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ASIPP – IPM Guidelines

Comprehensive Evidence-Based Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain

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Background: Comprehensive, evidence-based guidelines for interventional techniques in the management of chronic spinal pain are described here to provide recommendations for clinicians.

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

Design: Systematic assessment of the literature.

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 at least 6 months and long-term relief was defined as longer than 6 months, except for intradiscal therapies, mechanical disc decompression, spinal cord stimulation and intrathecal infusion systems, wherein up to one year relief was considered as short-term.

Results: The indicated evidence for accuracy of diagnostic facet joint nerve blocks is Level I or II-1 in the diagnosis of lumbar, thoracic, and cervical facet joint pain. The evidence for lumbar and cervical provocation discography and sacroiliac joint injections is Level II-2, whereas it is Level II-3 for thoracic provocation discography.

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 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; for lumbar transforaminal epidural injections; for percutaneous adhesiolysis in management of pain secondary to post-lumbar surgery syndrome; and spinal cord stimulation for post-lumbar surgery syndrome.

The indicated evidence for intradiscal electrothermal therapy (IDET), mechanical disc decompression with automated percutaneous lumbar discectomy (APLD), and percutaneous lumbar laser discectomy (PLDD) is Level II-2.

Limitations: The limitations of these guidelines include a continued paucity of the literature, lack of updates, and conflicts in preparation of systematic reviews and guidelines by various organizations.

Conclusion: The indicated evidence for diagnostic and therapeutic inverventions is variable from Level I to III. These guidelines include the evaluation of evidence for diagnostic and therapeutic procedures in managing chronic spinal pain and recommendations for managing spinal pain. However, these guidelines do not constitute inflexible treatment recommendations. Further, these guidelines also do not represent "standard of care."

Key words: Interventional techniques , chronic spinal pain, diagnostic blocks, therapeutic interventions, facet joint interventions, epidural injections, epidural adhesiolysis, discography, radiofrequency, disc decompression, spinal cord stimulation, intrathecal implantable systems

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1.0 Introduction

The American Society of Interventional Pain Physicians (ASIPP) Interventional Pain Management (IPM) guidelines entitled "Comprehensive Evidence-Based Guidelines for spinal interventional techniques in the Management of Chronic Spinal Pain" are systematically developed statements to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances. These guidelines present statements of best practice based on a thorough evaluation of the evidence from published studies on the outcomes of treatment (1-6). For further information and detailed analysis, readers may review the related publications, including systematic reviews and individual articles.

1.1 Chronic Pain

Chronic pain is defined as a complex and multifactorial phenomenon with pain that persists 6 months after an injury and/or 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 pathology and may not be amenable to routine pain control methods with healing never occurring (2).

1.2 Interventional Pain Management (IPM)

The National Uniform Claims Committee (NUCC) defined IPM as the discipline of medicine devoted to the diagnosis and treatment of pain and related disorders by the application of spinal interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatments.

1.3 Interventional techniques

The Medicare Payment Advisory Commission (MedPAC) described spinal interventional techniques as minimally invasive procedures, such as needle placement of drugs in targeted areas, ablation of targeted nerves, and some surgical techniques, such as discectomy and the implantation of intrathecal infusion pumps and spinal cord stimulators (1).

1.4 Purpose

Evidence-based clinical practice guidelines for spinal interventional techniques in the management of chronic spinal pain are statements developed to improve the quality of care, patient access, treatment outcomes, appropriateness of care, efficiency and effectiveness, and achieve cost containment by improving the cost-benefit ratio (7-10).

1.5 Objectives

The objectives of the ASIPP guidelines for spinal spinal interventional techniques are to provide a set of recommendations that can support existing and future guidelines by:

1. Focusing on a range of interventions that are the essential elements of effective management of chronic spinal pain.
2. Providing strategies to manage chronic spinal pain and/or its consequences in the general populations and in workers to improve the quality of clinical care.
3. Developing methods that are sound and transparent and highlighting the areas where further research is needed by noting deficiencies in knowledge.
4. Utilizing a process which is valid, reliable, reproducible, clinically applicable, and flexible, providing clarity with a multidisciplinary process with documentation of the process in developing guidelines, along with a scheduled review.
5. Providing recommendations that are generally acceptable to a wide range of specialties and agencies.
6. Increasing compliance, dispelling misconceptions, contributing to appropriate patient expectations, and facilitating the improved relationship between patients, physicians, and payors.

1.6 Population and Preferences

The population covered by these guidelines includes all patients suffering with chronic spinal pain eligible to undergo commonly utilized and effective interventional technique(s). The treatment plan must take into consideration the evidence, patient preferences, and risk-benefit ratio.

1.7 Application

While these guidelines may be applied by any specialty, they are specifically intended for use by interventional pain physicians. These guidelines do not constitute inflexible treatment recommendations. It is expected that a provider will establish a plan of care on a case-by-case basis, taking into account an individual patient's medical condition, personal needs, and preferences, and the physician's experience. Based on an individual patient's needs, treatment different from that outlined here could be warranted. Consequently, these guidelines do not represent a "standard of care."

The goal of these guidelines is to provide patients, practitioners, regulators and payors information to determine whether the available evidence supports the notion of a "standard" for interventional techniques . "Standard" refers to what is applicable to the majority of patients, with a preference for patient convenience and ease of administration without compromising treatment efficacy or morbidity (11). It is essential to recognize the difference between "standard" and "standard of care," as utilized as a legal definition.

1.8 Rationale

Despite advances in biomedical knowledge and the highest per capita health care expenditures in the world, the quality and outcomes of health care vary dramatically across the United States (12,13). Accordingly, the trend to develop and implement research in support of evidence-based practice has been a focus of medical practice for the past decade. For example, in the modern era, the central premise is that decisions about the care of individual patients should be based on "the conscientious, explicit, and judicious use of current best evidence" (14). This means that individual clinical expertise should be integrated with the best information from scientifically based, systematic research, and should be applied in light of the patient's unique values and circumstances (15).

Towards these ends, ASIPP has provided evidence-based guidelines (7-10), methodology for evidence synthesis (16-23), systematic reviews (24-52), and critical analysis (53-55) based on a methodical critical appraisal of existing data using established and uniform criteria.

As an emerging speciality, IPM faces multiple problems which may be disproportionate compared to established medical specialities. IPM is faced with increasing utilization of effective safe techniques due to its emergent nature as well as potentially inappropriate care that may be ineffective or unsafe (56-64). The available evidence at the present time documents a wide degree of variance in the definition and the practice of medicine in general and IPM in particular (6-10,12,13,56-63). The application of spinal interventional techniques by physicians of different specialties is highly variable for even the most commonly performed procedures and treated conditions (12,13,53-64).

The data for spinal interventional techniques in the Medicare population from 1997 to 2006 shows an increase of 235% (56). The 22.2% yearly increase in expenditures in the Medicare population for IPM procedures has been even more significant from 2002 to 2006. Yet, during the same period, the U.S. population increased by 12% and the Medicare population increased by 13% as a proportion of the population (56). The number of patients receiving spinal interventional techniques increased by 169% from 1997 to 2006 (Fig. 1). This increase in utilization paralleled the rising prevalence of low back pain, advancement of new and innovative fluoroscopic injection techniques and the evolution of IPM into a distinct medical specialty (1-6,56-64).

1.9 Importance

Many of the causes of spinal pain and other chronic pain conditions are considered to be either acute recurrent problems characterized by periods of quiescence punctuated by flare-ups or chronic diseases, like diabetes or hypertension, requiring long-term treatment with ongoing care. The importance of spinal interventional techniques in managing chronic spinal pain has been established on the basis of advances in imaging, neuroanatomic findings, the development of precision diagnostic and therapeutic injection techniques, and reported non-operative treatment successes. Many guidelines, systematic reviews, Cochrane Reviews, and other articles pertaining to IPM have been published (6-10,12,24-55,65-107). However, most of these guidelines are ambiguous and may not be applicable in managing chronic spinal pain utilizing contemporary IPM. Further, there are quality issues with inclusion or exclusion of significant literature of randomized trials and observational studies.

1.10 Technology

Diagnostic and therapeutic spinal interventional techniques in the management of chronic spinal pain have been evaluated. These include facet joint interventions, sacroiliac joint interventions, epidural injections, lumbar epidural adhesiolysis, discography and intradiscal therapies, mechanical disc decompression, and implantable therapies.

1.11 Implementation and Review

The dates for implementation and review were established:

- Effective date – August 1, 2009
- Expiration date – July 31, 2012
- Scheduled review – August 1, 2011

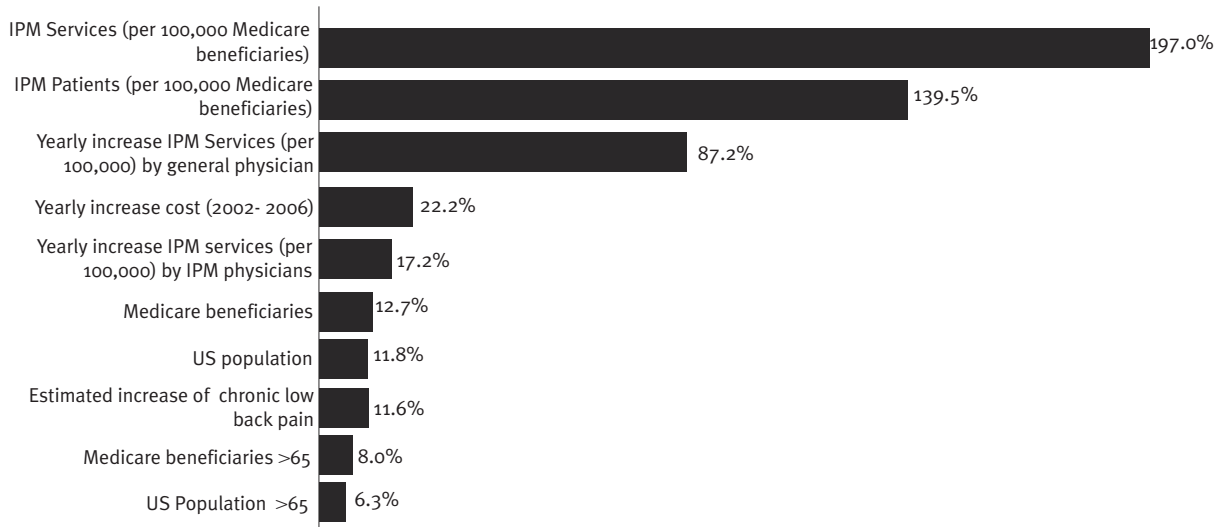

Fig. 1. *Illustration of overall growth patterns (percent) from 1997 to 2006 in Medicare beneficiaries.*

2.0 Methodology of Guideline Development

The methodology of development for the present guidelines is described in an Introduction to Evidence-Based Approach to spinal interventional techniques in the Management of Chronic Spinal Pain (1). Unanimity is strikingly absent when different guidelines are compared, while it is almst always present in individual guidelines (108). The next issue is with regards to lack of independent review, followed by conflict of interests. By favoring one test over another, or one therapy over another, guidelines often create commercial winners and losers, who cannot be disinterested in the result and who therefore must be separated from the process (108). Those who write the guidelines and those who issue them have significant conflicts of interest (109,110).

ASIPP launched the development of practice guidelines for spinal interventional techniques in the management of chronic pain in 1999 and published the first set of guidelines in 2000 (10). These guidelines were started to create a document to help practitioners by synthesizing the available evidence utilizing a combination of evidence and consensus. The synthesis of evidence, committee composition, and the development process have been revised, refined, and expanded with frequent evaluation (6-55,111-116). Further, ASIPP guidelines meet most of the criteria described by Shaneyfelt et al (117), AGREE (118), IOM (119), as well as the majority of recommendations by Sniderman and Furberg (108).

2.1 Hierarchy of Strength of Evidence

A hierarchy of strength of evidence for treatment decisions provided by Guyatt and Drummond (120) is as follows:

- N of 1 randomized controlled trial
- Systematic reviews of randomized trials
- Single randomized trial
- Systematic review of observational studies addressing patient-important outcomes
- Single observational study addressing patient-important outcomes
- Physiologic studies (studies of blood pressure, cardiac output, exercise capacity, bone density, and so forth)
- Unsystematic clinical observations

2.2 Level of Evidence

The translation of systematic reviews into practice recommendations is not straightforward. The same information can be interpreted in different ways by different panelists, resulting in the provision of different guidance (121). Often, even when there is substantial consensus about what the scientific evidence says, there are disagreements about what the evidence means for clinical practice. Conclusions about clinical effectiveness can vary widely as a result of conflicting viewpoints, such as which outcomes are the most important and which course of action is appropriate given that the evidence is imperfect. Thus, systematic reviews assess the quality of the individual studies and provide the quality and level of evidence. In developing guidelines both are important, that is the quality of evidence and the strength of recommendation which takes into account the balance of the benefits and harms that are associated with the intervention.

The evidence base that supports clinical practice guidelines is often quite limited and guideline developers must often wrestle with what to do when "the irresistible force of the need to offer clinical advice meets with the immovable object of flawed evidence" (122-124). The authors of guidelines must consider the best way to address the trade-off between rigor and pragmatism, and between adherence to evidence and broader clinical utility (122,124,125). The authors may nonetheless state their evaluation and recommendations based upon the current best available evidence.

2.2.1 Determination of Level of Evidence

Level of evidence is derived from quality assessment and the results of individual studies. While there is no universally accepted approach to presenting levels of evidence, a rigorous approach in widespread use was developed by the United States Preventive Services Task Force (USPSTF) (126). Table 1 illustrates the modiefied quality of evidence developed by the USPSTF, utilized in preparation of the present guidelines.

Methodologic quality assessment of systematic reviews is crucial for guideline preparation and grading recommendations. West et al (127) described a set of high-performing scales or checklists pertaining to systematic reviews, with 7 key domains: study question, search strategy, inclusion and exclusion criteria, data abstraction, study quality and validity, data synthesis and analysis, and funding or sponsorship (Table 2), utilized in preparation of the present guidelines.

Multiple systems are available for the quality assessment and reporting of randomized trials, observational studies, and diagnostic accuracy studies

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

I:	Evidence obtained from at least one properly randomized controlled trial or multiple properly conducted diagnostic accuracy studies.
II-1:	Evidence obtained from one well-designed controlled trial without randomization or at least one properly conducted diagnostic accuracy study of adequate size.
II-2:	Evidence obtained from at least one properly designed small diagnostic accuracy study.
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 and modified from the U.S. Preventive Services Task Force (USPSTF) (126).

Table 2. *Domains in the Agency for Healthcare Research and Quality (AHRQ) criteria for evaluating systematic reviews.*

DOMAIN	ELEMENTS*
Study question	• **Question clearly specified and appropriate**
Search strategy	• ***Sufficiently comprehensive and rigorous with attention to possible publication biases*** • *Search restrictions justified (e.g., language or country of origin)* • Documentation of search terms and databases used • Sufficiently detailed to reproduce study
Inclusion and exclusion criteria	• **Selection methods specified and appropriate, with a priori criteria specified if possible**
Interventions	• **Intervention(s) clearly detailed for all study groups**
Outcomes	• **All potentially important harms and benefits considered**
Data extraction †	• Rigor and consistency of process • Number and types of reviewers • Blinding of reviewers • Measure of agreement or reproducibility • Extraction of clearly defined interventions/exposures and outcomes for all relevant subjects and subgroups
Study quality and validity	• ***Assessment method specified and appropriate*** • Method of incorporation specified and appropriate
Data synthesis and analysis	• *Appropriate use of qualitative and/or quantitative synthesis, with consideration of the robustness of results and heterogeneity issues* • Presentation of key primary study elements sufficient for critical appraisal and replication
Results	• **Narrative summary and/or quantitative summary statistic and measure of precision, as appropriate**
Discussion	• **Conclusions supported by results with possible biases and limitations taken into consideration**
Funding or sponsorship	• ***Type and sources of support for study***

* Elements appearing in italics are those with an empirical basis. Elements appearing in bold are those considered essential to give a system a Yes rating for the domain.
† Domain for which a Yes rating required that a majority of elements be considered.

Adapted from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016. Rockville, MD: Agency for Healthcare Research and Quality, 2002. www.thecre.com/pdf/ahrq-system-strength.pdf (127).

(78,86,127-134). Various methodologic quality assessment instruments were utilized in the evidence synthesis, preparation of systematic reviews, and preparation of ASIPP-IPM guidelines.

Atkins et al (135) evaluated the quality of evidence and strength of recommendations in a pilot study group to examine the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system. They concluded that judgments about evidence and recommendations are complex with some subjectivity, especially regarding recommendations. Guyatt et al (136) published a description of grading the strength of recommendations and quality of evidence in clinical guidelines as shown in Table 3 that was utilized in the preparation of the ASIPP-IPM guidelines.

2.3 Outcomes Assessment Parameters

Short-term pain relief was defined as relief lasting of at least 6 months and long-term relief was defined as longer than 6 months, except for radiofrequency neurotomy procedures, intradiscal procedures, mechanical disc decompression procedures, and implantable therapy with spinal cord stimulation or intrathecal infusion systems, wherein up to one year relief was considered as short-term and longer than one year was considered as long-term.

3.0 Epidemiology, Scope, and Impact of Spinal Pain

Pain arising from various structures of the spine constitutes the majority of the problems in chronic pain settings. The lifetime prevalence of spinal pain has been reported as 54% to 80% (2,7-10, 137-165).

3.1 Neck Pain

The annual prevalence estimates of any neck pain among adults ranged from 12.1% to 71.5% with most estimates of annual prevalences between 30% and 50% (157,160-162,164-183). Côté et al (160) illustrated various grades of chronic neck pain with 5% of the patients suffering with grades III and IV neck pain associated with high pain intensity and disability.

Chronic neck pain resulting from whiplash associated disorders (WAD) has been described (184-186). Similarly, the incidence of compensated musculoskeletal disorders such as back and neck pain has been increasing (156,158,187-203). The annual prevalence of neck pain varies among occupations and populations (16.5%in spinning industry to 74% in crane operators (199,204). Each year neck pain is responsible for a significant burden of disability in workers (185,186,188).

Table 3. *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 (136).

While it is well known that neck pain is a common human phenomenon, what is not known is whether neck pain is likely to improve, reoccur, persist, or worsen. Most of the evidence indicates that between 50% to 75% of people who experience neck pain initially report neck pain one to 5 years later (145,174,179,205-209). Further, evidence also indicates that in adults, recovery of WAD is prolonged, with approximately 50% of those affected reporting neck pain symptoms one year after the injury (209-213).

3.2 Thoracic Pain

A review of epidemiology of thoracic pain showed the incidence ranging from 3% to 26% and prevalence ranging from 5% to 34% (162,163, 214). Despite the lower prevalence compared to low back and neck pain, the degree of disability resulting from thoracic pain disorders was similar to that of the other regions (215,216).

3.3 Low Back Pain

The annual prevalence of chronic low back pain ranges from 15% to 45%, with a point prevalence of 30% (139,159,161,217-234). The studies evaluating chronic low back pain estimated the average age related prevalence of persistent low back pain to be approximately 15% in adults and 27% in the elderly (139,161,223,224). Lawrence et al (139) estimated that among the working population (age 20 to 64), more than 26 million Americans have frequent low back pain, whereas among Americans aged 65 and older, almost 60 million have frequent low back pain. Cassidy et al (159) evaluated pain associated with disability and graded them into Grade I to Grade IV. Based on this, 11% of the patients had Grade III and Grade IV pain levels with high pain intensity and significant disability. In an extensive review of the international literature on the incidence of disabling low back pain, Nachemson (225) reported that the problem of low back pain was even greater in Canada, Great Britain, Netherlands, and Sweden, in comparison to the United States and Germany. It is estimated that 28% of the U.S. industrial population will experience disabling low back pain at some time and 8% of the entire working population will be disabled in any given year, contributing to 40% of all lost work days (220,226-231).

Remarkably, studies have shown increasing prevalence of chronic pain (147), specifically low back pain (187). Freburger et al (187) reported the rising prevalence of chronic low back pain following an evaluation of North Carolina households conducted in 1992 and repeated in 2006. The results showed an increasing prevalence of chronic impairing low back pain over the 14-year interval from 3.9% (95% CI, 3.4% – 4.4%) in 1992 to 10.2% (95% CI, 9.3% – 11.0%) in 2006. The overall prevalence of low back pain increased by 162% (an annual increase of 11.6%), across all demographic groups.

The duration of back pain and its chronicity have been topics of controversy. It is widely believed that most of the episodes will be short-lived with 80% to 90% of attacks resolving in about 6 weeks, irrespective of the administration or type of treatment, with only 5% to 10% of patients developing persistent back pain (235,236). However, this widely held belief has been frequently questioned as the condition tends to relapse and most patients will experience multiple episodes and long lasting back pain is common (187,237-259). However, Stanton et al (260) reported that the recurrence of low back pain was found to be much less common than previous estimates, ranging from 24% using 12 months as the definition of recurrence, to 33% using pain at follow-up as the definition of recurrence. Even then, this is higher than the conventionally believed proportion of 4% to 10%.

Bressler et al (261) reported a prevalence of back pain among the elderly within the community ranging from 13% to 49%; within the medical practice setting, the range was from 24% to 51%; and in the long-term care setting, the prevalence was 40%, with an overall prevalence of 27%. They suggested that the prevalence of low back pain in the elderly is not known with certainty and is not comparable with that in the younger population.

3.4 Health and Economic Impact

Spinal pain is associated with significant economic, societal, and health impact (156,175,185,222,228,262-322). Estimates and patterns of direct health care expenditures among individuals with back pain in the United States have reached $90.7 billion for the year 1998 (303). On average, individuals with back pain incurred health care expenditures about 60% higher than individuals without back pain ($3,498 versus $2,178) (309). In the United States, it was estimated that the cost of treatment in the first year after failed back surgery for pain was approximately $18,883 in 1997 (312). The majority of these costs are associated with disability compensation, lost productivity, and lost tax revenue. Disability secondary to spinal pain is enormous (174,265,293-298,303,315,316).

4.0 Neurophysiologic Basis of Spinal Pain

The birth and rise of the biopsychosocial model is credited to some difficult and important medical problems which have proven resistant to the biomedical model (323,324). Multiple disease states without a unique underlying pathoanatomic/pathophysiologic lesion have been identified, and the outcomes of treatments even when they are extensive and costly are less than ideal. Along with many of the difficult problems such as pelvic pain, facial pain, myofascial pain syndromes, and some psychiatric illnesses, persistent spinal pain (with its associated societal and health care impact in the billions of dollars) has been included in this category (13,56,58,278,280-311,325-329). The biopsychosocial model of illness was proposed by Engel in 1977 (330). The proponents of this model believe that the complex, multidimensional nature of persistent spinal pain does not lend itself to the clean reductionist program of the biomedical model. Consequently, the clinician is presented with a set of biologic and psychosocial factors, with which to explain why people have persistent spinal pain and a set of alternative tools, addressing these factors, with which to treat patients (331). However, multiple concerns related to the biopsychosocial model have been described (324). These concerns include the reliance on self-report of outcomes, the disconnection between physical pathology and self-report, and the scientific status of the biopsychosocial model.

By definition, "bio" "psycho" "social" underscores the important contribution of various factors in each of the 3 defining domains (324). The rise of the biopsychosocial models' application to spine problems is tied to the disconnection between our current understanding of spinal pathology and back pain/disability and the apparent connections between psychosocial factors and pain-disability (270,324,332-336). Historically, we may find that embracing a biopsychosocial orientation may actually hamper the development of a better understanding of many disease etiologies (270,324). While acknowledging the current shortcomings of the persistent spinal pain biomedical mode, historically, pathoanatomically based biomedical theories of causation have often worked well.

The multi-dimensional mechanism of pain and multidisciplinary management has taken different meanings for different specialties, sometimes ignoring the fundamental facts that pain is not explained by pure theories of either physical or psychological origins. Thus, pain management in some circles has reached a stage of psychosocial reductionism, which has essentially eliminated the bio part from the biopsychosocial approach, leaving "psychosocial," "psychological," or "functional" approaches.

5.0 Controlled Diagnostic Interventional Techniques

In contrast to the mixed picture provided by history, physical examination, imaging, and nerve conduction studies in non-radicular pain, controlled diagnostic blocks have been shown to determine the cause of pain in as many as 85% of the patients in contrast to 15% of the patients with other available techniques (337-339).

Precision diagnostic blocks are used to clarify multiple challenging situations, in order to determine the pathophysiology of clinical pain, the site of nociception, and the pathway of afferent neural signals.

The theoretical basis of controlled diagnostic blocks is based on the fact that if a patient genuinely has pain from a particular target structure, complete relief of that pain should be obtained consistently whenever that structure is anesthetized, and repeating the diagnostic block can increase the diagnostic accuracy by testing for consistency of response and for the effect of different aesthetic agents.

For a diagnostic block to have face validity it must be shown that the block actually does what it is supposed to do in an anatomical and a physiological sense (340). If a particular structure is said to be the target, it must be shown that the structure is anesthetized and either does or does not produce a result within the distribution of that structure. Face validity can be tested and established either by a study whose results can be replicated or by testing for face validity in each and every case. The face validity may be established by radiographic imaging with injection of a contrast agent or by a physiological approach utilizing a detectable and testable function other than pain (e.g., distal extremity temperature monitoring with a sympathetic block).

Construct validity establishes if the test actually achieves what it is supposed to achieve by measuring the extent to which a test correctly distinguishes the presence, but also the absence, of the condition that the test is supposed to detect. Construct validity measures if the test actually works or not, and how well it works (340).

For diagnostic interventional techniques , there is no conventional criterion standard, such as imaging findings, operative findings, or pathological findings. However, long-term relief may be used to provide a criterion standard for certain type of blocks. Thus, Bogduk (340) has developed testing for construct validity of diagnostic blocks by other means. Features such as the false-positive rate can be estimated by determining how often a diagnostic block is positive

in patients who should not, or demonstrably do not, have the condition in question. Once the false-positive rate is known, the specificity of the test can be derived as the complement of the false-positive rate.

One form of control involves using a placebo agent in which the protocol requires a sequence of 3 blocks. The first block must involve an active agent, in order to establish, prima facie, that the target structure does appear to be the source of pain. The other 2 agents are administered in randomized double-blind basis. Under these conditions, a true-positive response would be the one in which the patient obtained relief on each occasion that an active agent was used, but no relief when the inactive agent was used.

A second approach, most commonly utilized in the United States because it is also a more pragmatic approach, is to use comparative local anesthetic blocks. The blocks are performed on separate occasions using local anesthetic agents with different durations of action (340-348). In this approach, the consistency of response and the duration of response are tested. Failure to respond to the second block constitutes inconsistency, and indicates that the first response was false-positive. A response concordant with the expected duration of action of the agent used strongly suggests a genuine, physiologic response.

5.1 Diagnosis of Low Back Pain

Lumbar intervertebral discs, facet joints, sacroiliac joint, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the lumbar spine with resulting symptoms of low back pain and lower extremity pain (3,4). The diagnostic blocks applied in the precision diagnosis of chronic low back pain include lumbar facet joint nerve blocks, lumbar provocation discography, and sacroiliac joint blocks (40,45,46).

5.1.1 Lumbar Facet or Zygapophysial Joint Blocks

Controlled diagnostic blocks of a lumbar facet or zygapophysial joint can be performed by anesthetizing the joint via injection of local anesthetics intraarticularly or in close proximity to the medial branches of the dorsal rami that innervate the target joint.

The rationale for using facet joint blocks for diagnosis is based on the fact that lumbar facet joints are capable of causing pain and they have a nerve supply (349-360). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (29,361-373). The value, validity, and clinical effectiveness of diagnostic facet joint nerve blocks has also been illustrated by the application of therapeutic modalities based on the diagnosis with controlled comparative local anesthetic blocks (7,8,29,80,361,362,374-377).

The face validity of lumbar medial branch or facet joint nerve blocks has been established by injecting small volumes of local anesthetic and contrast material onto the target points for these structures and by determining the spread of contrast medium in the posteroanterior and lateral radiographs (340,351,352,363). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (340,346,348,363). The hypothesis that testing a patient first with lidocaine and subsequently with bupivacaine provides a means of identifying the placebo response has been tested and proven (342,347,378).

The specificity of the effect of lumbar facet joint blocks was demonstrated in controlled trials (351,352). Provocation response of facet joint pain was shown to be unreliable in one study (378). The false-negative rate of diagnostic facet joint blocks was shown to be 8% due to unrecognized intravascular injection of local anesthetic (351).

The validity of comparative local anesthetic blocks was determined not only by short-term relief with controlled diagnostic blocks, and ability to perform movements which were painful prior to the blocks, but also with application of another appropriate reference standard (long-term follow-up) as described in the literature (376). Utilizing the modified criteria established by the International Association for the Study of Pain (IASP) (379), false-positive rates varying from 17% to 50% were demonstrated. Minimal effect of sedation (380,381) and lack of influence of psychological factors on the validity of controlled lumbar diagnostic local anesthetic blocks of facet joints was demonstrated (382,383). Other variables includding prior opioid exposure were also evaluated (384-386).

5.1.1.1 Cost Effectiveness

Diagnostic lumbar facet joint nerve blocks were not evaluated for cost effectiveness systematically. However, the feasibility and cost-effectiveness of appropriately performed controlled comparative local anesthetic blocks has been described (267,338,387-389).

5.1.1.2 Safety and Complications

The common reported complications of facet joint injections or nerve blocks though rare, include hemorrhage, dural puncture, spinal cord trauma, infection, intraarterial or intravenous injection, chemical meningitis, neural trauma, paralysis, radiation exposure, facet capsule rupture, hematoma formation, steroid side effects, and epidural, subdural, or subarachnoid spread (6,29,40,361,362,390-408).

5.1.1.3 Evidence Assessment

Our search yielded 5 systematic reviews (29,40,361,362,409) and multiple other manuscripts (338,351,352,361-369,371,373,376,378,383-386,410).

The recent systematic review by Datta et al (40) utilized 7 studies (338,364,365,368,369,372,373) meeting inclusion criteria with 80% pain relief and ability to perform previously painful movements with controlled diagnostic blocks of lumbar facet joint nerves.

5.1.1.4 Prevalence

Based on the systematic review by Datta et al (40), prevalence is 21% to 40% in heterogenous population with chronic low back pain and 16% in post lumbar surgery syndrome with confidence intervals (CIs) ranging from 9% to 23% in post surgery syndrome and 14% to 53% in heterogenous population (Table 4). The overall prevalence is 31% (95% CI; 28%–33%).

5.1.1.5 False-Positive Rate

Based on Datta et al's (40) systematic review, false-positive rates of 17% to 49% are demonstrated with CIs ranging from 10% to 59% with overall false-positive rate of 30% (95% CI 27%-33%) (Table 4).

5.1.1.6 Level of Evidence

Evidence is Level I or II-1 based on the (USPSTF) criteria (126).

Rubinstein and van Tulder (411) in a best-evidence review of diagnostic procedures for low-back pain concluded that there is strong evidence for the diagnostic accuracy of lumbar facet joint blocks in evaluating spinal pain.

5.1.1.7 Recommendations

Based on the present comprehensive evaluation and other described guidelines (3,29,40,53,338,361-365,368,369,372,379,412,413), diagnostic lumbar facet joint nerve blocks are recommended in patients with suspected facet joint pain.

- Indications include:
  - Patients suffering with somatic or non-radicular low back and lower extremity pain, with duration of pain of at least 3 months.
  - Average pain levels are of greater than 6 on a scale of 0 to 10.
  - Pain is at least intermittent or continuous causing functional disability.
  - Condition has failed to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
  - Lack of preponderance of evidence of either discogenic or sacroiliac joint pain and lack of disc herniation or evidence of radiculitis.
  - No evidence of contraindications is present for the needle placement and injection of local anesthetics.
  - Presence of contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate non-steroidal anti-inflammatory drugs.
- A positive response is based on the following evidence:
  - Patient has met the above indications.
  - Patient responds positively to controlled local anesthetic blocks either with placebo control or comparative local anesthetic blocks with appropriate response to each local anesthetic (< 1 mL per level).
  - At least 80% relief as criterion standard with ability to perform previously painful movement without deterioration of the relief (i.e., extension, lateral rotation, flexion, etc.).
  - The patient's response should be recorded independently by the assessor - generally a registered nurse familiar with patient or another physician.

5.1.2 Lumbar Provocation Discography

Discography is a procedure that is used to characterize the pathoanatomy/architecture of the intervertebral disc and to determine if the intervertebral disc is a source of chronic low back pain. Implicitly, discography is an invasive diagnostic test that should only be applied to those chronic low back pain patients in whom one suspects a discogenic etiology. Discography literally means the opacification of the nucleus pulposus of an intervertebral disc to render it visible under radiogra-

Table 4. *Data of prevalence with controlled diagnostic blocks and false-positive rates in the lumbar region.*

Study	Methodological Criteria *	Participants	Prevalence	False-Positive Rate
Manchikanti et al 2002 (369)	75	120	40% (95% CI 31%–49%)	30% (95% CI 20%–40%)
Manchikanti et al 2004 (365)	75	397	31% (95% CI 27%–36%)	27% (95% CI 22%–32%)
Manchukonda et al 2007 (364)	75	303	27% (95% CI 22%–33%)	45% (95% CI 36%–53%)
Schwarzer et al 1995 # (372)	75	63	40% (95% CI 29%–53%)	NA
Manchikanti et al 2001 (338)	75	120	40% (95% CI 31%–49%)	47% (95% CI 35%–59%)
Manchikanti et al 2003 (368)	75	300	I. 21% (95% CI 14%–27%) II. 41% (95% CI 33%–49%)	I. 17% (95% CI 10%–24%) II. 27% (95% CI 18%–36%)
Manchikanti et al 2007 (373)	75	117	16% (95% CI 9%–23%)	49% (95% CI 39%–59%)
Overall		1,420	31% (95% CI; 28%–33%)	30%# (95% CI; 27%–33%)

CI = confidence interval; NA =not available; # Schwarzer et al (372) was without evaluation of false-positive rates.

*Methodologic quality assessment adapted and modified from West S, et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (127).

Adapted with permission from Datta S et al. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. *Pain Physician* 2009; 12:437-460 (40).

phy (414-416). The commonly practiced technical and evaluative components of discography include sterile needle placement into the center of the intervertebral disc (nucleus pulposus), radiopaque contrast injection to provoke pain, radiological assessment of disc morphology, and clinical assessment of the intensity and concordance of evoked pain in relation to baseline pain.

Basic and clinical studies have shown that the lumbar discs are innervated and can be a source of pain that has pathomorphologic correlates (354,417-486). Even though the specific neurobiological events involved in how discography causes pain have not been elucidated, sound anatomic, histopathological, radiological, and biomechanical evidence suggests that lumbar discography may help to identify symptomatic and pathological intervertebral discs (28,46,114,487,488).

The rationale is well established for lumbar discography (28,46,114,414,488). Discography is helpful in patients with low back or lower extremity pain to acquire information about the structure and sensitivity of their lumbar intervertebral discs and to make informed decisions about treatment and modifications of activity. Although the clinical exam may demonstrate a favorable correlation with discography or disc-related pain (451,489-498), this information may not be sufficient to guide invasive treatment for discogenic pain.

Examinations of cadaver lumbar discs typically confirm the presence of annular tears and disc degeneration, as revealed by discograms (499-503). Multiple authors also have investigated the accuracy of lumbar discographic and CT/discographic findings based on the ability to demonstrate accurate pathology confirmed at the time of surgery. There is a high inter- and intra-observer agreement in assessing discographic morphology, i.e., the Adams classification (499,504,505). It was reported that the exact reproduction of pain was more likely in ruptured or fissured discs and less likely in degenerative discs; based on the Adams classification (499).

Lumbar discography was compared with myelography, computed tomography (CT), magnetic resonance imaging (MRI), and results of surgical and conservative management. CT discography was reported to be more accurate than myelography (506-516). On similar grounds, discography was shown to be superior to plain CT (517,518). While comparing the results of lumbar discography with MRI, some found discography to be as good as MRI, even though MRI was preferable as it was non-invasive and allowed assessment of more levels with one test, with minimal risk of complications and minimal discomfort (519,520). However, others have identified advantages of discography with pain provocation, when MRIs were normal or equivocal (487,518,521). Strong correlation was demonstrated between MR/discography and CT/discography in as-

sessing annular tears and degeneration of lumbar discs (518,522,523). A good correlation between MRI, discography, and the high intensity zone has been established by some (522-528), while others have reported poor correlation and limited value of discography (529-536).

The technique of lumbar discography is standardized by the IASP criteria (415) and has been well studied (28,46,105,114,414,488,537-543). The definition of a positive discogram, per International Spine Intervention Society (ISIS) guidelines (416) is pain > 7/10, concordance, pressure < 50 psi above opening pressure, Grade III anular tear, and a painless control disc. ASIPP guidelines (3) have defined a positive discogram only if the target disc produces concordant pain with an intensity of at least 7 on a 10-point pain measurement scale or 70% of the highest reported pain (i.e., worst spontaneous pain of 7 = 7 x 70% = 5), and 2 adjacent discs with provocation discography do not produce any pain at all or only one disc in the case of L5/S1 with low volume and low pressure injection.

In an ideal situation, a gold standard or criterion is obtained by tissue confirmation of the presence or absence of a disease; however, surgical inspection of a degenerated disc cannot determine if discogenic pain is present or not. Thus, the greatest challenge concerning discography continues to be the gold standard problem. Three systematic reviews exhaustively discussed these issues (28,46,114). However, the gold standard problem is not unique to discography. Knottnerus et al (543) stated that there are several methodological challenges that must be addressed in diagnostic accuracy studies. These include the gold standard problem, spectrum and selection bias, "soft" measures (subjective phenomena), observer variability and bias, complex relations, clinical impact, sample size, and the rapid progress of knowledge (543). In systematic reviews (28,46,105,114), these concerns have been explored.

5.1.2.1 Cost Effectiveness

There are no cost effectiveness studies of lumbar provocation discography available in the literature.

5.1.2.2 Safety and Complications

Complications related to discography include discitis, subdural abscess, spinal cord injury, vascular injury, annular strains, epidural and paravertebral abscess (6,28,46,114,414-416,544-555).

5.1.2.3 Evidence Assessment

The literature search provided 5 systematic reviews (28,46,53,105,114,409). All of the systematic reviews met the inclusion criteria. Hancock et al (409) focused on the diagnostic criteria comparing discography with other tests. Wolfer et al (105) evaluated false-positive rates. Shah et al (114), Buenaventura et al (28), and Manchikanti et al (46) performed the systematic assessment of value of provocation discography utilizing West et al's AHRQ criteria for systematic reviews. Manchikanti et al (46) utilized modified IASP criteria (415). For a disc to be judged positive, stimulation of the target disc produces concordant pain with an intensity of at least 6 on a 10 point pain measurement scale and 2 adjacent discs with provocation discography do not produce any pain at all except for L5-S1 disc wherein only one negative disc is required. Manchikanti et al (46) utilized 9 studies meeting strict inclusion criteria and considered all other studies performed under controlled conditions. Wolfer et al (105) utilized multiple studies with methodologic quality evaluation and scoring of lumbar discographic studies in their evaluations.

Thus, the 2 latest systematic reviews by Manchikanti et al (46) and Wolfer et al (105) were utilized in the evidence synthesis for the guidelines.

5.1.2.4 Prevalence of Lumbar Discogenic Pain

Prevalence of pain due to internal disc disruption (IDD) was reported as 39% of patients suffering with chronic low back pain in the United States (451). In contrast, primary discogenic pain was reported in 26% of patients suffering with chronic low back pain in the United States (338). Table 5 illustrates the data of prevalence of lumbar discogenic pain utilizing IASP criteria.

5.1.2.5 False-Positive Rate

A series of published studies specifically investigated the potential false-positive rate of lumbar discography (539,555-567). The Holt study (560) was performed on prisoners, with outdated techniques and noxious, irritating contrast dye (561). False-positive rate meta-analysis by Wolfer et al (105) pooled all extrctable data from high quality studies performed in subjcts asymptomatic of low back pain and reported the following false-positive rates: 3% in subjects without confounding factors, 0% in the pain-free group, 10% in the low pressure positive chronic pain group, 15% in prior discectomy patients, and 12.5% in patients with residual pain after iliac crest bone harvesting. If all patients from all

subgroups are combined, a total false-positive rate of 9.3% (95% CI, 3%, 16%) is obtained in contrast to the high false-positive rates of 40% to 83% described by Carragee et al (562,563).

5.1.2.6 Level of Evidence

Based on USPSTF (126) criteria, the indicated evidence is Level II-2 for lumbar discography.

5.1.2.7 Recommendations

The recommendations for lumbar provocation discography include appropriate indications with patients with low back pain to prove the diagnostic hypothesis of the discogenic pain specifically after exclusion of other sources of lumbar pain and identification of the disc that should be targeted for treatment, or to establish either that no disc or too many discs are symptomatic, in which case surgery may not be indicated.

5.1.3 Sacroiliac Joint Blocks

Due to the inability to make the diagnosis of sacroiliac joint-mediated pain with non-invasive tests, sacroiliac joint blocks appear to be the evaluation of choice to provide appropriate diagnosis. Further, controlled studies have established sacroiliac joints as a potential source of low back and lower extremity pain (6,27,45,116,338,568-575). Based on the controlled diagnostic blocks, the sacroiliac joint block has been implicated as the primary source of pain (6,27,45,116,338,569,570,576,577).

The face validity of sacroiliac joint blocks has been established by injecting small volumes of local anesthetic with contrast into the joint and determining contrast spread. Construct validity of sacroiliac joint blocks has been established by determining the false-positive rate of single, uncontrolled, sacroiliac joint injections of 20% to 54% (338,569,570,577). Positive responses may occur with extravasation of an anesthetic agent out of the joint due to defects in the joint capsule (578). Negative results may occur from faulty needle placement, intravascular injection, or inability of the local anesthetic to reach the painful portion of the joint due to loculations (27,45,116,568,574,575,579-583).

5.1.3.1 Cost Effectiveness

There are no studies evaluating the cost effectiveness of diagnostic sacroiliac joint blocks.

5.1.3.2 Safety and Complications

Complications of sacroiliac joint injection include infection, trauma to the sciatic nerve and complications related to drug administration (6,27,45,116).

5.1.3.3 Evidence Assessment

Rupert et al (45) provided the latest evidence with consideration of 13 manuscripts for inclusion and having 5 studies which met methodologic quality assessment (338,569,570,577,578).

5.1.3.4 Prevalence

The prevalence of sacroiliac joint pain is estimated to range between 10% and 38% with 95% confidence intervals of 0% – 51% (338,569,570,577,578) (Table 6).

5.1.3.5 False-Positive Rate

The false-positive rate of a single block is estimated to range between 20% and 54% with 95% CIs of 3% – 64% (338,569,570,578). However, in one study (577), the false-positive rate was 0%.

Table 5. *Data of prevalence of lumbar discogenic pain utilizing IASP criteria.*

Study	Methodological Quality Scoring	Participants	Prevalence
Schwarzer et al 1995 (451)	70	92 consecutive patients with chronic low back pain and no history of previous lumbar surgery referred for discography.	The diagnostic criteria for internal disc disruption were fully satisfied in 39% of the patients, most commonly at L5/S1 and L4/5.
Manchikanti et al 2001 (338)	70	From a group of 120 patients with low back pain, 72 patients negative for facet joint pain underwent discography.	The prevalence of discogenic pain was established in 26% of total patient sample and 43% of patients negative for facet joint pain.

Adapted from Manchikanti L et al. Systematic review of lumbar discography as a diagnostic test for chronic low back pain. *Pain Physician* 2009; 12:541-560 (46).

5.1.3.6 Level of Evidence

The indicated evidence for the accuracy of sacroiliac joint diagnostic injections is Level II-2 for the diagnosis of sacroiliac joint pain utilizing controlled diagnostic blocks.

Rubinstein and van Tulder (411) in a best-evidence review of diagnostic procedures for low-back pain concluded that there is moderate evidence for the diagnostic accuracy of sacrioliac joint injections in evaluating spinal pain.

5.1.3.7 Recommendations

Controlled sacroiliac joint blocks with placebo or controlled comparative local anesthetic blocks are recommended when indications are satisfied. A positive response is considered ≥ 80% relief with ability to perform previously painful movements.

- The primary indication for sacroiliac joint blocks is the need to know if a patient's pain is arising from the sacroiliac joint or not.
- Sacroiliac joint injections are indicated in patients
  - with chronic low back pain that is maximal below the level of L5 vertebra
  - with or without somatic referred pain in the lower limb, in whom no other diagnosis is readily apparent
  - no other possible diagnosis is more likely
  - a diagnosis has been made or cannot be made using less invasive options
  - lack of resolution of pain with the passage of time or conservative therapy.

5.2 Diagnosis of Neck Pain

Cervical intervertebral discs, facet joints, atlanto-axial and atlanto-occipital joints, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the cervical spine with resulting symptoms of neck pain, upper extremity pain, and headache (3,4,584-586). Cervical facet joint nerve blocks and cervical provocation discography are the commonly practiced interventional diagnostic techniques (39,45).

5.2.1 Cervical Facet or Zygapophysial Joint Blocks

Diagnostic blocks of a cervical facet or zygapophysial joint can be performed by anesthetizing the joint or the medial branches of the dorsal rami that innervate the target joint, to test whether the joint is the source of pain. Valid information is obtained by performing controlled blocks, either in the form of placebo injections of normal saline or comparative local anesthetic blocks.

The rationale for using cervical facet joint blocks for diagnosis is based on the fact that facet joints are capable of causing pain and they have a nerve supply (353,587-591). They have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (339,364,365,369,383, 385). Conventional clinical and radiologic techniques are unreliable in diagnosing cervical facet or zygapophysial joint pain (3,41).

The value, validity, and clinical effectiveness of cervical diagnostic facet joint nerve blocks was also illus-

Table 6. *Data of prevalence of sacroiliac joint pain based on controlled diagnostic blocks.*

Study	Methodologic Quality Assessment Score	# of Subjects	Prevalence Estimates	False-Positive Rate
Manchikanti et al 2001 (338)	65	20	10% (95% CI, 0% – 23%)	22% (95% CI, 3% – 42%)
Maigne et al 1996 (569)	65	54	18.5% (95% CI, 8% – 29%)	20% (95% CI, 8% – 33%)
Irwin e et al 2007 (570)	65	158	26.6% (95% CI, 20% – 34%)	53.8% (95% CI, 43% – 64%)
Laslett et al 2003 (577)	65	43/48	25.6% (95% CI, 12% – 39%)	0%
van der Wurff et al 2006 (578)	65	60	38% (95% CI, 26% – 51%)	21% (95% CI, 7% – 35%)

CI = confidence interval
Methodological criteria and scoring adapted from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. E016 (127).

Adapted from Rupert MP et al. Evaluation of sacroiliac joint interventions: A systematic appraisal of the literature. *Pain Physician* 2009; 12:399-418 (45).

trated by application of therapeutic modalities based on the diagnosis with controlled comparative local anesthetic blocks (6,24,30,41,112,361-363,592-599).

Controlled diagnostic blocks of cervical facet joints with 2 local anesthetics (or placebo-controlled) are the major means of confirming the diagnosis of facet joint pain. The face validity of cervical medial branch blocks has been established by injecting small volumes of local anesthetic and contrast material onto the target points for these structures and by determining the spread of contrast medium in posteroanterior and lateral radiographs (589). Construct validity of cervical facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (3,41,339, 364,365,369,600-605). Potential and real confounding factors were assessed in several studies. Influence of age, surgery, psychopathology, and prior opioid exposure were evaluated in 3 reports and found not to have significant impact on the prevalence of cervical facet joint related chronic neck pain (381,383,385,386,602,606).

5.2.1.1 Cost Effectiveness

Diagnostic cervical facet joint nerve blocks were not evaluated for cost effectiveness systematically. However, multiple authors (267,338,388) have described the feasibility and cost-effectiveness of appropriately performed controlled local anesthetic blocks.

5.2.1.2 Safety and Complications

Though rare and minor, the commonly reported complications of cervical facet joint injections or nerve blocks include hemorrhage, dural puncture, spinal cord trauma, infection, intraarterial or intravenous injection, chemical meningitis, neural trauma, paralysis, pneumothorax, radiation exposure, facet capsule rupture, hematoma formation, steroid side effects, and epidural subdural or subarachnoid spread (6,7,29,30,41,112,361-363,390,393-400).

5.2.1.3 Evidence Assessment

Our search yielded 4 systematic reviews (29,41,361,362) and multiple other publications (339,364,365,369,600-605). The recent systematic review by Falco et al (41) utilized 9 studies (339,364,365,369,601-605) meeting inclusion criteria with 80% pain relief and ability to perform previously painful movements with controlled diagnostic blocks.

5.2.1.4 Prevalence

The estimated prevalence is 36% to 67% with CIs ranging from 27% to 75% in patients in heterogenous population with an average of 49% with 95% CI of 45% to 52%. In addition, the prevalence was shown to be 36% with 95% CI of 22% to 51% in patients after surgical intervention (602) (Table 7).

5.2.1.5 False-Positive Rate

Based on the systematic review by Falco et al (41), false-positive rates with a single block are 27% to 63% with CIs ranging from 15% to 78% with an average of 49% with 95% CI of 44% to 54% (Table 7).

5.2.1.6 Level of Evidence

The evidence for diagnosis of cervical facet joint pain is Level I or II-1 based on the USPSTF criteria (126).

Rubinstein and van Tulder (411) in a best-evidence review of diagnostic procedures for neck pain concluded that there is strong evidence for the diagnostic accuracy of cervical facet joint blocks in evaluating spinal pain.

5.2.1.7 Recommendations

Based on the present comprehensive evaluation and other described evaluations (3,29,41,361-363,607,608), diagnostic cervical facet joint nerve blocks are recommended in patients with the following criteria:

- Patients suffering with somatic or non-radicular neck pain or headache and upper extremity pain, with duration of pain of at least 3 months.
- Average pain levels of greater than 6 on a scale of 0 to 10.
- Pain is at least intermittent or continuous causing functional disability.
- Problem has failed to respond and has not resolved with more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
- Lack of preponderance of evidence of discogenic pain, disc herniation, or evidence of radiculitis.
- There is no evidence of contraindications for the needle placement and injection of local anesthetics.
- Contraindications or inability to undergo physical therapy, chiropractic management, or inability to

Table 7. *Data of prevalence and false-positive rates of cervical diagnostic facet joint blocks.*

Study	Methodologic Criteria	# of Subjects	Prevalence Estimates	False-Positive Rate
Barnsley et al 1995 (604)	75	50	54% (95% CI, 40%, 68%).	NA
Barnsley et al 1993 (605)	75	55	NA	27% (95% CI, 15%, 38%)
Lord et al 1996 (603)	75	68	60% (95% CI, 46%, 73%)	NA
Manchikanti et al 2002 (369)	75	120	67% (95% CI, 58%,75%)	63% (95% CI 48%, 78%)
Manchikanti et al 2004 (365)	75	255 of 500	55% (95% CI, 49%, 61%)	63% (95% CI 54%, 72%)
Manchukonda et al 2007 (364)	65	251 of 500	39% (95% CI, 32%, 45%)	45% (95% CI 37%, 52%)
Manchikanti et al 2008 (602)	65	Non-Surgery: 206 Post-Surgery: 45	Non-Surgery 39% (95% CI, 33%, 46%) Post-Surgery 36% (95% CI, 22%, 51%)	Non-Surgery 43% (95% CI 35%, 52%) Post-Surgery 50% (95% CI 32%, 68%)
Speldewinde et al 2001 (601)	50	97	36% (95% CI, 27%, 45%)	NA
Yin and Bogduk 2008 (339)	60	84 of 143	42%# (95% CI, 31%, 52%)	NA
OVERALL		980	49% (95% CI, 45%, 52%)	49% (95% CI, 44%, 54%)

# Authors reported adjusted prevalence as 55% (95% CI, 38%, 62%) and crude prevalence as 24%.
NA = not available or not applicable; CI = confidence interval
Adapted from Falco FJE et al. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician* 2009; 12:323-344 (41).

tolerate non-steroidal anti-inflammatory drugs.

- A positive response is based on the following evidence:
  - Patient has met the above indications.
  - Patient responds positively to controlled local anesthetic blocks either with placebo control or comparative local anesthetic blocks with appropriate response to each local anesthetic with < 1 mL of local anesthetic.
  - At least 80% relief as criterion standard with ability to perform previously painful movement without deterioration of the relief (i.e., extension, overhead activity, lateral rotation, flexion, etc.).
  - The patient's response should be recorded independently by the assessor - generally a registered nurse familiar with patient or another physician.

5.2.2 Cervical Provocation Discography

Cervical provocation discography is intended to both identify a painful cervical intervertebral disc and depict internal derangements (609-611).

Imaging studies such as radiographs, myelography, CT, CT-myelography, and MRI are incapable of identifying a cervical degenerated disc as painful (28,114,612-618). Thus, it appears that cervical provocation discography can diagnose discogenic pain without disc herniation and radiculitis.

Over 50 years ago, Smith and Nichols (619,620) emphasized pain reproduction as the principal feature of cervical discography. Cloward (621-623) described 2 types of pain during cervical disc stimulation: pain arising from IDD (i.e., discogenic pain) and neurogenic pain that stems from a herniated disc fragment causing nerve root or dural irritation.

In a report published in 1964, Holt (624) questioned the validity and role of cervical discography, citing a high false-positive rate in asymptomatic subjects. He based this assumption on the contention that fissures and pain provocation were normal features in people without neck pain. Klafta and Collis (625,626) also found that cervical discography was less accurate than myelography in predicting surgical findings.

Studies conducted in cadavers and patients have re-examined Holt's conclusions (561,612). These studies have established fissures to be normal age-related findings that do not necessarily indicate symptomatol-

ogy, and that demonstrating them with discography is immaterial (609,627,628). Supporting this assertion, Schellhas et al (612) found that pressurizing normal discs failed to provoke pain in both symptomatic and asymptomatic patients, whereas abnormal discs tended to produce concordant pain. Roth (629) and Kofoed (630) proposed the concept of analgesic discography.

The major obstacle confronting proponents of cervical discography is the lack of consensus as to what constitutes a positive response. Widespread variations in criteria exist not only for pain provocation (i.e., designation of concordance and threshold for a positive response), but also for morphological classification. While some investigators have interpreted certain patterns of contrast dispersion as being indicative of disc pathology, others have found a lack of correlation between morphology and pain reproduction (28,39,114,609-613,628-633).

Multiple questions have been raised regarding the utility of cervical discography, including the high reported false-positive rate, the lack of standardization; the discrepancies regarding the need for "control levels," pain concordance, and pain intensity threshold; and utilization (28,39,53,58,105,114,608-611,618,634-636).

Validity is exemplified by disc stimulation symptom mapping (114,612) in patients with pain and asymptomatic volunteers. Ohnmeiss et al (637) found a significant relationship between imaging and symptom provocation, with 86% of normal-looking discs either producing no pain (60%) or atypical pain (26%). Conversely, 78% of disrupted discs were clinically painful on injection. Viikari-Juntura et al (503) demonstrated that discography provides additional information regarding structural changes not available by any other non-invasive methods of examination. In general, nuclear signal changes observed on MRI in cadavers tended to underestimate the degree of pathology appreciated with discography or gross examination. Parfenchuck and Janssen (631) found that while certain MRI patterns correlated well with positive and negative cervical discography responses, many other patterns revealed equivocal responses. They concluded that MRI is a useful adjunct to cervical discography, but that some MRI patterns should not be considered pathologic, and discography is necessary to identify a painful disc(s).

The proportion of cervical discs identified as symptomatic varies among studies. Grubb and Kelly (638) found that 50% of discs are capable of producing concordant pain upon injection. Schellhas et al (612) reported that among 11 discs that appeared normal on MRI in pain patients, 10 proved to have annular tears discographically. Discographically normal discs (n = 8) were never painful in either pain patients or an asymptomatic cohort, whereas intensely painful discs all exhibited tears of both the inner and outer annulus.

Holt's 1964 study (624) in asymptomatic prisoners reflected negatively on cervical discography. But these studies (560,625) have been repeatedly refuted and better overriding data have since been generated. Holt utilized an irritant contrast and failed to employ fluoroscopic guidance. Even aside from these significant flaws, the technique itself was suspect. Extravasation of contrast material was noted with every injection, which continued even after reducing the volume.

5.2.2.1 Cost Effectiveness

There are no cost effectiveness studies of provocation discography available in the literature.

5.2.2.2 Safety and Complications

Complications related to cervical discography include discitis, subdural abscess, spinal cord injury, vascular injury, epidural and paravertebral abscess (544-551,639-643).

5.2.2.3 Evidence Assessment

Three systematic reviews were identified evaluating cervical discography. Of these, the recent systematic review of cervical discography (39) utilized 3 evaluations meeting inclusion criteria (339,644,645). This systematic review also included various outcome studies comparing surgical outcomes.

5.2.2.4 Prevalence

Based on IASP criteria (608) and systematic review (39), the data show a prevalence rate ranging between 16% and 20% (339,644,645).

5.2.2.5 False-Positive Rate

Overall, false-positive results with cervical provocation discography are a serious concern, with cited prevalence rates exceeding 50%. Schellhas et al (612) found that the numerical rating pain score produced by discography in asymptomatic subjects was significantly lower ($P \leq 0.0001$) than in patients with neck

pain. Schellhas et al (612) recommended adding an operational criterion whereby the patient must rate the intensity of produced pain as ≥ 7 on a 10-point numerical pain rating scale or an equivalent magnitude on another suitable scale.

5.2.2.6 Level of Evidence

The indicated level of evidence is Level II-2 based on the modified USPSTF criteria (126).

5.2.2.7 Recommendations

Based on the systematic review (39), IASP criteria (608), ISIS criteria (609), and ASIPP criteria (3) the following recommendations are made:

1) Cervical discography is indicated to test the diagnostic hypothesis of discogenic pain of the cervical spine in individuals who have been properly selected and screened to eliminate other sources of cervical pain.
2) The discography should be performed utilizing appropriate criteria and results are considered positive only if the stimulation of the target disc produces concordant pain with an intensity of at least 7 on a 10-point pain measurement scale or reproduces at least 70% of the most severe pain the patient has experienced (i.e., 5 of 7) and 2 adjacent discs with low volume contrast injection with low pressure discography do not produce any pain at all.

5.3 Diagnosis of Thoracic Pain

The multiple structures which may be responsible for chronic thoracic pain include thoracic facet joints and intervertebral discs. Thoracic facet joints have been evaluated with controlled diagnostic techniques.

5.3.1 Facet or Zygapophysial Joint Blocks

Controlled diagnostic blocks of thoracic medial branch blocks that innervate the target joint provide valid information whether the facet joints are the source of pain. The rationale for using thoracic facet joint blocks for diagnosis is based on the fact that facet joints are capable of causing pain and they have a nerve supply (363,646-657). Further, they have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (364,365,658). Conventional clinical and radiologic techniques are unreliable in diagnosing thoracic facet joint pain.

The value, validity, and clinical effectiveness of thoracic diagnostic facet joint nerve blocks was illustrated by application of therapeutic modalities based on the diagnosis with controlled, comparative local anesthetic blocks (29,361,362,659,660)

The face validity of thoracic medial branch blocks is extrapolated from cervical and lumbar facet joint nerve blocks (351,352,589). The construct validity of thoracic facet joint blocks to eliminate placebo effect as the source of confounding results and to secure true-positive results, controlled, comparative local anesthetic blocks have been performed (361-365,658).

5.3.1.1 Cost Effectiveness

Diagnostic thoracic facet joint nerve blocks were not evaluated for cost effectiveness systematically. However, multiple authors (338,387-390) have described the feasibility and cost-effectiveness of appropriately performed controlled local anesthetic blocks.

5.3.1.2 Safety and Complications

Complications from facet joint nerve blocks or intraarticular injections in the thoracic spine may include pneumothorax, dural puncture, spinal cord trauma, subdural injection, neural trauma, hematoma formation, iepidural abscess, meningitis; and side effects related to the administration of steroids, local anesthetics, and other drugs (30,80,390,397,408,661-665).

5.3.1.3 Evidence Assessment

Our search yielded 4 systematic reviews (29,31,361,362). The recent systematic review by Atluri et al (31) utilized 3 studies (364,365,658).

5.3.1.4 Prevalence

Based on the controlled local anesthetic blocks, utilizing 80% pain relief, the prevalence is estimated as 34% to 42% with 95% CIs ranging from 22% to 53%. (Table 8).

5.3.1.5 False-Positive Rate

Based on the controlled local anesthetic block with 80% pain relief, false-positive rates of single local anesthetic blocks range from 42% to 55% with CIs ranging from 26% to 78%. (Table 8).

5.3.1.6 Level of Evidence

The evidence for the diagnosis of thoracic facet joint pain with controlled comparative local an-

esthetic blocks is Level II-1 based on USPSTF criteria (126).

5.3.1.7 Recommendations

Based on the systematic review (31), IASP criteria (666), ISIS criteria (667), and ASIPP criteria (3) the following recommendations are made.

- Somatic or nonradicular upper back or mid back pain.
- Duration of pain at least of 3 months.
- Average pain levels of greater than 6 on a scale of 0 to 10.
- Intermittent or continuous pain causing functional disability.
- Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and nonsteroidal anti-inflammatory agents.
- Lack of obvious evidence for discogenic pain.
- Lack of disc herniation or evidence of radiculitis.
- No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation.
- No history of allergy to contrast administration, local anesthetics, steroids, Sarapin, or other drugs potentially utilized.
- Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs.
- A positive response is based on the following evidence:
    - Patient has met the above indications.
    - Patient responds positively to controlled local anesthetic blocks either with placebo control or comparative local anesthetic blocks with appropriate response to each local anesthetic with (< 1 mL of local anesthetic).
    - At least 80% relief as criterion standard with ability to perform previously painful movement without deterioration of the relief (i.e., extension, overhead activity, lateral rotation, flexion, etc.).
    - The patient's response should be recorded independently by the assessor - generally a registered nurse familiar with patient or another physician.

5.3.2 Thoracic Provocation Discography

Provocation thoracic discography has been studied by very few authors and there is a paucity of literature (511,668-671). Wood et al (669) evaluated the validity of concordant pain and the role of false-positive responses. They reported the mean pain response in the asymptomatic volunteers as 2.4/10 even though 3 discs exhibiting prominent endplate irregularities and annular tears typical of thoracolumbar Scheuermann's disease were intensely painful. Further, of the 48 discs studied, only 21 appeared normal on MRI and only 10 were judged as normal after provocation discography. The discs which exhibited concordant pain (24 of 48 or 50%) exhibited a pain response of 8.5/10, statistically higher pain levels than the 17 discs that exhibited non-concordant pain pressure with an average pain of 4.8/10, and 5 discs with no pain response at all. Schellhas et al (668) evaluated concordant pain and also at least one nearby controlled level disc. They demonstrated clinical concordance in approximately 50% of the discs, with controlled levels being painless.

5.3.2.1 Cost Effectiveness

There are no cost effectiveness studies of tho-

Table 8. *Data of prevalence with controlled diagnostic blocks and false-positive rates in thoracic region.*

Study	Methodological Quality Scoring (AHRQ)	Participants	Prevalence	False-Positive Rate
Manchikanti et al 2004 (365)	70	72	42% (95% CI 30%–53%)	55% (95% CI 39%–78%)
Manchukonda et al 2007 (364)	60	65	34% (95% CI 22%–47%)	42% (95% CI 26%–59%)

AHRQ=Agency for Healthcare Research and Quality; CI = confidence interval

Source: Atluri S et al. Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions. *Pain Physician* 2008; 11:611-629 (31).

racic provocation discography available in the literature.

5.3.2.2 Safety and Complications

Complications relating to thoracic discography include discitis, nerve root injury, epidural abscess, allergic contrast reaction, subarachnoid puncture, meningitis, direct trauma to the spinal cord, pneumothorax, and trauma to retroperitoneal structures including the kidney and the spleen (32,668-672).

5.3.2.3 Evidence Assessment

While there were 3 systematic reviews (28,32,114) evaluating thoracic discography, only one systematic review (32) evaluated thoracic discography as a diagnostic test separately. This review utilized IASP criteria and methodologic quality assessment criteria.

5.3.2.4 Prevalence

The prevalence of thoracic discography has not been determined.

5.3.2.5 False-Positive Rate

Utilizing the data by Wood et al (669), it appears that the false-positive rate with thoracic discograms is 0 if a pain response of 7 or above is considered as positive with concordant pain with negative contiguous discs. However the evidence is preliminary.

5.3.2.6 Level of Evidence

The indicated level of evidence is Level II-3 for thoracic discography.

5.3.2.7 Recommendations

The recommendations based on IASP criteria (666), ISIS criteria (670), and ASIPP criteria (3) are as follows:

1) The thoracic discography is indicated to decide if an intervertebral disc is painful or not.
2) The discography should be performed utilizing appropriate criteria and results are considered positive only if the stimulation of the target disc produces concordant pain with an intensity of at least 7 on a 10-point pain measurement scale or reproduces at least 70% of the most severe pain the patient has experienced (i.e., 5 of 7) and 2 adjacent discs with low volume contrast injection with low pressure provocation discography do not produce any pain at all.

6.0 Therapeutic Interventional Techniques

Multiple therapeutic spinal interventional techniques are applied in managing chronic spinal pain. The rationale includes the commonality and complexity of spinal pain problems and ability of diagnostic blocks to identify sources of chronic spinal pain. Facet joints, discs and sacroiliac joints are proven sources of chronic spinal pain and are accessible to neural blockade (1-3,7-9,24-31,33-43,45-47,64,96,105,112-116,137,362,673-681). Removal or correction of structural abnormalities of the spine may fail to cure and may even worsen painful spinal conditions (1,2,7-9,13,33,34,42,43,47,96,98,113,270,271,275,280,325,326,572,586,682-706). The degenerative processes of the spine and the origin of the spinal pain are complex without correlation of radiographic changes to clinical picture and prognosis (1,2,7-9,24-31,34-41,43,45,46,96,105,112-116, 270, 362,409,411,458,680,681). The effectiveness of a large variety of therapeutic interventions used to manage chronic spinal pain has not been demonstrated conclusively (1,2,7-9,24-31,34-41,43,45,46,96,105,112-116,270,362,680,681). Finally there is increasing evidence supporting the use of spinal interventional techniques in managing spinal pain (1,2,7-9,24-31,34-41,43,45,46,96,105,112-116,270,362,680,681).

6.1 Facet Joint Interventions

Based on a detailed review of the literature, the general consensus appears to be that facet joint pain can be diagnosed with reasonable certainty on the basis of controlled diagnostic local anesthetic blocks (29,30,31,40,41,361,363,379,391,409,411,413,606,607,646,666,667,707,708). 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 medial branches (1,2,7-9,30,31,40,41,112,391,646,708).

6.1.1 Intraarticular Injections

6.1.1.1 Evidence Assessment

The comprehensive search identified 9 systematic reviews and 2 other publications evaluating the therapeutic role of intraarticular facet joint injections (30,

31,40,41,53,78,103,112,709-711). Recent reviews of cervical, thoracic, and lumbar facet joint interventions met inclusion criteria (31,40,41).

Staal et al (103) utilized 6 weeks of relief as short-term and longer than 6 weeks as long-term, whereas Atluri et al (31), Falco et al (41), and Datta et al (40) utilized 6 months of relief as short-term and over 6 months as long-term. Further, the 2 systematic reviews (40,41) utilized 80% pain relief with controlled diagnostic blocks as the inclusion criteria, whereas one systematic review (31) utilized 50% relief with controlled diagnostic blocks. In contrast, Staal et al (103) had no inclusion criteria based on the validity of diagnosis. In addition, there were 6 studies (712-717) either considered or included in one or more systematic reviews.

Staal et al (103) included the studies by Carette et al (712) and Lilius et al (715) in their analysis and qualified them as one high quality (712) and one low quality study (715) 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. Datta et al (40) 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 (31) and Falco et al (41) concluded that there were no studies meeting the criteria for inclusion in the cervical and lumbar spine.

6.1.1.2 Cost Effectiveness

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

6.1.1.3 Safety and Complications

Complications of intraarticular injections are rare but can be serious (30,31,40,41,53,78,90,103,112,390,397,399,401-404,406,408,718-721). 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.

6.1.1.4 Indications

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

6.1.1.5 Level of Evidence

The evidence for lumbar intraarticular injections is Level III (limited) with 2C/very weak recommendation. The evidence for cervical intraarticular injections is lacking. There was no evidence available for thoracic intraarticular facet joint injections.

6.1.1.6 Recommendations

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

6.1.2 Medial Branch Blocks

6.1.2.1 Evidence Assessment

Six systematic reviews (30,31,40,41,103,112) evaluating the effectiveness of therapeutic medial branch injections included one update (30) of an original publication (112), whereas 3 publications (31,40,41) 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 (375,596,659,722-724) and 2 observational studies (660,725) evaluating the effectiveness of the therapeutic role of medial branch blocks were considered.

Following the comprehensive review of all the available systematic reviews, 4 systematic reviews (31,40,41,103), met the inclusion criteria (127). Staal et al (103) utilized more than 6 weeks of relief as long-term, whereas others (31,40,41) utilized over 6 months of relief as long-term. Further, 3 systematic reviews utilized strict diagnostic criteria. Staal et al (103) included one study by Manchikanti et al (722). Staal et al (103) concluded that there was no difference; however, they failed to take into consideration the design of the study – non-inferiority or equivalence trial versus efficacy trial (20,130).

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 (375,596,659,722) utilizing an active control design. These studies are referred to as non-inferiority or equivalence trials. Consequently, they lack placebo. However, 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) (130). All the studies except the earliest one (722) were double-blind, ran-

domized, 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 involved confirmation of the existence of facet joint pain based on 80% relief with controlled local anesthetic blocks. All the studies showed positive results with 71% to 92% of the patients showing positive results on a long-term basis (i.e., 6 months). The limitations of these studies include lack of placebo, non-academic setting, and single center studies.

Manchikanti et al also published 2 prospective evaluations on therapeutic effectiveness of cervical and thoracic facet joint nerve blocks in managing chronic spinal pain. Both studies showed positive results with cervical facet joint nerve blocks (725), showing positive response in 82% of the patients at 6 months and 56% at 12 months. In contrast, thoracic facet joint nerve blocks showed improvement in 71% of the patients at 6 months, 76% at 12 months, 71% at 24 months, and 69% at 36 months (660).

6.1.2.2 Cost Effectiveness

The cost effectiveness of lumbar facet joint nerve blocks was evaluated by Manchikanti et al (722) with 1-year improvement of quality of life (QOL) at $3,461.

6.1.2.3 Safety and Complications

Complications of medial branch blocks 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 (390,397,399,401-404,406,718-721,726).

6.1.2.4 Indications

Indications are described for diagnostic facet joint nerve blocks. For therapeutic interventions, the diagnosis must be established with a positive response to controlled local anesthetic blocks with 80% relief.

6.1.2.5 Level of Evidence

Table 9 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 (126) the indicated level of evidence for lumbar, thoracic, and cervical facet joint nerve blocks is Level II-1 or II-2.

6.1.2.6 Recommendations

Based on Guyatt et al's criteria (136) 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.

6.1.3 Medial Branch Neurotomy

Percutaneous neurotomy of medial branches may be performed by radiofrequency thermoneurolysis utilizing a thermal or pulsed mode, cryoneurolysis, or laser denervation. However, in these guidelines, due to the paucity of the literature and emerging nature of multiple modalities of treatments, we have considered only thermal radiofrequency neurotomy.

6.1.3.1 Evidence Assessment

Among the 9 systematic reviews (30,31,40,41,79-81,112,709) of medial branch radiofrequency neurotomy available only 3 systematic reviews (31,40,41) 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 (79) 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 (81), 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 (709) concluded that the evidence for radiofrequency denervation is Level III or moderate. The systematic reviews by Manchikanti et al (80) and Boswell et al (30,112) concluded that the evidence for pain relief with radiofrequency neurotomy of medial branch nerves was moderate to strong in cervical and lumbar spine.

The therapeutic role of medial branch neurotomy was evaluated in 9 randomized trials

(374,597,727-733), and in 21 observational studies (593-595,598,648,662,734-748).

For cervical and lumbar medial branch neurotomy, 2 randomized trials (374,597) and 5 observational studies (593,595,598,741,749) met inclusion criteria with methodologic quality assessment for evidence synthesis, with none of the studies meeting inclusion criteria for radiofrequency thermal neurotomy. The manuscripts meeting the diagnostic criteria of 80% relief with ability to perform previously painful maneuvers were included in methodologic quality assessment (31,40,41).

Nath et al (374), in a randomized controlled trial (RCT) of 40 patients with chronic low back pain (20 active and 20 controls), found that the active treatment group showed significantly greater improvements with pain and analgesic use. 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 (749) provided a favorable opinion and highlighted the selection criteria, generalizability, and relief of index pain.

In 1996, Lord et al (597) evaluated the effectiveness of percutaneous radiofrequency neurotomy for chronic cervical zygapophyseal joint pain in a randomized, double-blind clinical trial with strict diagnostic selection criteria in 24 patients. At 3 months all patients were interviewed by completing the visual-analogue scale, 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.

Among the 2 observational studies, Sapir and Gorup (593) evaluated patients with neck pain after whiplash and showed no significant difference among the patients with or without litigation. The second study was by Barnsley (598) assessing outcomes in a series of con-

Table 9. *Results of published reports of effectiveness of cervical, thoracic, and lumbar medial branch blocks.*

Study	Study Characteristics	Methodological Quality Score(s)	No. of Patients	Long-term Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Cervical								
Manchikanti et al 2008 (596)	RA, DB	76	76	83% vs 85%	87% vs 95%	85% vs 92%	P	P
Manchikanti et al 2004 (725)	O	69	100	92%	82%	56%	P	P
Thoracic								
Manchikanti et al 2008 (659)	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 (660)	O	69	55	71%	71%	76%	P	P
Lumbar								
Manchikanti et al 2008 (375)	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 (722)	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 (41).
Atluri S et al. Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions. *Pain Physician* 2008; 11:611-629 (31).
Datta S et al. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. *Pain Physician* 2009; 12:437-460 (40).

secutive patients with percutaneous radiofrequency neurotomy of chronic neck pain showing positive results. A third study was performed by McDonald et al (595), and similar to the one performed by Barnsley (598) produced positive results. There were 2 studies evaluating lumbar facet joint nerve neurotomy by Dreyfuss et al (741) and Gofeld et al (739). Dreyfuss et al (741) prospectively evaluated 15 patients with 87% of patients reporting 60% pain relief at 12 months status post-radiofrequency neurotomy, whereas Gofeld et al (739) reported long-term improvement in 68.4% of the patients.

6.1.3.2 Cost Effectiveness

No cost effectiveness evaluations were performed with medial branch neurotomy.

6.1.3.3 Safety and Complications

Complications 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, pneumothorax, and deafferentation pain ((390,397,399, 402,403,406,718,719,750-752).

6.1.3.4 Indications

Indications are the same as described for diagnostic facet joint nerve blocks. For therapeutic interventions, the diagnosis must be established with a positive response to controlled local anesthetic blocks with 80% relief.

6.1.3.5 Level of Evidence

Table 10 illustrates the results of published studies of cervical and lumbar facet nerve neurotomy. There were no studies meeting inclusion criteria in the thoracic spine.

Table 10. *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 mos.	Long-term relief > 6 mos.
Cervical							
Lord et al 1996 (597)	RA, DB	67	24-control 24-active	1 of sham 7 of active	58% in active treatment group	P	P
Sapir and Gorup 2001 (593)	O	87	46	NA	Mean VAS change 4.6 ± 1.8	P	P
McDonald et al 1999 (595)	O	65	28	NA	71%	P	P
Barnsley 2005 (598)	O	54	35	NA	74%	P	P
Lumbar							
Nath et al 2008 (374)	RA, DB	50	20-control 20-active	SI	NA	P	NA
Gofeld et al 2007 (739)	O	63	174	68%	NA	P	P
Dreyfuss et al 2000 (741)	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 (41).
Datta S et al. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. *Pain Physician* 2009; 12:437-460 (40).

Based on USPSTF criteria (126), 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, and with no evidence available for thoracic medial branch radiofrequency neurotomy.

6.1.3.6 Recommendations

Based on Guyatt et al's (136) criteria for cervical radiofrequency neurotomy and lumbar radiofrequency neurotomy, the recommendation is 1C/strong recommendation.

6.2 Epidural Injections

Access to the epidural space is available by caudal, interlaminar, and transforaminal approaches (4,7-10,24-26,34-37,111,753-762). Substantial differences with the technique and outcomes have been described among the 3 approaches. Thus, due to the inherent variations, differences, advantages, and disadvantages applicable to each technique (including the effectiveness and outcomes), caudal epidural injections, interlaminar epidural injections (cervical, thoracic, and lumbar epidural injections), and transforaminal epidural injections (lumbosacral) are considered as separate entities.

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

6.2.1 Caudal Epidural Injections

Several systematic reviews have evaluated the effectiveness of epidural steroids including caudal epidural injections (34,78,86,88,103,763-766). However, they failed to separate caudal and interlaminar techniques, arriving often at erroneous conclusions. Of importance are systematic reviews performed by Nelemans et al (78), updated by Staal et al (103), Koes et al (763), van Tulder et al (88), and Armon et al (766). All these reviews included essentially similar criteria as well as the same studies, uniformly arriving at inaccurate conclusions. In contrast, Abdi et al (24,111) and Boswell et al (767), Singh et al (50), and Bogduk et al (753) evaluated caudal epidural steroid injections as separate procedures, reaching opposite conclusions. They concluded that the effectiveness of caudal epidural injections in managing lumbar radiculopathy was moderate.

Conn et al (34) in a systematic review evaluating the effect of caudal epidural injections with or without steroids in managing various types of chronic low back and lower extremity pain emanating as a result of disc herniation or radiculitis, post lumbar surgery syndrome, spinal stenosis, and chronic discogenic pain without disc herniation or radiculitis has shown Level I evidence for short- and long-term relief of chronic pain secondary to disc herniation or radiculitis and discogenic pain without disc herniation or radiculitis. Further, the systematic review by Conn et al (34) also provides an indicated level of evidence II-1 or II-2 for caudal epidural injections in managing chronic pain of post lumbar surgery syndrome and spinal stenosis. The results of the systematic review were provided utilizing contemporary systematic review methodology utilizing randomized trials and observational studies, even though most of the evidence was derived from randomized trials.

6.2.1.1 Disc Herniation and Radiculitis

6.2.1.1.1. Evidence Assessment

Six randomized trials (768-773) were used in evidence synthesis. Dashfield et al (770) and Manchikanti et al (769) utilized fluoroscopy.

Of the 2 studies utilizing fluoroscopy, Dashfield et al (770) compared the effectiveness of caudal steroid epidural with targeted steroid placement during spinal endoscopy for chronic sciatica in a prospective, randomized, double-blind trial. Patients in the caudal group underwent caudal epidural corticosteroid injection 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 infusion of 50 to 150 mg mL of sodium chloride solution. 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; visual analog scale (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 (769) 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 measures were utilized with measurements of pain outcomes, employment status, and opioid intake assessed at 3 months, 6 months, and 12 months post-treatment. Sample size justification was provided for preliminary analysis and intent-to-treat analysis was performed. This report showed significant pain relief (≥ 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 IPM settings in the United States.

6.2.1.1.2 Effectiveness

Of the 6 randomized trials, 5 were judged to be positive for short-term relief (768-772). Of the 4 trials, 3 reported positive results with long-term follow-up of more than 6 months (769,771,773). The results in 2 studies utilizing fluoroscopy (769,770) were superior to blind epidural injections. Table 11 illustrates results of effectiveness of randomized trials in disc herniation and radiculitis.

6.2.1.2 Post Surgery Syndrome

6.2.1.2.1. Evidence Assessment

Three studies were identified evaluating the effectiveness of caudal epidural injections in post surgery syndrome (773-775). Only one study by Manchikanti et al (774) was performed under fluoroscopy. Of these, 2 studies (773,774) provided outcomes of longer than 6 months.

The only fluoroscopic study by Manchikanti et al (774) evaluated 40 patients in a randomized, double-blind equivalence trial with an objective to evaluate 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), whereas Group II patients received 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. 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 (≥ 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.

6.2.1.2.2 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 (773-775). Table 12 illustrates the results of randomized trials in managing chronic pain of post surgery syndrome with caudal epidural injections.

6.2.1.3 Spinal Stenosis

6.2.1.3.1. Evidence Assessment

One randomized trial (776) and 2 observational studies (777,778) evaluating the role of caudal epidural injections in spinal stenosis met inclusion criteria.

Manchikanti et al (776) 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.

Patients were assigned randomly into 2 groups, with Group I patients receiving caudal epidural injections of local anesthetic (lidocaine 0.5%), whereas Group II patients received caudal epidural injections with 0.5% lidocaine, 9 mL, mixed with 1 mL of non-particulate Celestone.

Multiple outcome measures were utilized including 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% more.

Significant pain relief (≥ 50%) was demonstrated in 55% to 65% of patients with functional status improvement with at least a 40% reduction in 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 IPM 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 evalu-

Table 11. *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 (769)*	RA, DB	72	84	81%	86%	79% to 81%	P	P
Dashfield et al 2005 (770)*	RA, DB	50	Caudal = 30 Endoscopy = 30	SI	SI	NA	P	NA
Bush and Hillier 1991 (768)	RA, DB	55	23	SI	NSI	NSI	P	N
Mathews et al 1987 (771)	RA, DB	62	C = 34 T = 23	SI	SI	SI	N	P
Hesla and Breivik 1979 (773)	RA, DB	58	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P
Breivik et al 1976 (772)	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 (34).

ating the role of caudal epidural injections in spinal stenosis.

6.2.1.3.2 Effectiveness

The one randomized trial evaluating spinal stenosis with or without steroids with local anesthetic (776) and 2 observational studies (777,778) showed positive results for short- and long-term relief (Table 13). Huntoon and Burgher (779) concluded in an editorial that results of caudal epidural were similar to surgery.

6.2.1.4 Discogenic Pain

6.2.1.4.1. Evidence Assessment

One randomized trial (780) and 2 observational studies (781,782) met inclusion criteria.

Manchikanti et al (780) 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 last-

Table 12. *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 ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (774)*	RA, DB	70	40	65% to. 70%	60%	60% to 65%	P	P
Revel et al 1996 (775)	RA	62	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (773)	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 (34).

Table 13. *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 (776)*	RA, DB	70	40	50% to 65%	60% to 65%	55% to 65%	P	P
Ciocon et al 1994 (777)	O	57	30	SI	SI	NA	P	NA
Botwin et al 2007 (778)*	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 (34).

ing pain relief and to evaluate 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%), whereas Group II patients received caudal epidural injections with 0.5% lidocaine, 9 mL, mixed with 1 mL of steroid. 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 (≥ 50%) was demonstrated in at least 72% to 81% of patients and functional status improvement was demonstrated by a reduction of 40% 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 (782) 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 three 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 $2550 for 1-year improvement of QOL. They concluded that the treatment is not only effective clinically, but also is cost effective.

Manchikanti et al (781) 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. Patients underwent 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. 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, with administration of one to 3 injections. Analysis with one to 3 injections, which included all (n = 62) patients 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.

6.2.1.4.2 Effectiveness

Table 14 illustrates the results of effectiveness of caudal epidural injections in managing discogenic pain without disc herniation or radiculitis. One randomized trial (780) and one observational study (782) showed positive long-term results, whereas one study (781) evaluated only short-term relief of 6 months or less.

6.2.1.5 Cost Effectiveness

The cost effectiveness of fluoroscopically directed caudal epidural steroids was $3,635 and that of transforaminal steroids $2,927 per year, whereas for inter-

laminar epidural steroids the cost was $6,024 (783). 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 (782).

6.2.1.6 Safety and Complications

Various complications of caudal epidural injections have been reported (24,111,390,401,406,665,720,753, 760,767,784-797). 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 have been reported. However, it has been shown that at therapeutic doses of epidural steroids administered, complications were not noted related to procedure (798-800).

Complications and side effects include infection, intravascular injection, extra epidural placement, hematoma formation, abscess formation, subdural injection, intracranial air injection, epidural lipomatosis, dural puncture, nerve damage, headache, increased intracranial pressure, vascular injury, cerebrovascular or pulmonary embolism. Other less common complications include transient blindness (801), retinal necrosis (802), central serous chorioretinopathy (791,803), retinal hemorrhage (790), persistent recurrent intractable hiccups (804), flushing (805), chemical meningitis, discitis (786,794), epidural hematoma (806-809), epidural abscess (794), and arachnoiditis (810,811).

6.2.1.7 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.

6.2.1.8 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 (126). Tables 11 to 14 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 discogenic pain without disc herniation or radiculitis.
- The indicated evidence is Level II-1 or II-2 for caudal epidural injections in managing low back pain of post-surgery syndrome and spinal stenosis.

6.2.1.9 Recommendations

Based on grading recommendations by Guyatt et al (136), 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/strong.

6.2.2 Interlaminar Epidural Injections

Multiple systematic reviews provided negative opinions for lumbar interlaminar epidural injections (24,35,78,88,103,111,763,764,766,767). Recently, 2 systematic reviews were performed evaluating lumbar and cervical interlaminar epidurals (35,36). They arrived at conflicting conclusions with the systematic review of the effectiveness of the cervical epidurals in the management of chronic neck pain illustrating a Level II-1 evidence in managing chronic neck and upper extremity pain (36); whereas, the evidence is Level II-2 for short-term relief of pain of disc herniation or radiculitis utilizing blind interlaminar epidural steroid injections with lack of evidence for long-term relief (35). Staal et al (103) updated Neleman et al's (78) systematic review, concluding that there was insufficient evidence to support the use of injection therapy in subacute and chronic low back pain.

6.2.2.1 Lumbar Interlaminar Epidural Injections

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

Table 14. *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 (780)	RA, DB	72	64	78%	75% to 81%	72%	P	P
Manchikanti et al 2001 (782)*	O	76	70	95%	85%	61% to 73%	P	P
Manchikanti et al 2002 (781)*	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 (34).

6.2.2.1.1 Disc Herniation and Radiculitis

Five blind lumbar interlaminar studies met inclusion criteria (812-816). However, most studies incorporated flawed methodology without fluoroscopy. The authors utilized a flawed process by considering local anesthetic injection as a placebo along with a small sample size, and also used poor methodology, and inadequate outcome assessments (813). Widely applauded, Carette et al's study (812) also contained numerous deficiencies including lack of fluoroscopy, performance of the procedure in the lateral decubitus position and injection of isotonic saline as placebo into the epidural space. Arden et al (815) utilized an unrealistic outcome expectation of reduction of ODI by 75% from the baseline, performed without fluoroscopy, and repeated the injections without concern about return of the pain for a total of 3 injections. Snoek et al (814) in a study of 51 patients with lumbar root compression found no significant differences between the 2 groups. Wilson-MacDonald et al (816) also showed no significant differences.

As shown in Table 15, 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.

6.2.2.1.2 Spinal Stenosis

Two blind lumbar interlaminar randomized trials (813,816) and one observational study (817) evaluating spinal stenosis were identified.

Cuckler et al (813) and Wilson-MacDonald et al (816) utilized flawed methodologic processes as described earlier and further, the number of patients studied was also small. The observational study by Campbell et al (817) showed significant confusion, basically demonstrating that epidural steroid injections performed blindly with an interlaminar approach in a series of 3 injections may still be effective.

Three evaluations studying the effectiveness of blind lumbar interlaminar studied injections in spinal stenosis (Table 16).

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

Only one observational study was available evaluating the effect of spinal steroid injections for degenerative disc disease under fluoroscopy, which included intradiscal injections as well as epidural injections (818).

Butterman (818) 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. 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. Over a period of 2 years, this study had an extensive dropout rate of 60%.

Table 15. *Results of randomized trials of effectiveness of blind lumbar interlaminar epidural steroid 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 (816)	RA	68	43	SI	NSD	NSD	NSD	P	N
Arden et al 2005 (815)	RA,DB,PC	86	228	75%	NSD	NSD	NSD	N	N
Carette et al 1997 (812)	RA,DB,PC	77	C = 80 T = 78	SIT	NSD	NSD	NSD	P	N
Cuckler et al 1985 (813)	RA,DB	60	C = 31 T = 42	NSD	NSD	NSD	NSD	N	N
Snoek et al 1977 (814)	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 (35).

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. 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 endplates at one to 3 and 4 to 6 month follow-up periods and pain drawing at the 4 to 6 month follow-up period. The authors concluded that patients may have short-term benefit by epidural steroid injection 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 injection at 2-year follow-up.

Only one observational study (818) 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.

6.2.2.2 Cervical Interlaminar Epidural Injections

6.2.2.2.1 Evidence Assessment

Only 3 systematic reviews evaluated the role of cervical interlaminar epidural injections (24,36,111). The recent systematic review of cervical epidural injections met inclusion criteria (24). Three blind cervical epidural studies met the inclusion criteria (819-821).

Castagnera et al (820) randomly allocated 24 patients into 2 groups with the steroid group treated with 0.5% lidocaine plus triamcinolone acetonide 10 mg/mL, whereas the morphine group received the same combination of 0.5% lidocaine and steroid plus 2.5% mg 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

Table 16. *Results of published studies of effectiveness of blind lumbar interlaminar epidural steroid 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 (813)	RA,DB	60	37	NSD	NSD	NSD	NSD	N	N
Wilson-MacDonald et al 2005 (816)	RA	68	32	SI	NSD	NSD	NSD	P	N
Campbell et al 2007 (817)	O	53	84	NA	NA	NA	40%	NA	N

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

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 (35).

which was stable, with a mean follow-up of 43 ± 18.1 months.

This is a well performed study; however, the authors attempted to evaluate the pain by increasing the volume of sodium chloride solution injection into the cervical epidural space, not to exceed 10 mL to exacerbate the patient's radicular pain. The mean volume injected in the epidural space was 6.6 ± 2.1 and 6.3 ± 1.9 mL in the respective groups. This report however showed results much superior to any other study reported 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. They also showed return to work in all the patients who were working prior to the cervical epidural steroid injections. However, there was no correlation found between pain relief and absenteeism. Furthermore, the addition of morphine to lidocaine and triamcinolone has not been shown to be superior to epidural lidocaine and triamcinolone 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 (819) 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 (821) 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 administering 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. 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 due to 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 injection 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.

Of the 3 randomized trials evaluating cervical interlaminar epidural steroid injections, all showed positive results for short-term relief (819-821), 2 were positive for long-term relief (819,820), and the results of long-term relief were not available for one study (821). Table 17 illustrates results of effectiveness of blind cervical interlaminar epidural steroid injections.

6.2.2.3 Cost Effectiveness

In the evaluation of cost effectiveness, Manchikanti et al (783) and Price et al (822) concluded that lumbar interlaminar epidural steroid injections were not cost effective. There were no studies evaluating the cost effectiveness of cervical interlaminar epidural injections.

6.2.2.4 Safety and Complications

The common complications of lumbar interlaminar epidural injections are related to either the needle placement or the drug administration as described for caudal epidural injections (7,24,111,405,407,665,753,767,785,786, 788-794,801-811,822-852).

In the cervical spine, additional or specific complications include spinal cord trauma, spinal cord or epidural hematoma formation, subarachnoid or subdural injections, intravascular injection, vascular injury, or vascular embolism (827-846).

Table 17. *Results of published studies of effectiveness of cervical interlaminar epidural steroid 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 (820)	RA	55	Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10	79%	79%	79%	P	P
Stav et al 1993 (819)	RA	50	C = 17 T = 25	12% vs 68%	12% vs 68%	12% vs 68%	P	P
Pasqualucci et al 2007 (821)	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 (36).

6.2.2.5 Indications

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

6.2.2.6 Level of Evidence

The evidence based on USPSTF critera (126) is Levle II-2. The indicated evidence for cervical interlaminar epidural steroid injections is Level II-1.

The indicated level of evidence 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 is Level II-2. 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.

6.2.2.7 Recommendations

Based on Guyatt et al's criteria (136), 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 which may change when higher quality evidence becomes available 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.

6.2.3 Lumbar Transforaminal Epidural Injections

6.2.3.1 Evidence Assessment

Two systematic reviews (24,111) showed the evidence of lumbar transforaminal epidural steroid injections for lumbar nerve root pain was strong for short-term and moderate for long-term improvement. The evidence is limited for lumbar radicular pain in post surgery syndrome. DePalma et al (853) 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 (37) indicated the evidence is Level II-1 for short-term relief and Level II-2 for long-term relief in managing chronic low back and lower extremity pain. They evaluated methodologic quality assessment, relief of longer than 6 months as long-term relief, and appropriate outcomes. Thus, this systematic review met all the criteria for inclusion in the guideline synthesis.

Jeong et al (854) compared transforaminal epidural injections to themselves and only altered the level (preganglionic vs. ganglionic) injected. The drugs injected were triamcinolone and bupivacaine. At the short-term the pre-ganglionic injection group did better than the ganglionic group. At long-term follow-up there was no statistically significant difference between the groups but a majority of the patients in both groups rated their outcomes as good to excellent (79% at short-term and 63.9% at long-term).

Karppinen et al (855) 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 (856) in their subgroup analysis of the randomized trial (855) showed significantly positive results for contained herniations at one-year.

Riew et al (857,858) 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 (857) showed positive long-term results with or without steroids.

Vad et al (859) studied the effect of transforaminal epidural betamethasone 9 mg and lidocaine and compared it to a lumbar paraspinal muscle trigger point injection of saline. Forty-eight patients were included. Outcomes included pain score, patient satisfaction, and other measures of function. The patients were followed for an average of 1.4 years but no set short- or long-term follow-up evaluations were scheduled. Patients improved in both groups but the transforaminal group did significantly better with a much lower pain score at the end and a larger percentage of patients (84% vs. 48%) achieving a successful outcome in a shorter period of time than the trigger point group (6 weeks vs. 12 weeks).

6.2.3.2 Cost Effectiveness

In the management of chronic low back pain, cost per one-year improvement of QOL was $2,927 per year with transforaminal epidural steroid injections (783). Furthermore, in patients treated with transforaminal steroids, operations were avoided for contained herniations, costing $12,666 less per responder in the steroid group (854). Cost effectiveness was also demonstrated by others by avoiding surgical intervention (857,858).

6.2.3.3 Safety and Complications

The most common and worrisome complications of transforaminal epidural steroid injections in the lumbar spine are related to neural trauma, vascular trauma, intravascular injection, and infection (7,24, 111,405,407,665,767,788-794,798,801-811,822,853-856,860-871). Complications including spinal cord injury and infarction (847,860), and paraplegia (864), have been reported. Side effects related to the administration of steroids are generally attributed either to the chemistry or to the pharmacology of steroids (24,111,665,753,767,798-800,868-871).

6.2.3.4 Indications

The indications for therapeutic lumbar transforaminal epidural injections include chronic low back and/or lower extremity pain resulting from herniated discs and radiculopathy, spinal stenosis, and failed back surgery syndrome (FBSS).

6.2.3.5 Level of Evidence

Table 18 illustrates the results of randomized trials of the effectiveness of lumbar transforaminal epidural injections. 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 (126).

6.2.3.6 Recommendations

Based on the criteria by Guyatt et al (136), the recommendation for lumbar transforaminal epidural injections, in managing chronic low back and lower extremity pain, is 1C/strong recommendation.

6.3 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 (872-875). 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.

6.3.1 Percutaneous Adhesiolysis

6.3.1.1 Evidence Assessment

Clinical effectiveness of percutaneous adhesiolysis was evaluated in 3 systematic reviews (43,46,113), and one health technology assessment (872). Epter et al (43) concluded that the indicated level of evidence is I or II-1 for short- and long-term relief for percutaneous adhesiolysis in post lumbar surgery syndrome.

Three randomized trials (876-878) and 4 observational studies (879-882) met inclusion criteria for percutaneous adhesiolysis.

Of the 3 randomized trials (876-878), 2 studies had similar patient characteristics (877,878). Manchikanti et al (878) reported that patients in all 3 studies failed multiple conservative modalities of treatments including fluoroscopically directed epidural steroid injections. They (878) also reported the proportion of patients included with a history of previous surgery ranged from 64% to 72% in all intervention groups.

Heavner et al (877) 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 (877) 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

(878,882) evaluated one-day adhesiolysis. Veihelmann et al (876) and Gerdesmeyer et al (879) 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 (877) included the short-form MPQ and VAS for back pain and leg pain. Manchikanti et al (878) 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 (876) 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 (878) 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.

The descriptive characteristics of observational studies are well described in the systematic review by Epter et al (43).

6.3.1.2 Cost Effectiveness

Cost effectiveness of percutaneous adhesiolysis for 1-year of improvement in the QOL varied from $2,028 to $5,564 (880-882).

6.3.1.3 Safety and Complications

The most commonly reported complications of percutaneous adhesiolysis were dural puncture, catheter shearing, and infection (7,46,113,874,876-886). 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 (7,46,113,874,885-888).

6.3.1.4 Indications

Indications for lysis of epidural adhesions are chronic low back and/or lower extremity pain resulting from post surgery syndrome, epidural fibrosis, and spinal stenosis.

6.3.1.5 Level of Evidence

Table 19 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 (126).

Table 18. *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 (855,856)	RA, DB	81	C = 80 T = 80	SICH	NSI	NSI	P	N
Riew et al 2000/ 2006 (857,858)	P, RA, DB	68	55	NA	NA	33% vs. 71% (avoided surgery)	P	P
Jeong et al 2007 (854)	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 (859)	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 (37).

Table 19. *Results of published studies effectiveness of percutaneous lysis of lumbar epidural adhesions.*

Study	Study Characteristics	Participants	Pain Relief				Results	
			≤ 3 mos.	3 mos.	6 mos.	12 mos.	Short-term ≤ 6 mos.	Long-term >6 mos.
Manchikanti et al 2004 (878)	RA, DB	G1 = 25 G2 = 25 G3 = 25	G1 = 33% G2 = 64% G2 = 72%	G1 = 0% G2 = 64% G3 = 72%	G1 = 0% G2 = 60% G3 = 72%	G1 = 0% G2 = 60% G3 = 72%	P	P
Heavner et al 1999 (877)	RA, DB	59	83%	49%	43%	49%	P	P
Veihelmann et al 2006 (876)	RA	99	SI	SI	SI	SI	P	P
Manchikanti et al 2001 (882)	O	G1 = 15 G2 = 30		97%	93%	47%	P	P
Manchikanti et al 1999 (881)	O	60	100%	90%	72%	52%	P	P
Manchikanti et al 1999 (880)	O	129	79%	68%	36%	13%	P	N
Gerdesmeyer et al 2005 (879)	O	61	SI	SI	SI	SI	P	P

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

Adapted from Epter 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 (43).

6.3.1.6 Recommendations

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

6.3.2 Spinal Endoscopic Adhesiolysis

6.3.2.1 Evidence Assessment

Spinal endoscopic adhesiolysis was evaluated in 3 systematic reviews (46,47,113), and one health technology assessment (872). Hayek et al (47) 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 surgery syndrome.

There was only one randomized trial (889) and 5 observational studies (881,890-893) that met inclusion criteria.

Manchikanti et al (889) 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 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.

Table 20 illustrates the description of observational studies included in the evidence synthesis for spinal endoscopic adhesiolysis.

Table 20. *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 (881)	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 (893)	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 (892)	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 methyl-prednisolone + 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 (891)	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 methyl-prednisolone + 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-Reganon 2008 (890)	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% was 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 (47).

6.3.2.2 Cost Effectiveness

The cost effectiveness of spinal endoscopy in patients 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 (881,893).

6.3.2.3 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 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 (881,888-898). Severe visual impairment following epiduroscopy has been reported (888).

6.3.2.4 Indications

Endoscopic epidural adhesiolysis is indicated for patients whose chronic low back and lower extremity pain secondary to postlumbar laminectomy syndrome and epidural adhesiolysis resulting in chronic, intractable pain, nonresponsive or poorly responsive, to other modalities of treatment (889,894).

6.3.2.5 Level of Evidence

The indicated level of evidence is II-1 or II-2 for short- and long-term relief for endoscopic adhesiolysis in post lumbar laminectomy syndrome, based on one randomized trial. (Table 21).

6.3.2.6 Recommendations

Based on Guyatt et al's grading strength of recommendations and quality of evidence in clinical guidelines, the recommendation is 1C/strong for endoscopic adhesiolysis in post lumbar laminectomy syndrome.

6.4 Sacroiliac Joint Interventions

Sacroiliac joint pain may be managed by intraarticular injections or neurolysis of the sacroiliac joint (27,45,116). Three systematic reviews have been conducted to evaluate the effectiveness of sacroiliac joint interventions (27,45,116). All of them illustrated either lack of evidence or limited evidence for both intraarticular sacroiliac joint injections and radiofrequency neurotomy of the nerve supply of the sacroiliac joint. Rupert et al (45) 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.

6.4.1 Intraarticular Sacroiliac Joint Injections

6.4.1.1 Evidence Assessment

Despite the availability of 17 publications with 4 randomized trials and 14 observational reports as shown by Rupert et al (45), there were no studies meeting inclusion criteria.

While 2 previous systematic reviews (27,116) showed limited evidence for intraarticular injections, utilizing more stringent criteria, Rupert et al (45) reported a lack of studies meeting the inclusion criteria.

6.4.1.2 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, complications related to drug administration, and radiation exposure (7,27,116,404,572,665,817).

Side effects related to the administration of steroids are generally attributed to the chemistry or to the pharmacology of the steroids (665).

6.4.1.3 Indications

Common indications for sacroiliac joint injections are the same as for diagnostict sacroiliac joint. In addition, the joint should have been positive utilizing controlled diagnostic blocks with 80% relief.

6.4.1.4 Level of Evidence

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

6.4.1.5 Recommendations

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

6.4.2 Radiofrequency Neurotomy

6.4.2.1 Evidence Assessment

The effectiveness of radiofrequency neurotomy was evaluated in 3 systematic reviews. Two systematic reviews (27,116) showed limited evidence for radio-

Table 21. *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 (889)	RA,DB	69	83	56%*	48%*	P	P
Manchikanti et al 1999 (881)	O	62	60	52%*	22%*	P	P
Manchikanti et al 2000 (893)	O	58	85	21%* 6-12 mos.	7%* >12 mos.	P	N
Richardson et al 2001 (892)	O	67	38	Yes	Yes	P	P
Geurts et al 2002 (891)	O	77	24	Yes	Yes	P	P
Avellanal and Diaz-Reganon 2008 (890)	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 (47).

frequency neurotomy in managing chronic sacroiliac joint pain. The recent systematic review (45) with more stringent criteria showed evidence of Level II-3 with inclusion criteria of controlled diagnostic blocks and long-term relief considered as longer than 6 months.

Three observational studies (899-901) met inclusion criteria in the systematic review by Rupert et al (45).

Vallejo et al (899) 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. This study consisted of 22 patients with confirmed SI joint pain were evaluated following dual diagnostic blocks with local anesthetic and corticosteroid using ≥ 75% relief as the success criterion. 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 (≥ 50%) to excellent (≥ 80%) results; however, in only 7 patients did this improvement exceed 17 weeks. 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 (375,596,659,665,788,793,814).

Burnham and Yasui (901) evaluated 9 subjects with sacroiliac joint pain confirmed by local anesthetic joint and lateral branch nerve blocks with bipolar radiofrequency neurotomy. 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. Significant reductions in back and leg pain frequency and severity, and analgesic intake were demonstrated at 3, 6, 9, and 12 months. The median improvement in pain intensity was 4.1 on a 0 – 10 NRS and the reduction in disability were 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 (900) 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 (902). Except for dual blocks, the study meets all the criteria for randomized trials and the reporting guidelines of CONSORT (130). 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 depomethylprednisolone. Those patient's allocated to the placebo group who failed to obtain significant benefit were eligible to crossover to an open-label parallel group that received conventional radiofrequency denervation. Three and 6 months after the procedure, 64% (n = 9) and 57% (n = 8) of patients respectively 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.

6.4.2.2 Cost Effectiveness

No cost effectiveness evaluations were performed with radiofrequency neurotomy of sacroiliac joint innervation.

6.4.2.3 Safety and Complications

Reported 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, inadvertent lesioning of the spinal nerve, ventral ramus, or sciatic nerve resulting in motor deficits, sensory loss, and possible deafferentation pain. (390,397,399,402,403,406,418,719,726,750,751).

6.4.2.4 Indications

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

6.4.2.5 Level of Evidence

Based on the available literature and the USPSTF criteria (126), the indicated evidence is Level II-3 (limited) for radiofrequency neurotomy of sacroiliac joint nerve supply.

6.4.2.6 Recommendations

The recommendations based on Guyatt et al's (136) criteria is 2B, a weak recommendation for radiofrequency neurotomy for sacroiliac joint pain.

6.5 Intradiscal Therapies

Multiple intradiscal therapies described to manage either discogenic pain or IDD includes intradiscal electrothermal therapy (IDET), radiofrequency annuloplasty, and intradiscal biacuplasty (IDB). Percutaneous intradiscal treatment of low back pain has been the subject of several reviews (38,53,65,96-98,903,904). The CMS has issued a non-certification for these procedures (68). CMS referred to them collectively as thermal intradiscal procedures, including IDET, percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty, IDB, percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression.

6.5.1 Intradiscal Electrothermal Therapy

6.5.1.1 Evidence Assessment

The evidence for IDET includes 5 systematic reviews (38,53,96-98), a technology assessment update (100), critical appraisal of the evidence (64), and multiple other reviews

Appleby et al (97) in a systematic review reviewed the literature from all the available studies and con-

cluded that there was compelling evidence for the relative efficacy and safety of IDET. This metaanalysis showed an overall mean improvement in pain intensity of 2.9 points, physical function of 21.1 points as measured by Short-Form 36 (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 (96) 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 procedure. However, the IDET procedure appeared to offer sufficiently similar symptom amelioration to spinal fusion without attendant complications. Gibson and Waddell (98) concluded that the preliminary results of 3 similar trials of intradiscal electrotherapy suggest it is ineffective, except possibly in highly selected patients. Freeman (903) 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 (38) in a recent systematic review evaluating IDET indicated the evidence of Level II-2. Two randomized trials (905,906) and 22 observational studies (448,907-927) met inclusion criteria. Descriptive characteristics of both randomized trials are illustrated in Table 22. Helm et al (38) provided descriptions of these studies.

Both studies were sponsored by device manufacters and have been criticized (907,908). 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 (905) 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 (905), but not according to Freeman et al (906), the benefits of IDET are worth the potential harms.

Table 22. *Description of randomized controlled trials of intradiscal electrothermal therapy.*

Study/Methods	Participants	Inclusion/Exclusion	Interventions	Outcomes	Results	Conclusion Short-term ≤ 12 mos. Long-term > 12 mos.
Pauza et al 2004 (905) Randomized, placebo-controlled, double-blind, prospective trial.	Of the 37 treated patients, 32 were included in the analysis; of the 27 sham patients, 24 were included in the analysis.	Inclusion: age 18-65 years; low back pain > leg pain of > 6 months duration; less than 20% loss of disc height; Positive discography and posterior annular tears on CT scan. Exclusion: abnormal neurological exam; Workers' Compensation; personal injury litigation or receiving disability.	IDET 37 had IDET; 27 had a sham procedure in which the introducer needle was advanced to the outer annulus, but no catheter placed.	SF-36 and VAS Unblinded at 6-months	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.
Freeman et al 2005 (906) Randomized, placebo- controlled, double-blind, prospective trial.	57 subjects from 3 spine practices in Australia.	Inclusion: symptoms of 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.	VAS, Low Back Pain Outcome Score, Oswestry Disability Index, 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 (38).

6.5.1.2 Cost Effectiveness

Andersson et al (96) in their systematic review of intractable low back pain treatment with IDET versus spinal fusion surgery concluded that more than half of patients treated with IDET can avoid surgery and therefore spare the cost of surgery and its complications.

6.5.1.3 Safety and Complications

Complications of IDET include catheter breakage, nerve root injuries, post-IDET disc herniation, progressive disc degeneration, cauda equina syndrome, infection, vertebral endplate osteonecrosis, epidural abscess, radiculopathy, disc herniation, and spinal cord damage (97,551,928-940).

6.5.1.4 Indications

The indications have been described as follows (941):

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) Results of MRI with no evidence of root compression, tumor, or infection.

6.5.1.5 Level of Evidence

Table 23 illustrates the results of published studies of effectiveness of IDET, which includes randomized and observational studies. The evidence for IDET is Level II-2 based on USPSTF criteria (126).

6.5.1.6 Recommendations

A recommendation of 2A/weak recommendation is provided based on Guyatt et al's (136) recommendation.

6.5.2 Intradiscal Biacuplasty

One systematic review of the evidence for IDB (38) and one pilot study (942,943) was identified. Kapural et al evaluated 15 patients undergoing one or two-level IDB treatments of their painful lumbar discs. All had chronic low back pain >6 months, back pain exceeding leg pain, concordant pain on provocation discography, disc height >50% of control, and evidence of single or 2-level degenerative disc disease without evidence of additional changes on MRI. IDB was performed under fluoroscopy using 2 radiofrequency probes positioned bilaterally in the intervertebral disc. Thirteen patients completed followup questionnaires, at 1, 3, and 6 months.

Median visual analo scale pain scores were reduces from 7 (95% C 6,8) to 4 (2,5) cm at 1 month, and remained at 3 (2,5) cm at 6 months. The Oswestry improved from 23.3 (SD 7.0) to 16.5 (6.8) points at 1 month and remained similar after 6 months. The SF-36 Physical Functioning scores improved from 51 (18) to 70 (16) points after 6 months, while the SF-36 Bodily Pain Score improved from 38 (15) to 54 (23) points. Daily opioid use did not change significantly from baseline.

6.5.2.1 Safety and Complications

No complications of biacuplasty have been reported thus far. However, expected potential complications are similar to IDET.

6.5.2.2 Indications

Indications are the same as for IDET as described above.

6.5.2.3 Level of Evidence

Based on the quality of evidence using the USPSTF criteria (126) the level of evidence for IDB is Level III (limited).

6.5.2.4 Recommendations

No recommendation is provided based on the available evidence.

6.5.3 Radiofrequency Posterior Annuloplasty

One systematic review (38) and 2 studies dealt with radiofrequency annuloplasty (927,944). Finch et al (944), in a case series, found the procedure to be effective. Kapural et al (927), in an observational study, found radiofrequency annuloplasty to be less effective than IDET. Table 24 describes effectiveness based on 2 published studies.

6.5.3.1 Indications

The indications are similar to IDET.

6.5.3.2 Safety and Complications

Potential complications are expected to be similar to those of IDET.

Table 23. *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 ≤ 12 mos.	Long-term relief > 12 mos.
Pauza et al 2004 (905)	RA	68	64	56% had 2 point decrease 40% had > 50 % decrease	NA	Yes	NA
Freeman et al 2005 (906)	RA	61	57	No change	NA	No	NA
Karasek and Bogduk 2000 and 2002 (909,910)	O	85	53	70%	57%	Yes	Yes
Gerszten et al 2002 (911)	O	50	27	75%	75%	Yes	Yes
Saal and Saal 2000 & 2002 (912-914)	O	52	53	SI	SI	Yes	Yes
Cohen et al 2003 (915)	O	80	70	48%	NA	Yes	NA
Freedman et al 2002 (916)	O	66	41	47%	16% > 50% decrease	Yes	No
Lee et al 2003 (917)	O	53	62	NA	53%	Yes	Yes
Lutz et al 2003 (918)	O	58	33	NA	70%	Yes	Yes
Davis et al 2004 (919)	O	52	60	NA	37%	No	No
Derby et al 2004 (448)	O	61	34 Injection 74 IDET	2.2 point decrease for injection 1.27 for IDET	NA	Yes	No
Derby et al 2004 (920)	O	52	99	NA	52% 1.56 point decrease back pain	Yes	Yes
Mekhail and Kapural 2004 (921)	O	58	34	SI	SI	Yes	Yes
Kapural et al 2004 (922)	O	74	34	SI	SI	Yes	Yes
Kapural et al 2005 (927)	O	81	21	SI	SI	Yes	Yes
Bryce et al 2005 (923)	O	58	86	SI	SI	Yes	Yes
Maurer et al 2008 (924)	O	62	56	SI	SI	Yes	Yes
Nunley et al 2008 (925)	O	60	53	SI	NA	Yes	NA
Ergun et al 2008 (926)	O	56	39	NA	79%	NA	Yes

O = observational; RA = randomized; VAS = visual analog scale; SI = significant improvement; 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 (38).

Table 24. *Results of published studies 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 (944)	O	69	46	37%	NA	No	NA
Kapural et al 2005 (927)	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 (38).

6.5.3.3 Level of Evidence

The indicated level of evidence for radiofrequency annuloplasty is II-3 based on USPSTF criteria (126).

6.5.3.4 Recommendations

No recommendation is provided.

6.6 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 (945-947). Several alternative techniques to open discectomy and microdiscectomy include automated percutaneous lumbar 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 (49-52).

6.6.1 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 (49,99,948-963).

6.6.1.1. Evidence Assessment

Gibson and Waddell (945) 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.

In a technology assessment report (99), negative evidence was illustrated. The systematic review by Hirsch et al (49) utilizing a combination of randomized trials and observational studies with only one randomized trial meeting inclusion criteria for evidence synthesis (948) and with 10 observational studies meeting inclusion criteria for evidence synthesis (952-959,962,963) concluded that the indicated level of evidence is II-2 in properly selected patients with contained lumbar disc prolapse.

Of the 2 published randomized trials (948,949), Revel et al (948) met the inclusion criteria for evidence synthesis. Revel et al (948) randomized patients with sciatica caused by a disc herniation to undergo as an APLD or chemonucleolysis. The trial included 72 chemonucleolysis and 69 APLD patients of whom 43% of 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. 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 (948), such as patient selection criteria, which led to poor results, have been criticized (49). The size of the disc hernia-

tion was an issue because for APLD it should not occupy more than 30% of the spinal canal, whereas in Revel et al's study (948) 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 of 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.

Multiple observational studies meeting inclusion criteria have been described in detail by Hirsch et al (49) and a summary of the results of eligible studies of APLD is provided in Table 25.

6.6.1.2 Cost Effectiveness

No cost effectiveness studies are available for APLD.

6.6.1.3 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 bowstring 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%.

Table 25. *Summary results of eligible studies of automated percutaneous lumbar discectomy included in this systematic review.*

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Pain Relief	Results
				> 12 mos.	Long-term > 12 mos.
Revel et al (948)	RA	70	69 APLD 72 Chemonucleolysis	37% APLD 66% Chemonucleolysis	N
Shapiro (952)	O	55	57	58%	P
Grevitt et al (953)	O	70	137 (115 remained at final follow-up interview)	72%	P
Onik et al (954)	O	68	506	75%	P
Davis et al (955)	O	59	518	85%	P
Maroon & Allen (956)	O	54	1054	85%	P
Teng et al (957)	O	71	1,582	83%	P
Bonaldi et al (958)	O	58	234	75%	P
Degobbis et al (959)	O	55	50	NA	NA
Marks (962)	O	66	103	63%	P
Bernd et al (963)	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 (49).

6.6.1.4 Safety and Complications

Percutaneous discectomy is associated with risks which include nerve injury, infection, bleeding, development of spinal instability, damage to endplate, and disc space collapse.

6.6.1.5 Level of Evidence

The indicated level of evidence based on USPSTF criteria (126) is Level II-2 for short- and long-term relief for APLD.

6.6.1.6 Recommendations

The recommendation is 1C/strong recommendation based on Guyatt et al's (136) criteria.

6.6.2 Percutaneous Lumbar Laser Discectomy (PLLD)

In percutaneous lumbar laser discectomy or PLLD, 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 (50,99,945).

6.6.2.1 Evidence Assessment

Based on the systematic review by Waddell et al (946) there is no acceptable evidence for laser discectomy. However, Singh et al (50) 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 (964-973).

Singh et al (50) described the characteristics of multiple studies included in the evidence synthesis and the details including methodologic quality scoring, and results are illustrated in Table 26.

6.6.2.2 Cost Effectiveness

No cost effectiveness studies are available for PLLD.

6.6.2.3 Indications

The indications for PLLD are the same as for APLD.

6.6.2.4 Safety and Complications

Complications of APLD include instrument failures, nerve damage, reflex sympathetic dystrophy (RSD), sigmoid artery injury, anomalous iliolumbar artery injury, spondylodiscitis, and cauda equina syndrome (974-977).

6.6.2.5 Level of Evidence

The indicated level of evidence based on USPSTF criteria (126) is II-2 for short- and long-term relief.

6.6.2.6 Recommendations

The recommendation based on Guyatt et al's (136) criteria is 1C/strong recommendation for PLLD.

Table 26. *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 (970)	O	69	576	56%	P
Bosacco et al (964)	O	58	63	66%	P
Choy (965)	O	55	518	75%	P
Zhao et al (972)	O	80	139	82%	P
Tassi (973)	O	61	419	84%	P
Grönemeyer et al (971)	O	75	200	73%	P
Nerubay et al (966)	O	55	50	74%	P
Ascher (967)	O	50	90	74%	P
Botsford (969)	O	63	292	75%	P
Casper et al (968)	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 (50).

6.6.3 Nucleoplasty

6.6.3.1 Evidence Assessment

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 reduction in intradiscal pressure (978-982). 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.

Gibson and Waddell (945) concluded that multiple minimally invasive decompression techniques including coblation therapy should be regarded as research techniques. Manchikanti et al (52) 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 of 7 studies met inclusion criteria (980,983-988). Manchikanti et al (52) described the characteristics of 5 studies included in the evidence synthesis (Table 27). All the studies showed improvement; however, no randomized trials were available for inclusion. The described complications of nucleoplasty include nerve damage, needle breakage, infection, and other complications similar to intradiscal therapies and percutaneous lumbar discectomy procedures (979,988).

6.6.3.2 Cost Effectiveness

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

6.6.3.3 Indications

The indications are the same as for APLD.

6.6.3.4 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 (984,985).

6.6.3.5 Level of Evidence

Based on USPSTF criteria (126), 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.

6.6.3.6 Recommendations

The recommendation based on Guyatt et al's (136) criteria is 2B/weak recommendation in managing radicular pain due to contained disc herniation. No recommendation is available in managing axial low back pain.

6.6.4 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 (51,99).

6.6.4.1. Evidence Assessment

Gibson and Waddell (945) have described all newer alternative minimally invasive techniques should

Table 27. *Results of published evaluations of nucleoplasty.*

Study	Study Characteristics	Methodological Quality Score	No. of patients	Pain Relief		Results	
				6 mos	1 year	Short-term relief ≤12 mos	Long-term relief >12 mos
Singh et al (980)	O	62	67	59%	56%	P	P
Singh et al (984)	O	62	80	76%	77%	P	P
Marin (985)	O	61	64	80%	80%	P	P
Mirzai et al (986)	O	77	52	85%	88%	P	P
Al-Zain et al (987)	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. (52).

be regarded as research techniques (989-992). Singh et al (51) in a systematic review utilizing 2 observational studies (990,991) meeting the inclusion criteria showed the indicated evidence as Level III for short- and long-term relief.

The studies by Alo et al (989,990) from a single study, Lierz et al (991), and Amoretti et al (992) all showed positive results. However, the number of participants was small in 2 studies meeting the inclusion criteria (990,991). Table 28 illustrates the results of published studies meeting inclusion criteria with 65% positive results by Alo et al at one year and 80% by Lierz et al. However, the total number of patients included in both studies is only 114.

6.6.4.2 Cost Effectiveness

Cost effectiveness studies were not available.

6.6.4.3 Indications

The indications are the same as for APLD.

6.6.4.4 Safety and Complications

The potential complications of Dekompressor include the same complications with either APLD or nucleoplasty. However, a critical failure of a Dekompressor probe was reported (993).

Other complications are similar to other intradiscal and mechanical disc decompression procedures, including nerve damage, infection, etc.

6.6.4.5 Level of Evidence

Based on USPSTF criteria (126), the indicated evidence for Dekompressor is Level III for short- and long-term relief.

6.6.4.6 Recommendations

No recommendation is provided for Dekompressor.

6.7 Spinal Cord Stimulation

Spinal cord stimulation (SCS) is primarily implanted in the United States for FBSS and complex regional pain syndrome (CRPS) (85,89,91-95,98,994-1000).

6.7.1 Evidence Assesment

Multiple systematic reviews have been performed with the first review published in 1995 (93). Taylor et al (85) 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 (94) in evaluating neuropathic back and leg pain secondary to FBSS concluded that the evidence was of Grade B. A Cochrane review for SCS (91) concluded that evidence was limited for SCS for FBSS. Frey et al (42) 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.

Kumar et al (1001,1002) compared SCS with conventional medical management (CMM) in patients with neuropathic pain secondary to FBSS with predominant leg pain of neuropathic radicular origin. 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 (1001). 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.

Table 28. *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 (990)	O	52	50	74%	65%	P	P
Lierz et al (991)	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; 12:589-600 (51).

North et al (1003) 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. Among 45 patients (90%) available for follow-up, SCS was more successful than reoperation (9 of 19 patients versus 3 of 26 patients, $P \leq 0.01$). The long-term success rates at 2.9 ± 1.1 years were for SCS, 47% versus reoperation 12% ($P \leq 0.01$).

Multiple observational studies showed positive results. Frey et al (42) included 9 observational studies (1004-1012) in the evidence synthesis as illustrated in Table 29.

6.7.2 Cost Effectiveness

Cost effectiveness of SCS has been performed in FBSS (995,996). Taylor et al (995) 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. Other investigators also showed similar findings illustrating cost effectiveness of spinal cord stimulation even though initial health care acquisition costs are higher than other treatments (996-999,1006).

6.7.3 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 or in the surgical pocket (1000,1013,1014). Overall up to 34% of SCS patients may experience an adverse event (89).

6.7.4 Indications

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

6.7.5 Level of Evidence

The indicated evidence for SCS is Level II-1 or II-2 for long-term relief in managing patients with FBSS.

6.7.6 Recommendations

Based on Guyatt et al's (136) criteria, the recom-

Table 29. *Results of published studies of 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 (1001)	RA	55	SCS=52 CMM=48	48% vs 9%	58% vs 17%	P	P
North et al (1003)	RA	56	SCS=24 Reoperation=26	SCS 9/19 Reoperation 3/26	SCS 9/19 Reoperation 3/26	P	P
Van Buyten et al (1004)	O	53	254	–	68%	P	P
Kumar and Toth (1005)	O	58	182	–	48%	P	N
De La Porte and Van de Kelft (1006)	O	56	78	–	58%	P	P
Devulder et al (1007)	O	56	69	–	77%	P	P
North et al (1008)	O	62	50	–	53%	P	P
Dario (1009)	O	56	49	–	71%	P	P
De La Porte and Siegfried (1010)	O	50	94	–	60%	P	P
Burchiel et al (1011)	O	57	219	–	55%	P	P
Ohnmeiss et al (1012)	O	57	40	–	70%	P	P

RA = randomized; O = observational; SCS = spinal cord stimulation; CMM = conventional medical management; *;* vs = versus; *P = 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 (42).

mendation is 1B or 1C/strong recommendation for clinical use on a long-term basis.

6.8 Implantable Intrathecal Drug Administration Systems

Continuous infusion of intrathecal medication is used for control of chronic, refractory, malignant and non-malignant pain (7,33,53,92).

6.8.1 Evidence Assessment

Turner et al (92), 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 (33) indicated the level of evidence for intrathecal infusion systems of either Level II-3 or III (limited). There were 5 observational studies which met inclusion criteria (1015-1019).

Three of the 5 observational studies (1015,1016,1019) with availability of outcomes showed positive results with only 232 patients (Table 30).

6.8.2 Cost Effectiveness

In post lumbar surgery 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 (1020).

6.8.3 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 (1021-1027).

6.8.4 Indications

The most common indication for the use of intrathecal pumps is disease of the spine (1020). Common specific diseases include adhesive arachnoiditis, postlaminectomy syndrome, spinal stenosis, and intractable low back and lower extremity pain.

6.8.5 Level of Evidence

The indicated evidence for intrathecal infusion systems (Table 30) 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 (126).

6.8.6 Recommendations

Based on Guyatt et al's criteria (136), the recommendation for intrathecal infusion systems is 1C/strong, with proper selection criteria.

Table 30. *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 (1015)	O	53	120	74%	74%	P	P
Roberts et al 2001 (1016)	O	50	88	82%	82%	P	P
Shaladi et al 2007 (1019)	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 (33).

7.0 Documentation

Documentation is to provide evidence or information. Documentation includes evaluation and management services, procedural services, and billing and coding. While the purpose of documentation is to provide information, it reflects the competency and character of the physician.

7.1 Medical Necessity

Medical necessity requires appropriate diagnosis and coding by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) to justify services rendered and indicates the severity of a patient's condition (1028). The Balanced Budget Act (HR 2015, Section 4317) requires all physicians to provide diagnostic information for all Medicare/Medicaid patients starting from January 1, 1998 (1029,1030). Medical necessity is defined in numerous ways (1031-1035):

- The CMS (1033) defines medical necessity as …"no payment may be made under Part A or Part B for any expense incurred for items or services which . . .are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a participant."
- The American Medical Association (AMA) (1035) defines medical necessity as, "health care services or procedures that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is:
    - In accordance with generally accepted standards of medical practice.
    - Clinically appropriate in terms of type, frequency, extent, site, and duration.
    - Not primarily for the convenience of the patient, physician or other healthcare provider."

7.2 Elements of Documentation

Federal, state, third party payor, and managed care plans rely heavily on provider documentation when assessing the claims for various parameters. These include:

- Was the billed service actually rendered or provided to the patient?
- Was the level of service or extent of the service accurately reported?
- Was the service or procedure medically necessary?
- Was the claim sent to the correct primary insurer for the service or procedure performed?

7.3 Types of Documentation

Documentation includes evaluation and management services and interventional techniques . Documentation for spinal interventional techniques may vary based on whether the procedure was performed in a facility setting such as hospital outpatient department or ambulatory surgery center versus in a physician's office.

7.4 Documentation of Interventional Procedures

All spinal interventional techniques are considered surgical procedures. Documentation requirements are as follows:

- History and physical.
- Indications and medical necessity.
- Intra-operative procedural description.
- Post-operative monitoring and ambulation.
- Discharge/disposition.

7.4.1 History and Physical

The physician's history should include the following elements:

- Documentation of the signs and symptoms warranting the interventional procedure.
- A listing of the patient's current medications including dosages, route, and frequency of admission.
- Any existing co-morbid conditions and previous surgeries.
- Documentation of any social history or conditions which would have an impact on the patient's care upon discharge from the facility following the procedure.

The physician's physical examination should not only reflect the relevance to interventional procedure, but also the type of anesthesia planned. Generally, for interventional techniques , if no anesthesia is to be administered, the physical examination is limited to the assessment of the patient's mental status and an examination specific to the proposed procedure, including any co-morbid conditions.

However, if intravenous sedation or any other type of anesthesia is planned, the physical examination should also include documentation of the results of an auscultatory examination of the heart and lungs, and an assessment and written statement about the patient's general health, in addition to the assessment of mental status and an examination specific to the proposed procedure and any co-morbid conditions.

7.4.2 Indications and Medical Necessity

Medical necessity must be established for each and every procedure and encounter. General documentation requirements for spinal interventional techniques for indications and medical necessity are as follows:

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

7.4.3 Procedural Documentation

This includes a description of the procedure, postoperative monitoring, and discharge/disposition (Table 31).

Table 31. *Key components of documentation of an interventional procedure.*

1.	**History and physical examination**
2.	**Informed consent**
3.	**Description of intravenous access, sedation, and physiologic monitoring (if utilized)**
4.	**Appropriate patient positioning and sterile preparation**
5.	**Anatomic needle placement**
	• Size, etc
	• Local Anesthetic / Steroids / Other Solutions
	• Volume
	• Concentration
	• Fluoroscopy
	• Contrast
	• Volume
	• Spread
	• Pain Provocation
6.	**Operating room staff**
7.	**Description of complications (if any) and if none stated as such**
8.	**Listing of post injection instructions to patient, including symptom monitoring as appropriate**
9.	**Patient status at discharge**
10.	**Post follow-up**

8.0 An Algorithmic Approach

The algorithmic approach described here is based on the best available evidence on the epidemiology of various identifiable sources of chronic spinal pain. This algorithmic approach is designed to promote the efficient use of IPM techniques based on the best available evidence. However, this may not be applicable in each and every patient. The purpose of the described algorithmic approach is to provide a disciplined approach to the use of spinal interventional techniques in managing spinal pain. This approach includes evaluation, diagnostic, and therapeutic approaches which in turn avoid unnecessary care as well as poorly documented practices.

This algorithmic approach does not dictate standard of care—these are guidelines. Further, with space constraints, comprehensive initial evaluation and all the findings are not provided. Thus, this should not be construed as the entire evaluation. Only relevant descriptions are provided. Further, changes in physical functional and psychological status are not described for each encounter.

8.1 Comprehensive Algorithm

Figure 2 illustrates an algorithmic approach for evaluation and management of a chronic pain patient. Appropriate history, physical examination, and medical decision-making are essential to provide appropriate documentation and patient care. Not covered in this algorithm are socioeconomic issues and psychosocial factors that may be important in the clinical decision-making process. A comprehensive and complete evaluation will assist in complying with the regulations and providing appropriate care and also fulfilling an algorithmic approach.

8.2 Low Back Pain

8.2.1 Diagnosis

Figure 3 illustrates a diagnostic algorithmic approach for chronic low back pain without disc herniation. This algorithm for the investigation of low back pain is based on the best available evidence on the epidemiology of various identifiable sources of chronic low back pain. Facet joint pain, discogenic pain, nerve root pain, and sacroiliac joint pain have been proven to be common causes of pain with proven diagnostic techniques (25,27,29,40,45,46,116,361-363).

If there is evidence of radiculitis, spinal stenosis, or other demonstrable causes resulting in radiculitis,

one may proceed with diagnostic transforaminal or therapeutic epidural injections (25). Otherwise an algorithmic approach should include the diagnostic interventions with facet joint blocks and sacroiliac joint injections, followed by discography. Lumbar discography at the present time suffers from significant controversy with Level II-2 evidence (46). In contrast, facet joint nerve blocks in the diagnosis of lumbar facet joint pain provide higher evidence with Level I or Level II-1 (40), whereas sacroiliac joint injections provide Level II-2 evidence (45).

An algorithm for investigating chronic low back pain without disc herniation commences with clinical questions, physical findings, and findings of radiological investigations. Controlled studies have illustrated the prevalence of lumbar facet joint pain in 21% to 41% of patients with chronic low back pain (29,40,338,361-365,368,369,372) and 16% in post laminectomy syndrome (373). The average prevalence of 31% (95% CI 28%–33%) and false-positive rate of 30% (95% CI 27%-33%) was shown by Datta et al (40). Thus, facet joints are entertained first in the algorithm because of their commonality as a source of chronic low back pain, available treatment, and ease of performance of the blocks. Further, among all the diagnostic approaches in the lumbosacral spine, medial branch blocks have the best evidence (Level I) with ability to rule out false-positives (27% to 47%) and demonstrated validity with multiple compounding factors, including psychological factors (382,383), exposure to opioids (1036), and sedation (44,380,1037). In this approach, investigation of facet joint pain is considered as a prime investigation, ahead of disc provocation and sacroiliac joint blocks. Multiple studies have indicated that facet joint pain may be bilateral in 60% to 79% of cases and involving 3 joints in 21% to 37% of patients (364,365,369).

The diagnostic blocks must be performed under controlled conditions. In the United States, commonly performed diagnostic blocks are often accomplished with 2 separate local anesthetics – in what is referred to as controlled comparative local anesthetic blocks with a small volume of local anesthetic. If a patient experiences at least 80% relief with the ability to perform previously painful movements within a timeframe that is appropriate for the duration of the local anesthetic used and the duration of relief with the second block relative to the first block is commensurate with the respective local anesthetic employed in each block, then, a positive diagnosis is made.

In this algorithm, to pursue the sacroiliac joint as the pain generator, pain must be caudal to L5 and must be positive for at least some provocative tests, along with tenderness over the sacroiliac joint (3,45,409). Sacroiliac joint blocks have a Level II-2 evidence in the diagnosis of sacroiliac joint pain utilizing comparative controlled local anesthetic blocks. The prevalence of sacroiliac joint pain is estimated to range between 2% and 38% using a double block paradigm in specific study populations (27,45,116,338,409,411,569,570,577, 578). The false-positive rates of single, uncontrolled, sacroiliac joint injections have been shown to be 20% to 54% (45). However, there has been a paucity of evidence in the evaluation of the effectiveness of sacroiliac joint blocks in the diagnosis of sacroiliac joint pain (27,45,116).

One or both sacroiliac joints may be blocked utilizing controlled comparative local anesthetic block paradigms in the United States. The relief obtained should be 80% with the ability to perform previously painful movements and also should be concordant based on the local anesthetic injection with a bupivacaine injection outlasting a lidocaine injection (3,45).

If pain is not suggestive of facet joint or sacroiliac joint origin, then the epidural injection algorithm is followed. Caudal and lumbar interlaminar epidurals are non-specific as far as identifying the source of pain. If a patient fails to respond to epidural injections, the discogenic approach may be undertaken.

Lumbar provocation discography is seldom performed as an initial test in the present algorithm. Provocative lumbar discography is performed as the first test in only specific settings of suspected discogenic pain and availability of a definitive treatment is offered or solely for diagnostic purposes prior to fusion. Otherwise, once facet joint pain, and if applicable sacroiliac joint pain, is ruled out and the patient fails to respond to at least 2 fluoroscopically directed epidural injections, discography may be pursued if determination of the disc as the source of pain is crucial. MRI will assist in ruling out any red flags and disc herniation, but will not determine if the disc is the cause of the pain. Hancock et al (409) in a systematic review of tests designed to identify the disc as a pain generator concluded that centralization was the only clinical feature associated with a discogenic pain etiology (1038). Provocation discography continues to be controversial with respect to diagnostic accuracy (28,46,105,114), utilization (13,56,58-60,278,327,328), and its impact on surgical volume (63,636). Lumbar discography has

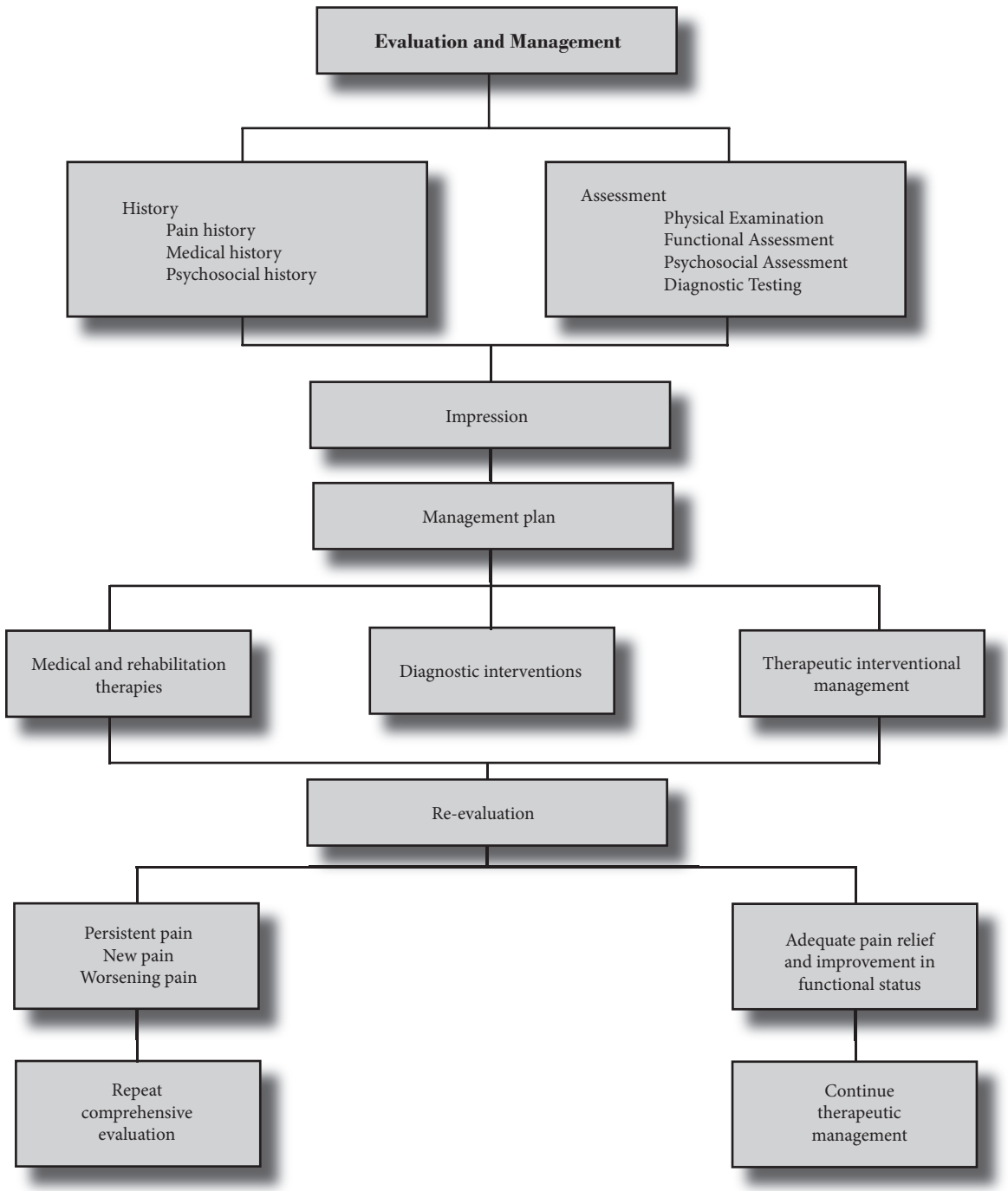

Fig. 2. *A comprehensive algorithm evaluation and management of chronic spinal pain.*

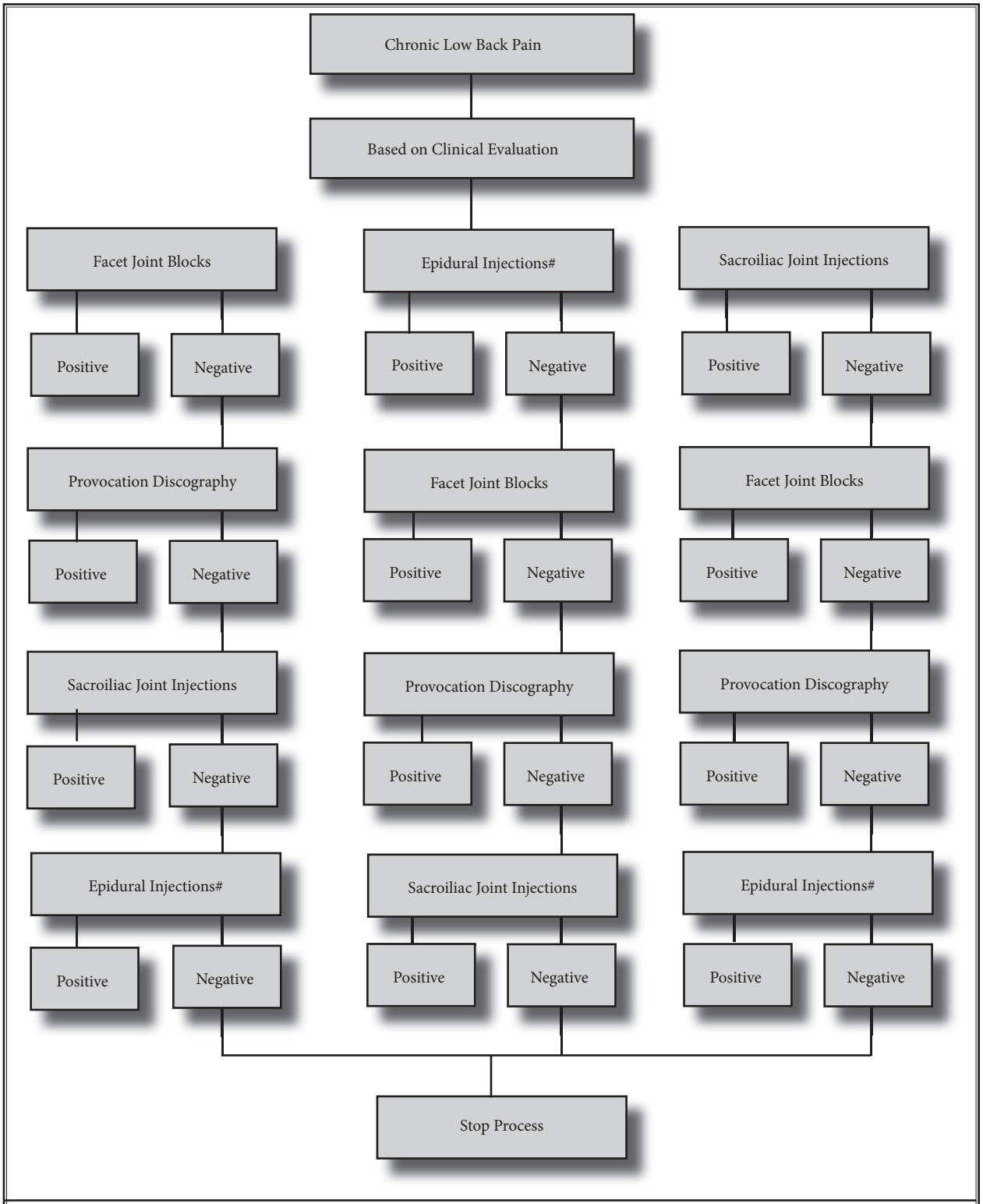

Fig. 3. *An algorithmic approach to diagnosis of chronic low back pain without disc herniation.*
Transforaminal epidural injections have been associated with reports of serious risks and adverse events.

been refined substantially since its inception and its diagnostic accuracy has been established as Level II-2 (3,46,53,105). However, to be valid, the provocation discography must be performed utilizing strict criteria of having concordant pain in one disc with at least 2 negative discs, one above and one below except when the L5/S1 is involved. In that case, only one negative disc is needed along with the suspect disc (L5/S1 in this case) displaying evoked intensity of a pain score of 7 on a scale of 0 to 10 or 70% of worst spontaneous pain (i.e., worst pain of 7 = 7 x 70% = 5) (3,46).

8.2.1.1 Diagnostic Efficiency

Under the present algorithmic approach, once facet joint pain is excluded, the patient may be treated with epidural injections or sacroiliac joint blocks may be pursued provided the patient meets the criteria for sacroiliac joint blocks. Lumbar provocation discography is the last step in the diagnostic algorithm and is utilized only when appropriate treatment can be performed if disc abnormality is noted. The only other indication is to satisfy patients' impressions if the patient does not improve with any other modalities of treatments.

Given the realities of health care in the United States and the available evidence from the literature, it appears that lumbar facet joints account for 30% of cases of chronic low back pain, sacroiliac joint pain accounts for less than 10% of cases, and discogenic pain accounts for 25% of the patients.

8.2.2 Management Algorithm

8.2.2.1 Somatic Pain Algorithm

Figure 4 illustrates therapeutic algorithmic management. The patients testing positive for facet joint pain may undergo either therapeutic facet joint nerve blocks or radiofrequency neurotomy based on the patients' preferences, values, and physician expertise. However, there is no evidence for lumbar intraarticular facet joint injections (40). In contrast, based on the review of included therapeutic studies (374,375,722), Level II-1 to II-2 evidence is presented for lumbar facet joint nerve blocks with an indicated level of evidence of II-2 to II-3 for lumbar radiofrequency neurotomy (40,374,375,722,741,739).

The next modality of treatment is epidural injections. Epidural injections have been shown to present with variable evidence. A recent systematic review of caudal epidural injections in the management of chronic low back pain (34) showed Level I evidence for relief of chronic pain secondary to disc herniation or radiculitis and discogenic pain without disc herniation or radiculitis (769,780,781). Further, the indicated evidence is Level II-1 or II-2 for caudal epidural injections in managing chronic pain of post lumbar surgery syndrome and spinal stenosis (34,774,776). A systematic review of therapeutic lumbar transforaminal epidural steroid injections (37) showed an indicated level of evidence of Level II-1 for short-term relief and Level II-2 for long-term relief in managing chronic lumbar radicular pain. The majority of the patients derived from the diagnostic algorithmic approach do not have radicular pain or disc herniation, thus, transforaminal epidural injections are applied with the proper indications for patients with radiculitis (37). In contrast, the evidence for lumbar interlaminar epidurals is lacking (35) with a paucity of contemporary literature and lack of fluoroscopically directed studies, and an indicated evidence of Level II-2 for short-term relief of pain of disc herniation or radiculitis with limited or lack of evidence for other conditions.

The indicated evidence for therapeutic sacroiliac joint interventions (27,45,116) is unavailable. Finally, the evidence for intradiscal procedures with thermal annular technology is also limited. The systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain (38) showed an indicated Level of evidence of II-2 for IDET, II-3 for radiofrequency annuloplasty, and limited or lack of evidence for IDB.

8.2.2.2 Radicular Pain Algorithm

While disc protrusion, herniation, and prolapse resulting in sciatica are seen in less than 5% of the patients with low back pain (945), approximately 30% of the patients presenting to IPM clinics will require either caudal, interlaminar, or transforaminal epidural injections as their initial treatment. Many patients with post-surgery syndrome, spinal stenosis, and radiculitis without disc protrusion may respond to epidural injections (24,26,34-37,111,113). Patients non-responsive to epidural injections will require either mechanical disc decompression (49-52), percutaneous adhesiolysis (26,43,113), spinal endoscopic adhesiolysis (26,48,113), or implantation of a spinal cord stimulator (42) or intrathecal infusion systems (33) depending on the clinical presentation, pathology, and other biopsychosocial factors. Transforaminal epidural injections may be performed for diagnostic purposes; however, these also lead to therapeutic improvement.

Buenaventura et al (37) in a systematic review of therapeutic lumbar transforaminal epidural steroid injections showed the indicated level of evidence as II-1 for short-term relief of 6 months or less and Level II-2 for long-term relief of longer than 6 months in managing chronic low back and lower extremity pain. Conn et al (34) in a systematic review of caudal epidural injections in the management of chronic low back pain showed variable evidence for various conditions causing low back and lower extremity pain. The evidence level shown is Level I for short- and long-term relief in managing chronic low back and lower extremity pain secondary to lumbar disc herniation and radiculitis, and discogenic pain without disc herniation or radiculitis. However, the indicated level of evidence is Level II-1 or II-2 for caudal epidural injections in managing low back pain of post-lumbar laminectomy syndrome and spinal stenosis.

In contrast to lumbar transforaminal epidural and caudal epidural injections, the evidence for lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain is limited due to the lack of availability of studies utilizing fluoroscopy. The evidence is delivered from blind interlaminar epidural injections. Based on Parr et al's (35) systematic review, the indicated evidence is Level II-2 for short-term relief of pain of disc herniation or radiculitis utilizing blind interlaminar epidural steroid injections with a lack of evidence and Level III for long-term relief of disc herniation and radiculitis. Furthermore, the evidence at present is lacking for short- and long-term relief of spinal stenosis and discogenic pain without radiculitis or disc herniation utilizing blind epidural injections.

Consequently, if a patient presents with unilateral, single, or 2 level involvement, one may proceed with transforaminal epidural injections (diagnostic and therapeutic). Bilateral or extensive involvement of multiple segments will lead to either interlaminar or caudal epidurals based on the upper or lower levels being involved, extensive stenosis (central or foraminal) and lack of response to caudal or interlaminar approaches. Except in specific documented circumstances with spinal stenosis also is based on the same philosophy as described above for transforaminal epidurals. For post-surgery syndrome, a caudal epidural is preferred and one may consider a transforaminal epidural if essential in patients without obstructing hardware.

8.2.3 Algorithm for Chronic Non-Responsive Pain

Patients non-responsive to epidural injections, may be considered for mechanical disc decompression, percutaneous adhesiolysis, spinal endoscopic adhesiolysis, spinal cord stimulation, or implantation of intrathecal infusion systems.

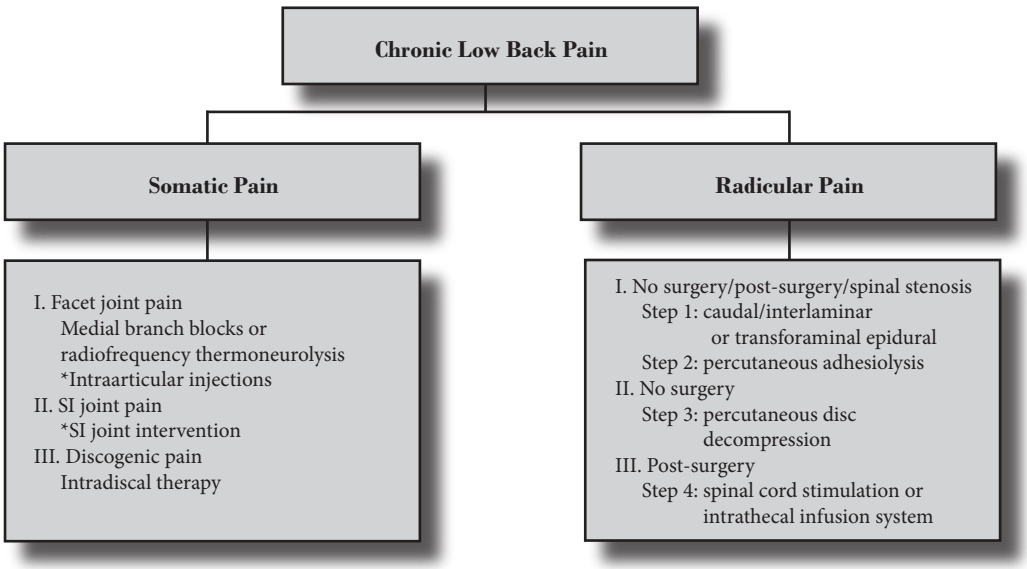

Fig. 4. *A suggested algorithm for therapeutic interventional techniques in management of chronic low back pain.*

* Not based on evidence

Percutaneous mechanical disc decompression (PMDD) is riddled with a lack of evidence even though there are 4 modalities, namely APLD, PLD, a mechanical high RPM device utilizing an Archimides' screw (DeKompressor®), and coblation nucleoplasty or plasma decompression. Recent systematic reviews (49-52) showed the evidence to be Level II-2 for short- and long-term (> one year) improvement for percutaneous automated lumbar discectomy and laser discectomy. The evidence for coblation nucleoplasty (Level II-3) and Dekompressor (Level III) is only emerging.

In patients with post-lumbar surgery syndrome after failure to respond to fluoroscopically directed epidural injections, percutaneous adhesiolysis is considered (43). Despite a paucity of efficacy and pragmatic trials, the systematic review by Epter et al (43) indicated the level of evidence as Level I or II-1 with short-term relief being considered as 6 months or less and long-term longer than 6 months (876-882), in managing post-lumbar laminectomy syndrome. Another type of adhesiolysis, spinal endoscopic adhesiolysis, which is considered to be an experimental procedure, also showed the indicated level of evidence of II-1 or II-2 for short-term and long-term (≤ 6 months or > 6 months) (30).

The next step in the radicular pain algorithm is implantable therapy. Frey et al (42) in a systematic review of SCS for patients with FBSS indicated the level of evidence as II-1 or II-2 for long-term relief (> one year) in managing patients with FBSS. In this systematic review (42), 2 randomized trials (1001,1003) and 8 observational studies were included (1004,1006-1012). Despite early increased expense, cost-effectiveness has been demonstrated for SCS (995-999).

Finally, long-term management of chronic non-cancer pain may be achieved with intrathecal infusion systems (33). Intrathecal infusion systems are also utilized for non-cancer pain in FBSS as an advanced stage intervention. While there is a lack of conclusive evidence, Patel et al (33), due to the paucity of quality literature concluded that the level of evidence for intrathecal infusion systems was indicated as Level II-3 or Level III with longer than one-year improvement considered as long-term response. There were no randomized trials meeting inclusion criteria for this systematic review (56).

8.3 Neck Pain

8.3.1 Diagnosis

Figure 5 illustrates an algorithmic approach to the diagnosis of chronic neck pain without disc herniation. This represents an algorithmic approach for the investigation of neck pain based on the best available evidence on the epidemiology of various identifiable sources of chronic neck pain. In a systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions, Falco et al (41), based on the controlled diagnostic blocks, determined the prevalence to be 36% to 67% with an average prevalence of 49% based on 8 studies (339,364,365,369,601-604) with a false-positive rate of 27% to 63% (average 49%) with single diagnostic blocks. In a systematic review of cervical discography as a diagnostic test for chronic spinal pain (39), the prevalence of cervical discogenic pain utilizing IASP criteria ranged between 16% and 20% based on 3 studies (339,644,645).

If there is evidence of radiculitis, spinal stenosis, post-surgery syndrome, or other demonstrable causes resulting in radiculitis, an interventionist may proceed with therapeutic epidural injections. For diagnostic purposes one may proceed with diagnostic cervical selective nerve root blocks or transforaminal epidural injections in rare circumstances. However, diagnostic accuracy of cervical selective nerve root blocks has not been established (25,115). Cervical transforaminal epidural injections have been associated with substantial risk (762,825,1039-1050). In contrast, therapeutic cervical interlaminar epidural injections have been shown with an indicated level of evidence of II-1 in managing chronic neck and upper extremity pain (36). Otherwise an algorithmic approach should include the diagnostic interventions with facet joint blocks, epidural injections, followed by discography. Discography at the present time suffers from significant controversy with Level II-2 evidence (39). In contrast, facet joint nerve blocks in the diagnosis of cervical facet joint pain provide evidence of Level I or Level II-1 (41).

An algorithm of investigation of chronic neck pain without disc herniation or radiculitis commences with clinical questions and physical and imaging findings. The controlled studies have illustrated the presence of facet joint pain on average in 40% to 50% of cases, ranging from 36% to 67% of the patients and 39% in a large recent study. Thus, the facet joints are entertained first in the algorithm in patients without radicular symptoms because of their commonality as a causative factor for chronic neck pain and headache and ease of performance. Consequently, the investigation of facet joint pain is considered as a prime investigation ahead of disc stimulation. Multiple studies have indicated the facet joint pain to be bilateral in

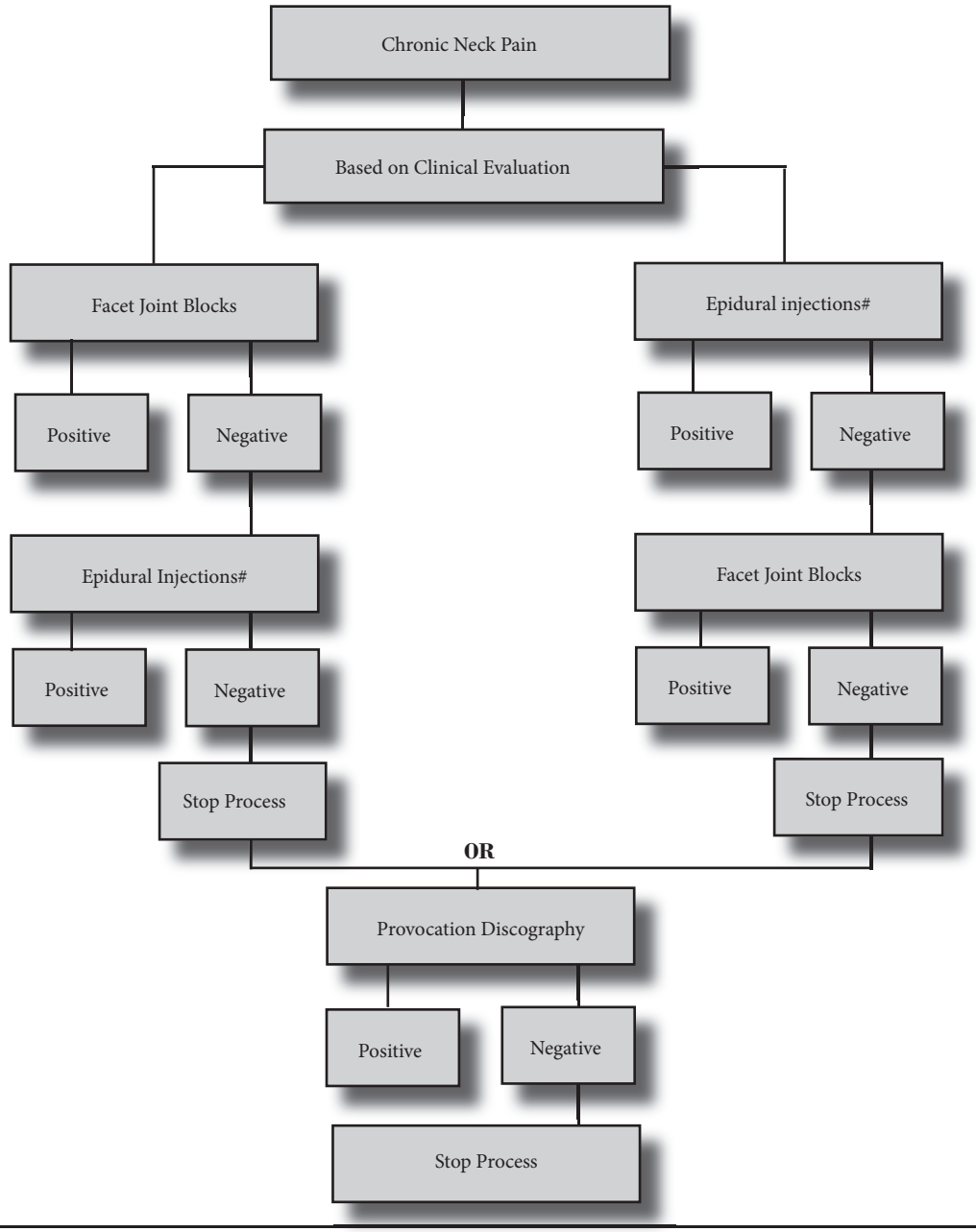

Fig. 5. *An algorithmic approach to diagnosis of chronic neck pain without disc herniation.*
Transforaminal epidural injections have been associated with reports of serious risks and adverse events

69% to 72% of cases and involving at least 3 joints in 50% to 85% of patients (364,365,369).

The diagnostic blocks must be performed under controlled conditions. In the United States, commonly performed diagnostic blocks are often achieved using 2 separate local anesthetics – controlled comparative local anesthetic blocks with a small volume of injectate.

If the facet joints are shown to be causative of chronic neck pain with 80% relief and the ability to perform previously painful movements with concordant response with 2 different local anesthetics, a positive diagnosis is made.

Cervical interlaminar injections are indicated if the facet joints are not suspected as a source for neck pain. However, if the patient fails to respond to epidural injections, further diagnostic interventions evaluating the disc may be undertaken provided a treatment can be offered.

Cervical provocation discography is seldom performed as an initial test in the present algorithmic approach. Once the facet joint pain is ruled out and the patient fails to respond to at least 2 fluoroscopically directed epidural injections, discography may be pursued if the determination of the disc as the source of pain is crucial. However, to be valid, the provocation discography must be performed utilizing criteria with concordant pain in one disc with at least 2 negative discs, with evoked intensity of pain of 7 of 10 or 70% of worst spontaneous pain (e.g., worst pain of 7 = > 7 x 70% = 5, being the pain score that would be significant upon disc provocation) (3,39).

8.3.1.1 Diagnostic Efficiency

Under the present algorithmic approach, which is simple, efficient, and cost-effective, once facet joint pain is excluded, the patient may be treated with epidural injections. Essentially, cervical provocation discography is the last step in the diagnostic algorithm and is utilized only when appropriate treatment can be offered if the disc abnormality is demonstrated. However, a rare but justifiable indication is to satisfy the patients' impressions if the patient does not improve with any other modalities of treatment. Thus far, studies have demonstrated the effectiveness of epidural injections in the cervical region as well as specifically in discogenic pain in the lumbar region (34,36,769,774,776,780,781,819,820,1051-1055).

In the United States, based on available literature, cervical facet joints account for 40% to 50% of cases of chronic neck pain without disc herniation, while discogenic pain accounts for approximately 20% of the cases.

8.3.2 Management Algorithm

8.3.2.1 Somatic Pain Algorithm

As illustrated in Fig. 6 showing the therapeutic algorithmic management of chronic neck pain, patients testing positive for facet joint pain may undergo either therapeutic facet joint nerve blocks or radiofrequency neurotomy based on patients' preferences, values, and physician expertise. However, there is no evidence for

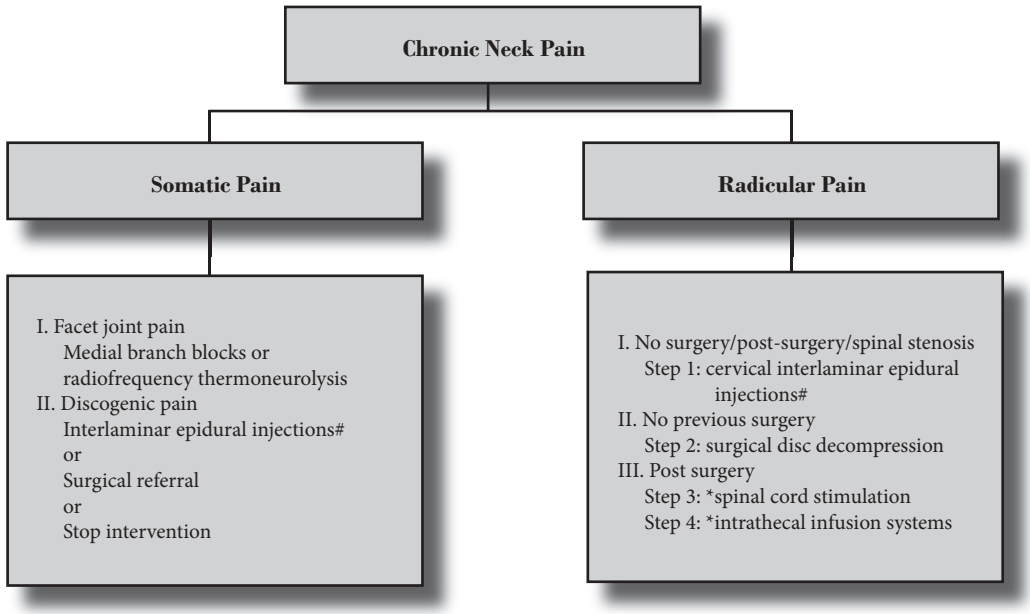

Fig. 6. *A suggested algorithm for therapeutic interventional techniques in the management of chronic neck pain.*

* Not based on evidence
\# Transforaminal epidural injections have been associated with reports of serious risks and adverse events

cervical intraarticular facet joint injections (41). In contrast to lack of evidence for intraarticular injections, Falco et al (41) have shown evidence for cervical medial branch blocks of II-1 or II-2 for cervical medial branch radiofrequency neurotomy based studies utilizing appropriate diagnostic criteria (575,592-594,596-598).

8.3.2.2 Radicular Pain Algorithm

Disc protrusions, herniations, or prolapses are less common in the cervical spine than in the lumbar spine. Radiculitis may also result from cervical spinal stenosis, spondylolisthesis, post-surgery syndrome, and discogenic pain without disc herniation. Approximately 30% of the patients presenting to IPM will require interlaminar epidural injections as their initial treatment. Transforaminal epidurals may be performed for diagnostic purposes, but they lack evidence and have increased risks (25,115,762,825,1039-1050).

8.3.2.3 Chronic Non-Responsive Pain Algorithm

Given a failure to respond to less invasive modalities of treatments, the consideration is then for SCS and intrathecal infusion systems. Evidence of these modalities in managing chronic intractable neck pain has not been evaluated. The evidence in the lumbar spine (42) is Level II-1 or II-2 for long-term relief in managing patients with FBSS. However, the evidence for intrathecal infusion systems is Level II-3 or Level III with one-year long-term improvement (33).

8.4 Thoracic Pain

8.4.1 Diagnosis

Figure 7 illustrates diagnostic algorithmic approach for chronic thoracic pain without disc herniation or radiculitis.

This algorithm for investigation of thoracic pain is based on the best available evidence on the epidemiology of various identifiable sources of chronic mid back and upper back pain. Facet joint pain has been proven to be one of the common causes of pain with proven diagnostic techniques (31,364,365,658). Based on the controlled, comparative local anesthetic blocks, thoracic facet joint pain has been shown to be present in approximately 40% of patients with mid-upper back pain when data from 3 studies were combined (34% to 48%) with false-positive rates of 42%. In contrast, the prevalence, as well as diagnostic accuracy of thoracic discogenic pain has not been well demonstrated (32).

Consequently, if a patient has any signs of radiculitis or disc herniation or other demonstrable causes resulting in radiculitis, one may proceed with therapeutic epidural injections. Otherwise, an algorithmic approach should include diagnostic interventions with facet joint blocks, epidural injections, and in rare circumstances, provocation thoracic discography and transforaminal epidural injections. Thoracic discography suffers from substantial controversy with low levels of evidence compared to cervical and lumbar discography. Thoracic transforaminal epidural injections are associated with high risk (860).

An algorithm for investigating chronic mid back or upper back pain without disc herniation commences with clinical questions, clinical findings, and findings of imaging. In this approach, investigation of facet joint pain is considered as the prime investigation, ahead of disc stimulation. Facet joint pain is bilateral in 64% to 84% of cases and involving 3 joints or more in 81% to 94% of patients (364,365,658).

The diagnostic blocks must be performed under controlled conditions. If a patient experiences at least 80% relief with the ability to perform previously painful movements with a concordant response in relation to duration of local anesthetics, a positive diagnosis is made.

Thoracic provocation discography is seldom performed, not only as an initial test, but in the settings of IPM. Once facet joint pain is ruled out and the patient fails to respond to at least 2 fluoroscopically directed epidural injections, investigations may cease or, under rare circumstances, discography may be pursued.

8.4.1.1 Diagnostic Efficiency

Under the present algorithmic approach, once facet joint pain is excluded, the patient may be treated with epidural injections. Thoracic provocation discography is an extremely rare and last step in the diagnostic algorithm and is utilized only when appropriate treatment can be performed if the disc abnormality is noted. The only very rare exception may be to perform discography to satisfy the patient's impressions if the patient does not improve with any other modalities of treatment.

Given the frequency of involvement of thoracic spine and the practice of medicine in the United States as well as the lack of significant pertinent literature,

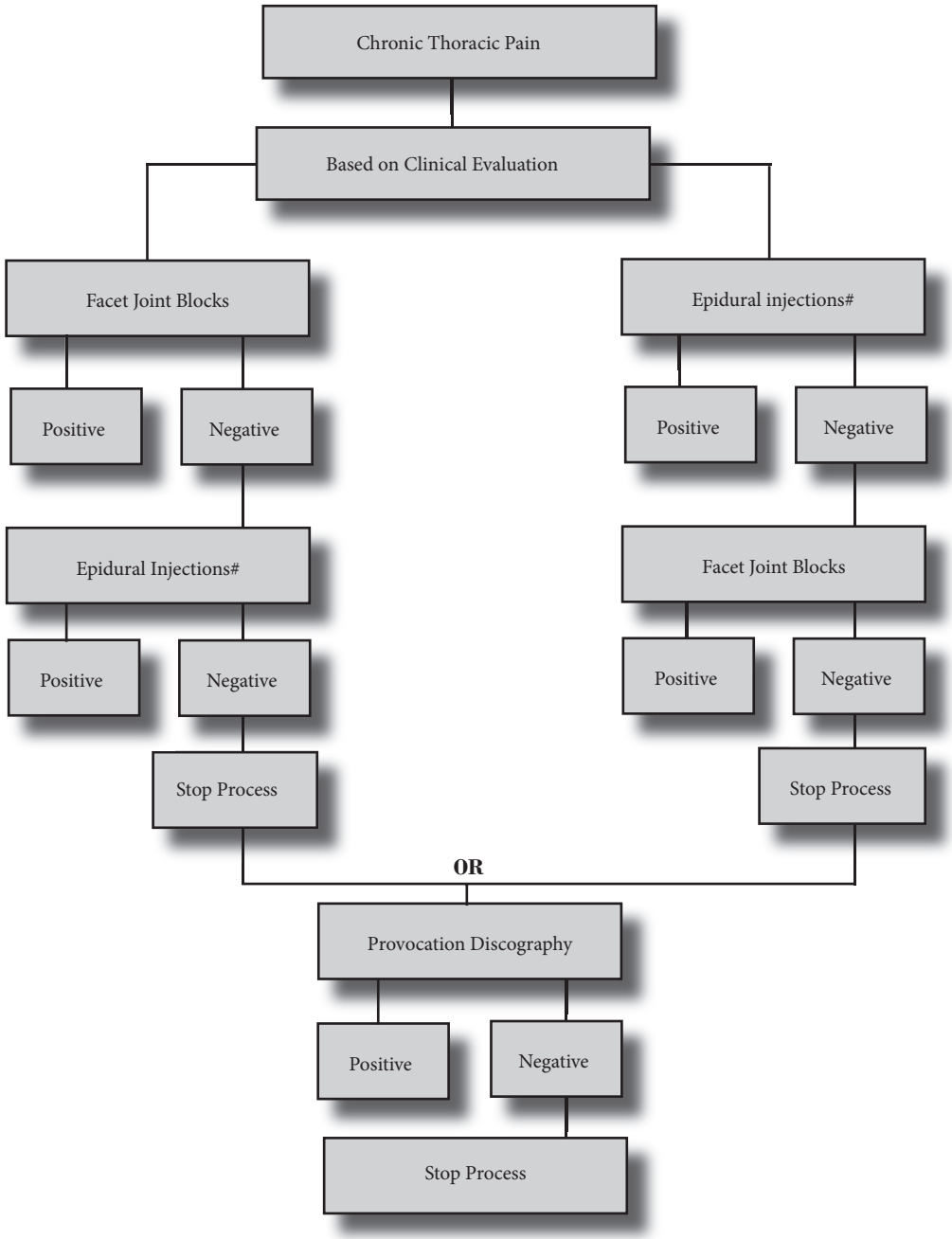

Fig. 7. *An algorithmic approach to diagnosis of chronic thoracic pain without disc herniation or radiculitis.*
Transforaminal epidural injections have been associated with reports of serious risks and adverse events

it appears that thoracic facet joints account for 40% of the cases of chronic mid back and upper back pain, whereas the remaining are considered to be discogenic pain or without specific diagnosis.

8.4.2 Management Algorithm

Figure 8 illustrates therapeutic algorithmic management. The patients testing positive for facet joint pain may undergo either therapeutic facet joint nerve

blocks or radiofrequency neurotomy based on the patient's preferences, values, and physician expertise. However, there is no evidence for either thoracic intraarticular facet joint injections or radiofrequency neurotomy (31). The only available evidence is for therapeutic thoracic medial branch blocks with a Level II-1 for short-term and long-term relief (31).

8.4.2.1 Somatic Pain Algorithm

As illustrated in Fig. 8 displaying the therapeutic algorithmic management of chronic thoracic pain, patients testing positive for facet joint pain may undergo therapeutic facet joint nerve blocks, however radiofrequency neurotomy may be offered based on the patients' preferences, values, and physician expertise. At present there is no evidence for either thoracic intraarticular facet joint injections or radiofrequency neurotomy. In contrast, based on the review of included therapeutic studies (31,659,660), Level II-1 or II-2 evidence is presented for thoracic facet joint nerve blocks.

The next modality of treatment is epidural injections. Epidural injections have been shown to have variable evidence in the cervical and lumbar regions with no analyzable evidence in the thoracic spine (34-37).

8.4.2.2 Radicular Pain Algorithm

Disc protrusions and herniations are much less common in the thoracic spine than the lumbar or cervical spine. Nonetheless, very few patients who present with thoracic radiculitis, post-surgery syndrome, spinal stenosis, and radiculitis without disc protrusion, and patients failing to show evidence of facet joint pain are candidates for epidural injections. Epidural injections are most commonly provided through an interlaminar route rather than transforaminal which is associated with high risk. Thoracic interlaminar epidural injections have not been evaluated or proven as to their effectiveness.

8.4.2.3 Algorithm for Chronic Non-Responsive Pain

Patients non-responsive to facet joint interventions and epidural interventions in the thoracic spine, in rare circumstances, may be considered for disc decompression or intrathecal implantables either with SCS or intrathecal infusion systems. However, there is no evidence available for any of the management modalities. Consequently, management is based on physician experience and patients' values and beliefs.

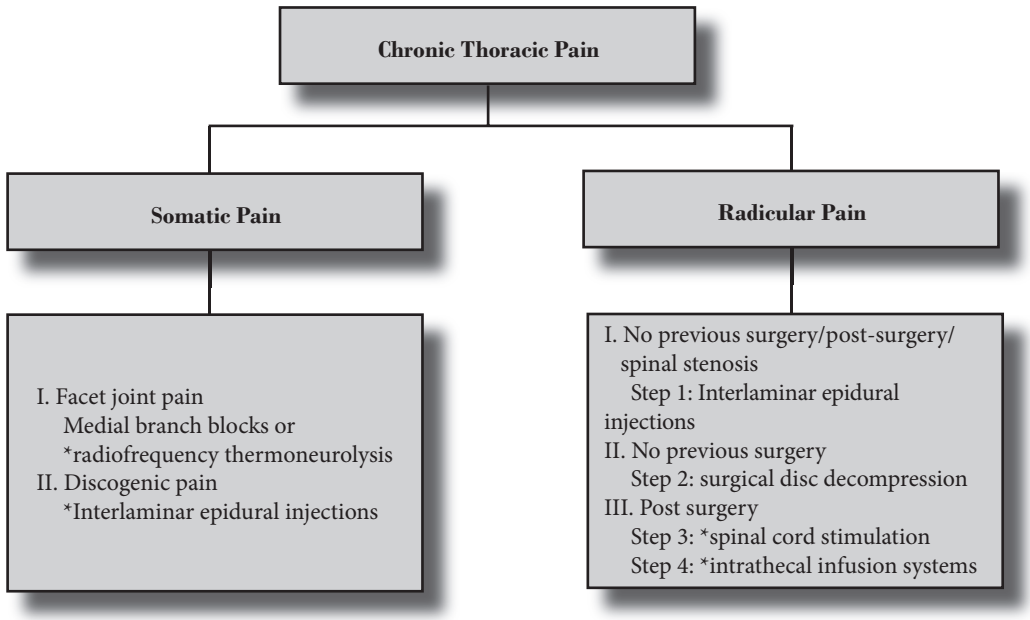

Fig. 8. *A suggested algorithm for therapeutic interventional techniques in the management of chronic thoracic pain.*
* Not based on evidence

9.0 Delivery of Interventional Technology

There is no consensus among IPM specialists with regards to type, dosage, frequency, total number of injections, or other interventions. Fortunately, the recent literature provides some guidance even though it is not conclusive. Based on the principles of EBM, the average relief per procedure is considered as the recommended duration if it is safely performed without complications.

The recent literature shows no significant difference in the outcomes with or without steroids with medial branch blocks (31,40,41,375) and epidural injections (34-37,659,660,769,774,776,780). Further many of the techniques including radiofrequency neurolysis and disc decompressions do not require any steroids.

The most commonly used formulations of long-acting steroids include methylprednisolone (Depo-Medrol), triamcinolone acetonide (Aristocort or Kenalog), and betamethasone acetate and phosphate mixture (Celestone Soluspan) (401,810,868,871,1056-1077).

The chemistry of neuraxial steroids has taken center stage in recent years due to the devastating complications following epidural injections, specifically transforaminals. Steroid particle embolization of small radicular arteries is believed to be an important causative factor (1076-1079). Tiso et al (1073) and Benzon et al (1074) extensively evaluated chemical properties and their relationship to IPM. Data from Tiso et al (1073) and Benzon et al (1074) regarding particle sizes were in general agreement with regards to methylprednisolone, triamcinolone, and commercial betamethasone. Though all formulations of steroids may be considered safe, formulations of betamethasone appear to be safer with no significant difference in the effectiveness (810). Formulations of commonly used epidural steroids are shown in Table 32 and the pharmacologic profile of commonly used epidural steroids is shown in Table 33 (659,660,1056,1057,1074,1080-1082).

Consistent with the present literature of the pharmacology of steroids, it appears that non-particulate steroids may be the agents of choice for transforaminal epidural injections, though no trials have compared particulate to non-particulate steroids. However, particulate steroids may be safely utilized for interlaminar or caudal epidural injections. Caution must be exercised in the use of particulate steroids in transforaminal epidural injections and specifically for cervical transforaminal epidural injections, particularly if sharp needles are used.

The frequency and total number of injections have been considered important issues, even though controversial and poorly addressed. These are based on flawed assumptions from non-existing evidence. Over the years, some authors have recommended one injection for diagnostic as well as therapeutic purposes.

Table 32. *Formulations of commonly used epidural steroids.*

	Depo-Medrol		Kenalog	Celestone	Decadron	Non-particulate Celestone
	Methylprednisolone		Triamcinolone acetonide	Betamethasone preservative free	Dexamethasone sodium phosphate	Betamethasone sodium phosphate
Amount of steroid	40 mg/mL	80 mg/mL	40 mg/mL	6 mg/mL	4 mg/mL	6 mg/mL
Polyethylene glycol 3350	29.1	28.2	—	—	—	—
Polysorbate 80	1.94	1.88	0.4	—	—	—
Monobasic sodium phosphate	6.8	6.59	—	3.4	—	3.0
Benzyl alcohol	9.16	8.8	9	—	—	—
Diabasic sodium phosphate	—	—	—	7.1	—	6.0
Edetate disodium	—	—	—	0.1	—	—
Benzalkonium chloride	—	—	—	0.2	—	—
Sodium sulfite	—	—	—	—	1 mg	—

Table 33. *Profile of commonly used epidural steroids.*

Drug	Equivalent Dose	Epidural Dose	Anti-Inflammatory Potency	Sodium Retention Capacity	Duration of Adrenal Suppression		
					IM	Single Epidural	Three Epidurals
Hydrocortisone	20 mg	N/A	1	1	N/A	N/A	N/A
Depo-Methylprednisolone (Depo-Medrol)	4 mg	40-80 mg	5	0.5	1-6 weeks	1-3 weeks	N/A
Triamcinolone acetonide (Kenalog)	4 mg	40-80 mg	5	0	2-6 weeks	N/A	2-3 months
Betamethasone (Celestone Soluspan)	0.6 mg	6-12 mg	33	0	1-2 weeks	N/A	N/A
Dexamethasone (Decadron)	0.75 mg	8-16 mg	27	1	N/A	N/A	N/A

N/A = Not available

Data adapted and modified from McEvoy et al (1057), Jacobs et al (1080) Kay et al (1081), Hsu et al (1082), Mikhail et al (871) Schimmer and Parker (1056) and Benzon et al (1074).

Some have preached 3 injections in a series irrespective of a patient's progress or lack thereof, whereas others suggest 3 injections followed by a repeat course of 3 injections after 3-, 6-, or 12-month intervals. There are also proponents who propose that an unlimited number of injections with no established goals or parameters should be available. A limitation of 3 mg per kilogram of body weight of steroid or 210 mg per year in an average person and a lifetime dose of 420 mg of steroid also has been advocated; however, with no scientific basis. The comprehensive review of the literature in preparation of these guidelines and review of all the systematic reviews has not shown any basis for the above reported assumptions and limitations. The administration must be based solely on patients' response, safety profile of the drug, experience of the patient, and pharmacological and chemical properties such as duration of action and suppression of adrenals.

9.1 Indications

Indications are variable for various types of interventional techniques .

9.2 Facet Joint Interventions

These guidelines apply for cervical, thoracic, and lumbar facet joint interventions.

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

9.2.1 Frequency of Interventions

- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks, with careful judgment of response.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 2-3 months or longer between injections, provided that ≥ 50% relief is obtained for 8 weeks.
- If the interventional procedures are applied for different regions, they may be performed at intervals of no sooner than one week or preferably 2 weeks for most types of procedures.
  - It is suggested that therapeutic frequency remain at least a minimum of 2 months for each region, it is further suggested that all the regions be treated at the same time provided that all procedures can be performed safely.
- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria, and it is suggested that these be limited to a maximum of 4 to 6 times for local anesthetic and steroid blocks over a period of one year, per region.
- Under unusual circumstances with a recurrent injury or cervicogenic headache, procedures may be repeated at intervals of 6 weeks after stabilization in the treatment phase.
- For medial branch neurotomy, the suggested frequency would be 6 months or longer (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 10 to 12 weeks.
  - The therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months per each region with multiple regions involved. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.
- Cervical and thoracic are considered as one region and lumbar and sacral are considered as one region for billing purposes.

9.3 Epidural Injections

Epidural injections include caudal, interlaminar, and transforaminal in cervical, thoracic, lumbar and sacral regions.

These guidelines apply to all epidural injections including caudal, interlaminar, and transforaminal.

9.3.1 Caudal

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

9.3.2 Lumbar Interlaminar

- Indications are same as for caudal epidural injections, except for post-surgery syndrome.
  - Caudal epidural is the modality of choice for post-surgery syndrome.

9.3.3 Cervical Interlaminar

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

9.3.4 Thoracic Interlaminar

- Common indications are as follows:|
  - Chronic mid back or upper back pain which

has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:
- Herniated, protruded, or extruded disc with or without radiculitis
- Thoracic spinal stenosis
- Thoracic post-surgery syndrome
- Degenerative disc disease
- Other causes

9.3.5 Lumbar Transforaminal

Lumbar transforaminal epidurals are provided for diagnostic and therapeutic purposes.

- Diagnostic indications:
  - To identify an inflamed nerve root in a patient with a history of radicular pain when results of visual anatomic studies and neurophysiologic studies are not collaborative.
  - To identify the pain generator when patients have multiple abnormalities on visual anatomic studies.
  - To determine the symptomatic level in multilevel disc herniation.
  - To determine a primary pain generator in the spine-hip syndrome.
  - To determine a previously undocumented nerve root irritation as a result of spondylolisthesis.
  - To determine the symptomatic level in multilevel stenosis.
  - To determine the symptomatic root in patients with documented postoperative fibrosis.
- Therapeutic indications:
  - Average pain levels of ≥ 6 on a scale of 0 to 10
  - Intermittent or continuous pain causing functional disability
  - Chronic low back and/or lower extremity pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management
  - Chronic low back and/or lower extremity pain resulting from:
    - Disc herniation
    - FBSS without extensive scar tissue and hardware
    - Spinal stenosis with radiculitis
    - Discogenic pain with radiculitis

9.3.6 Frequency of Interventions

- Guidelines of frequency of interventions apply to epidural injections caudal, interlaminar, and transforaminal.
- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks except in cancer-related pain or when a continuous administration of local anesthetic is employed for CRPS.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques should be 2 months or longer between each injection, provided that > 50% relief is obtained for 6 to 8 weeks.
- If the neural blockade is applied for different regions, they may be performed at intervals of no sooner than one week and preferably 2 weeks for most types of procedures. The therapeutic frequency may remain at intervals of at least 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures can be performed safely.
- In the treatment or therapeutic phase, the epidural injections should be repeated only as necessary according to medical necessity criteria, and it is suggested that these be limited to a maximum of 4–6 times per year.
- Under unusual circumstances with a recurrent injury, cancer-related pain, or CRPS, blocks may be repeated at intervals of 6 weeks or less after diagnosis/stabilization in the treatment phase.
- Cervical and thoracic regions are considered as one region and lumbar and sacral are considered as one region.

9.4 Percutaneous Adhesiolysis

- Common indications are as follows:
  - Chronic low back and/or lower extremity pain resulting from:
  - Failed back surgery syndrome/epidural fibrosis
  - Spinal stenosis
  - Disc herniation with radiculitis
- Duration of pain of at least 6 months.
- Intermittent or continuous pain causing functional disability.
- Average pain levels of ≥ 6 on a scale of 0 to 10.
- Failure to respond or poor response to non-interventional and non-surgical conservative management and fluoroscopically-directed epidural injections
- Absence of facet joint pain determined by con-

has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:
- Herniated, protruded, or extruded disc with or without radiculitis
- Thoracic spinal stenosis
- Thoracic post-surgery syndrome
- Degenerative disc disease
- Other causes

9.3.5 Lumbar Transforaminal

Lumbar transforaminal epidurals are provided for diagnostic and therapeutic purposes.

- Diagnostic indications:
  - To identify an inflamed nerve root in a patient with a history of radicular pain when results of visual anatomic studies and neurophysiologic studies are not collaborative.
  - To identify the pain generator when patients have multiple abnormalities on visual anatomic studies.
  - To determine the symptomatic level in multilevel disc herniation.
  - To determine a primary pain generator in the spine-hip syndrome.
  - To determine a previously undocumented nerve root irritation as a result of spondylolisthesis.
  - To determine the symptomatic level in multilevel stenosis.
  - To determine the symptomatic root in patients with documented postoperative fibrosis.
- Therapeutic indications:
  - Average pain levels of ≥ 6 on a scale of 0 to 10
  - Intermittent or continuous pain causing functional disability
  - Chronic low back and/or lower extremity pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management
  - Chronic low back and/or lower extremity pain resulting from:
    - Disc herniation
    - FBSS without extensive scar tissue and hardware
    - Spinal stenosis with radiculitis
    - Discogenic pain with radiculitis

9.3.6 Frequency of Interventions

- Guidelines of frequency of interventions apply to epidural injections caudal, interlaminar, and transforaminal.
- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks except in cancer-related pain or when a continuous administration of local anesthetic is employed for CRPS.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques should be 2 months or longer between each injection, provided that > 50% relief is obtained for 6 to 8 weeks.
- If the neural blockade is applied for different regions, they may be performed at intervals of no sooner than one week and preferably 2 weeks for most types of procedures. The therapeutic frequency may remain at intervals of at least 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures can be performed safely.
- In the treatment or therapeutic phase, the epidural injections should be repeated only as necessary according to medical necessity criteria, and it is suggested that these be limited to a maximum of 4–6 times per year.
- Under unusual circumstances with a recurrent injury, cancer-related pain, or CRPS, blocks may be repeated at intervals of 6 weeks or less after diagnosis/stabilization in the treatment phase.
- Cervical and thoracic regions are considered as one region and lumbar and sacral are considered as one region.

9.4 Percutaneous Adhesiolysis

- Common indications are as follows:
  - Chronic low back and/or lower extremity pain resulting from:
  - Failed back surgery syndrome/epidural fibrosis
  - Spinal stenosis
  - Disc herniation with radiculitis
- Duration of pain of at least 6 months.
- Intermittent or continuous pain causing functional disability.
- Average pain levels of ≥ 6 on a scale of 0 to 10.
- Failure to respond or poor response to non-interventional and non-surgical conservative management and fluoroscopically-directed epidural injections

- Absence of facet joint pain determined by controlled local anesthetic blocks

9.4.1 Frequency of Interventions

- The number of procedures are preferably limited to:
  - 2 interventions per year, with a 3-day protocol.
  - 4 interventions per year, with a one-day protocol.

9.5 Spinal Endoscopic Adhesiolysis

- Common indications are as follows:
  - Chronic low back and lower extremity pain nonresponsive or poorly responsive to conservative treatment, including fluoroscopically directed epidural injections and percutaneous adhesiolysis with hypertonic saline neurolysis.
  - Moderate to severe disability.
  - Absence of facet joint pain determined by controlled local anesthetic blocks.

9.5.1 Frequency of Interventions

- The procedures are preferably limited to a maximum of 2 per year provided the relief was > 50% for > 4 months.

9.6 Intradiscal Procedures

- Axial low back pain of at least 6 months duration.
- Failure to respond to conservative treatment.
- Abnormal nucleus signal on T2-weighed MRI images with > 60% residual disc height.
- Positive concordant discogram at low pressure.
- Normal neurologic exam (or at least no new deficits attributable to the level to be treated).
- Negative straight-leg raise.
- MRI with no evidence of root compression, tumor, or infection (if root compression is present, consider PMDD).

9.7 Mechanical Disc Decompression

- Common indications are as follows:
  - Unilateral leg pain greater than back pain
  - Radicular symptoms in a specific dermatomal distribution that correlates with MRI findings
  - Positive straight leg raising test or positive bowstring sign, or both
  - Neurologic findings or radicular symptoms
  - No improvement after 6 weeks of conservative therapy
  - Imaging studies (CT, MRI, discography) indicating a subligamentous contained disc herniation
  - Well maintained disc height of 60%

9.8 Sacroiliac Joint Injections

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

9.8.1 Frequency of Interventions

- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 2 months or longer between injections, provided that > 50% relief is obtained for 6 weeks.
- If the procedures are done for different joints, they should be performed at intervals of no sooner than one week or preferably 2 weeks. It is suggested that therapeutic frequency remain at 2

months for each joint. It is further suggested that both joints be treated at the same time, provided the injections can be performed safely.

- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria, and it is suggested that they be limited to a maximum of 4–6 times for local anesthetic and steroid blocks over a period of one year, per region.
- Under unusual circumstances with a recurrent injury, procedures may be repeated at intervals of 6 weeks after stabilization in the treatment phase.
- For sacroiliac joint radiofrequency neurotomy, the suggested frequency is 3 months or longer between each procedure (maximum of 3 times per year), provided that >50% relief is obtained for 10 to 12 weeks.

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Dr. Schultz is a paid consultant for Medtronic.
Dr. Hayek is a consultant for Boston Scientific, Valencia, CA
Dr. Hirsch is a consultant for Cardinal Healthcare and Medtronic, he has previously served as a consultant for Arthrocare, he serves on the Steering Committee for KAVIAR trial (volunteer position), and on the Data and Safety Monitoring Board (DSMB): CEEP trial (volunteer position).

Dr. Derby has stock options with Laurimed and Kyphon.

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