

## INTERVENTIONAL TECHNIQUES IN THE MANAGEMENT OF CHRONIC SPINAL PAIN: EVIDENCE-BASED PRACTICE GUIDELINES

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**Background:** The lifetime prevalence of spinal pain has been reported as 54% to 80%, with as many as 60% of patients continuing to have chronic pain five years or longer after the initial episode. Spinal pain is associated with significant economic, societal, and health impact. Available evidence documents a wide degree of variance in the definition and the practice of interventional pain management.

**Objective:** To develop evidence-based clinical practice guidelines for interventional techniques in the management of chronic spinal pain, with utilization of all types of evidence, applying an evidence-based approach, with broad representation of specialists from academic and clinical practices.

**Design:** A systematic review of diagnostic and therapeutic interventions applied in managing chronic spinal pain by a policy committee. Design consisted of formulation of essentials of guidelines and a series of potential evidence linkages representing conclusions, and statements about relationships between clinical interventions and outcomes.

**Methods:** The elements of the guideline preparation process included literature searches, literature synthesis, systematic review, consensus evaluation, open forum presentation, formal endorsement by the Board of Directors of the American Society of Inter-

ventional Pain Physicians (ASIPP), and blinded peer review.

Methodologic quality evaluation criteria utilized included AHRQ criteria, QUADAS criteria, and Cochrane review criteria. The designation of levels of evidence was from Level I (conclusive), Level II (strong), Level III (moderate), Level IV (limited), to Level V (indeterminate).

**Results:** The accuracy of facet joint nerve blocks was strong in the diagnosis of lumbar and cervical facet joint pain, whereas, it was moderate in the diagnosis of thoracic facet joint pain. The evidence was strong for lumbar discography, whereas, the evidence was limited for cervical and thoracic discography.

The evidence was moderate for transforaminal epidural injections or selective nerve root blocks in the preoperative evaluation of patients with negative or inconclusive imaging studies. The evidence was moderate for sacroiliac joint injections in the diagnosis of sacroiliac joint pain.

The evidence for therapeutic lumbar intraarticular facet injections of local anesthetics and steroids was moderate for short-term improvement and limited for long-term improvement, whereas, it was negative for cervical facet joint injections. The evidence for lumbar and cervical medial branch blocks was moderate. The evidence for medial branch neurotomy was moderate to strong for relief of chronic low back and neck pain.

The evidence for caudal epidural steroid injections was strong for short-term relief and moderate for long-term relief in managing chronic low back and radicular pain, and limited in managing pain of postlumbar laminectomy syndrome. The evidence for interlaminar epidural steroid injections was strong for short-term relief and limited for long-term relief in managing lumbar radiculopathy, whereas, for cervical

radiculopathy the evidence was moderate. The evidence for transforaminal epidural steroid injections was strong for short-term and moderate for long-term improvement in managing lumbar nerve root pain, whereas, it was moderate for cervical nerve root pain and limited for lumbar post laminectomy syndrome and spinal stenosis.

The evidence for percutaneous epidural adhesiolysis was strong. For spinal endoscopic adhesiolysis, the evidence was strong for short-term relief and moderate for long-term relief.

For sacroiliac intraarticular injections, the evidence was moderate for short-term relief and limited for long-term relief. The evidence for radiofrequency neurotomy for sacroiliac joint pain was indeterminate.

The evidence for intradiscal electrothermal therapy was strong for short-term relief and moderate for long-term relief in managing chronic discogenic low back pain, whereas, for nucleoplasty, the evidence was limited.

The evidence for spinal cord stimulation in failed back surgery syndrome and complex regional pain syndrome was strong for short-term relief and moderate for long-term relief. The evidence for implantable intrathecal infusion systems was moderate to strong.

**Conclusion:** These guidelines included 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. **These guidelines do not represent a "standard of care."**

**Keywords:** Interventional techniques, chronic spinal pain, diagnostic blocks, therapeutic interventions, facet joint interventions, epidural injections, epidural adhesiolysis, discography, radiofrequency, spinal cord stimulation, intrathecal implantable systems

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**CONTENTS****1.0 Introduction**

- 1.1 Purpose
- 1.2 Rationale and Importance
- 1.3 Population and Preferences
- 1.4 Implementation and Review
- 1.5 Application
- 1.6 Focus
- 1.7 Technology
- 1.8 Methodology

**2.0 Chronic Pain**

- 2.1 Definition
- 2.2 Prevalence
- 2.3 Spinal Pain
- 2.4 Chronicity
- 2.5 Health and Economic Impact

**3.0 Structural Basis**

- 3.1 Facet Joint
- 3.2 Intervertebral Disc
- 3.3 Dorsal Root Ganglion
- 3.4 Sacroiliac Joint
- 3.5 Postlaminectomy Syndrome
- 3.6 Spinal Stenosis

**4.0 Interventional Techniques****4.1 Mechanism of Action****5.0 Diagnostic Interventional Techniques**

- 5.1 Facet or Zygapophysial Joint Blocks
- 5.2 Provocative Discography
- 5.3 Transforaminal Epidural Injections or Selective Nerve Root Blocks
- 5.4 Sacroiliac Joint Blocks

**6.0 Therapeutic Interventional Techniques**

- 6.1 Facet Joint Interventions
  - 6.1.1 Intraarticular Blocks
  - 6.1.2 Medial Branch Blocks
  - 6.1.3 Medial Branch Neurotomy
- 6.2 Epidural Injections
  - 6.2.1 Caudal Epidural Injections
  - 6.2.2 Interlaminar Epidural Injections
  - 6.2.3 Transforaminal Epidural Injections
- 6.3 Epidural Adhesiolysis
  - 6.3.1 Percutaneous Adhesiolysis
  - 6.3.2 Endoscopic Adhesiolysis
- 6.4 Sacroiliac Joint Interventions
  - 6.4.1 Intraarticular Injections
  - 6.4.2 Radiofrequency neurotomy

**6.5 Intradiscal Therapies**

- 6.5.1 Intradiscal Electrothermal Therapy
- 6.5.2 Nucleoplasty

**6.6 Implantable Therapies**

- 6.6.1 Spinal Cord Stimulation
- 6.6.2 Implantable Intrathecal Drug Administration Systems

**7.0 Evaluation And Management**

- 7.1 Evaluation
- 7.2 Medical Necessity Management

**8.0 Delivery of Interventional Technology**

- 8.1 Facet Joint Injections and Medial Branch Blocks
- 8.2 Medial Branch Neurotomy
- 8.3 Epidural Injections
- 8.4 Percutaneous Adhesiolysis
- 8.5 Spinal Endoscopic Adhesiolysis
- 8.6 Sacroiliac Joint Injections
- 8.7 Sacroiliac Joint Radiofrequency Neurotomy

**9. An Algorithmic Approach****10. Conclusion****1.0 INTRODUCTION****1.1 Purpose**

Evidence-based clinical practice guidelines for interventional techniques in the management of chronic spinal pain are statements developed to improve quality of care, patient access, treatment outcomes, appropriateness of care, efficiency and effectiveness, and achieve cost containment by improving the cost-benefit ratio (1).

**1.2 Rationale and Importance**

Available evidence documents a wide degree of variance in the definition and the practice of interventional pain management (1). Application of interventional techniques by multiple specialties is highly variable for even the most commonly performed procedures and treated condition(s).

National Uniform Claims Commit-

tee (NUCC)<sup>1</sup> defines interventional pain management as the discipline of medicine devoted to the diagnosis and treatment of pain and related disorders by the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatments.

Medicare Payment Advisory Commission (MedPAC)<sup>2</sup> described interventional techniques as minimally invasive procedures including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain.

Many of the conditions of spinal pain and other chronic pain conditions are considered as either acute recurrent problems that are characterized by periods of quiescence punctuated by flares, or chronic diseases, like diabetes or hypertension, requiring long-term treatment with ongoing care. On the basis of advances in imaging, neural anatomic findings, new discoveries in chemical mediation, the development of precision di-

agnostic and therapeutic injection techniques, and reported non-operative treatment successes, the importance of interventional techniques in managing chronic spinal pain has been defined.

Many guidelines, systematic reviews, Cochrane Reviews, and other publications pertaining to interventional pain management have been seriously questioned (1-10). Neither cancer pain nor spine surgery guidelines may be applied to manage chronic spinal pain. It has been highlighted that such reviews have some major shortcomings, with potentially harmful health care implications for patients in the United States (10).

These guidelines address the issues of systematic evaluation and ongoing care of chronic or persistent pain. Primarily, these guidelines provide information about the scientific basis of recommended procedures. The guidelines, properly applied, should increase compliance, dispel misconceptions, contribute to appropriate patient expectations, and facilitate the relationship between patients, physicians, and the payers.

**1.3 Population and Preferences**

The population covered by these guidelines includes all patients suffering with chronic spinal pain eligible to under-

1 The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09.

2 Medicare Payment Advisory Commission Report to the Congress. Paying for Interventional Pain Services in Ambulatory Settings. December 2001.

go commonly utilized and effective interventional technique(s). A treatment plan must be established taking into consideration the evidence, patient preferences, and risk-benefit ratio.

#### 1.4 Implementation and Review

The dates for implementation and review were established:

- Effective date - February 1, 2005
- Expiration date - January 31, 2007
- Scheduled review - April 1, 2006

#### 1.5 Application

These guidelines are intended for use by interventional pain physicians. However, 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. These guidelines do not represent "standard of care."

#### 1.6 Focus

These guidelines focus on a range of interventions that are the essential elements of effective management of chronic spinal pain. It is recognized that management of chronic spinal pain takes place in a wide context of healthcare, involving multiple specialists, and multiple techniques which also include non-interventional techniques. Consequently, the decision to implement a particular management approach should be based on a comprehensive assessment of the patient's overall health status, requirements, and preferences.

#### 1.7 Technology

These guidelines describe multiple interventional techniques available in the management of chronic spinal pain, both diagnostic and therapeutic. The diagnostic interventional techniques include facet joint blocks, provocative discography, sacroiliac joint blocks, and transforaminal epidural injections. Therapeutic interventional techniques include facet joint interventions encompassing intraarticular injections, medial branch blocks, and medial branch neurotomy; sacroiliac joint interventions, including sacroiliac joint blocks, and radiofrequency neurotomy; epidural injections including caudal epi-

dural injections, interlaminar epidural injections, and transforaminal epidural injections; epidural adhesiolysis including percutaneous adhesiolysis, and spinal endoscopic adhesiolysis; intradiscal therapies including intradiscal electrothermal therapy (IDET), nucleoplasty, and implantable therapies, which include spinal cord stimulation and intrathecal drug administration systems.

These guidelines also describe evaluation and management services, delivery of interventional technology, and an algorithmic approach to diagnosis and management of chronic spinal pain.

#### 1.8 Methodology

In developing these guidelines, all types of evidence are utilized. If an evidence-based approach failed to provide adequate levels of evidence, consensus and expert opinions have been utilized. These approaches are described in separate publications (1, 11-19).

While an evidence-based approach may seem to enhance the scientific rigor of guideline development, recommendations may not always meet the highest scientific standards (11-17). Evidence-based medicine is defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (15).

In preparation of these guidelines, it is recognized that at the core of an evidence-based approach to clinical or public health issues is, inevitably, the evidence itself which needs to be carefully gathered and collated from a systematic literature review of the particular issues. Consequently, the process by which the strength of scientific evidence is evaluated in the development of evidence-based medicine recommendations and guidelines is crucial. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available clinical evidence from systematic research.

A policy committee, with broad representation, consisting of academic and clinical practitioners recognized as experts in one or more interventional techniques of concern and representing a variety of practices and geographic areas, were included and convened. This committee formalized the essentials of guidelines. This was followed by formulation of a series of potential evidence linkages, representing conclusions and statements

about relationships between clinical interventions and outcomes. The elements of the guideline preparation process included literature searches, literature syntheses, systematic review, consensus evaluation, open forum presentations, formal endorsement by the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP), and blinded peer review.

Descriptions of evidence synthesis and guideline preparation are described in multiple documents (11-20). In addition, multiple systematic, narrative, and/or best evidence synthesis reviews pertaining to interventional techniques have been considered and included (1-8, 21-40). In synthesizing the evidence, systematic reviews, randomized clinical trials, observational studies, and diagnostic accuracy studies were evaluated utilizing reporting criteria and quality evaluation criteria (7, 11, 12, 16, 18-20, 41-45). Details of evidence synthesis are described in multiple publications (11, 12, 16, 18, 19). For a particular technique, if at least ten randomized trials were not available, non-randomized or observational studies were also included.

Systems for grading the strength of a body of evidence are much less uniform and consistent than those for rating study quality. Consequently, the guideline committee designed levels of evidence from Level I through Level V, modified from various publications (Table 1) (1, 11, 12, 16, 18, 19).

## 2.0 CHRONIC PAIN

### 2.1 Definition

Chronic pain has numerous definitions. Consequently, single or a combination of multiple definitions are utilized (1).

- ♦ Pain which persists a month beyond the usual course of an acute disease or a reasonable time for any injury to heal that is associated with chronic pathologic processes that cause continuous pain or pain at intervals for months or years.
- ♦ Persistent pain that is not amenable to routine pain control methods.
- ♦ Pain that exists beyond an expected time frame for healing.
- ♦ Pain, where healing may never occur.

Pain is a highly disagreeable sensation that results from an extraordinarily

Table 1. *Designation of levels of evidence*

<b>Level I</b>	Conclusive: Research-based evidence with multiple relevant and high-quality scientific studies or consistent reviews of meta-analyses
<b>Level II</b>	Strong: Research-based evidence from at least one properly designed randomized, controlled trial; or research-based evidence from multiple properly designed studies of smaller size; or multiple low quality trials.
<b>Level III</b>	Moderate: a) Evidence obtained from well-designed pseudorandomized controlled trials (alternate allocation or some other method); b) evidence obtained from comparative studies with concurrent controls and allocation not randomized (cohort studies, case-controlled studies, or interrupted time series with a control group); c) evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
<b>Level IV</b>	Limited: Evidence from well-designed nonexperimental studies from more than one center or research group; or conflicting evidence with inconsistent findings in multiple trials
<b>Level V</b>	Indeterminate: Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees.

Adapted and modified from ref (1, 11, 12, 16, 18, 19)

complex and interactive series of mechanisms integrated at all levels of the neuraxis, from the periphery to higher cortical structures.

## 2.2 Prevalence

A review of 15 epidemiological studies led to the conclusion that, in the adult population, chronic pain ranges from 2% to 40%, with a median point prevalence of 15% (46). Various studies (47-51), defining chronic pain of >3 months duration, reported prevalence rates of chronic pain ranging from approximately 11% to 24%. A World Health Organization Study in primary care evaluating persistent pain and well being reported an overall prevalence of pain in 20% of primary care patients, with approximately 48% reporting back pain (52). Overall, literature has overwhelmingly and consistently described the prevalence of chronic pain in children, adults, and elderly (53-59).

In a 4-year follow-up study, it was concluded that chronic pain is a common, persistent problem in the community with relatively high incidence and low recovery rates (53). In a cross sectional study of prevalence of musculoskeletal symptoms in single and multiple body regions, it was demonstrated that musculoskeletal symptoms for multiple body regions (2 or more) were more prevalent (64% of all workers) than those for single body regions (19%) (54). They showed that approximately 85% of lower back symptoms were associated with dis-

orders in other body regions.

## 2.3 Spinal Pain

Among chronic pain disorders, pain arising from various structures of the spine constitutes the majority of problems. The lifetime prevalence of spinal pain has been reported as 54% to 80% (1, 53, 56-80). Studies of the prevalence of low back pain and neck pain (60, 64) and impact on general health showed 25% of patients reporting grade II to IV low back pain (high pain intensity with disability) vs 14% with neck pain. The studies evaluating chronic low back pain estimated the average age related prevalence of persistent low back pain as 12% in children and adolescents, 15% in adults, and 27% in the elderly (1, 56, 57, 60).

## 2.4 Chronicity

Duration of pain and its chronicity have been topics of controversy. Conventional beliefs are that most episodes of low back pain will be short-lived, with 80% to 90% of attacks resolving in about 6 weeks irrespective of the administration or type of treatment, and 5% to 10% of patients developing persistent back pain. However, this concept has been questioned, as the condition tends to relapse, so most patients will experience recurrent episodes. Modern evidence has shown that chronic persistent low back pain and neck pain in children and adults are seen in up to 60% of patients, 5 years or longer after the initial episode (1, 72-78).

## 2.5 Health and Economic Impact

Spinal pain is associated with significant economic, societal, and health impact (79-98). Estimates and patterns of direct healthcare expenditures among individuals with back pain in the United States have reached \$90.7 billion for the year 1998 (84). On average, individuals with back pain incurred healthcare expenditures about 60% higher than individuals without back pain (\$3,498 versus \$2,178). It was estimated that the cost of healthcare for patients with chronic pain might exceed the combined cost of treating patients with coronary artery disease, cancer, and AIDS (94). 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 (95). Even further, annual healthcare cost incurred by chronic pain patients, excluding cost for surgical procedures, may range from \$500 to as high as \$35,400, with the average ranging from \$12,900 to \$18,883 annually (95, 96). However, the majority of the costs are associated with disability compensation, lost productivity, and lost tax revenue. Disability secondary to spinal pain is enormous (84, 88-98).

## 3.0 STRUCTURAL BASIS

Chronic spinal pain is a multifactorial disorder with many possible etiologies. The biopsychosocial model, which emerged in the 1980s, views chronic spinal pain as a biopsychosocial phenomenon, in which biological, psychological and social factors dynamically interact with each other. In the 1990s, the biopsychosocial approach dominated chronic spinal pain management, at least among academicians, with the introduction of "psychosocial" approaches.

Proponents of a structural basis claim that proponents of psychopathologic basis should provide empirical evidence to prove that psychopathology causes pain and specify the mechanisms by which it is generated (99). Modern technology, including magnetic resonance imaging (MRI), computed tomographic axial scanning (CT), neurophysiologic testing, and comprehensive physical examination with psychological evaluation, can identify the cause of low back pain in only 15% of patients in the absence of disc herniation and neurological deficit (1, 100).

The majority of painful conditions

include various types of pain originating from the spine with pain in the neck, upper back, mid back, low back and upper or lower extremities. It was postulated that, for any structure to be deemed a cause of back pain (101):

- The structure should have a nerve supply;
- The structure should be capable of causing pain similar to that seen clinically, ideally demonstrated in normal volunteers;
- The structure should be susceptible to diseases or injuries that are known to be painful; and,
- The structure should have been shown to be a source of pain in patients, using diagnostic techniques of known reliability and validity.

Kuslich et al (102) identified intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura as tissues capable of transmitting pain in the low back. Facet joint pain, discogenic pain, and sacroiliac joint pain also have been proven to be common causes of pain with proven diagnostic techniques (1, 32, 33, 100, 101). In contrast, vertebrae, muscles and ligaments have not been proven to be common sources of spinal pain with proven diagnostic techniques. In one prospective evaluation (103), consecutive adult patients with intractable low back pain (who had failed conservative therapy) of undetermined etiology (by medical history, physical examination, x-ray, CT, MRI, EMG/NCV) had pain from facet joint(s) in 24%, combined lumbar nerve root and facet disease in 24%, combined facet(s) and sacroiliac joint(s) in 4%, lumbar nerve root irritation in 20%, internal disc disorder in 7%, sacroiliac joint in 6%, and sympathetic dystrophy in 2%. In a second study (104), the relative contributions of various structures in patients with chronic low back pain who failed to respond to conservative modalities of treatments (physical therapy, chiropractic and drug therapy), with lack of radiological evidence to indicate disc protrusion or radiculopathy, were evaluated utilizing controlled, comparative, double diagnostic blocks. In this study, 40% of the patients were shown to have facet joint pain, 26% discogenic pain, 2% sacroiliac joint pain, and possibly 13% segmental dural/nerve root pain. No cause was identified in 13% (103) and 19% (104) of the patients.

### 3.1 Facet Joint

The facet or zygapophysial joints are paired diarthrodial articulations between posterior elements of adjacent vertebrae (105). Spinal facet joints have been shown to be a source of pain in the neck and referred pain in the head and upper extremities (106-110); upper back, mid back and referred pain in chest wall (111); and the low back and referred pain in the lower extremity (112-117) in normal volunteers.

Facet joints are well innervated by the medial branches of the dorsal rami (118-127), contain free and encapsulated nerve endings (116, 119, 121, 127), and nociceptors and mechanoreceptors (119, 128-133).

Based on controlled diagnostic blocks of facet joints, in accordance with the criteria established by the International Association for the Study of Pain (IASP) (134), facet joints have been implicated as responsible for spinal pain in 15% to 45% of patients with low back pain (104, 135-143), 54% to 67% of patients with neck pain (141, 143-146), and 42% to 48% of patients with thoracic pain (141, 147).

### 3.2 Intervertebral Disc

The human intervertebral disc (IVD) is a complex structure, which is macroscopically composed of the nucleus pulposus (NP), the annulus fibrosus (AF), and the endplates (EP) (148). Intervertebral discs are innervated (116, 119, 149-170). The outer annulus is innervated (116, 119, 149, 150) to a depth of up to 3.5 mm (161, 162), but nerves may grow into the inner annulus and nucleus (163), particularly if the disc is degenerated or painful (152-154). IVD innervation density is concentrated in the periannular connective tissue and the endplates (159). These nerve fibers transmit both nociceptive and non-nociceptive information (116, 119, 149-151, 164-167). In addition, many of these nerve fibers, identifiable by immunohistochemistry, are accompanied by blood vessels; this process of neovascularization is associated with inflammation. Neural structures that express substance P and have the morphology of nociceptive nerve terminals are found in the nucleus of painful discs; this may distinguish painful versus painless disc degeneration (168).

Clinically, the IVD, depending on location, can produce pain in the neck, upper extremities, posterior thorax, chest

wall, abdominal wall, low back, and lower extremities (102, 171-174). IVD-related pain can be caused by structural abnormalities, such as disc degeneration or disc herniation; correspondingly, biochemical effects, such as inflammation, and neurobiological processes may play a role. Nerve growth factor (NGF) dependent neurons are the main neuronal subgroup, within the dorsal root ganglion (DRG), that transmit and modulate pain in response to inflammation. This subgroup is responsible for sensitizing the DRG to NGF and is present in the painful IVD. NGF may play an important role in discogenic back pain (169, 175-178). The nucleus pulposus is a biologically active tissue that can respond to pro-inflammatory stimuli (178).

The first to create widespread interest in the disc as a source of pain in American literature were Mixter and Barr (173) with their 1934 hallmark description of the herniated nucleus pulposus. However, soon after, Mixter and Ayers (174) in 1935 demonstrated that radicular pain can occur without disc herniation. Consequently, the pathophysiology of spinal radicular pain is a subject of ongoing research and controversy and discogenic pain has assumed a major role as a cause of non-specific low back pain, beyond the more specific disc herniation. Thus, in addition to the mechanical component, inflammation of the compressed nerve root is an important factor in the pathophysiology of radicular and discogenic pain (148, 179-184). Other proposed etiologies include neural compression with dysfunction and vascular compromise (185-189). While neurotoxicity has been attributed to many agents including phospholipase A<sub>2</sub> (PLA<sub>2</sub>), metalloproteinases, and interleukin-6, prostaglandin E<sub>2</sub> (177, 179-183, 190-196), tumor necrosis factor (TNF- $\alpha$ ) has been shown to have an essential role in intervertebral disc-induced nerve root damage (197-200).

The etiology of discogenic pain is unclear (101, 148, 201). Internal disc disruption (IDD) is a condition in which the internal architecture of the disc is disrupted, but its external surface remains essentially normal (202). IDD can be experimentally induced by endplate damage (203). Likewise, experimentally induced annular tears can lead to adverse and progressive mechanical changes in the disc. Annular degeneration has been shown to appear early in lumbar discs and

clearly related to back pain (204). Disrupted discs do not exhibit either bulging or herniation. These features with a normal or near normal contour of discs producing back pain, but with no evidence of herniation or prolapse were described by Crock (202) as internal disc disruption. It has been suggested that endplate damage would precede disc degeneration (205). Further, diminution of blood supply in the endplate initiates tissue breakdown, first in the endplate and thereafter in the nucleus in the first half of the second life decade (206), with visible tears in the nucleus in the age group of 11 to 16 years. The removal of proteoglycans from the endplate, which regulates the movement of solutes into and out of the disc, accelerates the loss of proteoglycans from the nucleus (207). It also has been shown that reduced lumbar artery blood flow may diminish nutrition through the endplates leading to an increased incidence of disc degeneration (208). Discs with internal disc disruption are rendered painful by either chemical nociception or mechanical stimulation. Explanted discs, following posterior lumbar interbody fusion in patients with lumbar discogenic pain, demonstrated a vascularized strip lesion extending from the NP to the AF; this lesion was accompanied by extensive innervation in the posterior disc (209).

In a controlled study, the prevalence of pain due to internal disc disruption was reported as 39% in patients suffering with chronic low back pain (210). Primary discogenic pain was reported in 7% (103) to 26% (104) when no other cause was suspected. The prevalence of cervical discogenic pain in patients with chronic neck pain of traumatic origin in informal studies was estimated to be 61% (211). Discogenic and radicular pain syndromes continue to pose challenges to patients, physicians, and the society-at-large.

### 3.3 Dorsal Root Ganglion

The dorsal root ganglion plays an important role in the mechanism of spinal pain. This holds true, when the DRG itself is injured or when other spinal structures are injured. Experiments have suggested that edema in the dorsal root ganglion underlies the production of nerve root pain in patients with disc herniation (212-221). Mechano- and chemosensitivity of dorsal root ganglia have been described (192, 193, 215-217). Experimentally applied nucleus pulposus from healthy and

degenerative discs reduces nerve root conduction velocity, suggesting a pathomechanism of neural injury (218). The NP can induce excitatory changes, rising endoneurial pressures—compartment syndrome, and cause intraneural thrombi in the DRG or the nerve roots (193, 197, 219). Anti-inflammatory agents, such as tumor-necrosis factor alpha inhibitors, may protect against NP-induced DRG and nerve root injury (192).

### 3.4 Sacroiliac Joint

The sacroiliac joint is a diarthrodial, synovial joint. The sacroiliac joint is well innervated receiving myelinated and unmyelinated axons capable of nociception (222-230). Referral patterns of sacroiliac joint provocation or irritation have been published (231-233).

Utilizing single diagnostic blocks, the prevalence of sacroiliac pain would appear to be at least 13% and perhaps as high as 30% in the United States (234) and 10% in Taiwan (103). Utilizing controlled, comparative local anesthetic blocks in patients with low back pain in whom there was a high index of suspicion for pathology, frequency of sacroiliac joint dysfunction was established as 18.5% (235), or 10% (104) in suspected patients. High prevalence may be seen in patients with lumbar fusion (236, 237).

### 3.5 Postlaminectomy Syndrome

Postlaminectomy syndrome and other synonyms, such as failed back surgery syndrome, represent a cluster of syndromes wherein the expectations of the patient and spine surgeon are not met, following spine surgery (238-243). Persistent pain following spine surgery is common (238-252). Since discectomies, decompressions, and spinal fusions and more recently, minimally invasive surgical and interventional therapies, represent the largest portion of the US spine market (with expenditures of \$2.5 billion in the United States in 2003 of the estimated \$3 billion for the worldwide spine market), one may reasonably anticipate that the costs of persistent pain following spine surgery will increase substantially (253-258). In the year 2002, more than 1 million spinal procedures were performed in the USA. Six hundred thousand cases were not instrumented, but 400,000 were instrumented (255-257). The estimated yearly growth rate of uninstrumented cases ranged from 3% to 5%; in

contrast, the growth rate of instrumented cases from 6% to 8% (257). The spine market may compound at 22% annually (257). Lieberman (253) cautioned that all parties involved in the spine market must be vigilant in not letting the spine market turn into a cancer, or even worse, allowing the “disc bulge bubble” to burst. A surgeon’s assessment of adverse post-operative outcomes may seriously underreport a patient’s self-assessment of surgical outcomes (259).

Animal models of postlaminectomy syndrome demonstrate paraspinous muscle spasms, tail contractures, behavioral pain behaviors, tactile allodynia, epidural and perineural scarring, and nerve root adherence to the underlying disc and pedicle (260). Speculated causes of postlaminectomy syndrome include acquired stenosis, adjacent segment degeneration, internal disc disruption, recurrent disc herniation, retained disc fragment, spondylolisthesis, epidural or intraneural fibrosis, degenerative disc disease, radiculopathy, radicular pain, deconditioning, facet joint pain, sacroiliac joint pain, discitis, arachnoiditis, pseudoarthrosis, segmental instability, and others (238-252). Among these, etiologies such as epidural fibrosis, facet joint dysfunction, sacro-iliac dysfunction, internal disc dysfunction, recurrent disc herniation, and spinal stenosis can be treated by interventional pain methods (251, 261-264). Ultimately, many of these etiologies are interrelated. Epidural fibrosis may occur following an annular tear, disc herniation, hematoma, infection, surgical trauma, vascular abnormalities, or intrathecal contrast media (251, 261, 263-273). Epidural fibrosis may account for as much as 20% to 36% of all cases of failed back surgery syndrome (FBSS) (239, 246, 247, 261, 263, 264, 274-276). Alternatively, there may be a final common pathway with all these etiologies, which results in peripheral and central facilitation potentiated by inflammatory and nerve injury mechanisms (260). Paraspinal muscles may become denervated and involved in the pathogenesis of FBSS (277).

### 3.6 Spinal Stenosis

Spinal stenosis can be defined as a narrowing of the spinal canal, resulting in symptoms and signs caused by entrapment and compression of the intraspinal vascular and nervous structures (278). Disc bulging, protrusion and herniation

in the cervical, as well as lumbar area, combined with osteophytes and arthritic changes of the facet joints can cause narrowing of the spinal canal, encroachment on the contents of the dural sac, or localized nerve root canal stenosis (279-283).

The pain and disability associated with lumbar spinal stenosis can interfere with a patient's lifestyle. Treatment options for low back pain and neurogenic claudication related to lumbar spinal stenosis include surgery, but also, nonoperative modalities including conservative treatment and interventional techniques.

#### 4.0 INTERVENTIONAL TECHNIQUES

Various types of injection techniques have been described with multiple benefits including pain relief that outlasts by days, weeks, or months the relatively short duration of pharmacologic action of the local anesthetics and other agents used. No clear-cut explanations for these prolonged improvements are currently available.

##### 4.1 Mechanism of Action

Neural blockade has been postulated to alter or interrupt nociceptive input, reflex mechanisms of the afferent limb, self-sustaining activity of neuron pools and neuraxis, and the pattern of central neuronal activities (284). Improvements may be explained in part based on the pharmacological and physical actions of local anesthetics, corticosteroids, and other agents. Local anesthetics interrupt the pain-spasm cycle and reverberating nociceptor transmission, whereas corticosteroids reduce inflammation either by inhibiting the synthesis or release of a number of pro-inflammatory substances and by causing a reversible local anesthetic effect (1, 28, 30, 215, 285-296).

Various modes of action of corticosteroids include membrane stabilization; inhibition of neural peptide synthesis or action; blockade of phospholipase A<sub>2</sub> activity; prolonged suppression of ongoing neuronal discharge; and suppression of sensitization of dorsal horn neurons. Local anesthetics have been shown to produce prolonged dampening of C-fiber activity. Physical effects include clearing adhesions or inflammatory exudates from the vicinity of the nerve root sleeve. The scientific basis of some of these concepts, at least in part, is proven for spinal pain management with epidural injections of betamethasone and intravenous methyl-

prednisolone (215, 288, 291-294).

Various mechanisms of benefits for longer periods of time than the duration of the anesthetics used have been described (297-300). Among the several theories listed include the influence on sympathetic nervous system (301); temporary abolition of spontaneous ectopic discharges, resulting in suppression of dynamically maintained central hyperexcitability, as well as reinforcing endogenous G-protein-couple receptor inhibition of N-type voltage-sensitive calcium channels (298, 301); and glial inactivation (300).

#### 5.0 DIAGNOSTIC INTERVENTIONAL TECHNIQUES

It has been postulated that for any structure to be deemed a cause of back pain, the structure should have been shown to be a source of pain in patients, using diagnostic techniques of known reliability and validity (32, 101). The diagnostic blockade of a structure with a nerve supply with the ability to generate pain can be performed to test the hypothesis that the target structure is a source of a patient's pain. Evidence-based interventional diagnostic techniques include facet joint blocks, discography, sacroiliac joint injections, and transforaminal epidurals or selective nerve root blocks.

##### 5.0.1 Rationale

The popularity of neural blockade as a diagnostic tool in painful conditions is due to multiple challenging clinical situations including the purely subjective nature of spinal pain and undetermined and uncertain pathophysiology in most painful spinal conditions. Precision diagnostic blocks are used to clarify these challenging clinical situations, in order to determine the pathophysiology of clinical pain, the site of nociception and the pathway of afferent neural signals. Precise anatomical diagnosis in low back pain has been described not only as elusive, but also the diagnostic evaluation is often frustrating for both physicians and patients (1, 32, 33, 99, 100, 101, 103, 104, 302-304). History, physical examination, and imaging provide limited information.

##### 5.0.2 Reliability and Validity

Clinical studies of precision diagnostic techniques are variable in sensitivity, specificity, accuracy and quality. False-positive rate (how often patients without a condition will nonetheless have a positive test), false-negative rate (how often a

patient with disease will have a negative test), and placebo response are crucial. Since none of the tests available in clinical medicine are ideal, there is a degree of uncertainty regarding the accuracy of each and every diagnostic test as applied to an individual clinical case.

The accuracy of a diagnostic test is best determined by comparing it to an appropriate reference standard (gold standard) such as biopsy, surgery, autopsy, or long-term follow-up. Tissue confirmation of the presence or absence of a disease at surgery, with a biopsy, or autopsy, which has served as the accepted gold standard across multiple medical disciplines, is not applicable to interventional pain management. Consequently, most pain provocative or relieving tests used to diagnose painful conditions of the spine are more closely related to the physical examination than to a laboratory test (36). Stability of the diagnosis over a long period of time with long-term follow-up may be also used as a gold standard. These facts are especially true in the diagnosis of facet joint pain, discogenic pain, and sacroiliac joint pain.

In interventional pain management, a diagnostic blockade of a structure with a nerve supply, which can generate pain is performed to test the hypothesis that the target structure is the source of a patient's pain. Pain provocation in any structure is an unreliable criterion, except in provocative discography (1, 22-24, 32, 33, 36, 37, 168, 234, 304-306). In an ideal world, all controlled blocks would include placebo injections of normal saline. However, in practical terms, it may be neither logistical, nor ethical to use placebo injections of normal saline in conventional practice. It would be necessary to perform three diagnostic blocks of the same structure with application of placebo. Consequently, the use of two local anesthetics with different durations of action, on two separate occasions, has been proposed. The use of comparative local anesthetic blocks with facet joint injections has been validated against challenge with placebo (307, 308).

##### 5.0.3 Environment

The requirements for safe use of diagnostic interventional techniques include a sterile operating room or a procedure room, appropriate monitoring equipment, radiological equipment, sterile preparation, resuscitative equipment, needles, gowns, injectable drugs, intrave-

nous fluids, anxiolytic medications, and trained personnel for preparation and monitoring of patients. Minimum requirements include history and physical examination, informed consent, and appropriate documentation of the procedure.

#### 5.0.4 Contraindications

Contraindications include ongoing bacterial infection, possible pregnancy, bleeding diathesis, and anticoagulant therapy. Precautions are warranted in patients with antiplatelet or anticoagulant therapy, diabetes mellitus and artificial heart valves.

### 5.1 Facet or Zygapophysial Joint Blocks

Diagnostic blocks of a facet or zygapophysial joint can be performed by anesthetizing the joint by intraarticular injections of local anesthetic 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 only obtained by performing controlled blocks, either in the form of placebo injections of normal saline or comparative local anesthetic blocks, in which on two separate occasions, the same joint is anesthetized using local anesthetics with different durations of action.

The rationale for using facet joint blocks for diagnosis is based on the fact that facet joints are capable of causing pain and they have a nerve supply. They have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity. Further, various patterns of referred pain described for facet joints in the spine are similar to other structures, such as discs (32, 33, 101, 106-117); most maneuvers used in physical examination are likely to stress several structures simultaneously, especially the discs, muscles, and facet joints, thus failing to provide any reasonable diagnostic criteria, and the evidence thus far on physical examination and diagnosis has been controversial (32, 33, 100, 101, 135-140, 144, 145, 309-315); demographic features, pain characteristics, and other signs and symptoms may not correlate and are unreliable (32, 33, 100, 101, 135-140, 144, 145, 302-315); and medical imaging provides little useful information (315) with radiographic investigations, including magnetic resonance imaging (MRI), revealing only some con-

ditions with certainty (315-321).

#### 5.1.1 Validity

Controlled diagnostic blocks with two local anesthetics (or placebo-controlled) are the only means of confirming the diagnosis of facet joint pain. The face validity of medial branch blocks has been established by injecting small volumes of local anesthetic onto the target points for these blocks and by determining the spread of contrast medium in posteroanterior and lateral radiographs (123, 125, 126). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and secure true positive results (304, 308). 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 (304, 307, 308).

The specificity of the effect of cervical and lumbar facet joint blocks was demonstrated in controlled trials (123, 125, 126). Provocation response was shown to be unreliable in one study (305). The false-negative rate of diagnostic facet joint blocks was shown to be 8% due to unrecognized intravascular injection of local anesthetic (125). False-positive rates were evaluated in multiple investigations (104, 138-143, 146, 147, 262, 322-335). Reported false-positive rates varied from 27% to 63% in the cervical spine, 55% to 58% in the thoracic spine, and 17% to 47% in the lumbar spine.

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 (326-328). Minimal effect of sedation (326, 327) in cervical and lumbar spine, and lack of influence of psychological factors on the validity of controlled diagnostic local anesthetic blocks of facet joints in the lumbar spine was demonstrated (329).

#### 5.1.2 Prevalence

Based on numerous evaluations utilizing controlled diagnostic blocks, facet or zygapophysial joints have been implicated as the source of chronic spinal pain in 15% to 45% of heterogeneous groups of patients with chronic low back pain (104, 135-143), 42% to 48% of the patients with

thoracic pain (141, 147), and 54% to 67% of the patients with chronic neck pain (141, 143-146).

#### 5.1.3 Cost Effectiveness

Diagnostic facet joint nerve blocks were not evaluated for cost effectiveness systematically. However, multiple authors (104, 330-332) described the feasibility and cost-effectiveness of appropriately performed controlled comparative local anesthetic blocks.

#### 5.1.4 Evidence

The accuracy of facet joint nerve blocks was strong in the diagnosis of lumbar and cervical facet joint pain, whereas it was moderate in the diagnosis of thoracic facet joint pain.

#### 5.1.5 Safety And Complications

Safety of facet joint interventions with intraarticular injections and medial branch blocks has been demonstrated. The most common and worrisome complications of facet joint injections or nerve blocks are related to needle placement and drug administration. These complications include hemorrhage, dural puncture, spinal cord trauma, infection, intra-arterial 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 (1, 26, 32, 33, 336-340).

### 5.2 Provocative Discography

Discography is a procedure that is used to characterize the pathoanatomy/architecture of the intervertebral disc and to determine if the IVD is a source of chronic spinal pain. Implicitly, discography is an invasive diagnostic test that should only be applied to those chronic spinal 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 radiographs (306). The commonly practiced technical and evaluative components of discography include: sterile needle placement into the center of the IVD (nucleus pulposus), radiopaque contrast instillation to provoke pain, radiological assessment of disc morphology, and clinical assessment of the intensity and concordancy of evoked pain in relation to baseline pain. Discography has been used extensively in the study of lumbar discs, somewhat less so in cervical



discs, and infrequently in thoracic discs.

### 5.2.1 Rationale

Formal studies have shown that the discs are innervated and can be a source of pain that has pathomorphologic correlates (101, 102, 119, 148-172). 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 IVDs. However, the cervical and thoracic discs differ from lumbar discs and do not appear to suffer the same pathology (306, 341-343).

Discography was performed in asymptomatic volunteers without spinal pain in the cervical spine (341), thoracic spine (342), and lumbar spine (343). It was shown that discographically normal discs were never painful in either symptomatic or asymptomatic groups.

The rationale is well established for lumbar discography (37, 306, 343). 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 (37). Although the clinical exam may demonstrate a favorable correlation with discography or disc-related pain (313, 344), this information may not be sufficient to guide invasive treatment for discogenic pain (314, 315). There is a significant overlap in evoked pain patterns among discs (345).

### 5.2.2 Validity

Examinations of cadaver discs typically confirm the presence of annular tears and disc degeneration, as revealed by discograms (204, 346-350). Multiple authors also have investigated the accuracy of 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 Adam's classification (351). While many authors (352-357) demonstrated significant correlation with confirmation of reliability of provocative discography, some (358, 359) have demonstrated poor correlation.

Discography was compared with myelography, CT, MRI, and results of surgical and conservative management. CT

discography was reported to be more accurate than myelography (345, 353, 354, 359-365). On similar grounds, discography was shown to be superior to plain computed tomography (362, 365, 366). While comparing the results of 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 (367, 368). However, others have identified advantages of discography with pain provocation, when MRIs were normal or equivocal (341, 342, 369-373). Alternatively, MR and CT/discography may provide complementary information. Strong correlation was demonstrated between MR/discography and CT/discography in assessing annular tears and degeneration (374). In the cervical spine, an MRI may have a false positive rate of 51% and a false negative rate of 27% in predicting which cervical spine levels to fuse, as compared to discography (375). Some authors have questioned the diagnostic accuracy of discography (376-381). The role of discography in a normal MRI is of questionable value and the routine performance of discography in this setting is not advised.

A good correlation between MRI, discography, and the high intensity zone (HIZ) has been established by some (382-387), while others have reported poor correlation and limited value of discography (388, 389). Finally, the relationship of discography to outcomes, including conservative management, minimally invasive surgery, and open procedures remains controversial (1, 37).

While the accuracy of discography as an imaging test is high, with high specificity and sensitivity for the diagnosis of disc degeneration, the key question with discography is whether this test is accurate for the diagnosis of discogenic pain. An integral part of the problem is the lack of an adequate reference or gold standard. Surgical exposure can confirm the presence of disc degeneration or disruption, but it cannot definitely confirm the presence or absence of discogenic pain. However, the results from both surgical and minimally invasive treatment of discogenic pain in patients whose diagnosis was confirmed by discography should provide a reference standard for discogenic pain. Pressure controlled discography may reduce false-positives and enhance

the value of discography (390).

The face validity of discography has been established by injecting small volumes of contrast into the disc and determining concordant pain, with spread of the contrast medium in posteroanterior and lateral radiographs and/or computed tomography. This 'face' validity can be challenged, since clinicians are relying on the transduction of a non-painful stimulus, pressure, into a painful stimulus. Nonetheless, discography may correlate with the use of frankly noxious intradiscal stimuli. Sixty-eight percent of patients undergoing intradiscal electrothermal therapy reported exact reproduction of their pain in quality and location; none reported unfamiliar pain (171). Construct validity of the discograms is also equally important to avoid a false-positive result and obtain a true positive response. Consequently, for a response to be considered positive, concordant pain must be produced; and for the test to be valid, there must be at least one disc (preferably two) that do not elicit pain upon injection, thereby serving as a control disc (134). Even then, some authors question the reliability of a patient's report of concordant pain (391).

Validity of cervical discography has been established in asymptomatic patients. However, there are no modern normative data that establish that cervical discography is a specific test for cervical discogenic pain (306). There is evidence indicating that up to 40% of the positive cervical discograms may be false-positive (211). With thoracic discography, unfamiliar or disconcertant pain may be produced in Schmorl's nodes, in lifelong asymptomatic individuals (342). Thoracic discography may demonstrate disc pathology that is not seen on MRI (342). The value of cervical and thoracic discography still warrants further investigation.

In the 1960's, Holt et al (392, 393) reported false-positive discograms in 37% of an asymptomatic prison population in the lumbar spine (392), with similar findings in the cervical spine (393). Simmons et al (394) reassessed Holt's data (392) and pointed out that discography as performed by Holt, although appropriate for its time, was quite different from discography as performed in 1988. Walsh et al (343), in a carefully controlled series of disc injections in asymptomatic volunteers, showed a 0% false-positive rate, refuting the findings of Holt (392). Stud-

ies by Carragee et al (391, 395-399) have shown a higher rate of false-positives than the study of Walsh et al (343). Carragee et al (391), however, did not evaluate 'truly' asymptomatic volunteers.

The assumption that mild, intermittent low back pain cannot be discogenic in origin (397) can be challenged. Additionally, patients that undergo limited lumbar discectomy (396) often develop disc degeneration. A multitude of methodological flaws have been pointed out with each of these similarly structured studies (36, 400). It is noteworthy that provocative discography provided similar results in patients with or without somatization or combinations of the psychological triad of somatization disorder, depression, and generalized anxiety disorder (400).

### 5.2.3 Indications

Much of the controversy about discography has arisen because the results of discography have been used to help decide whether a certain patient should or should not have surgery, even though patients have usually undergone other diagnostic tests, the results of which were either equivocal or non-diagnostic. Thus, discography should be performed only if the patient has failed to respond to adequate attempts at non-operative care, and if diagnostic tests such as MRI have not provided sufficient diagnostic information. Generally, discography should be viewed as an invasive test to be used to seek abnormalities when results from other tests are equivocal or inconsistent, in a patient with symptoms severe enough to require further evaluation (37). Thus, specific uses for discography include, but are not limited to:

- ◆ Further evaluation of demonstrably abnormal discs to help assess the extent of abnormality or correlation of the abnormality with clinical symptoms (in case of recurrent pain from a previously operated disc and a lateral disc herniation);
- ◆ Patients with persistent, severe symptoms in whom other diagnostic tests have failed to reveal clear confirmation of a suspected disc as the source of pain;
- ◆ Assessment of patients who have failed to respond to surgical procedures to determine if there is painful pseudoarthrosis or a symptomatic disc in a posteriorly fused segment, or to evaluate possible recurrent disc

herniation;

- ◆ Assessment of discs before fusion to determine if the discs within the proposed fusion segment are symptomatic and to determine if discs adjacent to this segment are normal; and
- ◆ Assessment of minimally invasive surgical candidates to confirm a contained disc herniation or to investigate contrast distribution pattern before intradiscal procedures.

### 5.2.4 Prevalence

Prevalence of pain due to internal disc disruption was reported as 39% of patients suffering with chronic low back pain (210) in the United States and 7% (103) in Taiwan. In contrast, primary discogenic pain was reported in 26% of patients suffering with chronic low back pain in the United States (104).

### 5.2.5 Cost Effectiveness

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

### 5.2.6 Evidence

The evidence for cervical and thoracic discography is limited. The evidence for lumbar discography was strong for discogenic pain provided that lumbar discography is performed based on the history, physical examination, imaging data, and analysis of other precision diagnostic techniques. There is no evidence to support discography without other non-invasive or less invasive modalities of treatments or other precision diagnostic injections.

### 5.2.7 Safety and Complications

Complications related to discography include discitis, subdural abscess, spinal cord injury, vascular injury, epidural and prevertebral abscess (1, 37, 401-409). Complications are less frequent with lumbar discography compared to cervical discography. Lack of permanent effects from discography has been reported (410-413). A review of lumbar discography and prophylactic antibiotics (414) concluded that with lumbar discography using a two-needle technique without prophylactic antibiotics, the risk of post discography discitis is minimal, and there is not enough support from the literature to justify the routine use of prophylactic antibiotics. They reported an overall incidence of 0.24% by patient, and 0.091% by disc. However, other studies have shown effective prevention of discitis with intrave-

nous cefazolin or vancomycin (415), and the combination of cefoperazone and sulbactam (416). The administration of intradiscal antibiotics accidentally into the intrathecal space can have significant complications (417).

## 5.3 Transforaminal Epidural Injections or Selective Nerve Root Blocks

Transforaminal epidural injection (modern nomenclature) or a selective nerve root block (old nomenclature) consists of injection of contrast, local anesthetic, or other substances around spinal nerves under fluoroscopy (1, 22, 23). Purists insist on describing them as two separate and distinct techniques. However, over the years authors have used them interchangeably. Consequently, we considered transforaminal epidural and selective nerve root blocks as the same procedure. Both the provocative response and analgesic response provide clinically useful information (418-436). The validity of provocative and analgesic spinal injections was recognized as early as 1938 (422). In 1971, the value of diagnostic, selective nerve root blocks in the preoperative evaluation of patients with negative or inconclusive imaging studies and clinical findings of root irritation was reported (423). Nerve blocks were utilized to diagnose the source of radicular pain when imaging studies suggested possible compression of several nerve roots (421, 424-433). The relief of usual symptoms following the injection of local anesthetic, 1 mL of 2% lidocaine, was the main determinant. Numerous authors (421, 424-428, 434) described results of diagnostic transforaminal epidural injections or selective nerve root blocks. The pattern of provoked symptoms from mechanical stimulation of nerve roots during selective nerve root blocks was described (418, 419, 427). The literature on diagnostic selective nerve root blocks in the evaluation of low back pain was analyzed with the conclusion that selective nerve root blocks provide important prognostic information about surgical outcomes (437).

### 5.3.1 Rationale

Diagnostic selective nerve block is typically performed in a patient with persistent pain when history, examination, imaging, and other precision diagnostic injections and electrophysiologic testing do not identify the pain generator.

### 5.3.2 Validity

The reported sensitivity of a diagnostic selective nerve root block ranges from 45% to 100% (421, 424, 427, 428, 432, 438). The face validity of selective nerve root blocks may be accomplished by providing the blockade under fluoroscopic visualization utilizing contrast and small volume of local anesthetic with provocative and analgesic response. However, thus far, there are no means to eliminate false positives and establish construct validity for selective nerve root blocks. North et al (438), examined the specificity and sensitivity of a battery of local anesthetic blocks. They evaluated lumbosacral nerve root blocks, medial branch blocks, sciatic nerve blocks, and compared to lumbar subcutaneous injection of an identical volume of 3 mL of 0.5% bupivacaine. They showed that false-positive results were common and specificity was low. They concluded that there was only a limited role for uncontrolled local anesthetic blocks in the diagnostic evaluation of sciatica and referred pain syndromes in general.

On the other hand, properly performed, controlled diagnostic selective nerve root blocks or transforaminal epidural injections can be an effective technique in evaluating patients with multi-level pathology to help identify the pain generator. Similarly, they are useful when the location of symptoms seems to conflict with abnormalities identified with imaging findings (433, 439) or when no other cause was found based on evaluation and application of precision diagnostic techniques (103, 104, 210).

### 5.3.3 Cost Effectiveness

Cost effectiveness of diagnostic transforaminal epidural injections or selective nerve root blocks has not been evaluated. However, several authors (104, 330-332) described the feasibility and cost-effectiveness of appropriately performed controlled comparative local anesthetic blocks.

### 5.3.4 Evidence

The evidence was moderate for transforaminal epidural injections or selective nerve root blocks in the preoperative evaluation of patients with negative or inconclusive imaging studies and clinical findings of nerve root irritation.

### 5.3.5 Safety and Complications

The most common and worrisome complications of transforaminal epidur-

al injections are related to dural puncture, infection, intravascular injection, air embolism, vascular trauma, particulate embolism, cerebral thrombosis, epidural hematoma, neural or spinal cord damage, and complications related to administration of steroids (1, 25, 30, 38, 440-450). Recent reports of paraplegia, vertebral artery dissection, neurological disorders, and death are concerning.

## 5.4 Sacroiliac Joint Blocks

The sacroiliac joint is accepted as a potential source of low back and/or buttock pain with or without lower extremity pain (222-233). Diagnostic blocks of a sacroiliac joint can be performed to determine whether the sacroiliac joint is the source of the patient's pain (103, 104, 234, 235). The sacroiliac joint can be anesthetized with intraarticular injection of local anesthetic.

### 5.4.1 Rationale

The rationale for sacroiliac joint blocks for diagnosis is based upon the fact that sacroiliac joints are innervated and have been shown capable of being a source of low back pain and referred pain in the lower extremity (222-233). There are no definite historical, physical, or radiological features to provide definite diagnosis of sacroiliac joint pain (234, 235, 312, 313, 451-455). Nevertheless, many authors (312, 313, 454-456) have advocated provocative maneuvers, which may enter into the differential diagnosis of sacroiliac joint pain. However, these signs may not be accurate in making a definitive diagnosis of sacroiliac joint syndrome. Many studies have evaluated the accuracy of plain films (457), computed tomography (458), single photon emission computed tomography (459), bone scans (460, 461), nuclear imaging (462-465), and magnetic resonance imaging (466) with variable results.

### 5.4.2 Validity

The face validity of sacroiliac joint block has been established by injecting small volumes of local anesthetic with contrast into the joint and determining contrast spread in posterior, anterior and lateral radiographs. Construct validity of sacroiliac joint blocks has been established by determining the false-positive rate of single, uncontrolled, sacroiliac joint injections of 20% (235). False-positive injection may occur with extrava-

sation of anesthetic agent out of the joint due to defects in the joint capsule. False-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 (24, 467, 468).

### 5.4.3 Prevalence

Several authors have shown the sacroiliac joint to be a source of pain in 10% to 30% of cases by a single block (103, 234) and 10% to 19% by a double block paradigm (104, 235).

### 5.4.4 Cost Effectiveness

There are no studies evaluating the cost effectiveness of diagnostic sacroiliac joint blocks. However, the feasibility and cost-effectiveness of appropriately performed controlled comparative local anesthetic blocks has been described (104, 330-332).

### 5.4.5 Evidence

The evidence for the accuracy of sacroiliac joint diagnostic injections was moderate for the diagnosis of sacroiliac joint pain.

### 5.4.6 Safety and Complications

Complications of sacroiliac joint injection include infection, trauma to the sciatic nerve, embolic phenomena, and complications related to drug administration. Without fluoroscopy, successful joint injection is low (467-469). Epidural spread was noted in 24% and foraminal filling in 44% (467).

## 6.0 THERAPEUTIC INTERVENTIONAL TECHNIQUES

Therapeutic interventional techniques in the management of chronic spinal pain include various types of neural blockade and minimally invasive surgical procedures. These include epidural injections, facet joint injections, neuroablation techniques, intradiscal thermal therapy, nucleoplasty, morphine pump implantation, and spinal cord stimulation.

### 6.0.1 Rationale

The rationale for therapeutic interventional techniques in the spine is based upon the following considerations.

- ◆ Cardinal source(s) of chronic spinal pain, particularly discs and joints, are accessible to neural blockade,
- ◆ Removal or correction of structural abnormalities of the spine may fail to cure and may worsen painful spinal

conditions,

- ◆ Degenerative processes of the spine and the origin of spinal pain are complex,
- ◆ The effectiveness of a large variety of therapeutic interventions used to manage chronic spinal pain has not been demonstrated conclusively, and
- ◆ There is increasing evidence supporting use of interventional techniques in managing spinal pain.

### 6.0.2 Environment

The requirements for safe use of therapeutic interventions include a sterile operating room or a procedure room, appropriate monitoring equipment, radiological equipment, special instruments based on technique, sterile preparation with all the resuscitative equipment, needles, gowns, injectable drugs, intravenous fluids, anxiolytic medications, and trained personnel for preparation and monitoring of the patients. Minimum requirements include history and physical examination, informed consent, appropriate documentation of the procedure.

### 6.0.3 Contraindications

Contraindications include ongoing bacterial infection, possible pregnan-

cy, bleeding diathesis, and anticoagulant therapy. Precautions are warranted in patients with anticoagulant or antiplatelet therapy, diabetes mellitus and artificial heart valves.

### 6.1 Facet Joint Interventions

A preponderance of the evidence supports the existence of facet joint pain (1, 26, 32, 33, 39, 100, 101, 103-147, 262, 304-317, 322-335), although there are a few detractors (470-472). Based on a detailed review of the literature, the general consensus appears to be that facet joint pain can be diagnosed with reasonable certainty only on the basis of controlled diagnostic local anesthetic blocks. 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.

Relief with intraarticular injections or medial branch blocks was considered as short-term if documented for less than 6 weeks, and long-term, if documented

for 6 weeks or longer. Relief with medial branch neurotomy was considered short-term if it was less than 3 months, and long-term if it was 3 months or longer.

#### 6.1.1 Intraarticular Blocks

Therapeutic benefit has been reported with the injection of corticosteroids, local anesthetics, or normal saline into the facet joints. The literature describing the effectiveness of these interventions is abundant. The only systematic review (4) in the literature evaluated intraarticular injections in conjunction with other interventional techniques. Five randomized clinical trials offer data on the use of intraarticular injections in the spine (26, 473-477). Open, controlled and uncontrolled clinical studies that evaluated the long term relief of back and leg pain from intraarticular facet joint injections are abundant (26, 478-482). Table 2 illustrates published results.

The effectiveness of intraarticular corticosteroid lumbar facet joint injections (473, 475-477) and cervical facet joint injections (474) was studied comparing the results to those of a similar group not receiving intraarticular steroids. Of these, two randomized trials, one by Carette et al (473) involving lum-

Table 2. Results of published reports of effectiveness of intraarticular injections of cervical and lumbar facet joints

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score(s)	Cochrane Score(s)			< 6 weeks	3 months	6 months	Short-term < 6 weeks
<b>Lumbar Spine</b>									
Carette et al (473)	PC, RA, DB	10/10	10/10	C=50 T=51	33% vs 42%	NA	15% vs 42%	N	N
Lynch and Taylor (480)	P	6/8	---	Extraarti.=15 Intraarti.=35	53% vs 89%	62%	56%	P	P
Murtagh (478)	P	6/8	---	100	N/A	54%	54%	P	P
Desoutet et al (479)	P	6/8	---	54	54%	38%	38%	P	N
Lippit (481)	R	5/8	---	99	42%	51%	14%	N	N
Lau et al (482)	R	6/8	---	34	56%	44%	35%	P	N
<b>Cervical Spine</b>									
Barnsley et al (474)	RA, DB	10/10	9/10	41	50%	N/A	N/A	N	N

R = Retrospective; P = prospective; RA = randomized; PC = placebo controlled; DB = double blind; C = control; T = treatment; N/A = not available; SI = significant improvement; P = positive; N = negative

bar facet joint injections and the second one by Barnsley et al (474) involving cervical facet joint injections were included (26). Even then, Carette et al (473) failed to exclude placebo responders, which may account for the relatively high incidence of patients in their study with presumed facet joint pain (58%), diluting the findings of true responses, making detection of differences between the study and control groups more difficult. Barnsley et al (474) included a small number of patients, a total of 41 patients, whose origin of neck pain was posttraumatic following whiplash. Consequently, these results, although from randomized trials, may not be applied across a heterogenous population.

Among the other 3 randomized trials, Marks et al (475) and Nash (476) compared the effects of intraarticular injections with medial branch blocks with a single injection, with only short-term evaluation. Lilius et al (477) used overly broad criteria for inclusion without confirming the diagnosis by controlled diagnostic blocks, and used excessive injectate volumes (3 mL to 8 mL) of active agents (26).

Both well-controlled trials of Carette et al (473) and Barnsley et al (474) were described as negative by the authors. Carette et al (473) showed that 42% of the methylprednisolone group (20 patients), whereas 33% of the saline group (16 patients) achieved significant relief at one month follow up. However, at 6-month follow-up, 46% of the patients in the methylprednisolone group compared to 15% of the patients in the saline group continued to experience marked pain relief, with a statistically significant difference. Barnsley et al (474) showed that the time to return to 50% of baseline pain was

3 days in the steroid group and 3.5 days in the local anesthetic group. Less than half of the patients reported relief of pain for more than 1 week, and fewer than 1 in 5 patients reported relief for more than 1 month, regardless of whether the injection was with steroids or local anesthetic.

Among the non-randomized trials, multiple observational studies were evaluated for inclusion. Among these, three prospective evaluations (478-480) and two retrospective evaluations (481, 482) met the inclusion criteria. Among the prospective trials included in the evidence synthesis, Lynch and Taylor (480) reported initial pain relief in 31 of 35 patients receiving intraarticular steroids, whereas 8 of 15 patients receiving extraarticular steroids reported initial pain relief. Long-term pain relief was reported in 62% at 3 months, and 56% at 6 months. Destouet et al (479) reported significant pain relief for 1 to 3 months in 54% of the patients and 3 to 6 months in 38% of the 54 patients. Murtagh (478) reported long-term relief of up to 6 months in 54% of the 100 patients. Among the retrospective evaluations, Lippitt (481) reported greater than 50% relief initially in 42% of patients, which declined to 14% at 6 months and 8% at 12 months in 99 patients. Lau et al (482) also reported initial relief in 56% of the patients, which declined to 44% at 3 months, and 35% at 6 to 12 months.

6.1.1.1 Cost Effectiveness

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

6.1.1.2 Evidence

For intraarticular injections of local anesthetics and steroids, there was moderate evidence for short-term and limited

evidence for long-term improvement in managing low back pain and the evidence was negative in managing neck pain.

6.1.2 Medial Branch Blocks

The therapeutic role of medial branch blocks was evaluated in four randomized clinical trials (475, 476, 483, 484) and one prospective controlled trial (485). Table 3 shows particulars of the included studies.

Among the randomized trials, Marks et al (475) and Nash (476) compared the effectiveness of intraarticular injections and medial branch blocks with one injection, without any long-term follow-up. Manchikanti et al (484) compared the effect of Sarapin on various types of nerve blocks including epidurals and medial branch blocks in a random manner. However, this was not a specific study of effectiveness of medial branch blocks. Thus, three (475, 476, 484) of four studies were excluded. One study by Manchikanti et al (483) met the inclusion criteria. In this study, 73 patients positive for lumbar facet joint pain by means of controlled, comparative local anesthetic blocks were randomly allocated into two groups, either receiving therapeutic medial branch blocks with a local anesthetic and Sarapin or with a mixture of local anesthetic, Sarapin, and methylprednisolone. Significant improvement was documented in both groups in various parameters of pain relief, functional status, opioid intake, return to work, and psychological status. Significant pain relief was seen with 1 to 3 injections in 100% of the patients up to 1 to 3 months, 82% of the patients for 4 to 6 months, and 21% for 7 to 12 months. The mean relief was 6.5 ± 0.76 months. Consequently, this study provided evidence of both short-term and long-term benefit with therapeutic medial branch blocks.

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

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score(s)	Cochrane Score(s)			< 6 weeks	3 months	6 months	Short-term relief < 6 weeks
		Manchikanti et al (483)	RA		8/10	6/10	73	100%	100%
Manchikanti et al (485)	P	8/8	---	100	92%	92%	82%	P	P

P = prospective; RA = randomized; P = positive; N = negative

Manchikanti et al (485) evaluated the therapeutic effectiveness of cervical facet joint nerve blocks in chronic neck pain in a prospective outcome study. They evaluated 100 consecutive patients meeting the diagnostic criteria of facet joint pain by means of comparative, controlled diagnostic blocks. There were significant differences in numeric pain scores and pain relief ( $\geq 50\%$ ) at 3 months (92%), 6 months (82%), and 12 months (56%) compared to baseline measurements. There was significant improvement in functional status, psychological status and employment among patients eligible

for employment (employed and unemployed) from baseline to 12 months.

6.1.2.1 Cost Effectiveness

The cost effectiveness of lumbar facet joint nerve blocks was evaluated by Manchikanti et al (483) with 1-year improvement of quality of life at \$3,461. The cost of one-year improvement was similar to various investigations with neural blockade, but also was significantly better than the cost-effectiveness with intrathecal morphine delivery or lumbar laminectomy, with or without instrumented fusion.

6.1.2.2 Evidence

The evidence for lumbar and cervical medial branch blocks in managing chronic low back and neck pain was moderate.

6.1.3 Medial Branch Neurotomy

Percutaneous radiofrequency neurotomy of medial branches is a procedure that offers pain relief by denaturing the nerves that innervate a painful joint. There have been three systematic reviews of medial branch neurotomy (5-7). Geurts et al (5) concluded that there was moderate evidence that radiofrequency lumbar facet denervation was more effective for chronic low back pain than

Table 4. Results of published reports on effectiveness of facet joint (medial branch) radiofrequency neurolysis

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief < 3 months	Long-term Relief		Results	
		AHRQ Score(s)	Cochrane Score(s)			6 months	12 months	Short-term relief <3 months	Long-term relief $\geq 3$ months
<b>Lumbar Spine</b>									
Van Kleef et al (487)	PC, RA, DB	9/10	7/10	C=16 T=15	38% vs 67%	19% vs 47%	13% vs 47%	P	P
Dreyfuss et al (493)	P	8/8	---	15	93%	87%	87%	P	P
Vad et al (495)	P	8/8	---	12	83%	83%	83%	P	P
Schofferman and Kine (496)	R	7/8	---	20	85%	85%	85%	P	P
Schaerer (499)	R	6/8	---	117	NA	NA	68%	N	N
Tzaan and Tasker (500)	R	6/8	---	90	NA	41%	NA	N	N
North et al (501)	R	7/8	---	42	45%	45%	45%	N	N
<b>Cervical Spine</b>									
Lord et al (486)	PC, RA, DB	9/10	9/10	LA=12 RFTN=12	50% vs 67%	8% vs 58%	8% vs 58%	P	P
McDonald et al (492)	P	7/8	---	28	71%	71%	71%	P	P
Sapir and Gorup (494)	P	7/8	---	46	NA	NA	NA	P	P
Schaerer (499)	R	6/8	---	117	NA	NA	68%	N	N
Tzaan and Tasker (500)	R	6/8	---	90	NA	41%	NA	N	N
<b>Thoracic Spine</b>									
Stolker et al (497)	P	7/8	---	40	83%	83%	83%	P	P
Tzaan and Tasker (500)	R	6/8	---	90	NA	41%	NA	N	N

R = Retrospective; P = prospective; RA = randomized; PC = placebo controlled; DB = double blind; C = control; T = treatment; N/A = not available; P = positive; N = negative; LA = Local Anesthetic; RFTN: Radiofrequency neurotomy

placebo, and there was only limited evidence existent for effectiveness of radiofrequency neurotomy for chronic cervical zygapophysial joint pain after flexion/extension injury. Manchikanti et al (6) evaluated medial branch neurotomy for the management of chronic spinal pain utilizing AHRQ criteria with inclusion of randomized and observational reports. They concluded that there was strong evidence for short-term relief and moderate evidence for long-term relief of facet joint pain. Niemesto et al (7) performed a systematic review of radiofrequency denervation for neck and back pain within the framework of the Cochrane Collaboration Back Review Group. The reviewers 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.

The systematic review by Manchikanti et al (6) met inclusion criteria. Due to several deficiencies (1, 26), two systematic reviews (5, 7) were excluded. The evaluation for guidelines yielded a total of 6 randomized trials (486-491), and 10 observational studies (492-501). Among these, as illustrated in Table 4, two randomized trials (486, 487) and 9 observational studies (492-497, 499-501) were included. Four of six randomized trials were excluded because of inappropriate inclusion criteria, inappropriate interventions, or inadequate follow-up (26). However, only 1 of 10 observational studies was excluded (Table 4).

Lord et al (486) evaluated percutaneous radiofrequency neurotomy in patients with cervical facet joint pain with controlled local anesthetic blocks, in a double-blind, placebo-controlled trial. The results showed that the median time that elapsed before the pain returned to at least 50% of the preoperative level was 263 days in the active treatment group and 8 days in the control group. The authors concluded that in patients with chronic cervical facet joint pain, percutaneous radiofrequency neurotomy with multiple lesions of target nerves can provide long lasting relief. In the second study, Van Kleef et al (487) showed that after 3, 6, and 12 months, the number of successes in the lesion and sham groups was 9 and 4, 7 and 3, and 7 and 2, respectively. These results demonstrated that radiofrequency denervation of the lumbar facet joints can

be effective for pain reduction in patients with lumbar facet joint pain.

Among the non-randomized or observational studies, McDonald et al (492) determined the long-term efficacy of percutaneous radiofrequency medial branch neurotomy in the treatment of chronic neck pain in 28 patients diagnosed as having cervical zygapophysial joint pain, on the basis of controlled diagnostic blocks. They reported complete relief of pain in 71% of patients after an initial procedure. The median duration of relief after a first procedure was 219 days when failures were included, but 422 days when only the successes were considered. Dreyfuss et al (493) described lumbar facet joint radiofrequency neurotomy in 15 patients utilizing strict criteria and procedural considerations, and noted 60% of the patients were improved at 1 year. Sapir and Gorup (494) studied 46 patients reporting overall reduction in cervical whiplash symptoms and visual analog pain scores in a significant proportion of patients at 1 year in both litigant and non-litigant patients. Vad et al (495) described the role of lumbar radiofrequency denervation in baseball pitchers. They reported a median pain relief of 1.3 years (range: 1 to 2.1 years) and improved function in 83%, or 10 of 12 patients. Stolker et al (497) studied thoracic facet joint neurolysis in 40 patients and reported positive results, with 47.5% of the patients being pain-free and an additional 35% having relief greater than 50% at 2-months follow-up. After a follow up of 18 to 54 months, they reported 83% of the patients with greater than 50% pain relief.

Among the retrospective evaluations, Schofferman and Kine (496), in a chart review of 20 patients, reported 10.5 months of mean relief (range: 4-9 months) following lumbar radiofrequency neurotomy. Tzaan and Tasker (500) evaluated 118 consecutive percutaneous radiofrequency facet rhizotomies performed on 90 patients. They reported that with the first procedure, 41% of patients had greater than 50% subjective reduction of pain. The study included cervical, thoracic and lumbosacral facets. North et al (501) evaluated radiofrequency lumbar facet denervation with long-term outcome assessment by disinterested third party interview. Forty-five percent of patients undergoing denervation reported at least 50% relief of pain at long-term follow-up. Schaerer (499) evaluated radiofrequency

facet rhizotomy in 117 consecutive patients with chronic neck and low back pain and reported that overall results were fair to excellent in 68% of patients, with an average follow-up of 13.7 months.

#### 6.1.3.1 Cost Effectiveness

No cost effectiveness evaluations were performed with medial branch neurotomy.

#### 6.1.3.2 Evidence

Evidence for radiofrequency neurotomy of medial branches was moderate to strong for short-term and long-term relief of lumbar and cervical facet joint pain.

### 6.1.4 Safety and Complications

The most common and worrisome complications of facet joint interventions are related to needle placement, drug administration, and neurolysis (1, 26, 32, 33, 336-340, 502-521). Complications include dural puncture, spinal cord trauma, infection, intraarterial or intravenous injection, spinal anesthesia, chemical meningitis, neural trauma, pneumothorax, radiation exposure, facet capsule rupture, hematoma formation, and steroid side effects. In addition, potential side effects with radiofrequency denervation include painful cutaneous dysesthesias, increased pain due to neuritis or neurogenic inflammation, anesthesia dolorosa, cutaneous hyperesthesia, pneumothorax and deaf-ferentation pain.

## 6.2 Epidural Injections

Several approaches are available to access the lumbar epidural space: caudal, interlaminar, and transforaminal (1, 23, 25, 28, 30). There are substantial differences between the three approaches. The interlaminar entry is directed more closely to the assumed site of pathology requiring less volume than the caudal route. The caudal entry is relatively easily achieved, with minimal risk of inadvertent dural puncture. The transforaminal approach is target specific with smallest volume in fulfilling the aim of reaching the primary site of pathology; namely ventrolateral epidural space.

Due to the inherent variations, differences, advantages, and disadvantages applicable to each technique (including the effectiveness and outcomes), caudal epidural injections; interlaminar epidural injections (cervical, thoracic, and lumbar epidural injections); and transforaminal epidural injections (cervical, thoracic, and lumbosacral) are considered as sep-

arate entities within epidural injections and are discussed as such below.

In this evaluation, we considered all relevant systematic reviews along with randomized, and non-randomized trials for each category, including caudal, interlaminar, and transforaminal epidural injections. Short-term effect was defined as a significant relief of less than 6 weeks and long-term effect was defined as 6 weeks or longer relief.

### 6.2.1 Caudal Epidural Injections

Several systematic reviews have evaluated the effectiveness of epidural steroids in general and interlaminar epidural steroids in particular (1, 4, 25, 28, 29, 30, 35). While all the reviews included caudal epi-

dural steroid injections, they failed to separate caudal and interlaminar techniques, arriving at erroneous conclusions (4, 29, 35). Of importance are systematic reviews performed by Nelemans et al (4), Koes et al (29), and Van Tulder et al (35). All these studies included essentially the same criteria as well as the same studies arriving at inaccurate conclusions, uniformly. In contrast, Boswell et al (28) in a systematic review and Bogduk et al (30) in a comprehensive review evaluated caudal epidural steroid injections as a separate procedure reaching opposite conclusions. They concluded that the effectiveness of caudal epidural injections in managing lumbar radiculopathy was moderate.

Among the multitude of trials, there were 9 randomized trials (522-529, 533), 5 prospective evaluations (530-532, 534, 535), and many retrospective evaluations (1, 536). The results of published reports of the randomized trials and prospective trials of caudal epidurals utilized in evidence synthesis and guideline preparation are shown in Table 5.

Of the 9 randomized trials, two studies were excluded (525, 526) from evidence synthesis, due to non-availability of analyzable information (526), and due to lack of data at 3 months (525). Of the 7 randomized trials, 3 trials evaluated predominantly patients with radiculopathy or sciatica (522-524), two trials evaluat-

Table 5. Results of published reports on caudal epidural steroid injections

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score(s)	Cochrane Score(s)		< 6 weeks	3 months	6 months	Short-term relief <6 weeks	Long-term relief ≥6 weeks
Breivik et al (522)	RA, DB	8/10	7/10	C=19 T=16	25% vs. 63%	20% vs 50%	20% vs. 50%	P	P
Bush and Hillier (523)	RA, DB	8/10	8/10	C=11 T=12	100%	N/A	64% vs 83%	P	N
Matthews et al (524)	RA, DB	8/10	7/10	C=34 T=23	56% vs 67%	SMPR	N/A	N	P
Helsa and Breivik (527)	RA, DB	7/10	7/10	69 crossover	NA	NA	59% vs 25%	P	P
Revel et al (528)	RA	7/10	6/10	Forceful injection=29 Regular=31	NA	NA	49% vs 19%	P	N
Meadeb et al (529)	RA	6/10	6/10	D= 16 D+G = 15 G = 16	N/A	N/A	N/A	N	N
McGregor et al (533)	RA	6/10	5/10	Caudal=14 Interlaminar =16	N/A	N/A	N/A	N	N
Manchikanti et al (531)	P	5/8	---	ND=45 PD=17	71% vs 65%	67% vs 65%	47% vs 41%	P	P
Yates (532)	P	5/8	---	20	N/A	N/A	N/A	P	P
Waldman (534)	P	5/8	---	53	63%	67%	71%	P	P
Ciocon et al (535)	P	5/8	---	30	SI	SI	SI	P	P
Manchikanti et al (530)	P	5/8	---	G1=15 G2=22 G3=33	0% 100% 97%	0% 59% 55%	0% 19% 15%	P	P

P = prospective; RA = randomized; PC = placebo controlled; DB = double blind; C = control; T = treatment; N/A = not available; P = positive; N = negative; ND=Negative Discography; PD=Positive Discography; D=Disruption, G=Glucocorticoid



Table 6. Results of published reports of cervical and lumbar interlaminar epidural steroid injections

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score(s)	Cochrane Score(s)		< 6 weeks	3 months	6 months	Short-term relief <6 weeks	Long-term relief ≥6 weeks
<b>Cervical Spine</b>									
Castagnera et al (546)	RA	7/10	6/10	Local anesthetic + steroids =14 Local anesthetic + steroids + Morphine =10	75% vs 96%	79%	79%	P	P
Stav et al (550)	RA	6/10	5/10	C=17 T=25	36% vs 76%	12% vs 68%	12% vs 68%	P	P
<b>Lumbar Spine</b>									
Carette et al (537)	RA, DB, PC	10/10	10/10	C=80 T=78	SIT	NSD	NSD	P	N
Snoek et al (538)	RA	7/10	6/10	C=24 T=27	NSD	NSD	NSD	N	N
Cuckler et al (539)	RA, DB	9/10	9/10	C=31 T=42	NSD	NSD	NSD	N	N
Dilke et al (540)	RA	7/10	7/10	C=48 T=51	31% vs 60%	SI	NA	P	P
Ridley et al (544)	RA	9/10	8/10	C=16 T=19	19% vs 90%	19% vs 90%	NA	P	N
Rogers et al (545)	RA, SB	6/10	5/10	C=15 T=15	SI	NSD	NSD	P	N
Kraemer et al (553)	RA	6/10	5/10	C=46 T=40	SI	NA	NA	P	N
Pirbudak et al (554)	RA	6/10	6/10	steroid = 46 steroid + amitriptyline = 40	SI (AM)	SI (AM)	SI (AM)	P	P
McGregor et al (533)	RA	6/10	5/10	14=caudal 16=interlaminar	NSD	NSD	NA	N	N
Rull et al (556)	P	5/8	--	149	66%	66%	66%	P	P
Caglar et al (557)	P	5/8	--	25	SI	NA	NA	P	N
Koning et al (560)	P	5/8	--	74	54%	NA	33%	P	N

P = prospective; RA = randomized; DB = double blind; PC = placebo controlled; NA = not available; SI = significant improvement; SIT = significant improvement in treatment group; AM = amitriptyline; NSD = no significant difference; vs = versus, C=control, T = treatment; P = positive; N = negative

ed post lumbar laminectomy syndrome (528, 529), one study (527) evaluated a mixed population with one half with post lumbar laminectomy syndrome and the other half with sciatica, and one study evaluated similarities between interlaminar and caudal. Two of the 3 trials of radiculopathy were positive for long-term relief (522, 524), whereas, only one of the

two trials (528) was positive for post lumbar laminectomy syndrome for short-term relief. The study of a mixed population (527) was positive for long-term relief. Thus, overall 3 of 4 studies were positive for pain of radiculopathy, and 1 of 3 were positive for post lumbar laminectomy syndrome.

Among the 5 prospective evaluations (530-532, 534, 535), the role of caudal epidural steroids was evaluated in two studies in patients with radiculopathy or sciatica (532, 534), in two studies in patients with chronic low back pain (530, 531), and in one study (535) with spinal stenosis. All showed positive results for short-term and long-term pain relief.

### 6.2.1.1 Cost Effectiveness

The cost effectiveness of epidural steroids was evaluated (530, 536). The cost-effectiveness of caudal epidural steroids was \$3,635 and that of transforaminal steroids was \$2,927 per year. In a prospective evaluation, the cost for 1-year improvement for quality-of-life, was \$2,550, in patients treated with caudal epidural with local anesthetic and Sarapin or steroids under fluoroscopy (530).

### 6.1.2.2 Evidence

The evidence for caudal epidural steroid injections with randomized trials and prospective trials was strong for short-term relief and moderate for long-term relief, in managing chronic low back and radicular pain. The evidence in post-lumbar laminectomy syndrome and spinal stenosis was limited.

### 6.2.2 Interlaminar Epidural Injections

Multiple systematic reviews provided conflicting opinions (1, 4, 8, 25, 29-31, 35). Further, most of the systematic reviews (4, 8, 29) utilized combined caudal and interlaminar epidural steroid injections. Consequently, no reasonable definitive conclusions may be drawn from these systematic reviews, and their conclusions may not be applied in clinical practice settings. Thus far, all the systematic reviews noted concluded that interlaminar epidural steroid injections lacked long-term effectiveness.

Nineteen randomized trials (533, 537-554), 9 prospective evaluations (555-563), and numerous other observational studies (564-573) were identified. Among the 19 randomized trials, 11 met inclusion criteria and were utilized for evidence synthesis with exclusion of 8 studies (25, 541-543, 547-549, 551, 552). Of the 8 prospective evaluations, 3 studies (556, 557, 560) were utilized for evidence synthesis. For evaluation of cervical pain and radiculopathy, 2 randomized trials (546, 550), one (555) prospective trial, and 8 retrospective evaluations were available (564-573).

Of the 11 randomized trials included in the evidence synthesis, 8 of them evaluated the effectiveness of interlaminar epidural steroid injections, either on disc herniation, sciatica, or radiculopathy in the lumbar spine (533, 537-540, 544, 545, 553, 554), whereas, 2 randomized evaluations included cervical disc herniation with radiculitis or brachialgia (546, 550). Of the 8 randomized trials evaluating lumbar ra-

diculitis, 5 were positive for short-term relief (537, 540, 544, 545, 553, 554), whereas only one study was positive for long-term relief (540). In the evaluation of cervical interlaminar epidural steroids in managing cervical radiculopathy, both randomized trials were positive (546, 550). None of the randomized evaluations were performed in managing either axial neck pain or low back pain. Among the negative studies, Cuckler et al (539) included patients suffering with post lumbar laminectomy syndrome. Results of included studies are illustrated in Table 6.

Of the 9 prospective evaluations, 3 studies in the lumbar spine (556, 557, 560) were included. In the only prospective study of the cervical spine (555), patients received cervical interlaminar epidural steroid injections for cervical radiculopathy and cervical transforaminal epidural steroid injections if they failed to respond to the interlaminar epidural steroid injections. Thus, it was difficult to assess the outcomes. Among the 3 prospective trials in the lumbar spine, 2 studies were positive for short-term relief (556, 560), whereas only one study was positive for long-term relief (556). A study evaluating management of lumbar radiculopathy (557), a study evaluating effect in spinal stenosis (564), and a study evaluating correlation of epidural steroid injection as a predictor of surgical outcome were negative (562).

### 6.2.2.1 Cost Effectiveness

In the evaluation of cost effectiveness, Manchikanti et al (536) showed that caudal epidural steroid injections, as well as lumbar transforaminal epidural steroid injections were significantly cost effective compared to blind interlaminar epidural steroid injections.

### 6.2.2.2 Evidence

The evidence of interlaminar epidural steroid injections in managing lumbar radiculopathy was strong for short-term relief and limited for long-term relief. In managing cervical radiculopathy, the evidence was moderate for short-term and long-term relief. The evidence was inconclusive in the management of neck pain, low back pain, and lumbar spinal stenosis.

### 6.2.3 Transforaminal Epidural Injections

Transforaminal epidural injections have emerged as a target-specific modality of treatment for management of spinal

pain. Review of the literature showed one systematic review (38), 8 randomized trials (553, 574-580), 14 prospective evaluations (555, 581-593), and multiple retrospective reports (594-608).

Among the 8 randomized controlled trials, 5 trials were included in evidence synthesis (574, 576, 577, 579, 580), whereas of 14 prospective evaluations, 6 were included (555, 581, 588-590, 593). A summary of reported studies is listed in Table 7.

Among the 5 randomized trials included in the evidence synthesis meeting inclusion criteria, 4 of them evaluated effectiveness in lumbar disc herniation and radiculopathy (574, 576, 579, 580), showing positive results in 3 of the 4, both in short-term and long-term with one negative study (575, 576). The fifth trial (577) studied effectiveness in post lumbar laminectomy syndrome with negative results. Among the 6 prospective evaluations included for evaluation, 2 studies evaluated the effectiveness of cervical transforaminal epidurals (555, 590), showing positive results. The remaining 4 studies (581, 588, 589, 593) evaluated lumbar transforaminal epidural steroid injections. One study (589) compared effectiveness of transforaminal epidural steroid injections in lumbar spine with discectomy. One evaluation reported the effect on spinal stenosis (593). Multiple retrospective evaluations also showed positive results.

### 6.2.3.1 Cost Effectiveness

Cost effectiveness of transforaminal epidural steroid injections in the management of chronic low back pain showed that cost per 1 year improvement of quality of life was \$2,927 per year (536). Further, in patients treated with transforaminal steroids, operations were avoided for contained herniations, costing \$12,666 less per responder in the steroid group (576). Cost effectiveness was also demonstrated by avoiding surgical intervention in 77% of the patients (574).

### 6.2.3.2 Evidence

The evidence for lumbar transforaminal epidural steroid injections in managing lumbar nerve root pain was strong for short-term and moderate for long-term improvement. The evidence was moderate in managing cervical nerve root pain. The evidence was limited in lumbar post laminectomy syndrome, and lumbar spinal stenosis. The effectiveness of transforaminal epidural steroid injections in ax-

Table 7. Results of published reports on lumbar and cervical transforaminal epidural steroid injections

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score(s)	Cochrane Score(s)		< 6 weeks	3 months	6 months	Short-term <6 weeks	Long-term ≥6 weeks
<b>Lumbar Spine</b>									
Riew et al (574)	RA, DB	8/10	7/10	LA = 27 La=S =28	33% vs 77%	33% vs 77%	33% vs 77%	P	P
Karppinen et al (575, 576)	RA, DB, PC	9/10	8/10	C=80 T=80	NA	NA	NA	N	N
Devulder et al (577)	RA	6/10	5/10	60	NS	NS	NS	N	N
Vad et al (579)	RA	7/10	7/10	48	48% vs 84%	8% vs 84%	8% vs 84%	P	P
Thomas et al (580)	RA	6/10	5/10	C=15 T=16	SI	SI	SI	P	P
Lutz et al (581)	P	4/8	---	69	75%	75%	75%	P	P
Butterman (588)	P	4/8	---	232	SI	SI	SI	P	P
Buttermann (589)	P	4/8	---	169	NA	NA	42%- 56%	P	P
Botwin (593)	P	4/8	---	34	75%	75%	75%	P	P
<b>Cervical Spine</b>									
Bush and Hillier (555)	P	4/8	---	68	93%	93%	93%	P	P
Cyteval et al (590)	P	4/8	---	30	60%	60%	60%	P	P

P = prospective; PC = placebo controlled; RA = randomized; DB – double blind; LA = Local Anesthetic; S = Steroids  
SI = significant improvement; C = control; T = treatment; NA = not available; P = positive; N = negative; vs = versus

ial low back pain, lumbar disc extrusions, and axial neck pain was indeterminate.

#### 6.2.4 Safety and Complications

The most common and worrisome complications of caudal, interlaminar, and transforaminal epidural injections are of two types: those related to needle placement and those related to drug administration (1, 25, 30, 336, 340, 440-450, 502, 511, 514, 517, 518, 609-639). Complications include dural puncture, spinal cord trauma, infection, hematoma formation, abscess formation, subdural injection, intracranial air injection, epidural lipomatosis, pneumothorax, nerve damage, headache, death, brain damage, increased intracranial pressure, intravascular injection, vascular injury, cerebral vascular or pulmonary embolus and effects of steroids. Spinal cord trauma and spinal cord or epidural hematoma formation are catastrophic complications, but rarely seen following epidural injections.

### 6.3 Epidural Adhesiolysis

Percutaneous epidural adhesiolysis or lysis of epidural adhesions or epidural adhesiolysis with a spinal endoscope (myeloscope) are interventional pain management techniques that play an active role in managing chronic intractable low back pain (1, 27, 263, 264, 640).

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

Duration of relief of less than 3 months was considered as short-term and longer than 3 months was considered as long-term.

#### 6.3.1 Percutaneous Adhesiolysis

Clinical effectiveness of percutaneous adhesiolysis was evaluated in 4 randomized controlled trials (641-644) and 7 retrospective evaluations (645-651). Of these 11 relevant articles, 3 randomized trials (641, 643, 644), and 3 retrospective evaluations (645-647) were included in the analysis. The remaining studies failed to meet inclusion criteria and were excluded from the evidence synthesis (27).

Three randomized trials (641, 643, 644) and one of the two retrospective studies (645) included patients with and without previous surgery. One study (646) included only post lumbar laminectomy syndrome patients. All the studies included patients with chronic, refractory low back pain and lower extremity pain.

Of the 3 randomized trials (641, 643, 644), all were positive for short-term and long-term pain relief. Among the two retrospective evaluations (645, 646), both were positive for short-term relief. How-

**Table 8. Results of published reports of percutaneous lysis of lumbar epidural adhesions and hypertonic saline neurolysis**

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief			Results	
		AHRQ Score(s)	Cochrane Score(s)		< 3 months	3 months	6 months	12 months	Short-term <3 months	Long-term ≥3 months
Manchikanti et al (643)	RA, DB	10/10	10/10	G1=25 G2=25 G3=25	33% 64% 72%	0% 64% 72%	0% 60% 72%	0% 60% 72%	<i>P</i>	<i>P</i>
Heavner et al (641)	RA, DB	7/10	7/10	59	83%	49%	43%	49%	<i>P</i>	<i>P</i>
Manchikanti et al (644)	RA	5/10	6/10	C=15 Tx=30	NSI 97%	NSI 97%	NSI 93%	NSI 47%	<i>P</i>	<i>P</i>
Manchikanti et al (645)	R	4/8	---	129	79%	68%	36%	13%	<i>P</i>	<i>N</i>
Manchikanti et al (646)	R	4/8	---	60	100%	90%	72%	52%	<i>P</i>	<i>P</i>

RA = randomized; DB = double blind; R = retrospective; NA = not available; NSI - no significant improvement; *P* = positive; *N* = negative

ever, only one study (646) was positive for long-term relief. The summary of the five studies included in the evidence synthesis is described in Table 8.

#### 6.3.1.1 Cost Effectiveness

Cost effectiveness of percutaneous epidural adhesiolysis was determined in 3 separate groups of patients (644-646). Cost effectiveness for 1-year of improvement in the quality of life varied from \$2,028 to \$5,564.

#### 6.3.1.2 Evidence

The evidence was strong in managing chronic low back and lower extremity pain.

#### 6.3.2 Endoscopic Adhesiolysis

Spinal endoscopic adhesiolysis and target delivery of steroids were evaluated in two randomized trials (652, 653), 3 prospective evaluations (654-656) and 3 retrospective trials (646, 657, 658) and multiple case reports.

There was one randomized double-blind trial meeting inclusion criteria (653). In addition, 3 prospective evaluations, and 2 of the 3 retrospective evaluations were included. One randomized trial (653) included in the analysis showed significant short-term and long-term improvement. Among the 3 prospective, observational studies, one study (655) evalu-

ated the effectiveness of spinal endoscopic adhesiolysis in lumbar spinal stenosis showing good short-term and long-term improvement in patients with low back pain, however, long-term improvement of leg pain was seen only in the mono-segmental group. The other 2 prospective evaluations (654, 656) also showed positive results. Both the retrospective evaluations (646, 647) showed positive short-term and long-term relief. Table 9 illustrates the results of various studies of spinal endoscopy. The majority of the studies included a heterogenous group of patients, most with post lumbar laminectomy syndrome or epidural fibrosis.

**Table 9. Results of published reports of spinal endoscopy**

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief			Results	
		AHRQ Score(s)	Cochrane Score(s)		< 3 months	3 months	6 months	12 months	Short-term <3 months	Long-term ≥3 months
Manchikanti et al (653)	RA, DB	10/10	10/10	C = 33 Tx=50	33% vs 90%	0% vs 80%	0% vs 56%	0% vs 48%	<i>P</i>	<i>P</i>
Igarashi et al (655)	P	5/8	---	Mono=34 Multi=24	SI	SI	SI in mono	SI in mono	<i>P</i>	<i>P</i>
Geurts et al (654)	P	6/8	---	20	55%	55%	40%	35%	<i>P</i>	<i>P</i>
Richardson et al (656)	P	4/8	---	34	SI	SI	SI	SI	<i>P</i>	<i>P</i>
Manchikanti et al (646)	R	4/8	---	60	100%	75%	40%	22%	<i>P</i>	<i>P</i>
Manchikanti et al (657)	R	4/8	---	85	100%	77%	52%	21%	<i>P</i>	<i>P</i>

*P* = prospective; *R* = retrospective; *PC* = placebo controlled; *RA* = randomized; *DB* = double blind; *NA* = not available; *N* = negative; *P* = positive *SI*=Significant Improvement; Mono: monosegmental; Multi: multisegmental

Table 10. Results of published reports of therapeutic sacroiliac joint injections

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score(s)	Co-chrane Score(s)		< 6 wks	3 months	6 months	Short-term relief <6 weeks	Long-term relief ≥6 weeks
Maugars et al (670)	RA	6/10	6/10	10 patients/ 13 w/ articulations	62%	62%	58%	<i>P</i>	<i>P</i>
Hanly et al (673)	P	5/8	---	19	SI	SI	NI	<i>P</i>	<i>N</i>
Slipman et al (674)	R	6/8	---	31	P	N/A	N/A	<i>P</i>	<i>P</i>

P = prospective; R = retrospective; RA = randomized; SI = significant improvement; NI = no improvement; NA = not available; *P*= positive; *N*= negative

### 6.3.2.2 Cost Effectiveness

The cost effectiveness of spinal endoscopy and adhesiolysis was determined in two separate groups of patients (646). The cost effectiveness of spinal endoscopy in patients failing to respond to all conservative modalities of treatments including percutaneous lysis with a spring-guided catheter was shown to be \$7,020 to \$8,127.

### 6.3.2.2 Evidence

Evidence for spinal endoscopy was strong for short-term relief and moderate for long-term relief, in managing chronic refractory low back and lower extremity pain.

### 6.3.3 Complications

The most common and worrisome complications of adhesiolysis and spinal endoscopy with lysis of adhesions are related to dural puncture, spinal cord compression, catheter shearing, infection, steroids, hypertonic saline, hyaluronidase, instrumentation with endoscope, and administration of high volumes of fluids potentially resulting in excessive epidural hydrostatic pressures (1, 27, 30, 440-450, 511, 514, 517, 518, 613-668). This may cause spinal cord compression, excessive intraspinal and intracranial pressures, epidural hematoma, bleeding, infection, increased intraocular pressures with resultant visual deficiencies, and even blindness and dural puncture. Unintended subarachnoid or subdural puncture with injection of local anesthetic or hypertonic saline is one of the major complications of the procedure with catheter adhesiolysis. Hypertonic saline injected into the subarachnoid space has been reported to cause cardiac ar-

rhythmias, myelopathy, paralysis, and loss of sphincter control.

## 6.4 Sacroiliac Joint Interventions

The present evidence supports the existence of sacroiliac joint pain (222-233). Based on a detailed review of the literature, the general consensus appears to be that sacroiliac joint pain can be diagnosed with reasonable certainty with controlled comparative local anesthetic diagnostic blocks (24).

Sacroiliac joint pain may be managed by intraarticular injections, or neurolysis of the sacroiliac joint. Relief with intraarticular injections was considered short-term if less than 6 weeks and long-term if 6 weeks or longer. Relief with radiofrequency neurotomy was considered short-term if less than 3 months, and long-term 3 months or longer.

### 6.4.1 Intraarticular Injections

Two randomized trials (669, 670), 3 prospective evaluations (671-673), and one retrospective evaluation (674) were identified. However, only one randomized trial (670), one prospective evaluation (673), and one retrospective evaluation (674) met the inclusion criteria (Table 10). Two of the studies evaluated spondyloarthropathy (670, 673). The retrospective evaluation (674) included patients with 6 weeks of pain. Due to lack of studies evaluating non-inflammatory SI joint arthritis, the above studies were included.

Maugars et al (670), in a double-blind study of evaluation of 10 patients suffering with painful sacroiliitis reported improvement in 5 of the 6 sacroiliac joints

injected with corticosteroid with 70% relief at 1-month and 0 of the 7 of the placebo joint injections reporting any significant relief. There was significant improvement in 62% of the patients at 3 months and 58% of the patients at 6 months. Hanley et al (673) showed only transient improvement with pain relief and spinal mobility, which was most pronounced at 1 to 3 months after intraarticular therapy. However, by 6 months, all outcome variables reverted to pre-therapy levels in both groups. Slipman et al (674) in a retrospective study with independent clinical review of 31 patients receiving an average of 2.1 therapeutic injections concluded that fluoroscopically guided therapeutic sacroiliac joint injections are a clinically effective intervention in the treatment of patients with sacroiliac joint syndrome.

#### 6.4.1.1 Cost Effectiveness

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

#### 6.4.1.2 Evidence

The evidence for intraarticular sacroiliac joint injections was moderate for short-term relief and limited for long-term relief.

### 6.4.2 Radiofrequency neurotomy

Percutaneous radiofrequency neurotomy of sacroiliac joints has been reported to provide long-term relief (229, 675-677).

Of all the evaluations performed on radiofrequency neurotomy in managing sacroiliac joint pain, one report was prospective (675) and 3 were retrospective (229, 676, 677). However, the prospective evaluation only had 3-months follow-up

Table 11. Results of published reports of sacroiliac joint radiofrequency thermoneurolysis

Study	Study Characteristics	Methodological Quality Criteria AHRQ Score	No. of Patients	Initial Relief	Long-term Relief				Results	
				<3 months	3 months	6 months	1 year	Short-term relief <3 months	Long-term relief ≥3 months	
Yin et al (229)	R	4/8	14	64%	64%	64%	64%	<i>P</i>	<i>P</i>	
Ferrante et al (676)	R	4/8	33	35%	35%	35%	NA	<i>N</i>	<i>N</i>	
Cohen and Abdi (677)	R	4/8	9	89%	89%	89%	NA	<i>P</i>	<i>P</i>	

R = retrospective; NA = not available; *P* = positive; *N* = negative

and consequently failed to meet inclusion criteria, as it reported only short-term relief. Hence, all 3 retrospective evaluations were included in the evidence synthesis (Table 11). Among the retrospective reports, Ferrante et al (676) evaluated effectiveness of sacroiliac joint radiofrequency denervations in 33 patients. They reported that only 36% of the patients met the criteria for successful denervation at 6 months.

Yin et al (229) in a retrospective evaluation of 14 patients reported that 64% of the patients experienced a successful outcome. Finally, Cohen and Abdi (677) evaluated radiofrequency lesioning on 9 patients and reported that 89% obtained ≥ 50% pain relief from this procedure that persisted at the 9-month follow-up.

#### 6.4.2.1 Cost Effectiveness

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

#### 6.4.2.2 Evidence

Evidence synthesis of radiofrequency neurotomy of sacroiliac joints included only retrospective evaluations with small numbers of patients, providing indeterminate evidence for managing sacroiliac joint pain.

#### 6.4.3 Safety and Complications

No complications have been reported in any of the studies included in this review. However, expected complications include infection, hematoma formation, neural damage, trauma to the sciatic nerve, potential gas and vascular particulate embolism, leakage of the drug from the joint, and other complications related to drug administration.

### 6.5 Intradiscal Therapies

Multiple percutaneously administered minimally invasive interventional techniques to achieve disc decompression have been described. Of these, intradiscal electrothermal therapy (IDET) and nucleoplasty are commonly employed minimally invasive techniques. Relief of less than 6 months was considered as short-term relief and relief of 6 months or longer was considered as long-term relief.

#### 6.5.1 Intradiscal Electrothermal Therapy.

Intradiscal electrothermal therapy (IDET) is performed by introducing a flexible catheter, containing a resistive coil, into the disc.

One randomized trial (678) and multiple prospective and retrospective trials (172, 679-697) were available. Among the prospective evaluations, 8 studies were included. All the studies evaluated chronic, refractory, discogenic pain (Table 12).

Paauw et al (678) in evaluation of the effectiveness of intradiscal electrothermal therapy for the treatment of discogenic low back pain in a randomized, placebo-controlled trial reported significant improvements in pain, disability and depression in the group treated with IDET. However, only 40% of patients treated with IDET achieved greater than 50% relief of pain at 6 months.

Karasek and Bogduk (679) and Bogduk and Karasek (680) studied 53 patients with back pain and followed them for 2 years. They concluded that in carefully selected cases, IDET can eliminate or dramatically reduce the pain of internal disc disruption in a substantial proportion of patients and appears to be superior to

conventional conservative care for internal disc disruption. At 24 months, 54% of the patients had achieved at least 50% relief with functional improvement.

Saal and Saal (681, 685, 691) reported results of their experience over a period of 6 months, 1 year, and 2 years, with overall improvement in 71% of the patients. They reported a VAS change for the entire group of 3.2 with a mean change on the SF-36 physical function subscale of 20, and the mean change on the SF-36 bodily pain subscale of 17.8.

Derby et al (682) reported that 63% of the 32 patients had a favorable outcome, with no change in outcome measures at 6 month and 12-month follow-ups.

A total of 8 prospective evaluations (679, 684-690) and one retrospective evaluation (682) were included in evidence synthesis, with 7 positive reports and 2 negative reports (689, 693).

#### 6.5.1.1 Cost Effectiveness

Cost effectiveness of intradiscal electrothermal anulooplasty has not been evaluated.

#### 6.5.1.2 Evidence

The evidence for intradiscal electrothermal therapy (IDET) was strong for short-term relief and moderate for long-term relief in managing chronic discogenic low back pain.

#### 6.5.1.3 Complications

Complications include catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage (698-699).

Table 12. Results of published reports of IDET

Study	Study Characteristics	Methodological Quality Score(s)		No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score(s)	Co-chrane Score(s)		< 6 months	6 months	1 year	Short-term relief <6 months	Long-term relief ≥6 months
Pauza et al (678)	RA, DB, PC	10/10	10/10	C = 27 T = 37	Equal	50% Treat	NA	P	N
Karasek & Bogduk (679, 680)	P	9/10	---	C = 17 T = 35	6% vs 70%	53%	53%	P	P
Saal and Saal (681, 685, 691)	P	6/10	---	58	SI	SI	SI	P	P
Gerszten et al (684)	P	6/10	---	27	75%	75%	75%	P	P
Mekhail and Kapural (686)	P	5/10	---	32	SI	SI	SI	P	P
Lee et al (687)	P	5/10	---	62	53%	53%	53%	P	P
Lutz et al (688)	P	5/10	---	33	SI	SI	SI	P	P
Freedman et al (689)	P	6/10	---	36	NA	47%	16%	N	N
Spruit (693)	P	5/10	---	20	NSI	NSI	NSI	N	N
Derby et al (682)	R	5/10	---	99	64%	64%	64%	P	P

P = prospective; PC = placebo controlled; RA = randomized; R = retrospective; C = control; T = treatment; SI = significant improvement; NA = not available; NSI = No significant improvement; P = positive; N = negative

6.5.2 Nucleoplasty

Percutaneous disc decompression (PDD) with nucleoplasty (coblation technology) is performed with RF energy to dissolve nuclear material through molecular dissociation. Bipolar RF coagulation denatures proteoglycans, changing the internal environment of the affected nucleus pulposus with reduction in intradiscal pressure (700-702).

The effectiveness of nucleoplasty has been reported in three prospective (702-704) evaluations. There were no randomized trials evaluating the effectiveness of percutaneous disc decompression with nucleoplasty. However, all the observational studies showed significant improvement in short-term, as well as long-term, in multiple parameters with pain

and functional status. All the studies were performed in patients either with discogenic pain or with small contained disc herniations (Table 13).

6.5.2.1 Cost Effectiveness

Cost effectiveness of percutaneous disc decompression with coblation nucleoplasty has not been evaluated.

6.5.2.2 Evidence

The evidence of nucleoplasty is limited in managing lumbar discogenic pain.

6.5.2.3 Complications

No significant complications have been described. However, possibilities include neural trauma, cauda equina syndrome and other neurological complications.

6.6 Implantable Therapies

Spinal cord stimulation systems and implantable intrathecal devices are frequently used in managing chronic intractable pain.

6.6.1 Spinal Cord Stimulation

In the United States, the primary indications for spinal cord stimulation are failed back surgery syndrome and complex regional pain syndromes type I and type II (21, 40, 705, 706). Significant improvements of less than one year were considered as short-term, whereas, one year or longer were considered as long-term.

Turner et al (40), in 2004, performed a systematic review of spinal cord stimulation for patients with failed back sur-

Table 13. Results of published reports of nucleoplasty

Study	Study Characteristics	Methodological Quality Score	No. of Patients	Initial Relief	Long-term Relief		Results	
		AHRQ Score		< 6 months	6 months	1 year	Short-term relief <6 months	Long-term relief ≥6 months
Singh et al (702)	P	5/10	67	82%	59%	56%	P	P
Sharps and Isaac (703)	P	5/10	49	79%	79%	79%	P	P
Singh et al (704)	P	5/10	47	80%	63%	53%	P	P

P = prospective; P = positive; N = negative

gery syndrome or complex regional pain syndrome. Following an extensive review, they concluded that the literature on spinal cord stimulation for failed back surgery syndrome and complex regional pain syndrome remains inadequate to make definitive statements about efficacy in reducing physical disability, work disability, and medication consumption. They also concluded that there is moderate evidence (one high quality RCT) that spinal cord stimulation plus physical therapy is more effective than physical therapy alone for patients with CRPS Type I in relieving pain at 6- and 12-months. They further added that both the RCT and lower-quality studies suggested a modest pain-relieving effect on average. They also felt that complications leading to the need for additional surgeries have been common. However, the same authors, in a previous systematic review in 1995 (706), which consisted mostly of retrospective case series, concluded that approximately 50% to 60% of patients with failed back surgery syndrome reported  $\geq 50\%$  pain relief with spinal cord stimulation.

Turner et al (40), in their recent review also excluded two commonly used randomized trials in the evidence synthesis (707, 708). They stated that North et al (708) failed to report either pain or functional outcomes. They also discussed North and Wetzel's report of 2002 (709) which reports SCS to be more effective than reoperation for 90% of patients at a 3-year follow-up, with significantly better outcomes and lower rates of crossover. They excluded a large prospective multicenter study (707) because only 70 of 182 failed back surgery syndrome patients who received a permanent spinal cord stimulator completed the follow-up.

Taylor et al (21), in a recent systematic review of spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome, studied one randomized controlled trial, one cohort study, and 72 case studies. They concluded that there is moderate evidence for spinal cord stimulation effectiveness.

Five randomized controlled trials (708, 710-713), two prospective trials (707, 714), multiple case series (715-720), and other reports were identified (721).

For this evaluation, 3 of the 5 randomized trials were included (710, 711, 713). Two reports by Kemlar et al (711, 712) and two studies by North et al (708, 713) were included as one each. Rapha-

el et al (710) reported positive results of spinal cord stimulation in failed back surgery syndrome. Kemlar et al (711, 712) evaluated the effectiveness in complex regional pain syndrome. They reported that pain, but not functional status or depression, improved significantly more in spinal cord stimulation with physical therapy than physical therapy alone at 6 months. However, at 1 year, pain and quality of life were improved more in the spinal cord stimulation group. In a second study, North et al (708, 713) studied failed back surgery syndrome patients as candidates for repeat laminectomy or spinal cord stimulation. They concluded that at long-term follow-up of 3 years, spinal cord stimulation continues to be more effective than reoperation, for 90% of the patients.

The two prospective trials included in the evidence synthesis (707, 714) showed positive results. Barolat et al (714), in a multicenter study, showed 83% to 92% of the patients had fair to excellent relief with either leg or back pain, and 69% to 88% of the patients fair to excellent relief in the legs or in the low back at 1 year, with significant improvement in function and quality of life. The second study by Burchiel et al (707) in a multicenter prospective study reported that at the 1-year follow-up evaluation of 70 patients, quality-of-life measures showed statistically significant improvement during the treatment year.

Among the case series (715-721), all were positive for short-term and long-term benefit. Overall pain relief was better in the leg than in the low back.

#### 6.6.1.1 Cost Effectiveness

Taylor et al (721) performed a systematic review of the literature. They reviewed 99 abstracts and found 14 studies that met the criteria of the review. They found across a range of health care institutions that the initial healthcare acquisition costs were offset by a reduction in post-implant healthcare resource demand and costs. Costs were \$29,123 in intervention group, compared to \$38,029 in the control group for failed back surgery syndrome. In contrast, for CRPS (722) in the lifetime analysis, spinal cord stimulation per patient was estimated to be \$60,000 cheaper than control therapy.

#### 6.6.1.2 Evidence

The evidence for spinal cord stimulation in failed back surgery syndrome

and complex regional pain syndrome was strong for short-term relief and moderate for long-term relief.

#### 6.6.1.3 Complications

Complications with spinal cord stimulation range from infection, hematoma, nerve damage, lack of appropriate paraesthesia coverage, paralysis, nerve injury, and death (40).

### 6.6.2 Implantable Intrathecal Drug Administration Systems

Continuous infusion of intrathecal medication is used for control of chronic, refractory, malignant and non-malignant pain. In an exhaustive review of available literature, Bennett et al (723) concluded that clinical efficacy in large-scale randomized controlled trials utilizing intrathecal delivery of most compounds has not been demonstrated and variations between study designs make useful comparisons of existing studies difficult. In another review, Walker et al (724) concluded that the evidence for the safety and effectiveness of combination spinal analgesic therapies is moderate in acute pain, whereas, they found limited or no evidence to support the combination analgesics in chronic pain. Various guidelines also have been published on intrathecal infusion systems (725).

The literature supporting the use of intrathecal infusion systems includes four randomized trials (726-729), multiple prospective trials (730-735), and multiple retrospective evaluations (1, 736-739).

Among the randomized trials, Siddall et al (726) compared the effectiveness of intrathecal morphine or clonidine, alone or in combination, in the treatment of neuropathic pain after spinal cord injury. They concluded that the combination of morphine and clonidine produced significantly more pain relief than placebo 4 hours after administration. van Hilten et al (727) evaluated the use of intrathecal baclofen for the treatment of dystonia in patients with complex regional pain syndrome, in a double-blind, randomized, controlled, crossover trial of bolus intrathecal injections of baclofen in various doses. They concluded that in some patients, the dystonia associated with reflex sympathetic dystrophy responded markedly to intrathecal baclofen. Smith et al (728) reported significant improvement in patients treated with intrathecal infusion systems when compared to patients treated with conventional aggressive med-



ical management in patients with malignant pain. Staats et al (729) in a multicenter, double-blind trial, reported that a neuron-specific calcium channel blocker delivered via an implanted intrathecal pump in patients with cancer and AIDS-related pain syndromes significantly decreased pain scores in 51% of the patients compared to 18% in the placebo group at the 7-day follow-up. Thus, all the randomized trials were performed for neuropathic pain utilizing various types of drugs and short-term follow-up.

Among the prospective studies, Hasenbusch et al (730) reported favorable results in patients with long-standing non-malignant neuropathic pain in a study of 14 patients, 61% reported good or fair pain control with a mean follow-up duration of 2.4 years. Angel et al (731) reported good to excellent analgesic response in 73% of 11 patients. Others (732-734) reported favorable results in chronic pain. In a recent evaluation, Deer et al (735) reported the results of the National Outcomes Registry for low back pain collected at 6- and 12-month follow-ups. They reported that in the implant group, numeric pain ratings dropped by more than 47% for back pain and more than 31% for leg pain at 12-month follow-up. They also reported improvement in Oswestry scores in 65% of the patients.

Retrospective reports dominate the literature on intrathecal pain management (736-740). Among the retrospective evaluations, the reports provided significant improvement at short-term and long-term follow-up.

#### 6.6.2.1 Cost Effectiveness

In post lumbar laminectomy syndrome, it was shown that intrathecal morphine delivery resulted in lower cumulative 60-month costs of \$16,579 per year and \$1,382 per month versus medical management at \$17,037 per year or \$1,420 per month (741).

In another study (96), the expected total cost of intrathecal morphine over 60 months was \$82,893 (an average of \$1382 per month).

#### 6.6.2.2 Evidence

The evidence for implantable intrathecal infusion systems was strong for short-term improvement in pain of malignancy or neuropathic pain. The evidence was moderate for long-term management of chronic pain.

#### 6.6.2.3 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.

## 7.0 EVALUATION AND MANAGEMENT

### 7.1 Evaluation

Appropriate history, physical examination, and medical decision making are essential (742). There are numerous acceptable medical methods to evaluate a chronic spinal pain patient. These methods vary from physician to physician and textbook to textbook. The guidelines established by the Centers for Medicare and Medicaid Services (CMS) aid the physician in performing a comprehensive and complete evaluation, and assist in complying with regulations. The CMS guidelines define five levels of services. The three crucial components of evaluation and management services are: history, physical examination, and medical decision-making. Other components include: counseling, coordination of care, nature of presenting problem, and time.

### 7.2 Medical Necessity Management

The following criteria should be considered carefully in performing interventional techniques:

1. Complete initial evaluation, including history and physical examination.
2. Physiological and functional assessment, as necessary and feasible.
3. Determination of indications and medical necessity:
  - Suspected organic problem.
  - Nonresponsiveness to less invasive modalities of treatments except in acute situations such as acute disc herniation, herpes zoster and postherpetic neuralgia, reflex sympathetic dystrophy, and intractable pain secondary to carcinoma.
  - 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 to justify repeat blocks or other interventions.
- Repeating interventions only upon return of pain and deterioration in functional status.

## 8.0 DELIVERY OF INTERVENTIONAL TECHNOLOGY

There is no consensus among the interventional pain management specialists with regards to type, dosage, frequency, total number of injections, or other interventions. Yet significant attention in the literature seems to be focused on the complications attributed to the use of epidural steroids in the entire arena of interventional pain management. Thus, various limitations of interventional techniques, specifically neural blockade, have arisen from basically false impressions. Based on the available literature and scientific application, the most commonly used formulations of long-acting steroids, which include methylprednisolone (Depo-Medrol<sup>®</sup>), triamcinolone diacetate (Aristocort<sup>®</sup>), triamcinolone acetonide (Kenalog<sup>®</sup>), and betamethasone acetate and phosphate mixture (Celestone Soluspan<sup>®</sup>), appear to be safe and effective (1, 25, 30, 743-764). Based on the present literature, it appears that if repeated within two weeks, betamethasone may be the best choice in avoiding side effects; whereas, if treatment is carried out at six-week intervals or longer, any one of the four formulations will be safe and effective.

Frequency and total number of injections or interventions are key issues, although controversial and rarely addressed. Descriptions of the frequency of various types of interventional techniques are described here. These are based on available evidence and consensus regarding the safety, clinical effectiveness, and cost effectiveness. However, they are not based on evidence synthesis methodology. Descriptions are provided only for commonly used procedures. Medicare, Medicaid and third party payers in each region and state may have rules and regulations different from these guidelines. Interventions permitted per year and per region are also variable.

### 8.1 Facet Joint Injections and Medial Branch Blocks

- In the diagnostic phase, a patient may receive two procedures at intervals of no sooner than 1 week or, preferably, 2 weeks.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 2 months or longer between injections, provided that  $\geq 50\%$  relief is obtained for 6 weeks.
- If the interventional procedures are applied for different regions, they may be performed at intervals of no sooner than 1 week or preferably 2 weeks for most types of procedures. It is suggested that therapeutic frequency remain at 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 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 six times for local anesthetic and steroid blocks over a period of 1 year, per region.
- Under unusual circumstances with a re-current injury or cervicogenic headache, procedures may be repeated at intervals of 6 weeks after stabilization in the treatment phase.

### 8.2 Medial Branch Neurotomy

- The suggested frequency would be 3 months or longer between each procedure, provided that  $\geq 50\%$  relief is obtained for 10 to 12 weeks.
- The therapeutic frequency for medial branch neurotomy should remain at intervals of at least 3 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.

### 8.3 Epidural Injections

- Epidural injections include caudal, interlaminar, and transforaminal.
- In the diagnostic phase, a patient may receive two procedures at intervals of no sooner than 1 week or preferably, 2 weeks, except in cancer pain or when a continuous administration

of local anesthetic is employed for reflex sympathetic dystrophy.

- 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  $\geq 50\%$  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 1 week and preferably 2 weeks for most type 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 interventional procedures should be repeated only as necessary according to medical necessity criteria, and it is suggested that these be limited to a maximum of 6 times per year.
- Under unusual circumstances with a recurrent injury, carcinoma, or reflex sympathetic dystrophy, blocks may be repeated at intervals of 6 weeks after diagnosis/stabilization in the treatment phase.

### 8.4 Percutaneous Adhesiolysis

- The number of procedures are preferably limited to:
  - With a 3-day protocol, 2 interventions per year,
  - With a 1-day protocol, 4 interventions per year.

### 8.5 Spinal Endoscopic Adhesiolysis

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

### 8.6 Sacroiliac Joint Injections

- In the diagnostic phase, a patient may receive two procedures at intervals of no sooner than 1 week or, preferably, 2 weeks.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 2 months or longer between injections, provided that  $\geq 50\%$  relief is obtained for 6 weeks.

- If the procedures are done for different joints, they be performed at intervals of no sooner than 1 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 six times for local anesthetic and steroid blocks over a period of 1 year, per region.
- Under unusual circumstances with a re-current injury, procedures may be repeated at intervals of 6 weeks after stabilization in the treatment phase.

### 8.7 Sacroiliac Joint Radiofrequency Neurotomy

- The suggested frequency is 3 months or longer between each procedure, provided that  $\geq 50\%$  relief is obtained for 10 to 12 weeks.
- The therapeutic frequency for neurotomy should remain at intervals of at least 3 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.

## 9.0 AN ALGORITHMIC APPROACH

In the changing paradigm of modern medicine, with its major focus on evidence-based medicine, interventional pain physicians may benefit from the practice of evidence-based interventional pain management. An algorithmic approach, if developed properly, may assist the physician in the clinical practice of interventional pain management.

An algorithmic approach was developed, based on the structural basis of spinal pain, and incorporated acceptable evidence of diagnostic and therapeutic interventional techniques available in managing chronic spinal pain. Consensus was utilized in the absence of specific evidence. Fig. 1 describes a proposed algorithmic approach for the diagnosis of chronic low back pain and Fig. 2 describes an algorithmic approach to management of chronic low back pain. Fig. 3 describes a proposed algorithmic approach for di-

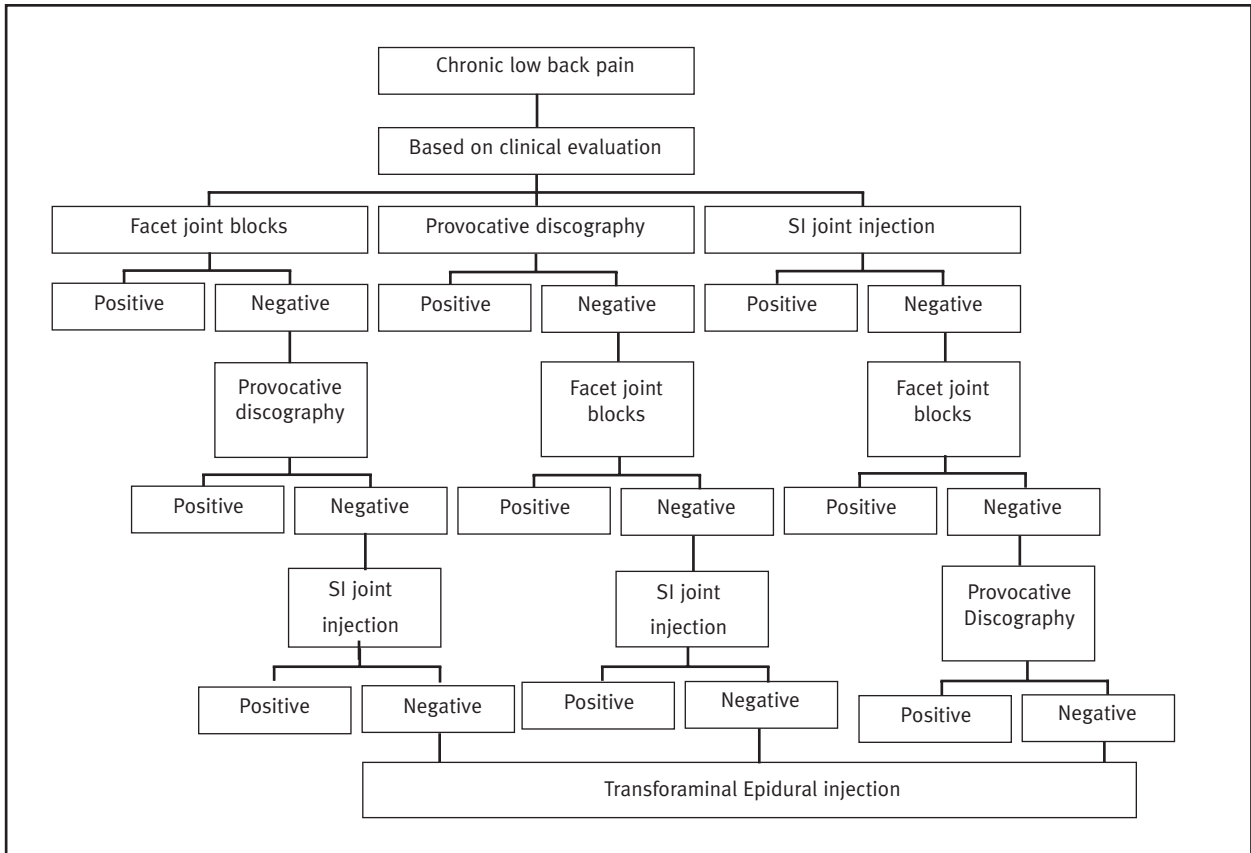


Fig. 1. An algorithmic approach to diagnosis of chronic low back pain without disc herniation

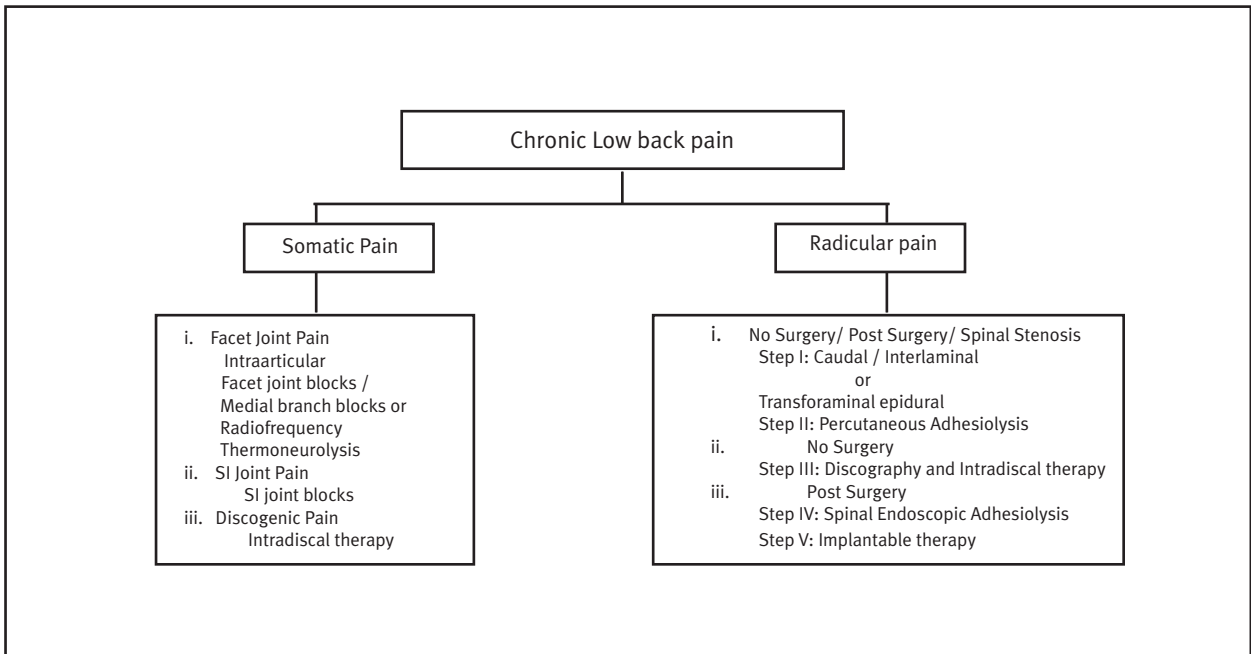


Fig. 2. A suggested algorithm for therapeutic interventional techniques in management of chronic low back pain

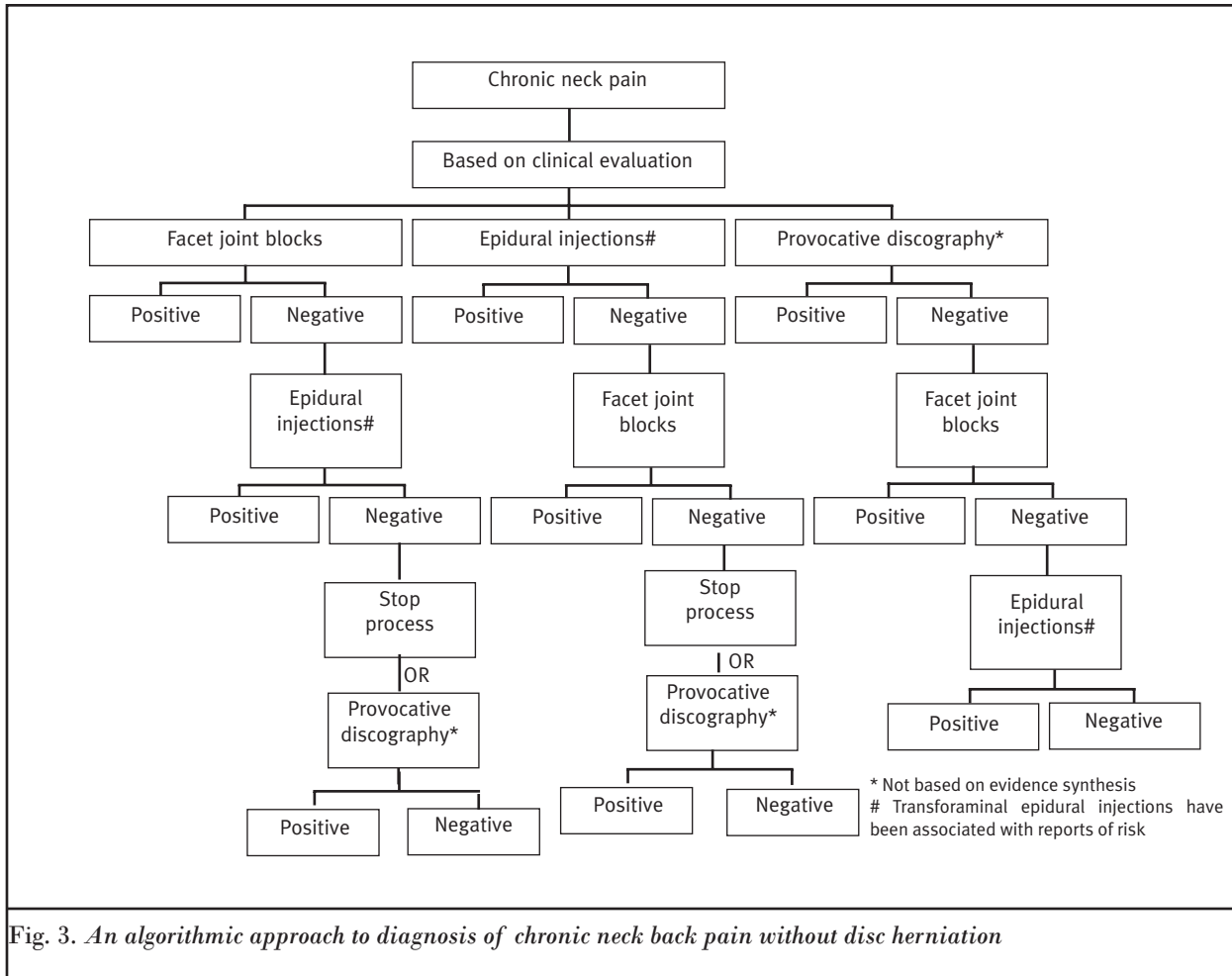


Fig. 3. An algorithmic approach to diagnosis of chronic neck back pain without disc herniation

agnosis and management of chronic neck pain.

## 10. CONCLUSION

Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain were developed by the American Society of Interventional Pain Physicians utilizing the

best available clinical evidence from systematic research. A policy committee with broad representation, consisting of academic and clinical practitioners recognized as experts in one or more interventional techniques under consideration and representing a variety of practices and geographic areas, assisted in preparation of these guidelines. All types of rele-

vant and published evidence and consensus were utilized. These guidelines are a comprehensive review of interventional techniques for managing chronic spinal pain. It is hoped that these guidelines will assist both physicians and patients in making appropriate health care decisions for the diagnosis and treatment of chronic spinal pain.

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