Group I and Group II, respectfully, with administration of one to 3 injections. Analysis with one to 3 injections, which included all patients (n = 62) showed significant relief in 71% and 65% of the patients at one month, in 67% and 65% at 3 months, and in 47% and 41% at 6 months, in Group I and Group II, respectively.

4.2.2.4.2 Effectiveness

Table 8 illustrates the results of effectiveness of caudal epidural injections in managing discogenic pain without disc herniation or radiculitis.

4.2.3 Cost Effectiveness

The cost effectiveness of fluoroscopically directed caudal epidural steroids was \$3,635, of transforaminal steroids was \$2,927 per year, and of interlaminar epidural steroids the cost was \$6,024 (263). In another study, the cost for one year improvement for QOL was \$2,550 in patients treated with caudal epidural with local anesthetic and/or steroids under fluoroscopy (262).

4.2.4 Safety and Complications

Various complications of caudal epidural injections have been reported (60,170,173,177,178,230,231,264-279). They are of 2 types: those related to needle placement and those related to drug administration. Side effects related to the administration of steroids are generally attributed either to the chemistry or the pharmacology of the steroids (60,230,231,236,264,276). The major theoretical complications of corticosteroid administration include suppression of pituitary adrenal axis, hypercorticism, Cushing's syndrome, osteoporosis, avascular necrosis of the bone, steroid myopathy, steroid psychosis, osteomyelitis, epidural lipomatosis, weight gain, fluid retention, and hyperglycemia. However, it has been shown that at therapeutic doses of epidural steroids administered, complications were not noted (280,281).

Other complications and side effects include infection, intravascular injection, extra epidural placement, hematoma formation, abscess formation, subdural injection, intracranial air injection, epidural lipomatosis,

Table 8. Results of randomized and observational studies of effectiveness of caudal epidural steroid injections in managing discogenic pain.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (260)*	RA, DB	72	64	78%	75% to 81%	72%	P	P
Manchikanti et al 2001 (262)*	O	76	70	95%	85%	61% to 73%	P	P
Manchikanti et al 2002 (261)*	O	73	62	86%	60%	NA	P	NA

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; O = observational; NA = not available; P = positive; N = negative

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (69).

dural puncture, nerve damage, headache, increased intracranial pressure, vascular injury, and cerebrovascular or pulmonary embolism. Other less common complications include transient blindness (282), retinal necrosis (283), central serous chorioretinopathy (272,284), retinal hemorrhage (271), persistent recurrent intractable hiccups (285), flushing (286), chemical meningitis, discitis (267,275), subdural and epidural hematoma (287-290), epidural abscess (275), and arachnoiditis (291,292).

4.2.5 Indications

Caudal epidural steroid injections are indicated in patients with chronic low back pain who have failed to respond to conservative modalities of treatments. While caudal epidural steroid injections may be performed for any type of low back pain with or without lower extremity pain nonresponsive to conservative modalities of treatments, they are properly indicated in patients negative for facet or sacroiliac joint pain or patients who have at least a combination of discogenic component with facet joint pain. Caudal epidural steroids are the preferred modality of treatment for lower lumbar and sacral involvement in postsurgical patients and in patients with bilateral involvement or multilevel involvement for which transforaminal epidurals will require multiple procedures at multiple levels.

4.2.6 Level of Evidence

The level of evidence is variable for the 4 conditions evaluated. The evidence is based on randomized trials and observational studies utilizing the USPSTF criteria (30). Tables 5 to 8 illustrate the results of effectiveness of caudal epidural injections.

- ◆ The evidence is Level I for short- and long-term relief in managing chronic low back and lower extremity pain secondary to lumbar disc herniation and/or radiculitis and pain of discogenic origin without disc herniation and radiculitis.
- ◆ The indicated evidence is Level II-1 or II-2 for caudal epidural injections in managing low back and lower extremity pain of post-surgery syndrome and spinal stenosis.

4.2.7 Recommendations

Based on the methodologic assessment and quality of evidence in grading recommendations by Guyatt et al (34), the recommendation for caudal epidural steroid injections is as follows:

- ◆ In managing lumbar spinal pain with disc herniation and radiculitis or discogenic pain without disc

herniation or radiculitis, the recommendation is 1A or 1B/strong.

- ◆ The recommendation for caudal epidural injections in managing patients with post-lumbar laminectomy syndrome and spinal stenosis is 1B or 1C.

4.3 Interlaminar Epidural Injections

Multiple systematic reviews provided negative opinions for lumbar interlaminar epidural injections (32,33,60,70,157,231-233,236,237). Recently, 2 systematic reviews were performed evaluating lumbar and cervical interlaminar epidurals (70,71). They arrived at conflicting conclusions with the other systematic reviews of the effectiveness of cervical epidurals in the management of chronic neck pain, illustrating a Level II-1 evidence in managing chronic neck and upper extremity pain (71) and Level II-2 for short-term relief of pain of disc herniation or radiculitis utilizing blind interlaminar epidural steroid injections and there was a with lack of evidence for long-term relief (70). Staal et al (157) updated Neleman et al's (32) systematic review, concluding that there was insufficient evidence to support the use of injection therapy in subacute and chronic low back pain.

4.3.1 Lumbar Interlaminar Epidural Injections

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

4.3.1.1 Disc Herniation and Radiculitis

Five blind lumbar interlaminar studies met inclusion criteria (239,240,293-295).

4.3.1.1.1 Study Characteristics

Cuckler et al (240) performed a prospective, randomized, double-blind study of the use of epidural steroids in the treatment of lumbar radicular pain with inclusion of 73 patients with a clinical diagnosis of either acute herniated nucleus pulposus or spinal stenosis. All the procedures were performed without fluoroscopy in a lateral decubitus position, between the third and fourth lumbar vertebra, lying on the side of the painful limb. Either 2 mL of sterile water containing 80 mg of methylprednisolone acetate combined with 5 mL of 1% procaine or 2 mL of saline combined with 5 mL of 1% procaine was injected. They provided a second injection if there had been less than 50% improvement 24 hours after the first injection with methylprednisolone acetate and procaine in a

non-blind fashion. They defined a short-term successful result as subject to improvement of 75% or more as judged by the patient 24 hours after injection. Anything less than 75% was considered as short-term failure. They also described all patients who received a second injection as having a failed result. Additional criteria of failure included any patient who had had a laminectomy during the period of follow-up (which was over 20 months). The long-term results showed 25 (61%) of 41 patients who received an epidural steroid injection as the first injection reported some degree of improvement, while 20 (62.5%) of the 32 patients who received placebo injection reported some degree of improvement.

These authors utilized a flawed process by considering a local anesthetic injection as a placebo. Consequently, this is not an efficacy trial, but it is an equivalency or non-inferiority trial (182-184,247,252,254,260). Further, the effectiveness of local anesthetics has been demonstrated and shown to be equal to steroids, both in clinical and experimental studies (182-185,187,243,247,252,260-262,296). When multiple variables are considered, the procedure was performed with a blind technique between L3 and L4 in the lateral decubitus position with the affected side down with an inability to reach the targeted area in almost half of the patients (297-307). Other flaws of this study include the small sample size, poor methodology, lack of description of concealment, and inadequate outcome assessments. Statistically detailed data were not provided to calculate the patients receiving greater than 50% relief at any point in the evaluation. Further, evaluation was performed only at 2 points.

Carette et al's (239) study has been described as the best study evaluating the role of epidural steroids in managing sciatica due to herniated nucleus pulposus. However, this study also contains numerous deficiencies. Between October 1992 and January 1996, they enrolled 158 patients with 78 patients in the methylprednisolone group and 80 patients in the placebo group. The patients received injections of either 80 mg (2 mL) of methylprednisolone acetate mixed with 8 mL of isotonic saline or 1 mL of isotonic saline in the epidural space according to the technique described by Barry and Kendall (307), without fluoroscopy, in a physiatric practice, dating back to 1962. The procedure was performed without fluoroscopy in the lateral decubitus position and isotonic saline was administered, in fact, into the epidural space. No information is available with regards to the

effect of injection of an inert substance into the epidural space. Further, the disadvantages of the spread of the drug, level of the injection, lack of ventral placement of the drug, and lack of fluoroscopy fail to generalize the results to contemporary interventional pain management practice. The results showed that at 3 weeks, the ODI score had improved slightly better in the methylprednisolone group compared to the placebo group, along with significant differences noted with finger-to-floor distance ($P = 0.006$) and sensory deficits ($P = 0.003$), which were greater in the methylprednisolone group. However, after 6 weeks, the only significant difference was the improvement in leg pain, which was greater in the methylprednisolone group ($P = 0.03$). After 3 months, there were no significant differences between the groups. Further, at 12 months, the cumulative probability of back surgery was 25.8% in the methylprednisolone group and 24.8% in the placebo group. The authors concluded that even though epidural injections of methylprednisolone may afford short-term improvement in leg pain and sensory deficits in patients with sciatica due to a herniated nucleus pulposus, this treatment offers no significant functional benefit, nor does it reduce the need for surgery compared to saline epidural injection. However two-thirds of the patients in both groups avoided surgery.

In 2005, Arden et al (294) published results of the effectiveness and predictors of response to lumbar epidural corticosteroid injections in patients with sciatica in a 12-month, multi-center, double-blind, randomized, placebo-controlled, parallel-group trial in 4 secondary pain-care clinics in the United Kingdom in 228 patients. Of these, one-third of the patients were acute and two-thirds were chronic (4 weeks to 18 months). The details of the procedure are not provided, hence, it is assumed they were performed blindly without fluoroscopy and in the lateral position between L3-4 or L4-5. The active group received epidural steroids via the lumbar route of 80 mg of triamcinolone acetonide and 10 mL of 0.25% bupivacaine at weeks 0, 3, and 6. The placebo group received injections of 2 mL of normal saline into the intraspinal ligament. Sixty patients achieved a 75% improvement on the ODI before week 6 and therefore did not receive 3 injections. The patients were assessed at 3, 6, 12, 26, and 52 weeks, with the primary outcome measure being the ODI and the criterion of response being a reduction of 75% from baseline. Based on the available literature, a reduction of 75% from baseline

on the ODI is an unusual and unrealistic outcome measure as the literature considers a clinically important difference as an improvement of 4 points to 15 points (102-104,173-175). Even then, they reported a statistically significant improvement in self-reported function compared with placebo at 3 weeks. At the same time they reported that lumbar epidural corticosteroid injections did not produce a significant improvement in VAS leg pain, but did increase the number of patients reporting any improvement in leg pain using the Likert scale (61% versus 40%, $P < 0.01$). However, they reported that by 6 weeks the benefit of epidural steroids was lost, and at all subsequent visits there were no differences between the groups on any measures of outcome. At 52 weeks, 32.5% of the active group and 29.6% of the placebo group had achieved a 75% improvement in ODI – an expected natural course of disease. They also reported that after 12 months, 26 patients were pain free, with no difference between treatment groups, again illustrating the disadvantages of including patients with acute problems. Another outcome was that neurological symptoms and signs tended to improve throughout the trial, even though, at the end of the study, 44.8% of the patients still had decreased sensation and 24.6% decreased strength. The authors boast that for the first time, a single large RCT confirmed that epidural injections of corticosteroids offered short-term relief of symptoms in patients with sciatica at 3 weeks; however, they do not offer any medium- or long-term benefit in terms of symptoms, function, return to work, or the need for surgery. Further, the authors ignored many of the fundamental principles of contemporary interventional pain management, namely that no injections should be repeated unless the pain returns, and the effect of steroids generally lasts approximately 4–6 weeks. They also provided blind injections potentially providing non-targeted injections in approximately 50% to 80% of the patients.

Snoek et al (293) compared the effects of 80 mg of methylprednisolone (2 mL) and 2 mL of normal saline injected into the epidural space by the lumbar route in 51 patients. They found no significant differences between the 2 groups with respect to relief of pain and a variety of physical parameters.

Wilson-MacDonald et al (295) compared lumbar epidural steroid injections to interspinous ligament steroid injections in 93 patients. Patients were randomized to receive either a blind lumbar epidural (44 patients) or an injection into the interspinous ligament

(48 patients). Each patient was injected with 8 mL 0.5% bupivacaine and 80 mg of methylprednisolone. There was no difference in the rate of subsequent surgery through the period of follow up.

4.3.1.1.2 Effectiveness

As shown in Table 9, 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.

4.3.1.2 Spinal Stenosis

Two blind lumbar interlaminar randomized trials (240,295) and one observational study (308) evaluating spinal stenosis were identified.

4.3.1.2.1 Study Characteristics

Cuckler et al (240) included 37 patients from a sample of 73 patients with spinal stenosis of longer than 6 months. They injected in a randomized, double-blind fashion either 7 mL of methylprednisolone acetate and procaine or 7 mL of physiological saline solution and procaine. No statistically significant difference was observed between the control and experimental patients. Long-term follow-up, averaging 20 months, failed to demonstrate the efficacy of a second injection of epidural steroids administered to the patients whose pain did not respond within 24 hours to an injection of either 80 mg of methylprednisolone acetate combined with 5 mL of 1% procaine or 2 mL of sterile saline combined with 5 mL of 1% procaine. The multiple disadvantages of this study and various flaws are described in the disc herniation section.

Wilson-MacDonald et al (295) evaluated 18 patients in the epidural group and 14 patients in the control group with spinal stenosis only. Further, there were also 18 (control = 15, epidural = 3) patients with disc herniation and stenosis. Patients were treated either with an epidural steroid injection or an intramuscular injection of local anesthetic and steroids. Even though the results were negative, there was no significant difference in any of the groups on a long-term basis. However, there was a significant reduction in pain early on in those having an epidural steroid injection.

Campbell et al (308) in 2007 published results of the correlation of spinal canal dimensions to efficacy of a series of 3 blind lumbar interlaminar epidural steroid injections in spinal stenosis in 84 patients. Of these, 50 re-

quired surgical decompression and 34 patients improved after the epidural steroid injection. They concluded that spinal canal dimension is not predictive of success or failure of epidural steroid injection in patients with spinal stenosis. The study has been criticized that, on the basis of the study protocol, these conclusions may lead to confusion, rather than clarification (306). Further, injections were performed without fluoroscopic guidance, using an interlaminar approach, and were performed by 3 anesthesiologists from a single pain management clinic. Campbell et al (308) did not describe the volume of injectate or the site of the injection. Additionally, 3 epidurals were performed routinely without any consideration as to whether the prior injection provided any relief or not, or if the patient continued to have pain or not. There were also other deficiencies with the presentation of the data. Overall it appears that 40% of the patients did not require decompression. Thus, it could be considered to be a success. Consequently, the study results may be extrapolated to indicate that epidural steroids may be significantly effective in spinal stenosis if they are performed with the appropriate delivery of medication to the target site with a specific approach under fluoroscopy.

4.3.1.2.2 Effectiveness

Of the 3 evaluations studying the effectiveness of blind lumbar interlaminar epidural injections in spinal

stenosis, none were shown to be positive for long-term relief (Table 10).

4.3.1.3 Chronic Low Back Pain of Discogenic Origin without Radiculitis or Disc Herniation

There were no randomized trials in the evaluation of low back pain without disc herniation or radiculitis. However, there was one observational study available evaluating the effect of spinal steroid injections for degenerative disc disease under fluoroscopy, which included intradiscal injections as well as interlaminar epidural injections (309).

4.3.1.3.1 Study Characteristics

Butterman (309) reported epidural steroid injections were performed in 93 patients with degenerative disc disease and inflammatory endplate changes and in 139 patients without inflammatory endplate changes. The patients with inflammatory endplate changes (n = 78) or without inflammatory endplate changes (n = 93), all of whom were considered fusion candidates, underwent discography with or without intradiscal steroid in a randomized fashion. Pain and function were prospectively determined by a self-administered outcome survey (VAS pain, ODI, pain diagram [PD], and opinion of success) before and after the patients' injections for a 2-year follow-up. MRI and discography results were correlated with patient outcome scores.

Table 9. Results of randomized trials of effectiveness of blind lumbar interlaminar epidural injections in managing disc herniation and radiculitis.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief				Results	
				< 3 mos.	3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Wilson-MacDonald et al 2005 (295)	RA	68	43	SI	NSD	NSD	NSD	P	N
Arden et al 2005 (294)	RA,DB,PC	86	228	75%	NSD	NSD	NSD	N	N
Carette et al 1997 (239)	RA,DB,PC	77	C = 80 T = 78	SIT	NSD	NSD	NSD	P	N
Cuckler et al 1985 (240)	RA,DB	60	C = 31 T = 42	NSD	NSD	NSD	NSD	N	N
Snoek et al 1977 (293)	RA	72	C = 24 T = 27	NSD	NSD	NSD	NSD	N	N

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

Adapted and modified from Parr AT et al. Lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain: A systematic review. *Pain Physician* 2009; 12:163-188 (70).

Table 10. Results of published studies of the effectiveness of the blind lumbar interlaminar epidural injections in managing spinal stenosis.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief				Results	
				< 3 mos.	3 mos.	6 mos.	12 mos.	Short-term relief < 6 mos.	Long-term relief > 6 mos.
Cuckler et al 1985 (240)	RA,DB	60	37	NSD	NSD	NSD	NSD	N	N
Wilson-MacDonald et al 2005 (295)	RA	68	32	SI	NSD	NSD	NSD	P	N
Campbell et al 2007 (308)	O	53	84	NA	NA	NA	40%	NA	N

RA = randomized; DB = double blind; O = observational; SI = significant improvement; NSD = no significant difference; NA = not available; P = positive; N = negative

Adapted and modified from Parr AT et al. Lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain: A systematic review. *Pain Physician* 2009; 12:163-188 (70).

Patients received either interlaminar or transforaminal epidural steroid injections, all of which were performed under fluoroscopy; however, the proportion of patients receiving interlaminar epidural steroid injections is not described. Also, this study over a period of 2 years had an extensive dropout rate of 60%. Ultimately, at 2 years, 49 of the 139 patients (35%) in this group had undergone a fusion. Of the patients who had inflammatory endplate changes (n = 93), approximately one-half of the patients expressed a positive opinion as to whether the epidural steroid injection was successful in the treatment of their symptoms during the first 3 months. Over subsequent follow-up periods, the success rate declined. The use of pain medication was found generally to have decreased during follow-up periods. The outcome scores for pain and disability showed significant improvement for back and leg pain (VAS and pain drawing) ($P < 0.001$).

Of the 139 patients who did not have inflammatory endplate changes and were treated with epidural steroid injections, 98 had not changed treatment after 3 month follow-up. Patients' self assessment of success slowly declined over time so that after one year, only 32 of the original 139 patients in this group considered their injection therapy to have been successful. However, a significant improvement in all outcome scales was found at all follow-up periods for those patients who did not drop out ($P < 0.001$). A comparison of the 2 epidural steroid groups (inflammatory versus non-inflammatory endplates) revealed greater improvement for ODI scores for the patients with inflammatory end-

plates at one to 3 and 4 to 6 month follow-up periods and pain drawings at the 4 to 6 month follow-up period. In addition, epidural steroid injection patients in the subgroup without inflammatory endplates were found to be using less pain medication in the early post-treatment period. In addition, dropout rates were greater, although not significantly, for those without inflammatory endplates at all follow-up periods. The authors concluded that patients may have short-term benefits from epidural steroid injections without disc herniation or stenosis. Overall, 25% to 35% of patients with chronic low back pain resulting from degenerative disc disease had improved pain and function after epidural steroid injections at 2-year follow-up.

4.3.1.3.2 Effectiveness

Only one observational study (309) showed moderate results with short-term positive results and with negative long-term results in patients with chronic low back pain of discogenic origin without radiculitis or disc herniation.

4.3.2 Cervical Interlaminar Epidural Injections

Three blind cervical epidural studies met the inclusion criteria (310-312) for methodological assessment and clinical relevance.

4.3.2.1 Study Characteristics

Castagnera et al (311) randomly allocated 24 patients into 2 groups with the steroid group treated with 0.5% lidocaine plus triamcinolone acetonide 10

mg/mL, and the morphine group received the same combination of 0.5% lidocaine and steroid plus 2.5% of morphine. Pain relief was assessed as the percentage of pain decrease on a VAS at months 3, 6, 8, and 12 after cervical epidural steroid injection, up to 48 months. They reported a success rate of 78.5% in the steroid group and 80% in the steroid and morphine group with pain relief which was stable, and a mean follow-up of 43 ± 18.1 months.

This report showed superior results to other studies in the literature. They also showed that pain relief remained stable for 48 months and in some cases for more than 60 months. The intensity of medical treatment also decreased significantly 3 months after cervical epidural steroid injection and remained unchanged over subsequent periods. All the patients who were working prior to the cervical epidural steroid injections returned to work. The use of morphine has not been shown to be superior in this study. Even though significant differences were observed, this study was limited by the small sample sizes of 14 and 10 in the 2 groups.

Stav et al (310) treated 25 patients with epidural steroid and lidocaine injections and 17 patients with steroid and lidocaine injections into the posterior neck muscles. They administered one to 3 injections at 2 week intervals based on the clinical response. Pain relief was evaluated by the VAS one week after the last injection and then one year later. One week after the last injection, good pain relief was reported in 76% of the patients receiving epidural steroids and local anesthetic as compared to 35.5% of the patients receiving extra-epidural steroids and local anesthetic. One year after the treatment, 68% of the patients in the epidural steroid group still had very good pain relief, whereas only 11.8% of the patients receiving intramuscular or extra-epidural with local anesthetic reported good pain relief. The study also reported that patients were able to increase range of motion, a few of them reduced their daily dose of analgesics, and recovery of the capacity for work was significantly better in the epidural steroid group.

The disadvantages of this study include lack of fluoroscopic visualization, epidural entry at multiple levels with some between C4 and C5, and lack of patient blinding with administration of intramuscular steroid lidocaine injection.

Pasqualucci et al (312) evaluated the efficacy of epidural local anesthetics plus steroids for the treatment of cervicobrachial pain in 160 patients randomized based on the duration of the pain and admin-

istering 2 types of treatments with a maximum of 9 blocks of single injections or 30 days of continuous epidural with the achievement of pain control of 80% or greater. The enrolled 160 patients were divided into 4 groups with 40 patients per group on the basis of the time of pain onset with Group A with 40 patients with pain onset of 15 to 30 days; Group B with 40 patients with pain from 31 to 60 days; Group C with 40 patients with pain from 61 to 180 days; and Group D with 40 patients with pain of greater than 180 days. Patients of each group were randomized based on their received therapy with 20 in the single injection group and 20 with a continuous epidural.

Patients in the single injection group were administered a series of epidural blocks every 4 to 5 days with administration of 0.25% bupivacaine 6 mL, with 80 mg of methylprednisolone, for a maximum of 9 blocks. In the continuous epidural group, catheterization was carried out and bupivacaine, a volume of 6 mL, combined with 80 mg of methylprednisolone was administered initially, followed by bupivacaine 6 mL every 6, 12, or 24 hours, along with methylprednisolone 40 mg every 4 to 5 days for a period of 30 days. They evaluated pain control and pain-free sleep status. Of the 160 enrolled patients, 19 were excluded for various reasons. None of the patients had any major complications. The results of this evaluation showed a statistically significant efficacy of the treatment of cervicobrachial pain with epidural local anesthetic plus corticosteroids in continuous infusion rather than in single injection, in patients with chronic pain who did not respond to conservative therapies with pain duration of 6 months or longer. However, there was no statistically significant difference between the 2 treatments in patients with pain of less than 6 months. This data suggested that continuous epidural local anesthetic plus corticosteroid has greater efficacy than single injections of these drugs for the treatment of chronic cervicobrachial pain of greater than 6 months.

Although this study provides important information, it has several drawbacks: lack of long-term follow-up, lack of fluoroscopy, and inadequate blinding of patients and physicians.

4.3.2.2 Effectiveness

Of the 3 randomized trials evaluating cervical interlaminar epidural steroid injections, all showed positive results for short-term relief (310-312), 2 were positive for long-term relief (310,311), and the results of long-term relief were not available for one study

Table 11. Results of published studies of effectiveness of cervical interlaminar epidural injections.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 months	Long-term relief > 6 months
Castagnera et al 1994 (311)	RA	55	Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10	79%	79%	79%	P	P
Stav et al 1993 (310)	RA	50	C = 17 T = 25	12% vs 68%	12% vs 68%	12% vs 68%	P	P
Pasqualucci et al 2007 (312)	RA	56	Single = 20 Continuous = 20 Over 180 days	NA	58% vs 74%	NA	P	NA

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

Adapted from Benyamin RM et al. Systematic review of the effectiveness of cervical epidurals in the management of chronic neck pain. *Pain Physician* 2009; 12:137-157 (71).

(312). Table 11 illustrates results of effectiveness of blind cervical interlaminar epidural steroid injections.

4.3.3 Cost Effectiveness

In the evaluation of cost effectiveness, Manchikanti et al (263) and Price et al (313) concluded that lumbar interlaminar epidural steroid injections were not cost effective. There were no studies evaluating the cost effectiveness of cervical interlaminar epidural injections.

4.3.4 Safety and Complications

The common complications of lumbar interlaminar epidural injections are of 2 types: those related to the needle placement and those related to drug administration (2,60,230,231,236,266,267,269-276,282-292,314-345). Infectious complications include epidural abscess, meningitis, and osteomyelitis/discitis. Epidural hematomas are potentially the most serious of the epidural injection complications. Neurological injuries are an uncommon complication that can occur when performing lumbar epidural steroid injections. Other complications include increased pain, seizures, chemical meningitis, dural puncture, subdural air, pneumocephalus, transient blindness, retinal necrosis, chorioretinopathy, hiccups, flushing, and arterial gas embolism (173,266,269,270,272,273,275-286,291,292,313-315,340-346). Side effects related to the administration of steroids are generally attributed either to the chemistry or the pharmacology of the steroids (273,276,280,291,292). Finally, radiation expo-

sure is also a potential problem with damage to eyes, skin, and gonads (179,314,315).

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

4.3.5 Indications

Indications include disc herniation, radiculopathy, spinal stenosis, and post laminectomy syndrome. However, caudal epidural injection is the preferred mode of delivery for post lumbar laminectomy syndrome.

4.3.6 Level of Evidence

The indicated evidence based on USPSTF criteria (30) is Level II-2 for blind lumbar interlaminar epidural injections for short-term relief in managing chronic low back and lower extremity pain secondary to lumbar disc herniation and/or radiculitis. The evidence is Level III for blind lumbar interlaminar epidural injections in managing low back pain of spinal stenosis, and chronic low back pain of discogenic origin without disc herniation or radiculitis.

The indicated evidence for cervical interlaminar epidural steroid injections is Level II-1.

4.3.7 Recommendations

Based on Guyatt et al's criteria (34), the recommendation for cervical interlaminar epidurals is 1C/strong.

The recommendation for disc herniation and radiculitis for blind lumbar interlaminar epidural injections is 1C, a strong recommendation for short-term relief. However, for long-term relief, the recommendation is 2B, with weak recommendation, with best action differing depending on circumstances or patients' or societal values. For spinal stenosis and discogenic pain without disc herniation and radiculitis, the recommendation is 2C/very weak.

4.4 Lumbar Transforaminal Epidural Injections

Lumbar transforaminal epidural injections have been described as a target-specific modality for the treatment for management of spinal pain.

4.4.1 Effectiveness Assessment

Review of the literature showed 6 systematic reviews (60,74,159,231,236,347) and 4 randomized trials (243,244,348-351).

Two systematic reviews (60,231) 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 was limited for lumbar radicular pain in post surgery syndrome. DePalma et al (347) 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 (74) indicated the evidence was 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.

4.4.2 Descriptive Characteristics

Jeong et al (348) compared transforaminal epidural injections with 2 techniques (preganglionic vs. ganglionic). The question they sought to answer was where it is best to inject, at the site where the disc is contacting the presumed affected nerve or at the foramen where that nerve exits. If a patient has a disc herniation at L4-5 that contacts the L5 nerve root then one could perform a pre-ganglionic injection at the L4-5 foraminal level or a ganglionic injection at the L5-S1 level. Jeong's group performed 239 transforaminal injections, 127 ganglionic and 112 pre-ganglionic. The drugs injected were triamcinolone and bupivacaine. The authors concluded that the implication for patient care is that a pre-ganglionic ap-

proach may be considered an alternative to a ganglionic approach when the needle tip cannot be advanced adjacent to the neuroforamen or adequate amounts of the drug cannot be injected into the epidural space through the neuroforamen owing to severe neuroforaminal stenosis. However, the use of transforaminal epidural steroids injection with a pre-ganglionic (99 of 112 patients) approach is more effective than a ganglionic (90 of 127 patients) approach at short-term follow-up and is almost as effective (64 of 106 patients) as a ganglionic approach (78 of 116 patients) at mid-term follow-up.

Karppinen et al (244) evaluated transforaminal epidural steroid injections in patients with sciatica. Eighty patients received transforaminal epidural injections of methylprednisolone and bupivacaine and another 80 received saline injections via a transforaminal injection. Pain and Oswestry scores were recorded. Both groups showed improvement with the steroid group doing better than the saline at 2 weeks and the saline group doing better at the 3 and 6 month points. Interestingly, the steroid and local anesthetic infiltration seemed to be associated with a rebound phenomenon at 3 and 6 months. This was manifested by little or no improvement in pain and disability between 3 and 6 months but then equal pain and disability scores at 12 months. Karppinen et al (349) in their subgroup analysis of the randomized trial (244) showed significantly positive results for contained herniations at one year.

Riew et al (243,350) evaluated whether selective nerve root injections might help patients with lumbar radicular pain to avoid spine surgery. Fifty-five patients who were deemed surgical candidates were treated and randomized to receive either a selective nerve root injection of betamethasone 6 mg with bupivacaine or a selective nerve root injection of bupivacaine alone. The patients were allowed up to 4 injections of the same study medicine during the evaluation. The patients were followed for between 13 and 28 months. There was no set follow-up evaluation at a short- or long-term point. At the end of the period, 18 of the 27 patients receiving only bupivacaine had chosen to undergo surgery. Of the 28 patients receiving the combination of betamethasone and bupivacaine, only 8 had undergone surgery. The difference was highly significant. In the follow-up study, Riew et al (243) showed positive long-term results with or without steroids.

Vad et al (351) 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 satis-

faction, 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 with 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).

4.4.3 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 (263). Furthermore, in patients treated with transforaminal steroids, operations were avoided for contained herniations, costing \$12,666 less per responder in the steroid group (348). Cost effectiveness was also demonstrated by others by avoiding surgical intervention (243,350).

4.4.4 Safety and Complications

The most common and worrisome complications of transforaminal epidural steroid injections in the lumbar spine are related to neural and vascular trauma, intravascular injection, and infection (2,60,231,347-382). Complications including spinal cord injury and infarction (340,374), paraplegia (355), and intracord injection (340) have been reported. Side effects related to the administration of steroids are generally attributed either to the chemistry or to the pharmacology of steroids (60,230,231,236,276,280,281,359-362). Radiation

exposure is also a potential problem with damage to eyes, skin, and gonads (179,314).

4.4.5 Indications

The indications for therapeutic lumbar transforaminal epidural injections include:

- 1) Intermittent or continuous pain causing functional disability.
- 2) Chronic low back and/or lower extremity pain resulting from herniated discs and radiculopathy, spinal stenosis, and failed back surgery syndrome (FBSS).
- 3) Chronic low back and/or lower extremity pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management.

4.4.6 Level of Evidence

Table 12 illustrates the results of randomized trials of effectiveness of lumbar transforaminal epidural injections.

The indicated evidence for lumbar transforaminal epidural steroid injections 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 based on the USPSTF criteria (30).

4.4.7 Recommendations

Based on Guyatt et al's criteria (34), the recommendation for lumbar transforaminal epidurals is 1C/strong recommendation, in managing chronic low back and lower extremity pain.

Table 12. Results of randomized trials of effectiveness of lumbar transforaminal epidural injections.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos	6 mos	12 mos	Short-term relief ≤ 6 mos	Long-term relief > 6 mos
Karppinen et al 2001/2001 (244,349)	RA, DB	81	C = 80 T = 80	SICH	NSI	NSI	P	N
Riew et al 2000/2006 (243,350)	P, RA, DB	68	55	NA	NA	33% vs. 71% (avoided surgery)	P	P
Jeong et al 2007 (348)	RA, DB	63	239	PG 99 of 112 G 90 of 127	PG 64 of 106 G 78 of 116	NA	P	NA
Vad et al 2002 (351)	RA	58	48	NA	NA	48% vs. 84%	P	P

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.

Adapted from Buenaventura RM et al. Systematic review of therapeutic lumbar transforaminal epidural steroid injections. *Pain Physician* 2009; 12:233-251 (74).

5.0 LUMBAR EPIDURAL ADHESIOLYSIS

The purpose of percutaneous epidural lysis of adhesions is to minimize the deleterious effects of epidural scarring, which can physically prevent direct application of drugs to nerves and other spinal tissues and to treat chronic back pain (383-386). Epidural lysis of adhesions and direct deposition of corticosteroids in the spinal canal can also be achieved with a 3-dimensional view provided by epiduroscopy or spinal endoscopy.

5.1 Percutaneous Adhesiolysis

5.1.1 Effectiveness Assessment

Clinical effectiveness of percutaneous adhesiolysis was evaluated in 3 systematic reviews (49,58,76), and one health technology assessment (383).

Chopra et al (58) and Trescot et al (73) concluded that there was strong evidence to indicate effectiveness of percutaneous epidural adhesiolysis with administration of epidural steroids for short-term and long-term in chronic, refractory low back pain and radicular pain.

Epter et al (76) concluded that the indicated level of evidence is I or II-1 for short- and long-term relief for percutaneous adhesiolysis in post lumbar laminectomy syndrome.

5.1.2 Study Characteristics

Three randomized trials (387-389) and 4 observational studies (390-393) met inclusion criteria for percutaneous adhesiolysis.

5.1.2.1 Randomized Trials

Of the 3 randomized trials (387-389), 2 studies had similar patient characteristics (388,389). Manchikanti et al (389) reported that patients in all 3 studies failed multiple conservative modalities of treatments including fluoroscopically directed epidural steroid injections. Manchikanti et al (389) also reported the proportion of patients included with a history of previous surgery, which ranged from 64% to 72% in all intervention groups.

The study by Veihelmann et al (387) evaluated patients with a history of chronic low back pain and sciatica. Inclusion criteria were radicular pain with a corresponding nerve root with compressing substrate found on MRI or CT scans. Prior to randomization, all patients received physiotherapy, local injections, and analgesics. Local injections were not defined. All patients were evaluated for radicular pain by an independent neurologist. Exclusion factors were paraly-

sis, spinal canal stenosis, rheumatologic disease, and malignancy. They did not identify which of these patients had post laminectomy syndrome. However, post laminectomy syndrome or epidural fibrosis were not exclusion criteria, and thus, it is believed that some of the patients probably included post laminectomy syndrome or epidural fibrosis patients.

Heavner et al (388) compared various types of solutions used after mechanical adhesiolysis; Group A received a combination of hyaluronidase and hypertonic saline; Group B, hypertonic saline solution; Group C, isotonic saline solution; and Group D, hyaluronidase and isotonic saline solution. Heavner et al (388) evaluated a 3-day procedure where the catheter was inserted on the first day and the drugs were injected on the second and third day, whereas Manchikanti et al (389,393) evaluated one-day adhesiolysis. Veihelmann et al (387) and Gerdesmeyer et al (390) used a 3-day protocol in both studies. They also used hyaluronidase as part of the treatment protocol. The outcome parameters by Heavner et al (388) included the short-form MPQ and VAS for back pain and leg pain. Manchikanti et al (389) utilized VAS pain scale, ODI 2.0, work status, opioid intake, range of motion measurement, and psychological evaluation by Pain Patient Profile (P-3). Veihelmann et al (387) used VAS scores for back pain and leg pain, ODI score, Gerbershagen score, and a quantified score for the use of analgesics. They also used a blinded observer.

Manchikanti et al (389) divided 75 patients randomly into 3 groups, with Group I consisting of a control group without adhesiolysis, with injection of local anesthetic, steroid, and normal saline; Group II consisting of patients undergoing adhesiolysis, with injection of local anesthetic, steroid, and normal saline; and Group III consisting of patients undergoing adhesiolysis, with an injection of 10% sodium chloride solution, in addition to local anesthetic and steroid.

5.1.2.2 Observational Studies

Gerdesmeyer et al (390) evaluated 98 patients initially and of these, 61 patients met inclusion criteria. Based on the current review, even though specifically not mentioned, it appears that patients with disc herniation, as well as post lumbar laminectomy syndrome were included.

Among the 2 observational reports included (391,392), patient demographics were described in both studies. In one of the studies, the proportion of patients in Group II was 37% compared to 65% in

Group I (391). In addition, work-related injury was lower in Group II (30%) than Group I (50%). Duration of pain was also longer in Group II compared to Group I. Patients in Group I received adhesiolysis and hypertonic saline neurolysis on 2 consecutive days with the catheter in place for the second day. In contrast, Group II patients received a single day procedure with percutaneous adhesiolysis, as well as hypertonic saline neurolysis. In another study (392), only patients with post lumbar laminectomy were included. Also, Manchikanti et al (393) studied 45 patients with 30 patients in the treatment group and 15 patients in the conservative management group with one-day adhesiolysis showing improvement with pain relief in 93% of the patients at 6 months and 47% of the patients at one year. However, procedures were repeated one to 3 times. Patients in the treatment group also showed significant improvement in functional and psychological status. The results of this study have not been considered significant, as it was neither blinded, nor did it include a control group undergoing placebo injections.

5.1.3 Cost Effectiveness

Cost effectiveness of percutaneous adhesiolysis for one year of improvement in the QOL varied from \$2,028 to \$5,564 (391-393).

5.1.4 Safety and Complications

The most commonly reported complications of percutaneous adhesiolysis were dural puncture, catheter shearing, and infection (2,49,58,385,387-397). Other potential complications include intravascular injection; vascular injury; cerebral vascular or pulmonary embolus; reaction to the steroids; hypertonic saline or hyaluronidase, and administration of high volumes of fluids potentially resulting in excessive epidural hydrostatic pressures; death; and brain damage (2,49,58,385,396-399).

5.1.5 Indications

Indications for lysis of epidural adhesions are as follows:

- 1) Chronic low back and/or lower extremity pain resulting from post surgery syndrome, epidural fibrosis, and spinal stenosis.
- 2) Duration of pain of at least 6 months.
- 3) Average pain levels of greater than 6 on a scale of 0 to 10.
- 4) Intermittent or continuous pain causing functional disability.

- 5) Chronic function-limiting low back and lower extremity pain non-responsive to non-interventional; and non-surgical conservative management and fluoroscopically directed epidural injections.

5.1.6 Level of Evidence

Table 13 illustrates the results of published studies of effectiveness of percutaneous adhesiolysis.

The effectiveness of percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome indicated Level I to II-1 evidence based on the USPSTF criteria (30).

5.1.7 Recommendations

The recommendation is strong, with 1B or 1C for percutaneous adhesiolysis in post lumbar laminectomy syndrome.

5.2 Endoscopic Adhesiolysis

Spinal endoscopic adhesiolysis was evaluated in 3 systematic reviews (49,58,77) and one health technology assessment (383).

The systematic reviews by Chopra et al (58) and Trescot et al (73) concluded that there was strong evidence to indicate the effectiveness of spinal endoscopic adhesiolysis and epidural steroid administration for short-term improvement, and moderate evidence for long-term improvement in managing chronic, refractory low back and lower extremity pain.

Hayek et al (77) concluded that spinal endoscopic adhesiolysis may be used as an effective treatment modality for chronic refractory low back pain and lower extremity pain of post lumbar laminectomy syndrome.

5.2.2 Descriptive Characteristics

There was only one randomized trial (400) and 5 observational studies (392,401-404) that met inclusion criteria (77).

5.2.2.1 Randomized Trials

Manchikanti et al (400) evaluated the effectiveness of spinal endoscopic adhesiolysis in chronic refractory low back and lower extremity pain in an RCT. A total of 83 patients were evaluated, with 33 patients in Group I and 50 patients in Group II. Group I served as an active control, with endoscopy into the sacral level without adhesiolysis, followed by injection of local anesthetic and steroid. In contrast, Group II received spinal endoscopic adhesiolysis, followed by an

Table 13. Results of published studies of the effectiveness of percutaneous lysis of lumbar epidural adhesions.

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term ≤ 6 mos.	Long-term > 6 mos.
Manchikanti et al 2004 (389)	RA, DB	G1 = 25 G2 = 25 G3 = 25	0% 64% 72%	0% 60% 72%	0% 60% 72%	P	P
Heavner et al 1999 (388)	RA, DB	59	49%	43%	49%	P	P
Veihelmann et al 2006 (387)	RA	99	SI	SI	SI	P	P
Manchikanti et al 2001 (393)	O	G1 = 15 G2 = 30	97%	93%	47%	P	P
Manchikanti et al 1999 (392)	O	60	90%	72%	52%	P	P
Manchikanti et al 1999 (391)	O	129	68%	36%	13%	P	N
Gerdesmeyer et al 2005 (390)	O	61	SI	SI	SI	P	P

RA = randomized; DB = double blind; O = observational; G = group; SI = significant improvement; P = positive; N = negative

Adapted from Eptner RS et al. Systematic review of percutaneous adhesiolysis and management of chronic low back pain in post lumbar surgery syndrome. *Pain Physician* 2009; 12:361-378 (76).

injection of local anesthetic and steroid. Among the 50 patients in the treatment group receiving spinal endoscopic adhesiolysis, significant improvement without adverse effects were shown in 80% at 2 months, 56% at 6 months, and 48% at 12 months. The control group showed improvement in 33% of patients at one month and none thereafter.

Based on the definition that less than 6 months of relief is considered short-term and longer than 6 months of relief is considered long-term, a significant number of patients obtained long-term relief with improvement in pain, functional status, and psychological status. In this study, the authors performed an intention-to-treat analysis. Outcome assessments included VAS, ODI 2.0, work status, opioid intake, range of motion, and psychological evaluation.

5.2.2.2 Observational Studies

Table 14 illustrates the description of observational studies included in the evidence synthesis for spinal endoscopic adhesiolysis.

5.2.3 Cost Effectiveness

The cost effectiveness of spinal endoscopy in pa-

tients failing to respond to all conservative modalities of treatments, including percutaneous adhesiolysis with a spring-guided catheter, was shown to be \$7,020 to \$8,127 (392,404).

5.2.4 Safety and Complications

Common complications reported following spinal endoscopic adhesiolysis include pain at the site of the procedure/low back pain, dural puncture headache and cerebrospinal fluid (CSF) leak, infection, paresthesiae, and transient subarachnoid block. However, despite characterization of spinal endoscopic adhesiolysis as a generally safe procedure several case reports describe serious potential complications (392,399-410). Severe visual impairment following epiduroscopy has been reported (399). Despite the technical difficulty of manipulating an endoscope in the spinal canal, there are no reports in the literature of permanent neurological damage or reports of epidural hematoma or meningitis.

5.2.5 Indications

Endoscopic epidural adhesiolysis is indicated for patients whose chronic low back and lower extremity pain has failed to respond to conservative modalities

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Table 14. Summary description of observational studies for spinal endoscopic adhesiolysis.

Study/ Methods	Participants	Intervention	Outcome	Results	Conclusion(s) Short-term ≤6 mos. Long-term > 6 mos.	Complications
Manchikanti et al 1999 (392)	60 FBSS patients – excluded facet and SI joint pain	Epiduroscope to level of pathology, adhesiolysis, 10 mL 1% lidocaine + steroid injection	Pain relief: 1) none 2) < 50% 3) 50% (successful) Duration: < 1 month, 1, 2, 3, 6, and 12 months	Initial success (> 50% relief) in 100% of patients declining to 80% at 3 months, 52% at 6 months, and 22% at one year	Safe and possibly cost effective procedure in patients with FBSS (long-term)	Dural puncture in 7 procedures. “Suspected” infection in 8 patients who were given antibiotics but no “obvious” infection was noted.
Manchikanti et al 2000 (404)	85 consecutive patients (86% with FBSS) underwent 112 epiduroscopic adhesiolysis procedures (27 patients had a second procedure). Follow up for 1–2 years	Epiduroscopic adhesiolysis and application of 10 mL 1% lidocaine + 6 mg betamethasone	Pain relief: 1) none 2) < 50% 3) > 50% (significant) Duration: < 1 month, 1, 2, 3, 6, and 12 months	Significant (> 50%) relief for a mean of 19 ± 1.79 weeks. After one procedure, initial relief in 100% of patients, declined to 94% at 1–2 months, 77% at 2–3 months, 52% at 3–6 months, 21% at 6–12 months, and 7% after one year.	Relatively safe and possibly cost effective procedure in patients who have failed other modalities of treatment (long-term)	Dural puncture in 8 patients. Subarachnoid block in 4 patients. 2 documented infections (one requiring skin grafting and prolonged antibiotics) and 6 “SUSPECTED” infections.
Richardson et al 2001 (403)	38 patients with lumbar radicular pain who failed analgesics, TENS, and epidural injections were recruited; 19 had FBSS. Procedure aborted in 4 patients.	34 patients underwent mechanical adhesiolysis + 5 mL bupivacaine 0.25% + 80 mg methylprednisolone + 100 mcg clonidine	VAS + functional activity score at 2, 6, and 12 months post procedure	Preoperative VAS 8.2, 5.6, 6.8, and 6.7 at 2, 6, and 12 months respectively. A similarly significant functional improvement was noted.	Epiduroscopic adhesiolysis achieved moderate but sustained reduction in chronic lumbar radicular pain as well as improvement in functional status	Transient low back pain in some and transient lower limb paresthesiae in 2 patients. None required hospital admission.
Geurts et al 2002 (402)	24 patients were recruited: radicular pain below knee + evidence of radiculopathy by exam; leg pain > back pain. 2 patients unable to enter caudal space (excluded); 14 of the remaining 22 were FBSS patients.	Mechanical adhesiolysis + 120 mg methylprednisolone + 600 IU hyaluronidase + 150 mcg clonidine. 2 patients had no injection and were excluded: one with no adhesions and another because of dural puncture.	Median VAS score from 12 recordings over a 4 day period one week before intervention and assessment at 3, 6, 9, and 12 months. Global Subjective Efficacy Rating (GSER) at 12 months.	19/20 patients showed adhesions by epiduroscopy vs. 11/20 by MRI. Significant pain relief at 3, 6, 9, and 12 months occurred in 55%, 40%, 35%, and 35% of patients respectively. Similar findings by GSER at 12 months.	Epiduroscopy is useful in diagnosing spinal root pathology and targeted application of epidural medications can result in substantial and prolonged pain relief.	One accidental dural puncture noted; procedure aborted and patient was excluded from analysis. However, 3 patients had post-dural puncture headache and 2 required epidural blood patches. Transient intra-operative discomfort in some patients.
Avellanal and Diaz-Reaganon 2008 (401)	19 patients with h/o FBSS and severe sciatica (VAS ≥ 7) who have failed multiple treatment modalities including adhesiolysis with a Racz catheter. All patients had X-rays, MRI, and EMG within 2 months of enrollment.	Interlaminar epiduroscopic adhesiolysis at L5/S1 and occasionally at L4/L5 or L3/L4. 6 mL mixture of triamcinolone, 40 mg hyaluronidase 600 IU, and bupivacaine 0.0625% were injected.	VAS at 1, 2, 3, and 6 months.	Compared to VAS at baseline, there was significant reduction in pain at 1, 2, 3, and 6 months. Six patients had no improvement at 3 months or later, 7 experienced mild improvement, and 6 improved markedly (> 3 points on the VAS).	A 50% smaller diameter endoscope is effective in pain relief through adhesiolysis in patients with FBSS.	4 dural punctures (21%), one necessitating admission to the hospital for 5 days; transient headache and hypotension during the procedure lasting < 30 sec; some low back and leg pain relieved spontaneously within 2 days.

Adapted from Hayek SM et al. Effectiveness of spinal endoscopic adhesiolysis in post lumbar surgery syndrome: A systematic review. *Pain Physician* 2009; 12:419-435 (77).

of treatment, including epidural injections administered under fluoroscopic guidance, percutaneous lysis of adhesions with a spring-guided catheter, and other well-documented therapeutic modalities. Conditions in which spinal endoscopy is indicated include postlumbar laminectomy syndrome and epidural adhesiolysis resulting in chronic, intractable pain, nonresponsive or poorly responsive, to other modalities of treatment (400,405).

5.2.6 Level of Evidence

The single randomized trial evaluating endoscopic adhesiolysis (400) showed positive results for short-term relief. Of the 5 observational studies meeting methodologic quality criteria (392,401-404), all of them showed positive results for short-term improvement, whereas none of them were positive for long-term relief.

Table 15 illustrates results of effectiveness of endoscopic adhesiolysis.

The indicated level of evidence is II-I for short-term relief and Level III for long-term relief for endoscopic adhesiolysis in post lumbar laminectomy syndrome.

5.2.7 Recommendations

The recommendation is 1C/strong or 2A/weak for endoscopic adhesiolysis in post lumbar laminectomy syndrome.

6.0 SACROILIAC JOINT INTERVENTIONS

Sacroiliac joint pain may be managed by intraarticular injections or neurolysis of the sacroiliac joint (50,54,61).

6.1 Evidence Assessment

Three systematic reviews have been conducted to evaluate the effectiveness of sacroiliac joint interventions (50,54,61). All of them illustrated either lack of evidence or limited evidence for both intraarticular sacroiliac joint injections and radiofrequency neurotomy of nerve supply of the sacroiliac joint. Rupert et al (54) evaluated the role of intraarticular injections and radiofrequency neurotomy with inclusion criteria of diagnosis of sacroiliac joint pain by controlled diagnostic blocks and outcome parameters of 6 months or longer. There was limited evidence (Level II-3) for radiofrequency neurotomy.

6.2 Intraarticular Sacroiliac Joint Injections

Despite the availability of 17 publications (411-427) with 4 randomized trials (412,413,415,420) and 13 observational reports (411,414,416-419,421-427), there were no studies meeting the inclusion criteria.

Two systematic reviews (50,61) showed limited evidence for intraarticular injections. However, utilizing more stringent criteria, Rupert et al (54) in a recent

Table 15. Summary results of eligible studies of endoscopic adhesiolysis included in this systematic review.

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Significant Pain Relief		Results	
				≤ 6 mos.	>6 mos.	Short-term ≤ 6 mos.	Long-term > 6 mos.
Manchikanti et al 2005 (400)	RA,DB	69	83	56%*	48%*	P	P
Manchikanti et al 1999 (392)	O	62	60	52%*	22%*	P	P
Manchikanti et al 2000 (404)	O	58	85	21%* 6-12 mos.	7%* > 12 mos.	P	N
Richardson et al 2001 (403)	O	67	38	Yes	Yes	P	P
Geurts et al 2002 (402)	O	77	24	Yes	Yes	P	P
Avellanal and Diaz-Reganon 2008 (401)	O	53	19	Yes	N/A	P	N

*Denotes percentage of patients with > 50% pain relief

RA = randomized; DB = double blind; O = observational; P = positive; N = negative; NA = not applicable.

Adapted from Hayek SM et al. Effectiveness of spinal endoscopic adhesiolysis in post lumbar surgery syndrome: A systematic review. *Pain Physician* 2009; 12:419-435 (77).

systematic review reported a lack of studies meeting the inclusion criteria.

6.2.1 Cost Effectiveness

No studies were performed evaluating the cost effectiveness of therapeutic sacroiliac joint injections.

6.2.2 Safety and Complications

Potential complications include infection, hematoma formation, neural damage, trauma to the sciatic nerve, gas and vascular particulate embolism, leakage of the drug from the joint, and other complications related to drug administration (2,50,61,291,428-432). Radiation exposure could be an issue for the physician, patient, and facility personnel (179).

Side effects related to the administration of steroids are generally attributed to the chemistry or to the pharmacology of the steroids (276).

6.2.3 Indications

Common indications for sacroiliac joint injections are as follows:

- 1) Somatic or nonradicular low back and lower extremity pain below the level of L5 vertebra.
- 2) Duration of pain of at least 3 months; average pain levels of greater than 6 on a scale of 0 to 10.
- 3) Intermittent or continuous pain causing functional disability.
- 4) Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and nonsteroidal anti-inflammatory agents.
- 5) Lack of obvious evidence for disc-related or facet joint pain.
- 6) No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation.
- 7) No history of allergy to administration of contrast, local anesthetics, or steroids.
- 8) Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs.
- 9) The joint should have been positive utilizing controlled diagnostic blocks with low volume and a criterion standard of $\geq 80\%$ relief.

6.2.4 Level of Evidence

Based on the available literature, evidence is unavailable for intraarticular sacroiliac joint injections for therapeutic purposes.

6.2.5 Recommendations

Based on the available literature and evidence no recommendation is provided.

6.3 Radiofrequency Neurotomy

Percutaneous radiofrequency neurotomy of sacroiliac joints has been reported to provide long-term relief (433-441).

The effectiveness of radiofrequency neurotomy was evaluated in 3 systematic reviews. Two systematic reviews (50,61) showed limited evidence for radiofrequency neurotomy in managing chronic sacroiliac joint pain. The recent systematic review (54) with more stringent criteria showed evidence of Level II-3 or Level III with inclusion criteria of controlled diagnostic blocks and long-term relief considered as longer than 6 months.

6.3.1 Descriptive Characteristics

There were 9 relevant reports considered for inclusion (433-441) but there were no randomized trials meeting the inclusion criteria. Three observational studies (435,437,439) met inclusion criteria in the systematic review by Rupert et al (54).

Vallejo et al (435) tested the hypothesis that pulsed radiofrequency of the posterior rami from L4 to S3 would provide therapeutic benefit to patients with intractable sacroiliac joint dysfunction. One hundred and twenty-six patients with suspected sacroiliac joint pain were examined for this study. Dual diagnostic blocks with local anesthetic and corticosteroid using $\geq 75\%$ relief as the success criterion were done to minimize false-positive results and confirm the pain generator. This resulted in 52 patients with confirmed disease. Thirty of these patients obtained $\geq 50\%$ relief lasting longer than 12 weeks. The remaining 22 subjects were offered the treatment. The follow-up period was 6 months and outcome measures included VAS scoring and a QOL assessment tool. Sixteen of the 22 were found to have good ($\geq 50\%$) to excellent ($\geq 80\%$) results; however, in only 7 patients did this improvement exceed 17 weeks. There was no annotation about how many patients obtained 6 or greater months of relief. This study is limited by its observational nature and the small number of patients. In addition, only 7 of 22 patients experienced between 17 and 32 weeks worth of relief, which is similar to the duration of benefit obtained from local anesthetic blocks with or without steroids (182-184,269,274,276,293).

Burnham and Yasui (439) published the results

of a pilot study evaluating bipolar radiofrequency neurotomy. They evaluated 9 subjects with sacroiliac joint pain confirmed by local anesthetic joint and lateral branch nerve blocks. These subjects were treated with a series of radiofrequency strip lesions performed adjacent to the lateral dorsal foraminal aperture plus conventional monopolar lesioning at the L5 dorsal ramus. Follow-up visits were conducted at one, 3, 6, 9, and 12 months after the procedure. Significant reductions in back and leg pain frequency and severity, and analgesic intake were demonstrated at all points. Complications were minimal. Overall, 8 of the 9 subjects were satisfied with the procedure. The median improvement in pain intensity was 4.1 on a 0–10 NRS and the reduction in disability was 17.8 on the ODI. Overall satisfaction was 67% at 12 month follow-up. Limitations include the small number of patients (n = 9) recruited from one practice.

Cohen and Abdi (437) performed radiofrequency lesioning on 9 patients who experienced greater than 80% pain relief following intraarticular joint injection(s) and greater than 50% relief following L4-5 primary dorsal rami and S1-3 lateral branches blocks. Eight of 9 patients (89%) obtained 50% or greater pain relief from this procedure that persisted at their 9-month follow-up. The authors concluded that in patients with injection confirmed sacroiliac joint pain who respond to L4-L5 dorsal rami and S1-3 lateral branch blocks, radiofrequency denervation can be an effective treatment. Limitations of this study include the observational nature and small number of patients.

Among the studies failing to meet the strict criteria for this evaluation was a randomized, placebo-controlled study evaluating lateral branch radiofrequency denervation by Cohen et al (441). Except for dual blocks, the study meets all the criteria for randomized trials and the reporting guidelines of CONSORT (189). This study was also the first to utilize cooled probe radiofrequency technology, which can increase the lesion size by a factor of 8. The authors randomized 28 patients from amongst 90 potential candidates with predominantly axial low back pain to receive either cooled radiofrequency denervation from L4-S3 or sham lesioning. The main inclusion criterion was > 75% pain relief lasting at least 3 hours following a single intraarticular block performed with a 3 mL solution containing 2 mL of bupivacaine and 40 mg of dexamethasone. Those patients allocated to the placebo group who failed to obtain significant benefit were eligible to crossover to an open-label paral-

el group that received conventional radiofrequency denervation, 3 and 6 months after the procedure. Sixty-four percent (n = 9) of patients and 57% (n = 8) patients undergoing cooled radiofrequency lesioning experienced > 50% pain relief accompanied by significant functional improvement.

In contrast, none of the sham-treated patients experienced significant improvement 3 months after the procedure. In the crossover treatment group (n = 11), 6 (55%) and 4 (36%) patients experienced a positive outcome 3 and 6 months post-procedure. However, one year after treatment, only 2 patients (14%) in the treatment group continued to demonstrate persistent pain relief. The authors concluded that these results furnished preliminary evidence that L4 and L5 primary dorsal rami and S1 to S3 lateral branch radiofrequency denervation may provide intermediate-term pain relief and functional benefit in well-selected patients with suspected sacroiliac joint pain. They also conceded that larger studies were needed to confirm these results and identify the optimal candidates and treatment parameters for this therapy.

This study provides strong evidence that response to radiofrequency denervation is superior to placebo. The limitations of the study include the small number of patients, the failure to exclude false-positive responders with a single uncontrolled sacroiliac joint block, the utilization of different types of radiofrequency technology, and the abridged outcome measures after 6 months.

6.3.2 Cost Effectiveness

No cost effectiveness evaluations have been performed of radiofrequency neurotomy of the sacroiliac joint.

6.3.3 Safety and Complications

Complications of radiofrequency thermoneurolysis include a worsening of the usual pain, burning or dysesthesias, decreased sensation and allodynia in the skin overlying the joint, transient leg pain, persistent leg weakness, and inadvertent lesioning of the spinal nerve, ventral ramus, or sciatic nerve resulting in motor deficits, sensory loss, and possible deafferentation pain (429,435,437-441).

6.3.4 Indications

Indications for sacroiliac joint interventions are illustrated under intraarticular sacroiliac joint injections described in 6.2.3.

6.3.5 Level of Evidence

Based on the available literature and the USPSTF criteria (30), the indicated evidence is Level II-3 (limited) for radiofrequency neurotomy of the sacroiliac joint nerve supply.

6.3.6 Recommendations

The recommendation based on Guyatt et al's (34) criteria is 2B, a weak recommendation for radiofrequency neurotomy for sacroiliac joint pain.

7.0 INTRADISCAL THERAPIES

Multiple intradiscal therapies described to manage either discogenic pain or internal disc disruption include intradiscal electrothermal therapy (IDET), radiofrequency annuloplasty, and intradiscal biacuplasty (IDB). Percutaneous intradiscal treatment of low back pain has been the subject of several reviews (62,75,80,158,442-446). The Centers for Medicare and Medicaid Services (CMS) has issued a non-certification for these procedures (447). CMS referred to them collectively as thermal intradiscal procedures, including IDET, percutaneous intradiscal radiofrequency thermo-coagulation (PIRFT), radiofrequency annuloplasty, IDB, percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD).

7.1 Intradiscal Electrothermal Therapy (IDET)

The evidence for IDET includes 5 systematic reviews (62,75,80,158,442), a technology assessment update (446), critical appraisal of the evidence (443), and other multiple reviews. Evidence for IDET was also reviewed in multiple guidelines (2-4,158).

Appleby et al (442) in a systematic review reviewed the literature from all the available studies and concluded that there was compelling evidence for the relative efficacy and safety of IDET. This meta-analysis showed an overall mean improvement in pain intensity of 2.9 points, physical function of 21.1 points as measured by SF-36, and disability of 7.0 points as measured by the ODI; however, the lead author was an employee of the device manufacturer. Andersson et al (62) performed a systematic review of spinal fusion and IDET in the treatment of intractable discogenic low back pain. They concluded that the majority of patients reported improvement in symptoms following both spinal fusion and IDET. However, the IDET procedure appeared to offer sufficiently similar symptom amelioration to spinal fusion without attendant complications. Gibson and Waddell (80) concluded that the preliminary results of 3 similar trials of intradiscal electrotherapy suggest it is

ineffective, except possibly in highly selected patients. Freeman (443) performed a critical appraisal of the evidence of IDET and concluded that the evidence for the efficacy of IDET remains weak and has not passed the standard of scientific proof.

Helm et al (75) in a recent systematic review evaluating IDET indicated the evidence of Level II-2.

7.1.1 Randomized Trials

Two studies met inclusion criteria (448,449). Descriptive characteristics of both randomized trials are illustrated in Table 16.

Both studies have been criticized (450,451). Despite these criticisms, both describe patients in sufficient detail for a practitioner to identify them in a clinical setting. Both describe IDET sufficiently that the procedure can be provided outside of the academic setting. Both measured and reported clinically relevant effects. Pauza et al (448) did meet all the criteria for clinically important improvement, including a greater than 30% improvement in pain scores, a 2-point reduction in VAS in about 50% of patients, and a greater than 10% improvement in functioning scores, although the functioning score improvement was not clinically significant. According to Pauza et al (448), but not according to Freeman et al (449), the benefits of IDET are worth the potential harms.

7.1.2 Observational Studies

Table 17 illustrates descriptive characteristics of included observational studies for IDET (450-471).

7.1.3 Cost Effectiveness

Andersson et al (62) in their systematic review of intractable low back pain treatment with IDET versus spinal fusion surgery concluded that more than half of the patients treated with IDET can avoid surgery and therefore spare the cost of surgery and its complications.

7.1.4 Safety and Complications

Complications of IDET include catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage, progressive disc degeneration, vertebral endplate osteonecrosis, radiculopathy due to intradural migration of a broken catheter, instability, and disc herniation (442,472-485).

7.1.5 Indications

The indications have been described as follows (486):

Table 16. Descriptive characteristics of randomized controlled trials of IDET.

Study/Methods	Participants	Inclusion/Exclusion	Interventions	Outcomes	Results	Conclusion Short-term ≤ 6 mos. Long-term > 6 mos.
Pauza et al 2004 (448) Randomized, placebo-controlled, double-blind, prospective trial. Study sponsored by device manufacturer.	64 patients. Evaluated 1,360 patients between September 2000 and April 2002; 260 potentially met the criteria. Study was done in a private practice setting. Of the 37 treated patients, 32 were included in the analysis; of the 27 sham patients, 24 were included in the analysis. Pauza et al were unable to enroll enough patients to fully power his study at 80%, study was statistically significant at 60%.	Inclusion: age 18–65 years; low back pain > leg pain of > 6 months duration; failure to improve after nonoperative therapy; no surgery within the last 3 months; less than 20% loss of disc height. Exclusion: abnormal neurological exam; Workers' Compensation; personal injury litigation or receiving disability. Positive discography and posterior annular tears on CT scan.	IDET 37 had IDET; 27 had a sham procedure in which the introducer needle was advanced to the outer annulus, but no catheter placed. Sham patients were exposed to a fluoroscopic monitor showing passage of the electrode, with appropriate sounds during the putative procedure.	SF-36 and VAS Unblinded at 6-months	56% of the IDET group had a greater than 2.0 improvement in the VAS; 38% of the sham group did. 24% of the treated group had greater than 75% pain relief; 4% of the sham group did. The improvement in the IDET group was significantly better than the sham. 40% of patients treated with IDET obtained 50% relief at 6 months.	Positive short-term. A needed-to-treat value of 5 for achieving 75% relief indicates that it is a worthwhile intervention for some highly select patients.
Freeman et al 2005 (449) Randomized, placebo-controlled, double-blind, prospective trial. Study sponsored by device manufacturer.	57 subjects from 3 spine practices in Australia. Unable to enroll the 75 patients required to power study at 80%. Number of patients screened to enroll the 57 was not given. Patients enrolled from November 1999 to December 2001. Between 84% and 89% of enrollees had abnormal reflexes. 13% of the treated and 5 percent of the sham patients had positive Waddell signs. 10% of the treated group was on disability. Duration of low back pain was up to 20 years.	Inclusion: symptoms of degenerative lumbar disc disease > 3 months; failure to improve with at least 6 weeks of conservative treatment; MRI documented degenerative disease; one or 2 positive levels on discography; dye spread on post discography CT scan to or beyond the outer annulus; age > 18. Exclusion: loss of more than 50% disc height; severely disrupted disc; 3 or more symptomatic lumbar discs; previous back surgery; current injury litigation.	IDET Treated group had IDET, with catheter covering at least 75% of the annular tear. The control had a catheter placed in the annulus and the cable attached to it. The cable was then passed to an independent technician who would either attach or not attach the cable to the IDET generator. 100 mg of cefazolin injected at end of procedure.	VAS, Low Back Pain Outcome Score, ODI, SF-36, Zung Depression Index, and the Modified Somatic Perception Questionnaire.	At six months, neither group showed any benefit in any parameter.	Negative short-term

Adapted from Helm S et al. Systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. *Pain Physician* 2009; 12:207-232 (75).

- 1) Axial low back pain of at least 6 months duration.
- 2) Failure to respond to conservative treatment.
- 3) ≥ 60% residual disc height.
- 4) Positive concordant discogram at low pressure.
- 5) Normal neurologic exam (or at least no new deficits attributable to level to be treated).
- 6) Negative straight-leg raise.
- 7) MRI with no evidence of root compression, tumor, or infection.

7.1.6 Level of Evidence

Table 18 illustrates the results of published studies of effectiveness of IDET, which includes randomized and observational studies. The indicated evidence for IDET is Level II-2 based on USPSTF criteria (30).

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Table 17. Description of observational studies of IDET.

Study/Methods	Participants	Inclusion/Exclusion	Interventions	Outcomes	Results	Conclusion Short-term ≤ 6 mos. Long-term > 6 mos.
Bogduk and Karasek 2000, 2002 (452,453)	53 consecutive patients seen in private pain practice between May 1998 and November 1998	Inclusion: Positive discography at one to two levels, intact annulus. Disc height ≥ 80% of normal. Exclusion: Disc prolapsed, neurologic disease, tumor, or infection.	Patients assigned to treatment or control by whether insurance authorized procedure. Catheter placed around entire posterior annulus. 1 mg of cefazolin injected intradiscally after procedure. Control group given PT.	VAS, return to work and opioid use	Mean treated VAS decreased from 8.0 to 3.0 at 2 years; 57% of treated group had 50% relief.	Positive for short- and long-term relief. Powered at 76% at 2 years.
Gerszten et al 2002 (454)	23 consecutive patients. 19 patients were on Workers' Compensation.	Inclusion criteria: Back pain > 6 months duration. Low back pain > leg pain; pain with axial loading and relief with recumbency; discogenic disease on MRI or positive discography; failure of conservative treatment.	IDET with catheter covering symptomatic side. No antibiotics given. Co-interventions were limited to therapies given prior to the IDET.	Oswestry Low Back Pain Disability and the Short Form (SF)-36	47% of patients had significant (> 7 points) improvement in SF-36 scales. 75% had improvement in Oswestry. Workers' Compensation did not influence outcome.	Positive for short- and long-term relief.
Saal and Saal 2002 & 2000 (455-457)	53 patients selected from 1,162 low back pain patients. 34% Workers' Compensation.	Inclusion: Low back pain > 6 months duration; failure to improve with non-operative care; positive discography; normal neurological exam; no compressive lesion on MRI; positive discography at < 1.25 mL of dye, maximum 3 levels with negative control.	IDET passed "as far as possible around posterior annulus. 2-20 mg of cefazolin injected. No other medications injected into the disc.	VAS, sitting tolerance, and SF-36	At 24 months, at least 72% experienced at least a 2 point decrease in VAS and 50% had a 4 point reduction. 78% had at least a 7 point reduction in the bodily pain scale of the SF-36. Sitting tolerance increased from a mean of 32 to 85 minutes. 97% of the private pay and 83% of the Workers' Compensation returned to work.	Positive for short- and long-term results. Patients with chronic discogenic low back pain show sustained improvement in VAS, sitting tolerance, and SF-36.
Cohen et al 2003 (458)	70 patients with discogenic low back pain	Inclusion criteria: Abnormal MRI and positive discography. Annular tears were permitted. Low back pain > 6 months duration; age < 60; loss of disc height < 50%; failure to respond to conservative therapy; absence of prominent radicular signs and symptoms.	IDET limited to 1 or 2 discs. Coverage of at least 70% of the posterior annulus. Cefazolin and bupivacaine, dose not recorded, injected.	50% reduction in pain at 6-months.	48% had > 50% relief. 54% of the nonobese vs. 10% of the obese had a good outcome; 50% of 1-level vs. 38% of 2-level patients had good outcomes. No difference with smoking, diabetes, non-dermatomal leg pain, and previous surgery.	Positive short-term results. Long-term results not available.
Freedman et al 2002 (459)	41 active duty soldiers seen at Walter Reed between 1999 and 2001.	Inclusion: Low back pain > 6 months duration; positive discography with at least one normal disc; MRI absence of nerve root compression, tumor, infection or trauma; no radicular symptoms; failed nonoperative treatment.	IDET "using the protocol described by Saal and Saal."	50% reduction in pain	29% reported symptoms as improved at last follow-up. Overall satisfaction was 16%. 52% had a 2 point reduction in VAS.	Positive short-term and negative long-term outcomes.

Table 17 (cont.). *Description of observational studies of IDET.*

Study/Methods	Participants	Inclusion/Exclusion	Interventions	Outcomes	Results	Conclusion Short-term ≤ 6 mos. Long-term > 6 mos.
Lee et al 2003 (460)	62 consecutive patients. 51 patients were available for follow-up at 2 years. 20 patients were Workers' Compensation or no fault insurance.	Inclusion criteria: Low back pain > 6 months; sitting > standing pain; normal neurologic exam; failure of conservative care; no compressive lesion on imaging; positive discogram with annular tear; < 50% disc height.	VAS, Roland Morris, and NASS patient satisfaction index. 2-year follow-up.	IDET catheter passed "past midline." No mention of intradiscal antibiotics.	53% had VAS and RM improvements > 2 points. No difference with age, insurance (including Workers' Compensation), pre-IDET VAS, number of levels, or microdiscectomy.	Positive short- and long-term results.
Lutz et al 2003 (461)	33 patients in an academic-affiliated private physiatry practice. Dates of recruitment not given.	Inclusion criteria: Low back pain > 6 months duration; positive discography; non-responsive to conservative care. Exclusion: > 50% loss of disc height; > 5 mm disc extrusion or sequestration; severe stenosis; spondylolisthesis; previous spinal surgery; segmental instability; infection.	VAS, Roland Morris, and NASS patient satisfaction index. Success was a 2 point improvement in VAS or RM and a positive NASS satisfaction response. Follow-up at 15 months.	IDET Catheter "into the posterior annular wall past the midline."	Mean change in VAS was 3.9. 77% indicated they would repeat the procedure. Complete relief in 24% of patients and partial relief in 46%. 15% of patients required an epidural steroid injection for flare-up of leg pain.	Positive short- and long-term results.
Davis et al 2004 (462)	60 patients referred from 17 spine specialists. IDET performed by 4 physicians. 73% of patients responded to questionnaire.	Inclusion criteria: Diagnosis of discogenic low back pain > 6 months; positive discogram with provocation discography using < 2.5 ml of contrast, with annular fissure; disc height > 50%; failed conservative therapy.	Short and long questionnaires from the National Low Back Pain Study. Core questions were pain intensity, functional limitation, work status, analgesic use, other treatment for low back pain, overall satisfaction.	IDET. Technique not described.	37% of patients had a successful outcome. 14% had further surgery at one year. At 2 years, 4 more patients had had surgery. One patient developed discitis and one developed a Grade I spondylolisthesis requiring surgery.	Negative short- and long-term relief.
Derby et al 2004 (463)	35 patients for restorative injection therapy and 74 for IDET. "Retrospectively performed through the analysis of a prospectively collected data base." Patients seen between January 2000 and October 2002.	Inclusion criteria: Chronic low back pain not responsive to conservative therapy; being considered for additional surgery; positive discography. Prior surgery and, for the injection group, prior IDET at the treated level, was allowed. For IDET, no focal neurological signs; single level; disc height > 50%.	Compared effectiveness of restorative injection therapy and IDET. VAS Follow-up 15.5 months in IDET and 7.7 months for injection group.	For injection, chondroitin sulfate, glucosamine, DMSO, bupivacaine, 1-2 cc injected. For IDET, coverage of entire posterior annulus. Cefazolin (dose not recorded) injected at end of procedure.	Mean improvement for IDET was 1.27 on VAS, versus 2.2 for injection group. 47.8% of IDET group felt better; 65.5% of injection group did. Pain relief was statistically significant for both groups. 81% of injection group had flare-up compared to 60% of IDET. Duration of flare was 8.6 days for injection group and 33.1 days for IDET.	Positive short-term relief. Both IDET and injection therapy provided benefit. Results subsumed under Derby et al (464) as same patient population presumed to be evaluated.

Table 17 (cont.). Description of observational studies of IDET.

Study/Methods	Participants	Inclusion/Exclusion	Interventions	Outcomes	Results	Conclusion Short-term ≤ 6 mos. Long-term > 6 mos.
Derby et al 2004 (464)	99 patients seen in a single practice between January 1999 and December 2000 who did not have subsequent surgery and who met inclusion criteria. Study assessed changes in referred leg pain.	Inclusion criteria: Low back or low back and leg pain > 6 months duration unresponsive to conservative treatment; negative straight leg raising; non-focal neurological signs; no compressive lesions on MRI; disc protrusion < 2 mm; positive discogram with annular tear; no previous surgery; disc height > 50%.	IDET with catheter coverage of the entire posterior annulus. 18-month follow-up.	VAS and 5-point pain scale from the NASS low back pain assessment instrument. Patients divided into groups of leg pain dominant; back pain dominant; leg and back pain the same.	52% had an improvement in leg pain, with a mean improvement of 1.9 (5 point scale). Back pain decreased from 3.37 to 2.59 (5 point scale = Δ1.56/10). Relief of back pain correlated with relief of leg pain.	Positive short- and long-term relief. IDET can relieve associated limb pain.
Mekhail and Kapural 2004 (465)	34 consecutive patients in an academic pain practice. 32 followed for one-year. 10 patients Workers' Compensation.	Inclusion criteria: Disc height > 50%; no lumbar stenosis; 1-or 2-level DDD; no disc herniation on MRI; positive discography; no psychological issues.	IDET Catheter position not described.	Pain disability index (7 different activities of daily living plus VAS) Follow-up 1 year.	Non-Workers' Compensation had a 78% decrease in VAS versus 53% for Workers' Compensation. No significant difference in gender, smoking or age.	Positive short- and long-term relief.
Kapural et al 2004 (466)	17 consecutive patients with multilevel disc disease matched with 17 of 22 consecutive patients with 1- or 2-level disc disease.	Inclusion criteria: Low back pain > 6 months not responsive to conservative therapy; no compressive radiculopathy; no previous surgery at symptomatic levels; disc height > 50%; no signs or symptoms of stenosis; positive discography.	IDET Catheter position not described.	Pain disability index (7 different activities of daily living plus VAS). Follow-up 1 year.	The 1- or 2 level group had a pretreatment VAS of 7.7 versus 2.5 at 12 months. The multi-level group decreased from 7.4 to 4.9.	Positive short- and long-term relief. IDET results are better in patients with 1- or 2-level disc disease.
Kapural et al 2005 (471)	42 matched patients, 21 with IDET and 21 with radiofrequency annuloplasty in an academic pain practice.	Inclusion criteria: Low back pain > 6 months not responsive to conservative care; no compressive radiculopathy; positive discography; no prior surgery; disc height > 50%; not Workers' Compensation claimants.	IDET and radiofrequency annuloplasty.	Pain disability index questionnaire. 12 month follow-up.	IDET VAS decreased from 7.4 to 1.4; radiofrequency annuloplasty VAS decreased from 6.6 to 4.4. PDI scores mirrored these changes.	Positive short-term for IDET. Negative long-term for radiofrequency annuloplasty.
Bryce et al 2005 (467)	86 consecutive patients in a rural Wisconsin pain practice.	Inclusion criteria: Low back pain > 6 months duration unresponsive to conservative treatment; back pain > 60% of other symptoms; normal neurological exam; positive discography; annular tears; 18-50 years.	IDET	VAS and Roland Morris Disability Questionnaire 24 months follow-up	Significant (> 20 point) improvement in RMDQ. VAS improved. Improvement best in females and in those aged 18-45 years.	Positive short- and long-term relief.

Table 17 (cont.). Description of observational studies of IDET.

Study/Methods	Participants	Inclusion/Exclusion	Interventions	Outcomes	Results	Conclusion Short-term ≤ 6 mos. Long-term > 6 mos.
Maurer et al 2008 (468)	56 consecutive patients. 16% of patients on Workers' Compensation. Industry sponsored study.	Inclusion criteria: low back pain > 6 months duration; disc height > 50%; normal lower extremity neurological exam; 1–3 desiccated discs discography; and posterior annular tear. Exclusion: Previous back surgery.	IDET	Back pain severity, physical function, and QOL. Follow-up 24 months	VAS improved by 61%. There were also significant improvements in sitting, standing, and walking tolerances. 61% improvement in SF-36. 75% treatment successes.	Positive short- and long-term improvement.
Nunley et al 2008 (469)	53 consecutive Workers' Compensation patients with low back pain.	Inclusion criteria: persistent low back pain > 6 months with failure to respond to conservative therapy; prior spine surgery; abnormal neurological exam; disc height > 40%; positive discography with an annular tear; BMI between 20.1–44.2.	IDET	VAS, Oswestry, and self-assessment questionnaires of pain and disability. 12-month follow-up.	The mean reduction of VAS was 62.6%, while the mean reduction in Oswestry was 69.3%. There was no significant effect of age or BMI on outcome. Narcotic use dropped from 51% initially to 13.2% after treatment. 47% returned to work in a full or partial capacity.	Positive short- and long-term improvement.
Ergun et al 2008 (470)	39 consecutive patients in a Turkish pain practice.	Inclusion criteria: Low back pain > 6 months non-responsive to conservative therapy; 1- or 2-level disease; no evidence of nerve root compression; > 50% disc height.	IDET Catheter covered 75% of the annulus. No post procedure antibiotics.	Turkish version of the ODI. 18-month follow-up.	At 18 months, the mean decrease in ODI was 24.79.5% of patients benefited. No complications.	Positive short- and long-term improvement.

Adapted from Helm S et al. Systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. *Pain Physician* 2009; 12:207-232 (75).

7.1.7 Recommendations

A recommendation of 2A/weak recommendation is provided based on Guyatt et al's (34) recommendation for IDET.

7.2 Intradiscal Biacuplasty (IDB)

One systematic review of the evidence for IDB (75) and one pilot study with 2 publications (487,488) was identified.

7.2.1 Descriptive Characteristics

Kapural et al (487) evaluated 15 patients who underwent one or 2-level IDB treatment of their painful lumbar discs. IDB was performed under fluoroscopy using 2 radiofrequency probes positioned bilaterally in the intervertebral disc. Patients showed improvements in several pain assessment measures after undergoing IDB for discogenic pain.

7.2.2 Cost Effectiveness

No cost effectiveness studies have been performed.

7.2.3 Safety and Complications

No complications of biacuplasty have been reported thus far. However, similar to IDET, potential complications include catheter breakage, nerve root injuries, infection, epidural abscess, and spinal cord damage (442,472-486).

7.2.4 Indications

Indications are the same as for IDET as described above.

7.2.5 Level of Evidence

Based on the quality of evidence using the USPSTF criteria (30) the level of evidence for IDB is Level III (limited).

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Table 18. Results of published studies of effectiveness of IDET.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief		Results	
				≤ 12 mos.	> 12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Pauza et al 2004 (448)	RA	68	64	56% had 2 point decrease 40% had > 50% decrease	NA	Yes	NA
Freeman et al 2005 (449)	RA	61	57	No change	NA	No	NA
Karasek and Bogduk 2000 & 2002 (452,453)	O	85	53	70%	57%	Yes	Yes
Gerszten et al 2002 (454)	O	50	27	75%	75%	Yes	Yes
Saal and Saal 2002 & 2000 (455-457)	O	52	53	SI	SI	Yes	Yes
Cohen et al 2003 (458)	O	80	70	48%	NA	Yes	NA
Freedman et al 2002 (459)	O	66	41	47%	16% > 50% decrease	Yes	No
Lee et al 2003 (460)	O	53	62	NA	53%	Yes	Yes
Lutz et al 2003 (461)	O	58	33	NA	70%	Yes	Yes
Davis et al 2004 (462)	O	52	60	NA	37%	No	No
Derby et al 2004 (463)	O	61	34 Injection 74 IDET	2.2 point decrease for injection 1.27 for IDET	NA	Yes	No
Derby et al 2004 (464)	O	52	99	NA	52% 1.56 point decrease back pain	Yes	Yes
Mekhail and Kapural 2004 (465)	O	58	34	SI	SI	Yes	Yes
Kapural et al 2004 (466)	O	74	34	SI	SI	Yes	Yes
Kapural et al 2005 (471)	O	81	21	SI	SI	Yes	Yes
Bryce et al 2005 (467)	O	58	86	SI	SI	Yes	Yes
Maurer et al 2008 (468)	O	62	56	SI	SI	Yes	Yes
Nunley et al 2008 (469)	O	60	53	SI	NA	Yes	NA
Ergun et al 2008 (470)	O	56	39	NA	79%	NA	Yes

RA = randomized; O = observational; IDET = intradiscal electrothermal therapy; SI = significant improvement; NA = not available

Adapted from Helm S et al. Systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. Pain Physician 2009; 12:207-232 (75).

7.2.6 Recommendations

The recommendation is 2C/very weak based on Guyatt et al's criteria (34) for IDB.

7.3 Radiofrequency Posterior Annuloplasty

One systematic review (75) and 2 studies dealt with radiofrequency annuloplasty (471,489).

7.3.1 Descriptive Characteristics

Finch et al (489), in a case series, found the procedure to be effective. Kapural et al (471), in an observational study, found radiofrequency annuloplasty to be less effective than IDET.

7.3.2 Cost Effectiveness

The cost effectiveness of radiofrequency annuloplasty has not been evaluated.

7.3.3 Indications

The indications are similar to IDET.

7.3.4 Safety and Complications

Complications are similar to IDET with catheter breakage, nerve root injuries, discitis, disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage (442,472-480,486).

7.3.5 Level of Evidence

Table 19 shows results of effectiveness of radiofrequency annuloplasty. The indicated level of evidence for radiofrequency annuloplasty is II-3 based on USPSTF criteria (30).

7.3.6 Recommendations

The recommendation is 2C/weak based on Guyatt et al (34) for radiofrequency annuloplasty.

8.0 PERCUTANEOUS DISC DECOMPRESSION

The primary goal of surgical treatment of a disc prolapse, protrusion, or extrusion is the relief of nerve root compression by removing the herniated nuclear material (490-493). Several alternative techniques to open discectomy and microdiscectomy include automated percutaneous laser discectomy (APLD), percutaneous lumbar laser discectomy (PLLD), mechanical disc decompression with a high rotation per minute device or DeKompressor®, and nucleoplasty. All the techniques were assessed systematically (494-497).

8.1 Automated Percutaneous Lumbar Discectomy (APLD)

APLD is performed with a pneumatically driven, suction-cutting probe in a cannula with a 2.8 mm outer diameter with removal of one to 3 grams of disc material to reduce intradiscal pressure and decompress the nerve roots (491,494,498-513).

8.1.1 Effectiveness Assessment

Gibson and Waddell (490) in a Cochrane collaboration review indicated that the place for forms of discectomy other than traditional open discectomy is unresolved. They concluded that trials of percutaneous discectomy suggest that clinical outcomes following treatment are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged. They concluded that there is considerable evidence that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica due to lumbar disc prolapse that fails to resolve with conservative management. These authors noted that unless or until better scientific evidence is available, APLD should be regarded as a research technique.

Table 19. Results of effectiveness of radiofrequency annuloplasty.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief (VAS)		Results	
				≤ 12 mos.	> 12 mos.	Short-term relief ≤ 12 mos.	Long-term relief > 12 mos.
Finch et al 2005 (489)	O	69	46	37%	NA	No	NA
Kapural et al 2005 (471)	O	81	21	NSI	NA	No	NA

O = observational; RA = randomized; NSI = no significant improvement; NA = not available

Adapted from Helm S et al. Systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. Pain Physician 2009; 12:207-232 (75).

In a technology assessment report (491), negative evidence was illustrated. The systematic review by Hirsch et al (494) utilizing a combination of randomized trials and observational studies with only one randomized trial meeting inclusion criteria for evidence synthesis (498) and with 10 observational studies meeting inclusion criteria for evidence synthesis (502-509,512,513) concluded that the indicated level of evidence is II-2 in properly selected patients with contained lumbar disc prolapse.

8.1.2. Descriptive Characteristics

8.1.2.1 Randomized Trials

Among the published randomized trials, 2 trials (498,499) met inclusion criteria for evidence synthesis with at least one year follow-up. However, Revel et al (498) was the only study which scored 70, meeting the inclusion criteria for evidence synthesis. Revel et al (498) randomized patients with sciatica caused by a disc herniation to undergo an APLD or chemonucleolysis. The study measured outcomes with VAS to measure sciatica and low back pain, a straight leg test, the Schoebert Test, neurologic status, self-assessment, disc height and herniation size. Patients were followed at one month, 3 months, and 6 months. The trial included 72 chemonucleolysis and 69 APLD patients of whom 43% of the chemonucleolysis patients and 26% of APLD patients were considered sedentary subjects and the disc appeared degenerated more often in the chemonucleolysis group (92%) than in the APLD group (76%). The study had 32 patients withdrawing during trial as therapeutic failures. They described that there were no significant differences between the 2 groups in most of the demographic data, clinical, and radiographic variables between the 2 groups. They concluded that the results of both chemonucleolysis and APLD were generally disappointing, because 48% of the overall population entering the study considered treatment a failure and 20% submitted to open laminectomy within 6 months. They further described that while the failure rate of chemonucleolysis was similar to that observed in various controlled studies; the results observed in the APLD group were strikingly different from most reported previous uncontrolled series. They also postulated that the APLD success rate in this study approached that observed in the placebo groups in the chemonucleolysis trials. At one year follow-up, overall success rates were 66% in the chemonucleolysis group and 37% in the APLD group.

Many aspects of the Revel et al's study (498), such as patient selection criteria, which led to poor results, have been criticized (494). The size of the disc herniation was an issue because for APLD it should not occupy more than 30% of the spinal canal, whereas in Revel et al's study (498) in 59% of APLD and 64% of chemonucleolysis patients the disc herniation covered between 25% and 50% of the spinal canal. Further, in 71% of the APLD patients and 79% of chemonucleolysis patients, the disc herniation had migrated up to 5 mm cranially or caudally to the endplate levels, considered a contraindication for APLD. Other factors included that at discography, 39% of the tested discs showed epidural leakage, 76% of the discs were severely degenerated (APLD is not effective in diffuse annular bulging), 9% had marked disc space narrowing, and 21% of patients had severe back pain, but no correlation to leg pain was made.

8.1.2.2 Observational Studies

Among the observational studies (502-513), 10 studies met inclusion criteria with methodologic assessment (502-509,512,513).

Onik et al (504) carried out a prospective multi-institutional study to evaluate automated percutaneous discectomy in the treatment of lumbar disc herniation. From 1984 through 1987, 506 APLDs were performed by 18 different surgeons within this prospective multi-institutional study. Of these, 327 patients met the prospective study criteria. The remaining 168 patients also underwent the study group. Of the 327 patients who were followed for one year or longer within the protocol, the success rate was 75.2% (n = 246) of the procedures done in patients outside the protocol, 49.4% were successful (n = 83). Of the 81 patients within the protocol in whom the procedure was considered to have failed, 41 patients underwent either a laminectomy, a microdiscectomy, or a fusion. Nineteen patients had a second percutaneous discectomy with 3 of them requiring an open procedure and 21 patients had not had any other procedures as of the report date. They reported 2 cases of discitis, one psoas hematoma, and one patient who had a vasovagal attack. Further, of the 44 patients who underwent a subsequent open procedure, 30 had free disc fragments that were not seen on preoperative imaging studies, 6 patients had spinal stenosis, one patient had a vertebral fracture, and the remaining patients had bulging discs with no evident cause for failure. These authors believe that APLD is not appropriate for all patients with a herniated disc

and should be used only for those patients with a contained herniation, that is, with the annulus and/or posterior longitudinal still intact and without evidence of migration from the disc space. Nearly 70% of patients in whom the treatment failed and who subsequently had surgery had unrecognized sequester of free disc fragments. This remains the major inherent limitation of this approach to the treatment of herniated lumbar discs. However, with advances in imaging, this may not be a problem in modern times. They also described that the size of the herniation appears to be an important criterion in excluding patients with free fragments. They concluded that percutaneous discectomy is more efficacious for small-to-moderate sized disc herniations similar to chemonucleolysis (514). This study also included extensive conservative management and all the patients were facing open surgery as they failed to respond to conservative management. Thus, natural healing and improvement is not an issue.

Maroon and Allen (506) examined the results of 1,054 patients who had undergone APLD procedures from January 1987 to February 1988 at 35 U.S. hospital facilities. The primary goal of the study was to determine the net clinical results of the procedure when performed by private, non-academically based surgeons. Further, they also evaluated the impact of multiple factors on clinical results including the patient's age, gender, disc level, amount of material resected, and surgeon training. Of the 1,054 cases done, 865 or 82.9% were considered to have a successful result, both by the treating physician and the patient. There was no significant correlation between the disc level and success. However, the primary cause of the failure was the preoperative non-discernible presence of free disc fragments. Further, no other pathology appeared to impact the failure rate. They removed an average of 2.4 grams of nucleus pulposus material from the disc ranging from 1 gram to 8 grams with no correlation with the outcomes. They reported only 3 postoperative complications in the study group with 2 patients having disc infections and one patient with muscular hematoma with an overall complication rate of 0.002%.

Teng et al (507) utilizing an APLD technique with Teng's instrument, which was modified from Onik's instrument in China, reported results of 1,582 APLD procedures in a prospective study in 10 independent hospitals from 1992 to 1994. The success rate was 83% at one year, which was significantly greater for protrusion versus sequestration (86% vs 72%, $P < 0.01$); for

back pain alone versus leg and back pain (89% vs 80%, $P < 0.005$); for duration of symptoms less than 2 years versus more than 2 years (85% vs 79%, $P < 0.005$); and for age younger than 60 years versus older than 60 years (84% vs 76%, $P < 0.01$). They also reported a 77% success rate among post surgical patients in 17 of 22 patients. The only complication was discitis (0.06%) in 9 patients. They reported that good results were obtained in patients considered to have contraindications by other authors. These contraindications included extrusion/sequestration type of herniation, long-term duration of the symptoms, old age, calcification of longitudinal ligaments, interspaces and disc, and previous surgical discectomy. They also reported that patients who had only low back pain with little or no leg pain had significantly better results than those with classical sciatica in contradiction to reported indications and other reports. They recommended that patients who failed to respond to conservative treatment for 2 months or longer should be considered as candidates for APLD, even with low back pain, as long as the clinical findings correlate with the images. Further, 33% of the patients had more than one level involved with similar results, either with a multilevel treatment or a single level treatment. However, they felt that the superior results were due to wider and more effective disc removal with the Teng Nucleotome.

Davis et al (505) reported results in 518 compensation patients, elderly patients, and patients with previous surgery who were treated successfully using percutaneous discectomy on an outpatient basis. They reported no intraoperative or postoperative complications. A total of 439 patients or 85% were treated successfully with a 15% failure rate. The successful criteria included at least moderate to complete pain relief, not receiving narcotic medications, a return to the pre-injury functional status, and to minimize the bias of the investigators, the patient had to be satisfied with the results of the procedure. The results showed that in 427 non-compensation cases, there was a 87% success rate with a 13% failure rate, whereas of 91 compensation patients, the success rate was 74%. Of the 79 patients considered failures, 33 were found to have extruded disc fragments outside the interspace with subsequent microdiscectomy and successful results. Five patients had spinal stenosis sufficient to deny pain relief from the percutaneous discectomy, and later, surgery was successfully performed. The 41 patients who failed and later underwent extensive diagnostic investigation were either found to have no sufficient anatomic

explanation for their pain or refused further surgery and were considered failures. In addition, there were 44 patients in the original group of 518 who had previous laminectomy for a herniated disc. The results 6 months after surgery revealed 40 of these patients were successful, and 4 were failures, undergoing further open surgery. Among the patients over the age of 60 years, a successful result was obtained in 70% of the patients. Of all successfully treated patients, 70% returned to work in less than 2 weeks. They reported no intraoperative or postoperative complications, specifically with no disc space infection, no nerve damage, no vascular damage, and no damage to the dura. The average amount of disc material removed by the procedure was 2.1 gram.

Bernd et al (513) reported the results of 238 patients operated by APLD between 1988 and 1990. They had a written questionnaire response of 76.4% with a mean follow-up of 2.5 years. Overall, 60% reported pain relief and 52% were satisfied with APLD. The only significant parameters for improvement in condition and pain relief was age, where patients younger than 41 did better. Risk factors for re-operation were a positive Lasègue's sign and over 41 years of age. Patient satisfaction was significantly higher for patients without sensory deficit preoperative.

Grevitt et al (503) treated 137 patients with symptomatic lumbar disc prolapse by APLD. At a mean follow-up of 55 months, of those 72% reported an excellent or good result when reviewed at one year follow-up. There was no correlation between the success rate and the volume of disc material removed.

Shapiro (502) provided long-term follow-up results of 57 patients undergoing APLD. All 57 patients had unilateral sciatica with a mean follow-up period of 27 months, ranging from 6 to 45 months, 33 patients, or 58%, showed improvement in their sciatica, but only 3 (5%) were completely pain free. Of the 17 patients presenting with recurrent sciatica, 11 patients have undergone microdiscectomy, with 8 showing improvement. They removed on average 3.5 grams of disc material without any significant complications.

Marks (512), using a relatively novel approach, evaluated the role of percutaneous discectomy as a surgical option for treating lumbar internal disc derangement. One hundred three patients with low back pain with or without radiation to one or both lower extremities and an unsuccessful rigorous trial of conservative care underwent APLD. Internal disc derangement was defined either by discographic fis-

suring of the annulus with pain production and/or desiccation on MRI with or without disc bulging, protrusion, or herniation, in combination with intractable back or leg pain or both. The overall subjective rating was excellent in 33%, good in 30%, fair in 20%, and poor in 17%. Of patients less than 45 years old, 65 patients had an excellent or good subjective outcome, compared with 54% of patients 46 and older. The factors of gender, levels of disc surgery involved, and workers' compensation status had no statistically significant effect on the subjective rating outcome. For patients receiving workers' compensation, 55% returned to work at the same level, and 27% of patients returned to lighter duty work, which compared similarly to patients not receiving workers' compensation. Regression analysis of all factors found that age was a statistically significant factor ($P = 0.367$). Of the 17 patients whose results were rated as poor, 10 required subsequent surgery for continued symptoms.

Bonaldi et al (508) evaluated a total of 234 patients treated by percutaneous discectomy at 237 levels and followed-up between 11 months and 3 years 4 months who showed an overall success rate of about 75%. In a subgroup, 112 of these patients were checked for a second time and the clinical results remained consistently good even 24 months after surgery. In a special group of 28 patients who complained only of low back pain, percutaneous discectomy achieved a success rate of 85.7%. Complications consisted of one disc infection which cleared without clinical or radiological sequelae (0.26%).

Degobbis et al (509), between October 1989 and December 2003, performed 506 automated percutaneous nucleotomies according to Onik for the treatment of lumbar disc herniation. The survey of 50 reviewed cases after evaluation of the subjective and objective clinical pictures according to the Cabot method allowed them to come to the conclusion that percutaneous methodology is suitable to relieve damaged discs from compression. It is also well accepted by patients because it is not too traumatic, it requires short-term hospitalization, presents no risk of postoperative fibrosis, and does not create complications for the eventual traditional operation when unsuccessful. It is extremely important to accurately select the candidates, keeping in mind the original indications given by Onik for percutaneous discectomy for which—in case of contained disc herniation—leg pain (sciatalgia) is more severe than low back pain affecting the lumbar region.

8.1.3 Cost Effectiveness

No cost effectiveness studies are available for APLD.

8.1.4 Indications

Indications of percutaneous mechanical disc decompression include the following:

- 1) Unilateral leg pain greater than back pain.
- 2) Radicular symptoms in a specific dermatomal distribution that correlates with MRI findings.
- 3) Positive straight leg raising test or positive bow-string sign, or both.
- 4) Neurologic findings or radicular symptoms.
- 5) No improvement after 6 weeks of conservative therapy.
- 6) Imaging studies (CT, MRI, discography) indicating a subligamentous contained disc herniation.
- 7) Well maintained disc height of 60%.

8.1.5 Safety and Complications

Complications of percutaneous discectomy include nerve injury, infection, bleeding, damage to the adjacent endplate, the development of spinal instability, and/or the potential for disc space collapse with associated progressive degenerative changes.

8.1.6 Level of Evidence

The summary of results of eligible studies of APLD included in the systematic review by Hirsch et al (494) is illustrated in Table 20.

The indicated level of evidence based on USPSTF criteria (30) is Level II-2 for short- and long-term relief.

8.1.7 Recommendation

The recommendation is 1C/strong recommendation based on Guyatt et al's (34) criteria for APLD.

8.2 Percutaneous Lumbar Laser Discectomy (PLLD)

Percutaneous lumbar laser discectomy or PLLD is an alternative to the standard open discectomy treatment. Laser energy is used to reduce pressure by vaporizing a small volume of the nucleus pulposus. It is hypothesized that the change in pressure between the nucleus pulposus and the peridiscal tissue causes retraction of the herniation away from the nerve root (490,491,495).

8.2.1 Effectiveness Assessment

Based on the systematic review by Waddell et al (492) there is no acceptable evidence for laser discecto-

Table 20. Summary results of eligible studies of automated percutaneous lumbar discectomy.

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Pain Relief	Results
				> 12 mos.	Long-term > 12 mos.
Revel et al (498)	RA	70	69 APLD 72 Chemonucleolysis	37% APLD 66% Chemonucleolysis	N
Shapiro (502)	O	55	57	58%	P
Grevitt et al (503)	O	70	137 (115 remained at final follow-up interview)	72%	P
Onik et al (504)	O	68	506	75%	P
Davis et al (505)	O	59	518	85%	P
Maroon & Allen (506)	O	54	1,054	85%	P
Teng et al (507)	O	71	1,582	83%	P
Bonaldi et al (508)	O	58	234	75%	P
Degobbis et al (509)	O	55	50	NA	NA
Marks (512)	O	66	103	63%	P
Bernd et al (513)	O	68	238	60%	P

RA = randomized; O = observational; P = positive; N = negative; N/A = not available

Adapted from Hirsch JA et al. Automated percutaneous lumbar discectomy for the contained herniated lumbar disc: A systematic assessment of evidence. *Pain Physician* 2009; 12:601-620 (494).

my. However, Singh et al (495) in a systematic review of current evidence, which included observational studies, indicated the level of evidence for PLLD as Level II-2 for short- and long-term relief. The evidence was based on multiple observational studies (515-524).

8.2.2 Descriptive Characteristics

Relevant studies evaluating the effectiveness of laser disc decompression included 15 studies (515-529). There were no randomized trials. Of these, 10 studies (515-524) met PLLD methodologic quality assessment criteria for evidence synthesis.

Choy (515) conducted a non-randomized, non-blinded study in 518 patients in a 12-year period using PLDD as the only treatment modality. The overall success rate ranged from 75% to 89% with a complication rate of less than 1%.

Nerubay et al (516) in a prospective study of 50 patients with low back and radicular pain caused by an L4-L5 protruded disc were treated by percutaneous laser nucleolysis with a carbon dioxide laser. The follow-up ranged from 2 to 5 years, and all the patients were evaluated clinically and by imaging with CT scans and magnetic resonance images before and after the procedure. They concluded that laser disc decompression opens up new options in the treatment of discogenic pain, but it is still an experimental procedure.

Ascher (517) embarked on a project to determine the feasibility of treating carotid artery stenosis with the laser and the clinical results of recanalizing peripheral arteries as a by-product of these studies. In addition, they performed a 4-year follow-up of nearly 300 percutaneous disc denaturations in sciatic pain patients and concluded that both methods minimize traditional surgical procedures.

Casper et al (518) concluded that laser-assisted disc decompression appears to be a viable treatment modality for symptomatic, non-sequestered lumbar disc herniation recalcitrant to conservative treatment and may represent a more cost-effective and safer alternative to traditional surgical procedures.

Botsford (519) treated 90 patients with PLDD which were retrospectively reviewed to determine which of the 4 most commonly performed lumbar imaging exams, when abnormal, correlated with a successful outcome. Overall MacNab criteria improvement occurred in 73.3% of PLDD-treated patients. An abnormal CT discogram correlated with PLDD success in all patients treated (100%). An abnormal MRI, CT, or myelogram correlated with success in 75% or less

of patients treated. The theoretical reasons for the superiority of CT discography are discussed and the diagnostic potential of all major lumbar imaging modalities is reviewed.

Knight and Goswami (520) sought to determine the outcome of laser disc decompression and laser disc ablation in the management of painful degenerative disc disease with or without associated disc prolapse. Non-endoscopic percutaneous laser disc decompression was performed under x-ray control via the posterolateral approach with side-firing probes. All patients with chronic back pain who had reproduced pain during discography of a nature, pattern, and distribution similar to what they experienced normally were included in the study. A total of 52% of the patients demonstrated a sustained significant clinical benefit, with an additional 21% in whom functional improvement was noted. Long-term benefit of the laser disc ablation and decompression for discogenic pain suggests a mechanism other than principally mechanical as a cause of chronic back and sciatic pain.

Grönemeyer et al (521) described the long-term effect of image-guided PLDD. They concluded that image-guided PLDD is an effective and secure method to treat contained herniated lumbar disks. Advantages of the procedure include the minimally invasive approach on an outpatient basis and the low complication rate.

Zhao et al (522) in a non-randomized concurrent controlled trial treated patients with lumbar disc herniations by PLDD and evaluated the effects of PLDD in releasing pain and improving lumbar function after operation. They concluded that PLDD is a convenient, safe, and reliable procedure in treating lumbar disc herniation because of its high success rate, satisfactory results, and fewer complications.

Tassi (523) analyzed the neurosurgical results of 500 patients treated with microdiscectomies and 500 patients treated with PLDD. In the microdiscectomy group, 85.6% of patients (n = 428) had a good or excellent outcome; in the percutaneous laser disc decompression group, 83.8% of patients (n = 419) had a good or excellent outcome. Complications occurred in 2.2% (n = 11) in the microdiscectomy group and in 0% in the percutaneous laser disc decompression group. They concluded that PLDD is a safe, minimally invasive, and strong alternative treatment to microdiscectomy in patients affected by herniated discs.

Gangi et al (528) treated 119 patients with lumbar disk herniation treated with PLDD under CT and fluoroscopic guidance, 91 (76.5%) had a good or fair

response. PLDD performed with CT and fluoroscopic guidance appears to be a safe and effective treatment for herniated intervertebral disks.

8.2.3 Cost Effectiveness

No cost effectiveness studies are available for PLLD.

8.2.4 Indications

The indications for PLLD are the same as for APLD described in 8.1.4.

8.2.5 Safety and Complications

Complications of PLDD include instrument failures, nerve damage, RSD, sigmoid artery injury, anomalous iliolumbar artery injury, spondylodiscitis, and cauda equina syndrome (526,530-540).

8.2.6 Level of Evidence

Table 21 illustrates the results of percutaneous disc decompression with laser-assisted disc removal and the effectiveness of the technology.

The indicated level of evidence based on USPSTF criteria (30) is II-2 for short- and long-term relief.

8.2.7 Recommendations

The recommendation based on Guyatt et al's (34) criteria is 1C/strong recommendation for PLLD.

8.3 Nucleoplasty

PDD with nucleoplasty (coblation technology) is

performed with radiofrequency energy to dissolve nuclear material through molecular dissociation. Bipolar radiofrequency coagulation denatures proteoglycans, changing the internal environment of the affected nucleus pulposus with a subsequent reduction in intradiscal pressure (537-539). The proposed advantage of the coblation technology is that the procedure provides for a controlled and highly localized ablation, resulting in minimal thermal damage to surrounding tissues. The bi-products of this non-heat driven process are elementary molecules and low-molecular weight inert gases, which escape from the disc via the needle (537,540-542).

8.3.1 Effectiveness Assessment

Gibson and Waddell (490) concluded that multiple minimally invasive decompression techniques including coblation therapy should be regarded as research techniques. Manchikanti et al (497) in a systematic review showed the indicated evidence for nucleoplasty as Level II-3 in managing predominantly lower extremity pain due to contained disc herniation. In this systematic review, 5 studies met inclusion criteria (539,543-546).

8.3.2 Descriptive Characteristics

Mirzai et al (545) published the results of nucleoplasty in 52 consecutive patients with lumbar herniated discs. Of these, 34 had one disc treated and 18 had 2 discs treated. All procedures were considered technically successful, with the full treatment proto-

Table 21. Results of percutaneous disc decompression with laser assisted disc removal.

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Pain Relief > 12 mos.	Results
Knight & Goswami (520)	O	69	576	56%	P
Bosacco et al (524)	O	58	63	66%	P
Choy (515)	O	55	518	75%	P
Zhao et al (522)	O	80	139	82%	P
Tassi (523)	O	61	419	84%	P
Grönemeyer et al (521)	O	75	200	73%	P
Nerubay et al (516)	O	55	50	74%	P
Ascher (517)	O	50	90	74%	P
Botsford (519)	O	63	292	75%	P
Casper et al (518)	O	72	100	87%	P

O = observational; P = positive; N/A = not applicable.

Adapted from Singh V et al. Percutaneous lumbar laser disc decompression: A systematic review of current evidence. *Pain Physician* 2009; 12:573-588 (495).

col carried out to completion. There were no complications associated with the procedure during follow-up periods. Among the successful patients, complete resolution of symptoms was seen in 77% of the patients at 6 months, and in 84% at the latest follow-up. Eight patients did not have any clinical resolution at 6 months, and 4 had no resolution at the latest follow-up. Two patients had to be operated on 7 and 10 days after nucleoplasty because of severe pain continuing despite clinically successful procedures. The authors felt that favorable results were probably due to strict patient selection criteria, including radicular pain greater than back pain, failure of previous medical treatment and physiotherapy, and MRI evidence of small and medium-sized contained disc herniations (less than 6 mm). Further exclusion criteria included spondylolisthesis, segmental instability, and a large (≥ 6 mm) or extruded disc herniation. They also did not perform the procedures in patients older than 60 years, with disc height less than 50% compared with the adjacent disc segment, and back pain greater than leg pain. Discography was routinely performed prior to nucleoplasty. They postulated that discography is important to diagnose the integrity of the outer annulus. They stated that if the outer annulus is compromised, it is unlikely that the patient will benefit from this procedure. However, they did not include positive concordant discography as inclusion criteria. Thus, discography was performed to evaluate the annular integrity, not to determine whether concordant pain was produced.

Of 3 studies published by Singh et al (539,542,543), 2 studies (539,543) met inclusion criteria. Singh et al (539) reported results on a group of 67 patients with chronic low back pain and leg pain of long duration. Outcomes were available in 61 patients at 6 months and 41 patients at 12 months. The average decrease in numeric pain score was 38%, from a preoperative average of 6.8, while the numerical pain rating score decreased $> 50\%$ in 59% at 6 months and 56% at 12 months. The authors reported improvement in self-reported sitting and standing tolerance. They also studied a consecutive series of 84 low back pain patients with or without leg pain (543). They reported a 34% decrease in the numerical pain rating score at 12 months. Fifteen percent of the patients unemployed before nucleoplasty returned to work after the study intervention. The authors concluded that this analysis demonstrated an encouraging outcome following nucleoplasty. Functional improvement was observed in 62%, 59%, and 60% of the patients for sitting, standing, and walking abilities,

respectively. They also showed a significant correlation between pain relief and functional improvement. Overall, 75% of patients indicated a decrease in their numeric pain scores at 12 months with a statistically significant reduction in numeric pain scores compared to baseline. A total of 54% of patients indicated pain relief of 50% or more at 12 months. Additionally, significant improvement was reported by 54%, 44%, and 49% of patients in sitting, standing, and walking abilities, respectively, at 12 months. There were no complications noted. The authors concluded that nucleoplasty is a safe and efficacious procedure for reducing discogenic low back pain with or without leg pain.

Al-Zain et al (546) evaluated 69 patients undergoing nucleoplasty with one year follow-up. The mean age of the 27 females (39%) and 42 males in this study was 42 years, age ranging from 18 to 74. The mean duration of symptoms was 30.5 months. Forty-two percent of patients were smokers and the mean body mass index was 26.3. The results showed 73% of treated patients experiencing an improvement of more than 50% in their symptoms in the early post-operative period. This was reduced to 61% at 6 months and 58% after one year. A statistically significant reduction in analgesic consumptions, disability, and occupational incapacitation resulted from treatment with nucleoplasty. They concluded that nucleoplasty is an effective therapy for chronic, discogenic back pain which results in significant reductions in levels of disability and incapacity for work as well as decreased analgesic consumption.

Marin (544) analyzed 64 patients with contained disc herniation classified into those who underwent percutaneous disc decompression using coblation technology and patients who underwent coblation-assisted microdiscectomy (CAM). All patients who presented with percutaneous disc decompression were considered candidates for open surgery, but all of them opted for the new technique. There were no contraindications. They had discogenic low back and/or leg pain and the procedure was performed on an outpatient basis. Follow-up data was of 1–2 months. Patients' gender distribution for percutaneous disc decompression was 65% (41.6) male and 35% (22.4) female with a mean age of 43 years. The average duration of pain before nucleoplasty was of 18 months and none of them had previous lumbar surgery. At 6 to 12 months, 80% of the patients demonstrated an improvement in pain scores with 75% reporting very good responses while 5% reported a good response. None of the patients were worse. Results indicated

that nucleoplasty may be an efficacious minimally invasive technique for the treatment of symptoms associated with contained herniated disc.

The results of published studies of nucleoplasty are illustrated in Table 22.

8.3.3 Cost Effectiveness

Cost effectiveness of PDD with coblation nucleoplasty has not been evaluated.

8.3.4 Indications

The indications are the same as for APLD described in 8.1.4.

8.3.5 Safety and Complications

Side effects and complications after percutaneous disc decompression with coblation technology include nerve injury, infection, bleeding, development of spinal instability, and progressive degenerative changes (547,548).

8.3.6 Level of Evidence

Based on USPSTF criteria (30), the indicated evidence for nucleoplasty is Level II-3 in managing predominantly lower extremity pain due to contained disc herniation. There is no evidence available for axial low back pain.

8.3.7 Recommendations

The recommendation based on Guyatt et al's (34) criteria is 2B/weak recommendation in managing radicular pain due to contained disc herniation. No recommendation is available in managing axial low back pain.

8.4 Mechanical High RPM Device

The Dekompressor probe is a mechanical high rotation per minute device designed to extract the

nuclear material through an introducer cannula using an auger-like device that rotates at high speeds (491,496).

8.4.1 Effectiveness Assessment

Gibson and Waddell (490) have stated that all newer alternative minimally invasive techniques should be regarded as research techniques. Singh et al (496) in a systematic review utilizing 2 observational studies (549-551) meeting the inclusion criteria showed the indicated evidence as Level III for short- and long-term relief.

8.4.2 Descriptive Characteristics

Alo et al (549,550) published the findings on the outcome of disc herniations treated with the Dekompressor in 2 publications from one study. Clinical response in an initial cohort of 50 consecutive patients with chronic radicular pain was evaluated in a randomized prospective clinical trial. Data was collected on the 6-month outcomes. Their inclusion criteria were radicular pain with contained herniation ≤ 6 mm, correlating history and physical findings, pain for > 6 months, failure of conservative therapies, good to excellent short-term relief (< 2 weeks) after a fluoroscopically guided transforaminal injection, confirmatory selective segmental spinal nerve block with 0.5 – 1.5 mL of anesthetic providing $> 80\%$ relief lasting at least the duration of the local anesthetic, and preservation of disc height ($< 50\%$ loss). They excluded patients with progressive neurological deficits; more than 2 symptomatic levels; previous open surgery at the proposed treatment level; spine instability, fracture, or tumor; pain drawing inconsistent with clinical diagnosis; and significant coexisting medical or psychological conditions. After 6 months, 74% patients reported reducing their analgesic intake, 90% reported improvement in functional status, and overall satisfaction with the therapy was 80%. After one year follow-up, the data

Table 22. Results of published evaluations of nucleoplasty.

Study	Study Characteristics	Methodological Quality Score	No. of patients	Pain Relief		Results	
				6 mos	12 mos.	Short-term relief ≤ 12 mos	Long-term relief > 12 mos
Singh et al (539)	O	62	67	59%	56%	P	P
Singh et al (543)	O	62	80	76%	77%	P	P
Marin (544)	O	61	64	80%	80%	P	P
Mirzai et al (545)	O	77	52	85%	88%	P	P
Al-Zain et al (546)	O	74	69	61%	58%	P	P

O = Observational; P = Positive

Adapted and modified from Manchikanti L et al. A systematic review of mechanical lumbar disc decompression with nucleoplasty. *Pain Physician* 2009; 12:561-572. (497).

was published on 42 patients (54 levels). They noted an average reduction in pre-operative pain score (VAS) of 65%. Also noted was a reduction in the analgesic intake in 79% and functional improvement in 91% of patients.

Lierz et al (551) evaluated percutaneous lumbar discectomy using the Dekompressor system under CT guidance. They evaluated 64 patients with discectomy at 76 lumbar levels. Follow-up data after 12 months were obtained for all patients. The average reported pain level as measured by VAS was 7.3 before the procedure and 2.1 after 12 months. Before the procedure, 61 patients (95%) used opioid or non-opioid analgesics regularly; after one year a reduction in analgesic use was seen in 51 patients (80%). None of the patients reported procedure-related complications. They concluded that when standardized patient selection criteria is used, treatment of patients with radicular pain associated with contained disc herniation using the Dekompressor can be a safe and efficient procedure.

Amoretti et al (552) published results of a clinical follow-up of 50 patients treated by percutaneous lumbar discectomy using the Dekompressor. Although it is not a blinded and randomized study, the data collection was thought to be good. There were clearly defined inclusion and exclusion criteria. They included patients with "lumbar sciatica of disco-lumbar origin" secondary to a herniated disc documented by an MRI. Patients had undergone medical therapies such as "CT-guided infiltration" which one assumes to be a corticosteroid injection. There was no change in disc height and the discs possessed satisfactory hydration as documented by a T2 signal on MRI. They excluded patients with extruded herniations and inconsistency between MRI and clinical findings as well as other common exclusions like infection and coagulopathy. Patients being medically treated with morphine and anti-inflammatory drugs pre-operatively were also excluded from the study. Using a Dekompressor instrument under CT or fluoroscopic guidance, they per-

formed disc decompression on mainly L4-5 and L5-S1 discs with some L3-4 discs. They found that 11 patients did not respond satisfactorily to the treatment, but 39 patients were either able to suspend their medications (31 patients) or definitely reduce their medications (8 patients). The reduction in pain was found to be stabilized after about 7 days in most patients. Of the ones who responded favorably, 36 out of 50 showed > 70% relief. More importantly they noted > 70% improvement in 79% of patients with postero-lateral hernias versus 50% of patients with postero-medial hernias. However, this study failed to meet inclusion criteria as the follow-up was limited to 6 months only.

Table 23 illustrates results of published studies of Dekompressor meeting inclusion criteria.

8.4.3 Cost Effectiveness

Cost effectiveness studies were not available.

8.4.4 Indications

The indications are the same as for APLD.

8.4.5 Safety and Complications

The potential complications of Dekompressor are similar to complications reported with either APLD or nucleoplasty. However, a case of critical failure of a Dekompressor probe was reported (553).

8.4.6 Level of Evidence

Results of published studies of Dekompressor meeting inclusion criteria are illustrated in Table 23.

Based on USPSTF criteria (30), the indicated evidence for Dekompressor is Level III for short- and long-term relief.

8.4.7 Recommendation

No recommendation is provided for Dekompressor.

Table 23. Results of published studies of Dekompressor meeting inclusion criteria.

Study	Study Characteristics	Methodological Quality Score	No. of patients	Pain relief		Results	
				6 mos	12 mos.	Short-term relief ≤ 12 mos.	Long-term relief > 12 mos.
Alo et al (550)	O	52	50	74%	65%	P	P
Lierz et al (551)	O	52	64	80%	80%	P	P

O = Observational; P = positive

Adapted from Singh V. Systematic review of percutaneous lumbar mechanical disc decompression utilizing Dekompressor. *Pain Physician* 2009; 12:589-599 (496).

9.0 IMPLANTABLE THERAPIES

Spinal cord stimulation (SCS) systems and implantable intrathecal devices are frequently used in managing chronic intractable pain (2-4,78,79,158,554-568).

9.1 Spinal Cord Stimulation (SCS)

SCS is primarily implanted in the United States for FBSS and complex regional pain syndrome (CRPS) (555-568).

9.1.1 Effectiveness Assessment

Multiple systematic reviews have been performed with the first review published in 1995 (560). Taylor et al (555) concluded that the level of evidence for the efficacy of SCS in chronic back and leg pain secondary to FBSS was moderate. In another systematic study, Taylor (561) in evaluating neuropathic back and leg pain secondary to FBSS concluded that the evidence was of Grade B. A Cochrane review for SCS (557) concluded that evidence was limited for SCS for FBSS.

Frey et al (78) indicated the evidence to be Level II-1 or II-2 for clinical use on a long-term basis in relieving chronic intractable pain of FBSS.

9.1.2 Descriptive Characteristics

Frey et al (78) included 2 randomized trials (569-571) and 9 observational studies (572-580) in the evidence synthesis after methodologic quality assessment.

9.1.2.1 Randomized Trials

Kumar et al (570,571) compared SCS with conventional medical management (CMM) in patients with neuropathic pain secondary to FBSS with predominant leg pain of neuropathic radicular origin. In both groups CMM was "actively managed." By 12 months, the protocol analysis showed 48% of the SCS group and 9% of the medical management group achieving at least 50% pain relief. By 24-month follow-up, 42 out of 52 randomized patients continuing SCS reported significantly improved leg pain relief, QOL, and functional capacity; and 13 patients (31%) required a device-related surgical revision (570). At 24 months, of 46 out of 52 patients randomized to SCS and 41 of the 48 patients randomized to CMM who were available, the primary outcome was achieved by 34 (47%) out of 72 patients who received SCS as final treatment versus one (7%) of 15 for CMM. The authors concluded that compared with the medical management group, the spinal cord group experienced improved leg and back

pain relief, QOL, and functional capacity, as well as greater treatment satisfaction. The compliance rate in conventional treatment was low (33%), which raised questions by the authors of the ACOEM guidelines (571). Medical management was criticized as being unstructured, with numerous potential confounders and utilization co-interventions (581). They also criticized the sharp reduction in the number who achieved the 50% pain relief target at 12 months, suggesting that the benefits, even if real, are not long-term. However, even at 24-month follow-up, 34 of 72 patients (47%) who received SCS as their final treatment achieved the primary outcome compared to one of 15 or 7% for CMM ($P = 0.02$). Overall improvement in leg pain relief and improvement in functional capacity were more robust ($P = 0.0001$ and $P = 0.0002$). Further, some of the criticisms related to inherent difficulties including lack of blinding which is difficult in SCS because of the paresthesia associated with treatment. The study did not blind the outcome assessors and even though they reported that the groups were comparable, back pain scores in the control group were higher.

North et al (569) presented results of SCS versus repeated lumbosacral spine surgery for chronic pain in an RCT. Of the 99 patients from a consecutive series invited to participate in the study, 60 candidates consented to randomization and 50 proceeded to a treatment. The 39 patients who refused randomization chose to undergo reoperation. For an average of 3 years postoperatively, disinterested third party interviewers followed 50 patients selected for reoperation by standard criteria and randomized to SCS or reoperation. If the results of the randomized treatment were unsatisfactory, patients were allowed to cross over to the alternative. Success was based on self-reported pain relief and patient satisfaction. Among 45 patients (90%) available for follow-up, SCS was more successful than reoperation (9 of 19 patients versus 3 of 26 patients, $P \leq 0.01$). Patients initially randomized to SCS were significantly less likely to cross over than were those randomized to reoperation (5 of 24 patients versus 14 of 26 patients, $P = 0.02$). Patients randomized to reoperation required increased opiate analgesics significantly more often than those randomized to SCS ($P \leq 0.025$). However, other measures of activities of daily living and work status did not differ significantly. They concluded that SCS is more effective than reoperation as a treatment for persistent radicular pain after lumbosacral spine surgery and, in the great majority of patients, it obviates the need for reoperation. In sum-

mary, long-term success rates at 2.9 ± 1.1 years were 47% for SCS versus 12% for reoperation ($P \leq 0.01$). Some have criticized the study because reoperation is essentially a repeat of the same treatment, which in critics' opinions produced a potential bias in favor of the new treatment (571). However, long-term follow-up showed 15 of 29 in the successful group for SCS, while it was only 3 of 16 in the reoperation group.

Both studies showed greater patient satisfaction with SCS treatment than with control treatment either in terms of satisfaction with pain relief and agreeing with the treatment or in terms of crossover to alternative treatment.

9.1.2.2 Observational Studies

Table 24 shows characteristics of observational studies of SCS.

9.1.3 Cost Effectiveness

Cost effectiveness of SCS for FBSS has been performed (563,564). Taylor et al (563) found that initial health care acquisition costs were offset by a reduction in post implant health care resource demands and costs. Mean 5-year costs were \$29,123 in the intervention group compared to \$38,029 in the control group for FBSS.

Bala et al (564) in a systematic review of cost effectiveness of SCS for patients with FBSS showed that SCS is more effective and less costly in the long-term, but there is an initial high cost associated with device implantation and maintenance long-term. Kumar et al (566) showed the mean cost for SCS therapy over 5 years was less than conventional pain therapy. North et al (567) performed cost effectiveness and cost utility analysis based on a randomized, controlled trial (574), with a 3.1 year follow-up. The mean per-patient cost was US\$31,530 for SCS versus US\$38,160 for reoperation (intention to treat).

9.1.4 Safety and Complications

The most common adverse event reported in the literature is lead migration followed by lead fracture and infection at the incision site of implantable pulse generator (IPG) or in the surgical pocket (568,582-586). Overall up to 34% of SCS patients may experience an adverse event (556).

9.1.5 Indications

While multiple indications are available, the indications in the United States are related to neuropathic pain of FBSS or CRPS.

9.1.6 Level of Evidence

Table 25 illustrates effectiveness of SCS.

The indicated level of evidence based on USPSTF criteria (30) is Level II-1 or II-2 in managing neuropathic pain of post-lumbar surgery syndrome.

9.1.7 Recommendations

Based on Guyatt et al's (34) criteria, the recommendation is 1B or 1C/strong recommendation for spinal cord stimulation for clinical use on a long-term basis.

9.2 Implantable Intrathecal Drug Administration Systems

Continuous infusion of intrathecal medication is used for control of chronic, refractory, malignant, and non-malignant pain (2,79,158,544,554,587-593).

9.2.1 Effectiveness Assessment

Turner et al (558), in a systematic review of effectiveness and complications of programmable intrathecal opioid delivery systems for chronic non-cancer pain, found improvement in pain among patients who received a permanent intrathecal drug delivery system. Recently, Patel et al (79) showed the level of evidence for intrathecal infusion systems of either II-3 or III. There were 4 observational studies which met inclusion criteria (587-590).

9.2.2 Descriptive Characteristics

In 1996, Winkel Müller & Winkel Müller (587) evaluated the long-term effects of continuous intrathecal opioid treatment for chronic pain of nonmalignant etiology. The follow-up period was from 6 months to 5.7 years, with only 36 of 120 patients followed up for > 4 years. The deafferentation pain and neuropathic pain showed the best results on a long-term basis with 62% to 68% reduction in pain. Thirty-one or 25.8% of the 120 cases were considered treatment failures. Throughout the follow-up period, 74.2% of the patients benefited from the intrathecal opioid therapy, with an average pain reduction after 6 months of 67.4% and, as of the last follow-up examination, it was 58.1%. Ninety-two percent of the patients were satisfied with the therapy and 81% reported an improvement in their QOL.

Although the authors describe a lengthy follow-up period ranging from 6 months to 5.7 years, it is not clear how many patients had been followed up for more than 12 months. The last follow-up period is mentioned in several of the parameters but is not

Table 24. Characteristics of observational studies of spinal cord stimulation.

Study/ Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Positive = relief > 12 months
Van Buyten et al 2001 (575)	254 patients Over a 10-year period in a single center, 254 patients were subjected to trial period of SCS with an externalized pulsed generator. Of these, 217 of the patients showed satisfactory results justifying permanent implantation of the SCS system. The results were available to an independent physician in 153 patients.	SCS with externalized pulse generator	MPQ, VAS, QOL, sleep disturbance, global patient assessment, pain medication intake, and complications.	68% of the patients rated the result of the treatment as excellent to good after an average follow-up of almost 4 years. The resumption of work by 31% of patients who had been working before the onset of pain supports these positive findings.	Positive
Kumar and Toth 1998 (572)	Of the 221 patients with SCS for post laminectomy pain, 182 patients were considered for analysis of the effectiveness of SCS in post laminectomy pain, 153 men and 29 women were included.	All patients underwent trial stimulation of 3 to 7 days. Of the 182 patients included in the study, 165 patients (91%) experienced satisfactory initial pain relief and had their systems internalized.	Pain relief graded as poor, good, and excellent. 1) Greater than 75% relief (excellent). 2) 50% to 75% relief (good). 3) Less than 50% relief (poor).	Minimum follow-up period was 8 months and the maximum follow-up period was 204 months. Average follow-up was 8.8 ± 4.5 years. After an average 8.8 ± 4.5 years of follow-up, 87 internalized patients (53%) continued to receive satisfactory pain relief. Of the 87 patients that were considered successful, 44% reported excellent pain relief and 56% reported good pain relief. Thus, out of the 182 patients in this study 48% of patients experienced 50% or greater long-term relief with SCS.	Negative
De La Porte and Van de Kelft 1993 (574)	78 patients with post laminectomy syndrome underwent trial stimulation, of these, 64 underwent an internalization of the system and they were followed every 3 months for a mean follow-up period of 4 years (range 1-7 years).	SCS	Pain relief graded as excellent, good, fair, poor, worse. Excellent with pain relief of 75% to 100%. Good 50% to 74% pain relief. Fair 25% to 49% pain relief. 0% to 24% poor pain relief.	Thirty-seven or 58% of the patients reported satisfactory relief of good to excellent at one-year. At final follow-up 35 patients (58%) continued to experience at least 50% of pain relief at the latest follow-up. Fifty-eight patients (90%) were able to reduce their medication, 39 patients (61%) increased. Fifty-three patients (83%) continued to use their device at the latest follow-up.	Positive
Devulder et al 1997 (573)	69 patients with chronic FBSS received SCS. All patients underwent trial stimulation over a period of 2 weeks, however data is not available on trial to permanent stimulation.	SCS	Pain relief, return to work, concomitant use of pain killing drugs. Very good relief more than 80% relief. Almost very good pain relief, 50% to 80% relief. Good relief 50%. Little relief 30% to 50%. Poor relief less than 30%.	Forty-three of 69 (77%) patients continued with the therapy and obtained good pain relief. Ten patients obtained better pain relief than during the trial procedure. Eleven patients have returned to work. The application of SCS cost on an average \$3,660 per patient per year.	Positive

Therapeutic Interventions in Managing Chronic Spinal Pain

Table 24 (cont.). *Characteristics of observational studies of spinal cord stimulation.*

Study/ Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Positive = relief > 12 months
North et al 1991 (576)	A series of 50 patients with FBSS averaging 3.1 previous operations, who underwent spinal cord stimulator implantation.	SCS	Successful outcome was defined as 50% sustained relief of pain and patient satisfaction with the result, improvement in activities, return to work, reduction or elimination of analgesic intake.	Successful outcome was recorded in 53% of the patients at 2.2 years and in 47% of patients at 5 years postoperatively. 10 of 40 (25%) patients who were disabled preoperatively returned to work. Improvements in activities of daily living were recorded in most patients for most activities. Most patients reduced or eliminated analgesic intake.	Positive
Dario 2001 (577)	49 patients were included in the study from 1992 to 1997. 44 patients with 20 patients treated medically and 24 patients who did not respond to medical therapy, were treated with SCS implant, and 5 patients underwent further spine surgery.	1) Medical management with other interventions; 2) SCS; 3) Repeat surgery	VAS, pain disability index PDI, Oswestry scales, leg pain, back pain, work status or daily activities, drug side effects, and use of analgesic medications. Follow-up ranged from 24 to 84 months with a mean of 42 months.	All but 2 patients treated with SCS demonstrated good results for their leg pain (17 of 24 or 71%); but not for back pain. 40% of the patients treated medically demonstrated good results on leg and low back pain. In other cases, good results were transitory and several therapeutic courses were necessary.	Positive
De La Porte and Siegfried 1983 (578)	94 patients suffering from low-back pain, with or without spread into the lower extremities.	SCS	Working capacity, and changes in medication, subjective improvement.	The long-term results, based on a four-year follow-up, reveal a 60% subjective improvement of pain, a 40% substantial reduction of medication, and a 26% increase in working capacity.	Positive
Burchiel et al 1996 (579)	219 patients were entered at 5 centers throughout the United States. 45 patients or 64% of the sample included FBSS.	One hundred eighty-two patients were implanted with a permanent stimulating system. At the time of this report, complete 1-year follow-up data were available on 70 patients, 88% of whom reported pain in the back or lower extremities.	The average pain VAS, the MPQ, the Oswestry Disability Questionnaire, the Sickness Impact Profile, and the Back Depression Inventory. Overall success of the therapy was defined as at least 50% pain relief and patient assessment of the procedure as fully or partially beneficial and worthwhile.	All pain and quality-of-life measures showed statistically significant improvement during the treatment year. Therapy was shown in 55% of patients on whom 1-year follow-up was available. Complications requiring surgical intervention were reported by 17% (12 of 70) of patients. Medication usage and work status were not changed significantly.	Positive
Ohnmeiss et al 1996 (580)	40 patients with intractable leg pain with FBSS.	SCS	Sickness Impact Profile, VAS scores, pain status, walking, and overall lifestyle changes. Primary data collection periods were preoperative, 6 week after, and 12- and 24-month follow-up.	Significant improvements were shown in leg pain, sickness impact profile, walking capacity, overall lifestyle, and narcotic intake at 12- and 24-month follow-up in 70% of the patients.	Positive

Adapted from Frey ME et al. Spinal cord stimulation for patients with failed back surgery syndrome: A systematic review. *Pain Physician* 2009; 12:379-397 (78).

clearly defined. Based on the review of the data, it appears that 36 patients received intrathecal opioid medications for a period of more than 4 years. Further, there were multiple complications with undesirable incidents and failures. They removed 25 pumps for various reasons. Twenty-six percent of the cases were considered as treatment failures. The overall success rate in 89 of the 120 patients benefiting from continuous opioid therapy over an observation period of 0.5 to 5.7 years is highly variable.

Roberts et al (588) collected data for intrathecal opioid administration in chronic non-cancer pain in 88 patients, out of which 67 had returned the questionnaires. The majority of the patients had failed lumbar spine surgery syndrome (63%). The majority of the patients (82%) reported pain relief greater than 50% and an increase in their activity levels with a significant reduction in their oral medication intake. They reported difficulties with the system were high, and 40% of the patients required at least one surgical procedure to correct a technical problem

Deer et al (589) compared the effectiveness of a combination of bupivacaine with opioids and opioids alone. The majority of the patient population was suffering from non-cancer pain secondary to post laminectomy syndrome. Patients served as their own comparison arm as they were on opioid alone prior to the inclusion of bupivacaine. Inclusion criteria were VAS more than 6 on at least 3 consecutive visits while on opioid alone. All but one patient experienced some reduction in pain as well as need for opioids via other routes. The authors concluded that in patients treated with intrathecal opioids, the addition of bupivacaine may improve outcomes. Side effects were rare and there was no evidence of neurological sequelae from the addition of bupivacaine to opioids via intrathecal infusion devices.

Thimineur et al (590) evaluated the long-term outcome of intrathecal opioid therapy in chronic non-cancer pain prospectively and included 2 comparative groups to improve the understanding of the selection criteria and relative severity of intrathecal pump recipients. Data analysis suggests the study group of pump

Table 25. Results of published studies of the effectiveness of spinal cord stimulation in post lumbar surgery syndrome.

Study	Study Characteristics	Methodological Quality Scoring	Patients	Pain Relief		Results	
				≤ 12 mos.	> 12 mos.	Short-term ≤ 12 mos.	Long-term > 12 mos.
Kumar et al (570)	RA	55	SCS=52 CMM=48	48% vs 9%	58% vs 17%	P	P
North et al (569)	RA	56	SCS=24 Reoperation=26	SCS 9/19 Reoperation 3/26	SCS 9/19 Reoperation 3/26	P	P
Van Buyten et al (575)	O	53	254	-	68%	P	P
Kumar and Toth (572)	O	58	182	-	48%	P	N
De La Porte and Van de Kelft (574)	O	56	78	-	58%	P	P
Devulder et al (573)	O	56	69	-	77%	P	P
North et al (576)	O	62	50	-	53%	P	P
Dario (577)	O	56	49	-	71%	P	P
De La Porte and Siegfried (578)	O	50	94	-	60%	P	P
Burchiel et al (579)	O	57	219	-	55%	P	P
Ohnmeiss et al (580)	O	57	40	-	70%	P	P

RA = randomized; O = observational; SCS – spinal cord stimulation; CMM – conventional medical management; vs = versus; P = positive; N = negative

Adapted from Frey ME et al. Spinal cord stimulation for patients with failed back surgery syndrome: A systematic review. *Pain Physician* 2009; 12:379-397 (78).

Table 26. Results of published studies of effectiveness of intrathecal infusion systems.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief		Results	
				≤ 12 mos.	> 12 mos.	Short-term relief ≤ 12 months	Long-term relief > 12 months
Winkelmüller & Winkelmüller 1996 (587)	O	53	120	74%	74%	P	P
Roberts et al 2001 (588)	O	50	88	82%	82%	P	P
Deer et al 2002 (589)	O	53	109	NA	NA	NA	NA
Thimineur et al 2004 (590)	O	60	38 - pump 31 - non-pump	NA	NA	N	N
Shaladi et al 2007 (591)	O	55	24	100%	100%	P	P

O = observational; P = positive; N = negative; NA = not applicable

Adapted from Patel VB et al. Systematic review of intrathecal infusion systems for long-term management of chronic non-cancer pain. *Pain Physician* 2009; 12:345-360 (79).

participants had improvements in pain, mood, and function from baseline to 36 months. However, the average reductions in pain in this study were less impressive than several previous investigations. The authors did not describe the proportion of patients with significant pain relief of 50% or more. Confounding factors in this study included opioid medication administered to the recipients, along with injection treatments.

9.2.3 Cost Effectiveness

In post lumbar laminectomy syndrome, it was shown that intrathecal morphine delivery resulted in lower cumulative 60-month costs of \$16,579 per year and \$1,382 per month versus medical management at \$17,037 per year or \$1,420 per month (592).

9.2.4 Safety and Complications

The complications include post-dural puncture headache, infection, nausea, urinary retention, pruritus, catheter and pump failure, pedal edema, hormonal changes, granuloma formation, and decreased libido (554,593-604).

9.2.5 Indications

The most common indication for the use of in-

trathecal pumps is disease of the spine (554). Common specific diseases include adhesive arachnoiditis, postlaminectomy syndrome, spinal stenosis, and intractable low back and lower extremity pain.

9.2.6 Level of Evidence

The indicated evidence for intrathecal infusion systems (Table 26) is either Level II-3 or Level III, for long-term relief of chronic non-cancer pain of longer than one year based on USPSTF criteria (30).

9.2.7 Recommendations

Based on Guyatt et al's criteria (34) the recommendation for intrathecal infusion systems is 1C/strong, with proper selection criteria.

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