

## ASIPP Practice Guidelines

### Interventional Techniques in the Management of Chronic Pain: Part 2.0

Laxmaiah Manchikanti, MD, Vijay Singh, MD, David Kloth, MD, Curtis W. Slipman, MD, Joseph F. Jasper, MD, Andrea M. Trescot, MD, Kenneth G. Varley, MD, Sairam L. Atluri, MD, Carlos Giron, MD, Mary Jo Curran, MD, Jose Rivera, MD, A. Ghafoor Baha, MD, Cyrus E. Bakhit, MD and Merrill W. Reuter, MD

The practice guidelines for interventional techniques in the management of chronic pain are systematically developed statements to assist physician and patient decisions about appropriate health care related to chronic pain. These guidelines are professionally derived recommendations for practices in the diagnosis and treatment of chronic or persistent pain. They were developed utilizing a combination of evidence and consensus based techniques, to increase patient access to treatment, improve outcomes and appropriateness of care, and optimize cost-effectiveness. The guidelines include a discussion of their purpose, rationale, and importance, including the patient population served, the methodology and the pathophysiologic basis for intervention. Various interventional techniques will be discussed addressing the rationale for

their use in chronic pain with analysis of the outcomes data and cost effectiveness.

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.

**Keywords:** Interventional techniques, neural blockade, chronic pain, epidural injections, percutaneous epidural adhesiolysis, discography, facet joint mediated pain, radiofrequency

Practice guidelines in various formats have been a part of medical practice for well over 50 years, and by some accounts over 150 years (1-14). Clinical practice guidelines are “. . . systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (1). These are professional practice recommendations for practices for prevention, diagnosis and treatment of acute and chronic painful disorders, and in some cases, disability management. Guidelines have existed for centuries, in forms ranging from Sanskrit and Greek protocols and folk medicine practices, to rigorous, scientifically tested algorithms (1,

2). There has been a rapid increase in guideline development since 1985, in part propelled by the realization that medical practices for similar conditions vary widely among geographic areas, specialties, and countries (1, 2, 15-20). In recent years, practice guidelines have become more prominent to improve the quality of health care, protection of professional autonomy, reduction of litigation risk, minimization of practice variation, provision of standards for auditing medical records, reduction of health care costs, defining areas of practice, improvement in efficiency of practice, and identification of inappropriate care (4, 9, 12, 21-26).

Shaneyfelt et al (27) reviewed the methodological quality of clinical guidelines in the peer-reviewed medical literature, with evaluation of 279 guidelines developed by 69 different organizations and published from 1985 to 1997. It is expected that the guidelines published by various organizations and not included in the peer-reviewed literature are nearly 2500 in the US alone. Of significant importance are the various guidelines developed by the

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From the American Society of Interventional Pain Physicians, Paducah, Kentucky. Authors are members of American Society of Interventional Pain Physicians. Appendix I describes author affiliations. Address correspondence: Laxmaiah Manchikanti, MD, 2831 Lone Oak Road, Paducah, KY 42001. Email: [drm@asipp.org](mailto:drm@asipp.org)

Agency for Health Care Policy and Research (AHCPR), which replaced the National Center for Health Services Research and Health Care Technology Assessment (NCHSR) in 1989 (28). The Agency for Health Care Policy and Research developed approximately 15 guidelines, with a budget of \$750 million. The guidelines developed by AHCPR for managing acute low back pain are of significant importance for practice of interventional pain medicine (28). Other guidelines of significance for pain specialists include those developed by the Quebec Task Force in the management of spinal disorders and whiplash associated disorders (29, 30), chronic pain management guidelines by the American Society of Anesthesiologists (31), guidelines for performance of facet joint blocks by the International Spinal Injection Society (32), and interventional techniques in the management of chronic pain by the Association of Pain Management Anesthesiologists (33). Additionally, there are guidelines for migraine headaches (34), guidelines for managing pain in sickle cell disease (35), chronic pain management guidelines in the elderly (36), and guidelines for management of chronic pain syndrome (37, 38). Other guidelines include the ones developed by local Medicare carriers in the form of local Medicare Review Policies in various states; third-party payors including Blue Cross and Blue Shield, Aetna and others; entrepreneurial technological companies such as Hayes Technologies; and position statements by a multitude of individuals and organizations. Cochrane collaboration back review group for spinal disorders was also started in 1995 (39, 40). McQuay and Moore published a book of evidence based resource for pain relief (3). Many of these guidelines were developed at a cost of tremendous effort and resources to review the assessment and treatment literature and to develop evidence-based guidelines to treat various conditions. However, the cost of the guidelines by various organizations is much less than the ones developed by the federal government by the AHCPR. A serious examination of the guidelines shows that about 85% of the recommendations are not based on any significant evidence (27). Interventional pain management is no exception to the general rule.

## CLINICAL PRACTICE GUIDELINES

### *Purpose*

Clinical practice guidelines for interventional techniques in the management of chronic pain are professionally developed utilizing a combination of evidence, expert opinion and consensus. The purpose of these clinical guidelines is to:

1. Improve quality of care,
2. Improve patient access,
3. Improve patient outcomes,
4. Improve appropriateness of care,
5. Improve efficiency and effectiveness, and
6. Achieve cost containment by improving cost-benefit ratio.

### *Rationale*

The most compelling single reason for the development of these clinical practice guidelines is to improve the quality of care and life for patients suffering from painful disorders. Available evidence documents a wide degree of variance in the practice of interventional pain management and pain medicine for even the most commonly performed procedures and treated condition(s) (6, 23-38, 41-63). These guidelines also address the issue of systematic evaluation and ongoing care of chronic or persistent pain, and provide information about the scientific basis of recommended procedures, thus potentially increasing compliance, dispelling misconceptions among providers and patients, managing patient expectations reasonably, and forming the basis of a therapeutic partnership among the patient, the provider, and the payer.

### *Importance*

Interventional techniques are crucial both in the diagnostic, as well as the therapeutic, arena of managing pain and providing improvement in the quality of life of the pain sufferers. Some insurance carriers and other medical specialties have criticized the practice of interventional pain medicine and pain management using the wide variations in treatment protocols and the relative scarcity of conclusive evidence or consensus for their justification.

### *Methodology*

The two most common methods for the development of guidelines, often combined, are based on evidence and consensus. However, reviews, clinical decision analyses, and economic analyses are also very commonly utilized in the medical literature. Thus, clinicians are increasingly being asked to remain current in the aspects of clinical care and decision making by systematically gathering, analyzing, and combining evidence that links to outcome (6). However, many of these publications unfortunately do not always link information in a direct way to clinical recommendations (3-5, 24, 25, 64). Implicit in the definition of

clinical practice guidelines is that they not only be systematically and scientifically developed but also should be able to assist practitioner and patient in making real life clinical decisions. The Institute of Medicine (IOM) implicitly incorporates rigorous science-based procedures as a part of the development of practice guidelines and decision making includes both clinicians and patients with a focus on specific clinical circumstances, without direction toward technology or procedures (6). The American Medical Association (AMA) uses the term *practice parameter* and defines this practice as “. . . strategies for patient management, developed to assist physicians in clinical decision making. Practice parameters are highly variable in their content, format, degree of specificity, and method of development” (65). Thus, the methods that are used to develop practice guidelines vary among organizations and depend on objectives of the guideline and philosophic approach.

Methods of development are classified as informal consensus development, formal consensus development, evidence-based guideline development, and explicit guideline development (5-7, 10, 65). However, a combination of multiple approaches is commonly utilized. Evidence-based guideline development provides a link between the strength of recommendations and the quality of evidence. Even though this approach may seem to have enhanced the scientific rigor of guideline development, recommendations may not always meet the highest scientific evidence (27).

Evidence-based practice originated in the 50s with the advent of randomized, controlled trials. A randomized, controlled trial, also known as RCT, is a trial in which participants are randomly assigned to two groups: first, (experimental group) receiving the intervention that is being tested, and the other (the comparison or control group) receiving an alternative treatment or placebo. This design allows assessment of the relative effects of interventions. It is presumed that the strident debate between the proponents and opponents of evidence-based medicine has led to clarity (7). The current 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 (10). The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research. It should be construed that, apart from the results of the randomized controlled trials, there are many other factors that may weigh heavily in both clinical and policy decisions, such as patient preferences and resources,

and these must contribute to decisions about the care of the patients (7). Thus, all evidence should be considered and no one sort of evidence should necessarily be the determining factor in a decision. There are an increasing number of well-conducted randomized, controlled trials and systematic reviews. However, such studies are difficult to conduct in chronic pain management with interventional procedures as well as surgical procedures. Clinical trials of the efficacy of commonly used interventions in low back pain were reviewed by Koes and coworkers (66), and Tulder and coworkers (67), which led to the conclusion that the methodological quality in these studies was disappointingly low. Similar conclusions were drawn in other evaluations (27-30). The quality of meta-analytic procedures in chronic pain treatment also has been questioned (68). In addition, the issues of ethics, feasibility, cost and reliability pose challenges to the randomized trial, specifically in surgical settings and treatments involving interventional procedures (69-75). Most of the studies of interventional pain procedures have been performed by multiple specialty groups (rarely including pain specialists) and without radiographic control, especially in the case of epidural steroid injections.

Concato et al (76) conducted a study of randomized, controlled trials, observational studies, and hierarchy of research designs. They described that, in the hierarchy of research designs, the results of randomized, controlled trials have been considered to be evidence of the highest grade, whereas observational studies have been seen as having less validity because such studies reportedly overestimate treatment effects. Concato et al (76) showed that the average results of the observational studies were remarkably similar to those of the randomized, controlled trials, and concluded that the results of well-designed observational studies (with either a cohort or a case-controlled design) do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic. However, this is not to say that we do not need randomized, controlled studies. Pocock and Elbourne (77) observed that, in a systematic review of evidence on a therapeutic topic, one needs to take into account the quality of the evidence, since in any randomized or observational study, bias may exist either in design or analysis. The importance of the difficulty of a large randomized trial with interventional procedures is reinforced by the failure to complete a randomized, controlled trial to evaluate epidural steroid injections, which was funded by the American Society of Regional Anesthesia as a Koller Award (78). In addition, Turk (79) suggests that it is important to acknowledge that

**Table 1.** *Type and strength of efficacy evidence*

Level	Type of strength	Description of evidence
I	Conclusive	Research-based evidence with multiple relevant and high-quality scientific studies
II	Strong	Research-based evidence from at least one properly designed randomized, controlled trial of appropriate size (with at least 60 patients) and high-quality or multiple adequate scientific studies
III	Moderate	Evidence from well-designed trials without randomization, single group pre-post cohort, time series, or matched case-controlled studies
IV	Limited	Evidence from well-designed nonexperimental studies from more than one center or research group
V	Indeterminate	Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees

statistical significance and clinical significance are not necessarily equal and that there might be disagreements concerning how to judge the clinical significance of each study. Schulz et al (80) in describing the empirical evidence of bias, estimated that lack of randomization may overestimate the treatment effect by 30% to 41%; whereas if the study is not double-blind, overestimation may be approximately 17%. Of course, the study by Concato et al (76) disputes this assertion.

The publication of randomized, controlled trials concerning pain have increased significantly. However, only 14% of these studies were of invasive procedures, on the other hand, 54% of all reports were in acute pain, whereas 43% were in chronic noncancer pain, and 3% were in cancer pain (81, 82). The Agency for Health Care and Policy Research (28) described evidence rating for management of acute low back pain problems in adults. The AMA, office of quality assurance, also described five attributes for the development of practice parameters (65). The Institute of Medicine (6) described several attributes to the guideline content and guideline development, while McQuay and Moore (3, 7), and others (39, 40, 45, 66, 67) described type and strength of efficacy evidence. For the purpose of development of these guidelines, a blended approach for type and strength of efficacy evidence categorized into five types was utilized in Table 1.

Thus, in the development of these clinical guidelines of interventional techniques in managing chronic pain all applicable standards for evidence rating were utilized. Due to the poor methodological quality of a large number of published randomized clinical trials on the efficacy of in-

terventions in the management of low back pain, whiplash, and other painful conditions, even though the focus of these guidelines was on evidence that consisted of studies of randomized, well-controlled studies, other evidence was also utilized which included reports of meta-analysis and high quality observational studies with adequate size. Consequently, the focus of these guidelines is physiological, supported by peer-reviewed literature, based on the best cost-benefit balance for the patient both in the short and long term, expert opinion(s) and consensus.

**Population**

The population covered by these guidelines includes all patients suffering with chronic pain of either spinal or nonspinal origin eligible to undergo interventional technique(s).

**IMPLEMENTATION AND REVIEW**

The dates for implementation and review were established:

- ◆ Effective date - February 1, 2001
- ◆ Expiration date - January 31, 2003
- ◆ Scheduled review - July 1, 2002

**CONTROVERSIES**

Controversial aspects of guidelines range from the difference between a guideline and a pathway, targeted patient population, the definition of evidence, variability and evaluation of strength of studies and final conclusions of evidence, author bias, and finally the special interest group

influences. Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. In contrast, clinical pathways are tools to coordinate the time-dependent progress of a typical uncomplicated patient across many clinical departments specific to the condition or disease being managed (64). The differences between target patient population ranges from specific conditions such as acute low back pain, migraine headaches, sickle-cell disease, and complex pain syndromes, to much more general guidelines applicable across a variety of chronic painful conditions. The next issue of controversy and contention is the definition of evidence. All of the guidelines incorporate literature review. However, the categorization of evidence of strength differs across guidelines. Generally, evidence of strength ranges from prospective, double-blind, randomized, controlled studies to uncontrolled case reports. In addition to the evidence, panels also attempt to use expert consensus, the application of which varies across the development of the guidelines. Each panel developing the guidelines feel that their guidelines applied the most stringent and reasonable evidence. On the other hand, one group developing the guidelines tend to criticize another group when they differ philosophically (3, 7, 21, 24, 25, 27-39, 45, 46, 62, 64-67, 83, 84). In addition, the same evidence may be evaluated by different groups or authors with variability interpretation of results. Author bias also exists regardless of the desire to achieve substantially impartial, scientifically based recommendations. It is unavoidable that guidelines reflect authors' clinical and practice biases, personal philosophy, and the way the literature is interpreted. Certainly on the same spectrum, influences of the special interest groups are inescapable.

### CHRONIC PAIN

**“We must all die. But that I can save him from days of torture, that is what I feel as my great and ever new privilege. Pain is a more terrible Lord of mankind than even death itself.”**

**- Albert Schweitzer**

Schweitzer (85), the great humanitarian, physician, and Nobel laureate, elegantly described the nature of pain and the obligation and privilege of the physician and other health professionals to relieve it in 1931, after nearly two decades of experience of medical practice in the African jungle. Approximately four decades later in 1974, John Bonica, the father of pain medicine, observed: “Pain is the most pressing issue of modern times.” Today, in the

new millennium as then, proper management of pain remains one of the most important and most pressing issues of society in general and the scientific community in the health professions in particular.

### *Epidemiology*

In spite of the best efforts of the public, providers and the government, pain continues to be an epidemic (86, 87). In addition, inadequate treatment of pain also continues to be a public health problem, that is reaching epidemic proportions in the United States and across the world (86-96). The knowledge and understanding of this complex entity, including diagnosis and treatment, are in infancy, in spite of modern developments in medicine. Providers, patients, and the government all understand the devastating nature of chronic pain which destroys the quality of life by eroding the will to live, disturbing sleep and appetite, creating fatigue, and impairing recovery from illness or injury (86-100). In elderly patients it may make the difference between life and death by resulting in vocational, social, and family discord (100-105). Pahor et al (102) found that pain relief is particularly elusive for older women with disabling back and lower extremity problems. In this study, approximately two thirds of the women reported significant levels of pain and difficulty in controlling it. Asch et al (106) measured underuse of necessary care detecting substantial underuse problems for various conditions, including depression, and concluded that these problems likely result in negative outcomes in the elderly population.

The concept of chronic pain is beset with controversy, starting with its very definition. For some chronic painful conditions, it is defined as, “pain that exists beyond an expected time frame for healing.” For other conditions, it is recognized that, “healing may never occur.” Bonica defined chronic pain as, “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 causes a continuous pain or pain at intervals for months or years” (107). In many cases, chronic pain is understood as persistent pain that is not amenable to routine pain control methods. In a Gallup Survey of “pain in America” more than 4 out of 10 adults (42%) say they experience pain on a daily basis (108). Americans age 65 and older are more likely to experience pain for longer periods of time than younger Americans (108). Andersson et al (109) reported incidence of persistent pain for 6 months in 49% of the adult population, with functional disability in 13%. Perquin et al (97) reported

**Table 2.** Prevalence of low back and neck pain in general population ranked by severity and disability

Pain grade	Low back pain	Neck pain
Grade I Low pain intensity and disability	47%	39%
Grade II High pain intensity and low disability	12%	9%
Grades III and IV High pain intensity with moderate and severe disability	13%	5%
<b>Total</b>	<b>72%</b>	<b>53%</b>

Data modified and adapted from Cassidy et al (118) and Côté et al (119)

that chronic pain is a frequent complaint even in childhood and adolescence. The International Association for the Study of Pain (IASP) appointed task forces to study the epidemiology of pain in 1996 (110), and pain in the elderly in 1999 (111) with publication of two large reports of 137 and 320 pages. It was consistently shown that elderly suffered with not only pain of longer duration, but with higher frequency (100-105, 108, 111-116).

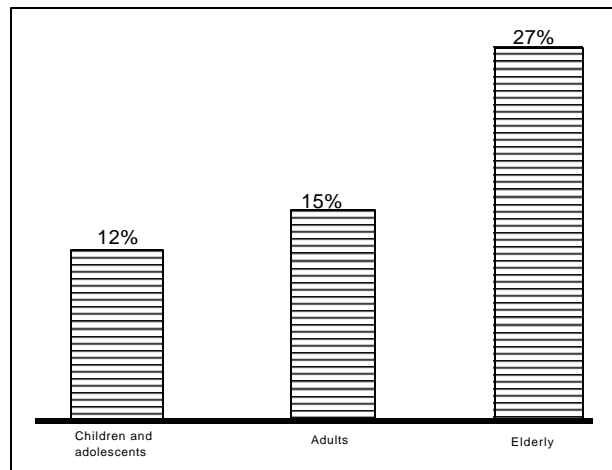
Among the chronic pain problems, spinal pain which includes pain emanating from cervical, thoracic and lumbosacral regions constitutes the majority of the problems. It is estimated that episodes of low back pain that are frequent or persistent have been reported in 15% of the US population, with a lifetime prevalence of 65% to 80% (103, 113). However, prevalence of neck pain, though not as common as low back pain, is estimated 35% to 40% (114, 115), of which 30% will develop chronic symptoms (116).

In contrast, the epidemiological data in relation of thoracic pain support the view that the thoracic spine is less commonly involved. Linton et al (117) estimated prevalence of spinal pain in the general population as 66%, with only 15% of those reporting thoracic pain; in comparison to 56% to 44% for the lumbar and cervical regions respectively. Cassidy and colleagues (118) assessed the 6-month prevalence of chronic low back pain and its impact on general health in the Canadian population. The results showed an 84% lifetime prevalence, with 47% of the patients reporting grade I pain (low pain intensity and low disability); 12% grade II pain (high pain intensity and low disability); 13% grade III (high pain intensity/moderate disability), and grade IV (high pain intensity/severe disability) (Table 2). They also reported that grade I low back pain was more common in the younger population while older age groups reported higher incidence of grade III/IV pain. Thus, a total 13% of the population suffers with high

**Table 3.** Chronicity of low back pain

Author(s)	Year of Publication	Prevalence	
		3 months	12 months
Anderson and Svensson (122)	1983	20%	10%
Van Den Hoogen et al (123)	1997	35%	35%
Croft et al (124)	1998	79%	75%
Carey et al (125)	1999	N/A	20% to 35%
Meidema et al (126)	1998	N/A	28%
Thomas et al (127)	1999	48%	42%

N/A = Not available



**Fig. 1.** Estimated average of age related prevalence of low back pain

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pain intensity with moderate or severe disability, whereas an additional 12% suffer with high pain intensity but with a low disability. In a similar study, Cote et al (119, 120), evaluating neck pain and its related disability, reported that overall, 39% of the sample experienced grade I neck pain, whereas 9% experienced grade II neck pain, and 5% had grade III and IV neck pain (Table 2). Almost 16% of the respondents reported having previously injured the neck in a motor vehicle collision (119, 120).

Duration of back pain and its chronicity have been a topic of controversy. It is believed that most of these episodes 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 (121, 122). However, this concept has been questioned, as the condition tends to relapse, so most patients will experience multiple episodes. As shown in Table 3, prevalence of low back pain ranged from 35% to 79% at 3 months and 35% to 75% at 12 months (123-127). The studies evaluating the chronicity of low back pain estimated the average of age related prevalence of persistent low back pain as 12% in children and adolescents, 15% in adults, and 27% in the elderly (Fig. 1). Bressler and colleagues (101), in a systematic review of the literature determined that overall prevalence of low back pain in the elderly was 27% derived from a total elderly population base of 17,173 with reports from 12 studies from community population, primary care settings and from the nursing homes with prevalence ranging from 13% to 51% (101, 109, 128-138).

### *Chronic Pain vs Chronic Pain Syndrome*

Two major and controversial terms in today's pain medicine are "chronic pain," also known as persistent pain, and a second category known as "chronic pain syndrome," which is a separate and distinct condition (139-142). Chronic pain or persistent pain persists beyond the expected healing time of an injury or an illness, usually considered beyond 6 months. Chronic pain may be associated with psychological problems such as depression, generalized anxiety disorder, and some behavioral problems. However, chronic pain improperly diagnosed or inadequately treated can result in deteriorating coping skills and limitations and reduction in functional capacity. In contrast, chronic pain syndrome is a complex condition with physical, psychological, emotional, and social components (141, 142). Both chronic pain and chronic pain syndrome can be defined in terms of duration and persistence of the sensation of pain, and presence or absence of psychological and emotional components. However, chronic pain syndrome, as opposed to chronic pain, has the added component of certain recognizable psychological and socioeconomic influences, with characteristic psychological and sociological behavior patterns inherent in chronic pain syndrome that distinguish the two conditions (141). According to the fifth edition of Guides to Evaluation of Permanent Impairment published in 2000 (142), the term chronic pain syndrome even though not official nomenclature, is frequently used to describe an individual who is markedly impaired by chronic pain with substantial psychological overlay. The guides (142) also state that chronic pain syndrome is largely a behavioral syndrome that affects a minority of those with chronic pain. It may best be understood as a form of an abnormal illness behavior that consists mainly of excessive adoption of the sick role. The guides also caution that while the term is useful in certain situations, it does not, however, substitute for a careful diagnosis of physiologic, psychological, and conditioning components that comprise the syndrome. The term chronic pain syndrome must be used with caution, as grouping pain problems together under a general disorder may mask and leave untreated important physiologic differences (142). Thus, chronic pain may exist in the absence of chronic pain syndrome, but chronic pain syndrome always presumes the presence of chronic pain. The terminology recommended by IASP has eliminated chronic pain syndrome from the glossary (140). The IASP Task Force on Taxonomy on classification of chronic pain describing definitions of pain terms described that it is common in North America to find patients as having "chronic pain syndrome" (140). In this case, the Task Force believed that the words

are being used as a diagnosis that usually implies a persistent pattern of pain that may have arisen from organic causes but which is now compounded by psychological and social problems resulting in behavioral changes. Even though the Task Force was asked to adopt such a label, particularly for use in billing in the United States, there was general agreement in the Task Force that this would not be desirable. The Task Force also noted that the term “chronic pain syndrome” is often, unfortunately, used pejoratively (140). However, the literature shows that chronic pain syndrome is not a common phenomenon in general, and it is particularly very infrequent in the elderly (143). In addition, Hendler et al (144), to whom a number of suspected “psychosomatic” cases have been referred, found organic origin of the pain in 98% of cases. Subsequently, Hendler and Kolodny (145) estimated that the incidence of psychogenic pain is only 1 in 3000 patients.

Chronic pain has been estimated to cost the American society approximately \$120 billion a year in treatment, lost revenues, and wages. Some frightening estimates show that annual total costs for back pain itself, including disability and litigation, are more than \$100 billion (146). Annual direct medical costs for back pain are estimated at around \$33 billion, with chronic pain around \$45 billion. Approximately 28% to 30% of the US population suffer with some kind of chronic painful condition(s).

### PATHOPHYSIOLOGIC BASIS

Spinal pain is inclusive of all painful conditions originating from spinal structures ranging from the discs to muscles and ligamentous attachments. In contrast, nonspinal pain encompasses a multitude of other painful conditions, ranging from peripheral neuralgias to reflex sympathetic dystrophy and arthritis. Any structure with a nerve supply capable of causing pain similar to that seen in clinically normal volunteers, which is susceptible to diseases or injuries that are known to be painful, can cause pain (32, 33, 41, 42, 56, 147-185). For a structure to be implicated, it should have been shown to be a source of pain in patients, using diagnostic techniques of known reliability and validity (32, 33, 41, 42, 151-169). The structures responsible for pain in the spine include the vertebrae, intervertebral discs, spinal cord, nerve roots, facet joints, ligaments, and muscles (32, 33, 41, 42, 147-165, 168, 170-185). Similarly, muscles, ligaments, various joints including (atlanto-occipital joints, atlantoaxial joints, and sacroiliac joints), sensory nerves, the sympathetic nervous system, and visceral organs have been implicated in pain of nonspinal origin (166, 167, 169, 186-215).

Facet joints have been implicated as responsible for spinal pain in 15% to 45% of patients with low back pain (178-183) and 54% to 60% of patients with neck pain utilizing controlled diagnostic blocks (184, 185). The degeneration of the disc resulting in primary discogenic pain is seen commonly with or without internal disc disruption alleged to be the number one cause of spinal pain (162, 163, 174, 180, 216-260). Disc degeneration is a well accepted sequela of the normal aging process, particularly of the lower lumbar levels. Kirkaldy-Willis et al (216) described the pathogenesis of degenerative changes in the aging spine entailing three phases, whereas Handel et al (217) described a structural degenerative cascade for the cervical spine with four phases. In this model, degenerative cascade is viewed in a context of a three-joint complex, with involvement of changes in the disc structure and composition paralleling changes in the articular cartilage and ligaments of joints. Internal disc disruption has been considered as a commonly overlooked source of chronic low back pain (163, 226). In fact, a controlled study reported the prevalence of pain due to internal disc disruption as 39% in patients suffering with chronic low back pain (174). The prevalence of cervical discogenic pain in patients with chronic neck pain of traumatic origin was shown to be 61% (162). However, the prevalence of cervical discogenic pain has not been formally studied. In contrast, disc herniation is seen in a small number of patients ranging from 4% to 6% (163, 173, 222-230, 255-260).

Postlaminectomy syndrome or pain following operative procedures of the spine is also becoming a common entity in modern medicine (261-292). Although the exact incidence and prevalence of postlaminectomy syndrome is not known, it is estimated that 20% to 30% of spinal surgeries (occasionally as high as 40%), may not be successful as a result of either the surgery being inadequate, incorrect, or unnecessary. Unfortunately, poor outcomes may result following a well indicated and well performed surgical procedure. It has also been shown that 20% to 30% of patients over 65 who underwent lumbar spine operations had one or more subsequent operations within four years (289). Waddell et al (290) noted that in all studies of back pain, 10% to 15% of patients account for 80% to 90% of the total health care compensation and cost for spinal disorders, and the 1% to 2% of patients who undergo surgery are the most expensive group. Keskimaki et al (292), in a study of population-based regional and interspeciality variations of lumbar disc surgery and reoperations described that back surgery in the United States has been shown to be five times more common than in the United



Kingdom, three times more common than in Sweden, and two times more common than in Finland. They also noted up to 15-fold variations across regions of the United States. Multiple studies evaluating surgical treatment of lumbar disc prolapse and degenerative lumbar disc disease have shown conflicting evidence on the effectiveness of surgical discectomy for lumbar disc prolapse (290, 291, 293). Evidence is limited and contradictory for automated percutaneous discectomy (290), with no acceptable evidence on the effectiveness of any form of fusion for back pain or instability (290), no acceptable evidence on the efficacy of any form of decompression for degenerative lumbar disc disease or spinal stenosis (290), and no evidence as to whether any form of surgery for degenerative lumbar disc disease is effective in returning patients to work (290).

The sacroiliac joint, which receives its innervation from lumbosacral roots, is alleged to be a source of back pain or referred pain; and prevalence has been shown to be 19% to 30% in selected population groups (191, 192). The exact incidence of pain emanating from atlantoaxial and atlantooccipital, and thoracic facet joints is not known (294-299). A multitude of other spinal conditions including, degenerative disorders and myofascial syndromes, contribute approximately to 5 to 10% of the spinal pain (163, 164, 171, 172, 186-190, 300-304).

Causes of nonspinal pain include the various causes responsible for headache; trigeminal neuralgia with facial pain; cancer pain with involvement of various musculoskeletal structures, either with the spread of the cancer into bones and muscles, with compression of the spinal cord, or pain after multiple surgical procedures radiotherapy or chemotherapy interventions; pain secondary to pressure on various nerve plexuses resulting in neuropathic pain; and, finally, pain resulting from visceral organs. Other causes include reflex sympathetic dystrophy and causalgia or complex regional pain syndromes Types I and II; postherpetic neuralgia, phantom limb pain; and finally, the controversial myofascial pain (171, 172, 186-215). Even though some prevalence studies have been published occasionally, there are no controlled or systematic studies to show the prevalence of various disorders resulting in chronic pain.

## EVALUATION

Appropriate history, physical examination, and medical decision making from the initial evaluation of a patient's presenting symptoms. A patient's evaluation should not only meet all the required medical criteria but also meet

the regulatory requirements (305). The guidelines of the Health Care Financing Administration (HCFA) provide various criteria for 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. AHCPR Guidelines for managing acute low back problems in adults (28) also have provided guidance on initial clinical assessment, assessment of psychosocial factors, imaging techniques, and assessment with electromyography and nerve conduction. While there are numerous techniques to evaluate a chronic pain patient, variable from physician to physician and text book to text book, following the guidelines established by HCFA not only will assist a physician in performing a comprehensive and complete evaluation but also assist them to be in compliance with regulations.

### History

The history includes:

- ◆ Chief complaint,
- ◆ History of present illness,
- ◆ Review of systems, and,
- ◆ Past, family, and/or social history.

**Chief Complaint:** The chief complaint is a concise statement describing the symptom, problem, condition, diagnosis, or other factor that is the reason for the encounter, usually stated in the patient's words.

**History of Present Illness:** The history of present illness is a chronological description of the development of the patient's present illness from the first sign and/or symptom. It includes the following elements:

- ◆ Location,
- ◆ Quality,
- ◆ Severity,
- ◆ Duration, timing,
- ◆ Context,
- ◆ Modifying factors, and
- ◆ Associated signs and symptoms.

**Review of Systems:** The review of systems is an inventory of body systems obtained through a series of questions seeking to identify signs and/or symptoms that the patient may be experiencing or has experienced.

**Past, Family, and/or Social History:** The past, family,

and/or social history consists of a review of the past history of the patient including past experiences, illnesses, operations, injuries, and treatment; family history, including a review of medical events in the patient’s family, hereditary diseases, and other factors; and social history appropriate for age reflecting past and current activities.

Past history in interventional pain medicine includes history of past pain problems, motor vehicle, occupational, or nonoccupational injuries; history of headache, neck pain, upper-extremity pain, pain in the upper, or mid back or

chest wall, pain in the lower back or lower extremities, and pain in joints; and disorders such as arthritis, fibromyalgia, or systemic lupus erythematosus.

Family history includes history of pain problems in the family, degenerative disorders, familial disorders, drug dependency, alcoholism, or drug abuse; and psychological disorders such as depression, anxiety, schizophrenia, and suicidal tendencies, etc. Family history of medical problems is also important.

Social history includes environmental information, educa-

**Table 4. Features of somatic and radicular pain**

	<b>Somatic or referred pain</b>	<b>Radicular pain</b>
<b>i. Causes</b>	<ul style="list-style-type: none"> <li>◆ Facet joint-mediated pain</li> <li>◆ Sacroiliac joint-mediated pain</li> <li>◆ Myofascial syndrome</li> <li>◆ Internal disc disruption</li> </ul>	<ul style="list-style-type: none"> <li>◆ Disc herniation</li> <li>◆ Annular tear</li> <li>◆ Spinal stenosis</li> </ul>
<b>ii. Symptoms</b>		
<b>Quality</b>	<ul style="list-style-type: none"> <li>◆ Deep, aching</li> <li>◆ Poorly localized</li> <li>◆ Back worse than leg</li> <li>◆ No paresthesia</li> <li>◆ Covers a wide area</li> <li>◆ No radicular or shooting pain</li> </ul>	<ul style="list-style-type: none"> <li>◆ Sharp, shooting</li> <li>◆ Well localized</li> <li>◆ Leg worse than back</li> <li>◆ Paresthesia present</li> <li>◆ Well defined area</li> <li>◆ Radicular distribution</li> </ul>
<b>Modification</b>	<ul style="list-style-type: none"> <li>◆ Worse with extension</li> <li>◆ Better with flexion</li> <li>◆ No radicular pattern</li> </ul>	<ul style="list-style-type: none"> <li>◆ Worse with flexion</li> <li>◆ Better with extension</li> <li>◆ Radicular pattern</li> </ul>
<b>Radiation</b>	<ul style="list-style-type: none"> <li>◆ Low back to hip, thigh, groin</li> <li>◆ Radiation below knee unusual</li> <li>◆ No radicular pattern</li> </ul>	<ul style="list-style-type: none"> <li>◆ Follows nerve root distribution</li> <li>◆ Radiation below knee common</li> <li>◆ Radicular and shooting pain</li> </ul>
<b>iii. Signs</b>		
<b>Sensory alterations</b>	<ul style="list-style-type: none"> <li>◆ Uncommon</li> </ul>	<ul style="list-style-type: none"> <li>◆ Probable</li> </ul>
<b>Motor changes</b>	<ul style="list-style-type: none"> <li>◆ Only subjective weakness</li> <li>◆ Atrophy is rare</li> </ul>	<ul style="list-style-type: none"> <li>◆ Objective weakness</li> <li>◆ Atrophy may be present</li> </ul>
<b>Reflex changes</b>	<ul style="list-style-type: none"> <li>◆ None</li> </ul>	<ul style="list-style-type: none"> <li>◆ Commonly described but seen occasionally</li> </ul>
<b>Straight leg raises</b>	<ul style="list-style-type: none"> <li>◆ Only low back pain</li> <li>◆ No root-tension signs</li> </ul>	<ul style="list-style-type: none"> <li>◆ Reproduction of leg pain</li> <li>◆ Positive root-tension signs</li> </ul>

Adapted and modified from Manchikanti (41)

tion, marital status, children, habits, hobbies, and occupational history, whenever available.

**Physical Examination**

Physical examination in interventional pain medicine involves general, musculoskeletal, and neurological examination.

Examination of other systems, specifically cardiovascular, lymphatic, skin, eyes, and cranial nerves is recommended based on the presenting symptomatology.

**Medical Decision Making**

Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option as measured by three components, including;

1. Diagnosis/management options with a number of possible diagnoses and/or the number of management options;
2. Review of records/investigations, with number and/or complexity of medical records, diagnostic tests, and other information that must be obtained, reviewed, and analyzed; and ,
3. Risk(s) of significant complications, morbidity and mortality, as well as comorbidities associated with the patient’s presenting problem(s), the diagnostic procedure(s), and/or the possible man-

agement options.

Psychological evaluation, laboratory evaluation, imaging techniques, electromyography and nerve conduction and somatosensory evoked potentials are also an extension of evaluation process. It is beyond the scope of these guidelines to discuss these techniques of assessment.

Appropriate history and physical examination with the assistance of other evaluations should direct a physician to formulate a provisional diagnosis. Features of somatic and radicular pain are outlined in Table 4. However, various pitfalls with conventional evaluation of low back pain are also illustrated in Table 5. A suggested algorithm for comprehensive evaluation and management of chronic pain is illustrated in Fig. 2. In summary, 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. Definition 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 neural-

**Table 5. Pitfalls with conventional evaluation of low back pain**

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“Specific anatomic etiology is clearly and objectively identified in only 10% to 20%.”

1. Radiographic “abnormalities” are frequently clinically irrelevant.
2. True sciatica occurs in only 1% to 2% of the patients.
3. No universal criteria are established for scoring the presence, absence, or importance of particular signs.
4. Quantification of the degree of disability and the association to treatment outcomes is difficult.
5. Interpretation of biomedical findings relies on “clinical judgments,” “physician’s experience,” and “quasi-standardized criteria.”
6. Routine clinical assessment is frequently subjective and unreliable.
7. Physical examination and diagnostic findings are subjective.
8. The discriminative power of common objective signs has been questioned.
9. Reliance on general “clinical impression” to detect gross psychological disturbances is “hopelessly inaccurate.”
10. It is usually not possible to make a precise diagnosis or identify anatomic origin of the pain by routine clinical assessment.

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Adapted and modified from Manchikanti (41).

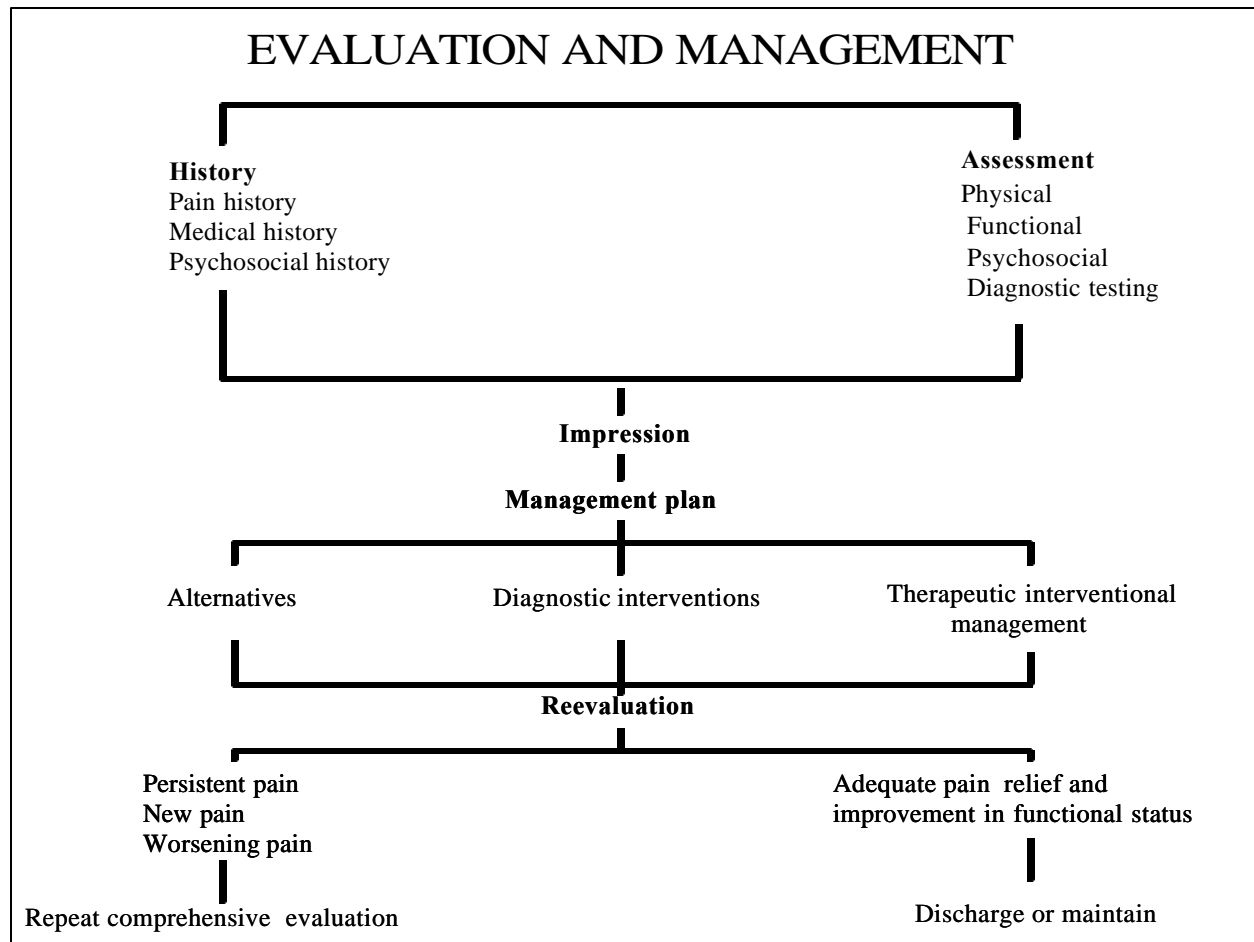


Fig. 2. Suggested algorithm for comprehensive evaluation and management of chronic pain

- Pain and disability of moderate-to-severe degree.
- No evidence of contraindications such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain.
- Responsiveness to prior interventions with improvement in physical and functional status for repeat blocks or other interventions.
- Repeating interventions only upon return of pain and deterioration in functional status.

**INTERVENTIONAL TECHNIQUES**

**History**

The history of the application of interventional techniques in pain management dates back to 1901, when epidural injections for lumbar nerve root compression were reported (307-309). Since then, substantial advances have been made in the administration of epidural injections, and a multitude of other interventional techniques have been described (310-324). Thus, percutaneous injection techniques have been distinguished as the favored, and at times decisive, intervention in the diagnostic and therapeutic management of chronic painful conditions.

**Mechanism**

The overall benefit of various types of injection techniques includes pain relief outlasting by days, weeks, or months the relatively short duration of pharmacologic action of

the local anesthetics and other agents used. Clear-cut explanations for these benefits are not currently available. It is believed that neural blockade alters or interrupts nociceptive input, reflex mechanisms of the afferent limb, self sustaining activity of the neuron pools and neuraxis, and the pattern of central neuronal activities (325). The explanations are based in part on the pharmacological and physical actions of local anesthetics, corticosteroids, and other agents. It is also believed that 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 (326-332). 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; suppression of sensitization of dorsal horn neurons; and reversible local anesthetic effect (327-340). In addition, local anesthetics have been shown to produce prolonged dampening of c-fiber activity (341-343). 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 methylprednisolone (330, 334-337).

### DIAGNOSTIC INTERVENTIONAL TECHNIQUES

Diagnostic blockade of a structure with a nerve supply, which can generate pain, can be performed to test the hypothesis that the target structure is a source of the patient's pain (32). Testing the hypothesis by provoking pain in any structure is an unreliable criterion except in provocative discography (175). However, neurodiagnostics of the involved nerve pathways has proven valuable. The relief of pain, however, is the essential criterion in almost all structures including analgesic discography in the cervical spine, the only deviation being lumbar discs (32). If the pain is not relieved, the source may be in another structural component of the spine similar to the one tested such as a different facet joint or a different nerve root or some other structure (32). Thus, precision diagnostic injections directed towards specific spinal pathology are potentially powerful tools for diagnosis of chronic spinal pain, but often technically challenging. Identifying the specific pathology responsible for pain is often difficult, leading to frustrated patients and clinicians. Nevertheless, these injections may be safely performed by properly trained anesthesiologists, physiatrists, neurologists, radiologists,

spine surgeons and physicians from other related specialties who take the time to learn the basis for and perfect the application of these techniques.

When the source of pain is more than one structure or multiple levels, it is not expected that all the pain will be relieved. For example, there may be painful facet joints bilaterally at a given segmental level, in which case anesthetizing the left joint should relieve the left side, but not the right side; there may be pain from two consecutive joints on one side, in which case anesthetizing the lower joint alone may relieve only the lower half of the pain; there may be more than one structure involved, such as pain contributed by discs and facet joints or facet joints and nerves (32).

True positive responses are secured by performing controlled blocks. Ideally, this should be in the form of placebo injections of normal saline; but logistical and/or ethical considerations prohibit the use of normal saline in conventional practice.

### *Rationale*

The rationale for diagnostic neural blockade in the management of spinal pain stems from the fact that clinical features and imaging or neurophysiologic studies do not permit the accurate diagnosis of the causation of spinal pain in the majority of patients in the absence of disc herniation and neurological deficit (28-30, 32, 33, 41, 42, 56, 58, 62, 151-153, 162-164, 174-185, 306, 344-357). It was also shown that sacroiliac joint pain is resistant to identification by the historical and physical examination data (166, 167, 191, 192, 358-360), even though some have claimed sensitivity in the range of 60% to 87% with multiple provocative maneuvers (361, 362). In addition, no corroborative radiologic findings have been identified in patients with sacroiliac joint syndrome (363-371). Further rationale is based on the recurring facts showing the overall rate of inaccurate or incomplete diagnosis in patients referred to pain treatment centers to range from 40% to 67%, the incidence of psychogenic pain to be only 1 in 3,000 patients, and the presence of organic origin of the pain is mistakenly branded as psychosomatic in 98% of the cases (144, 145). Finally, the most compelling reason is that chronic low back pain is a diagnostic dilemma in 85% of patients even in experienced hands with all the available technology (Table 5). It has been determined that utilizing alternative means of diagnosis including precision diagnostic blocks in cases where there is a lack of definitive diagnostic radiologic or electrophysiologic criteria can

enable an examiner to identify the source of pain in the majority of patients, thus reducing the proportion of patients who cannot be given a definite diagnosis from 85% to 35% or even as low as 15%.

### **Facet Joint Blocks**

The facet joints of the spine can be anesthetized by fluoroscopically guided injections of local anesthetic, either into the target joint or onto the medial branches of the dorsal rami that supply them (32, 33, 41, 163, 178-185, 372-380).

The rationale for facet joint blocks is based on the observation that if a particular joint is determined to be the source of pain generation, long-term relief can be sought by directing therapeutic interventions at that joint. In managing low back pain, local anesthetic injection into the facet joints or interruption of the nerve supply to the facet joints has been accepted as the standard for diagnosis of facet joint mediated pain. Since a single joint is innervated by at least two medial branches, two adjacent levels should always be blocked.

Instead of placebo-controlled diagnostic facet joint blocks, a convenient control is the use of comparative local anesthetic blocks, in which on two separate occasions the same structure is anesthetized, but using local anesthetic with different durations of action. However, one of the drawbacks of local anesthetic control is that comparative local anesthetic blocks may not be implementable for intra-articular blocks because it is not known whether the placement of local anesthetic in a relatively avascular environment such as a joint space affects its expected duration of action, and leakage of local anesthetic from the joint capsule onto the exiting nerve root may give a false positive response. On the contrary, these are implemented readily for medial branch blocks and probably for other types of nerve blocks. With medial branch blocks, the use of comparative local anesthetic blocks has been evaluated and found to be valid against challenge with placebo (32, 372-374).

A diagnosis cannot be rendered reliably on the basis of a single block because false-positive rates are seen in as many as 41% of patients (32, 178-185, 372-374). Hence, controlled blocks with comparative local anesthetics are required in essentially every case (32). Even then, comparative blocks are only 85% reliable.

### **Discography**

Once stifled by misinformation, discography now has applications in a number of clinical settings (173, 381-404). The first to create widespread interest in the disc as a source of pain was Mixter and Barr with their 1934 hallmark description of the herniated nucleus pulposus (222). This mechanical model detailed a lumbar posterolateral prolapse with direct nerve root compression and secondary radiculopathy. The work of Mixter and Barr (222) became the central model of spine pain, which preoccupied the medical community and diverted attention from other possible causes, even though Mixter and Ayers in 1935 demonstrated that radicular pain can occur without disk herniation.

Formal studies in normal volunteers have shown that lumbar disc stimulation provocative discography is a specific test as lumbar discs are presumed not to hurt in asymptomatic individuals (381, 392). Thus, finding a painful disc in a patient is considered as a significant observation. However, even so, controls are mandatory to exclude false-positive responses to refute the competing hypothesis that stimulating any disc reproduces the patient's pain (381, 393-402). The IASP has recommended that for disc stimulation to be considered valid, at least one, and preferably two, adjacent discs be stimulated as controls. Hence, for a disc to be deemed painful, stimulation of that disc, but neither of the adjacent discs, should reproduce the patient's pain. In contrast to lumbar discs, in the evaluation of cervical discogenic pain provocative cervical discography or cervical disc stimulation is not as well documented as the lumbar spine. It is not clear that cervical discs do not hurt in normal volunteers to the same extent as lumbar discs.

In 1988, the North American Spine Society (NASS) published a position statement about discography (395). Discograms were considered a procedure only for those with chronic low back pain (symptoms greater than 4 months duration). The document recognized that other than discography, no visualization tool offers the ability to precisely delineate disk morphology (396). The NASS updated its position paper through its diagnostic and therapeutic committee in 1995 (397). According to the position statement on discography by the NASS (395, 397):

Discography is indicated in the evaluation of patients with unremitting spinal pain, with or without extremity pain, of greater than four months' duration, when the pain has been unresponsive to all appropriate methods of conservative

therapy. Before discography, the patients should have undergone investigation with other modalities which have failed to explain the source of pain; such modalities should include, but not be limited to, either computed tomography (CT) scanning, magnetic resonance imaging (MRI) scanning and/or myelography. In these circumstances, discography, especially when followed by CT scanning, may be the only study capable of providing a diagnosis or permitting a precise description of the internal anatomy of a disc and a detailed determination of the integrity of the disc substructures. Additionally, the anatomic observations may be complemented by the critical physiological induction of pain, which is recognized by the patient as similar to or identical with his/her complaint. By including multiple levels in the study, the patient acts as his/her own control for evaluation of the reliability of the pain response.

Other indications for discography include: (1) ruling out secondary internal disc disruption or recurrent herniation in the postoperative patient; (2) exploring pseudoarthrosis; (3) determining the number of levels to include in a spine fusion; and (4) identifying the primary symptom-producing level when chemonucleolysis (enzymatic hydrolysis) or anular denervation (via thermocoagulation with an intradiscal catheter or a radiofrequency probe) is contemplated (173, 226).

There are several potential sources of both false-positive and false-negative responses with provocative discography. Carragee et al (398, 399) concluded, that in individuals with normal psychometrics and without chronic pain, the rate of false-positives is very low if strict criteria are applied; and that the false-positive rate increases with abnormal psychometrics and increased annular disruption. Carragee et al (400) also showed that a high percentage of asymptomatic patients (40%) with normal psychometric testing who previously have undergone lumbar discectomy will have significant pain on injection of their discs that had previous surgery. Carragee et al (401) showed that even though a high-intensity zone is seen more commonly in symptomatic patients, the prevalence of a high-intensity zone in asymptomatic individuals with degenerative disc disease also was too high (25%) for meaningful clinical

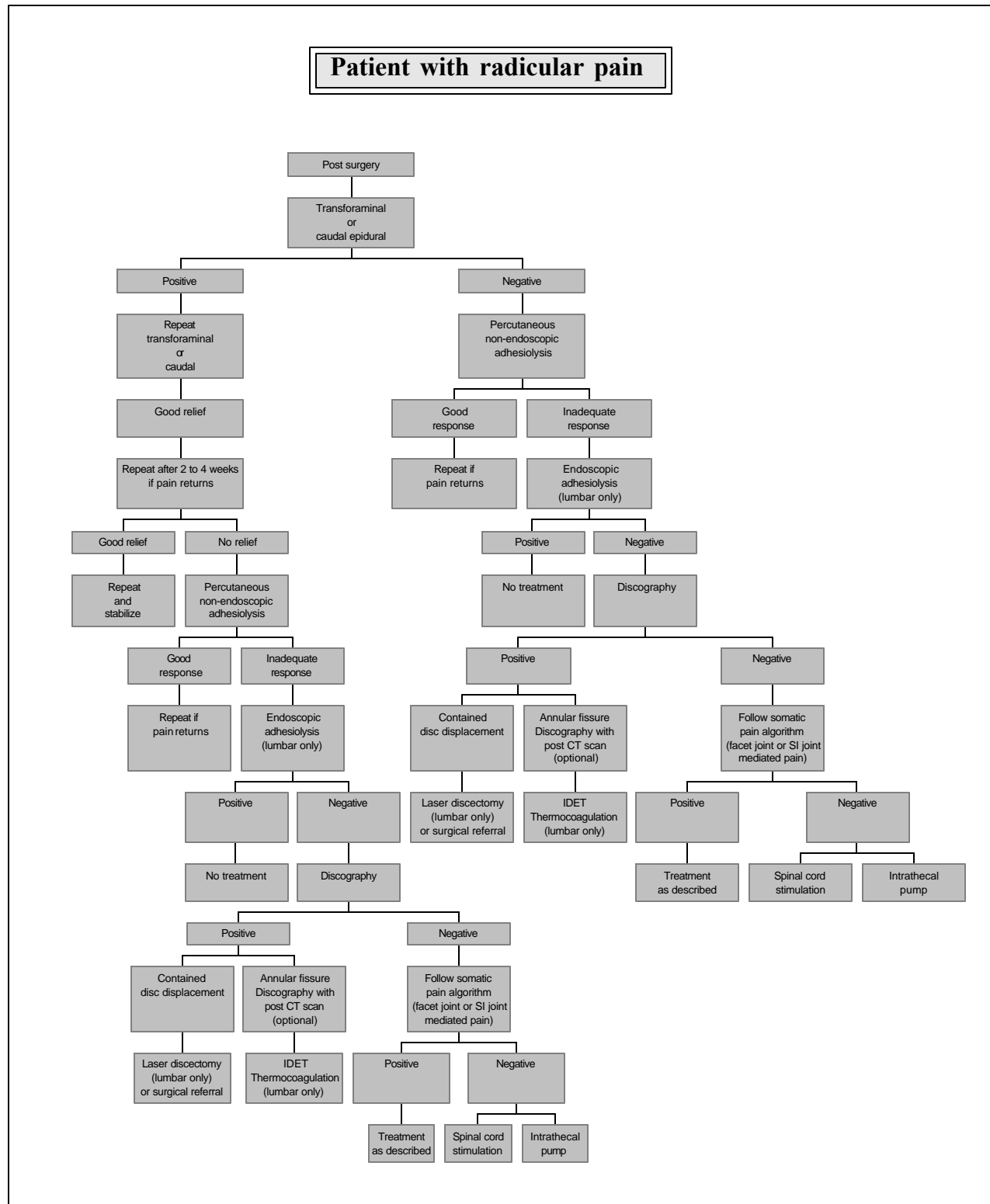
use. Carragee et al (402) also showed that discography does not cause long term back symptoms in previously asymptomatic subjects with normal psychometrics.

### ***Selective Epidural Injections***

As in the case with the intervertebral disc, spinal nerves can be injected with contrast, local anesthetic, or other substances (353). Both the provocative response and analgesic response provide clinically useful information. Steindler and Luck (318) recognized the validity of provocative and analgesic spinal injections as early as 1938. In 1971, McNab and coworkers (405) revealed the value of diagnostic, selective nerve root blocks in the preoperative evaluation of patients with negative imaging studies and clinical findings of root irritation. The nerve blocks were utilized to diagnose the source of radicular pain when imaging studies suggested possible compression of several nerve roots (406-418). The relief of usual symptoms following the injection of local anesthetic, 1 mL of 2% Xylocaine, was the main determinant for diagnostic information. Schutz and colleagues (407), Krempe and Smith (408), Tajima and colleagues (409), Haueisen and coworkers (410), Dooley and colleagues (411), and Stanley and coworkers (412) described positive results of diagnostic selective nerve root blocks. In 1992, Nachemson (419) analyzed the literature on low back pain and indicated that diagnostic, selective nerve root block provided important prognostic information about surgical outcome.

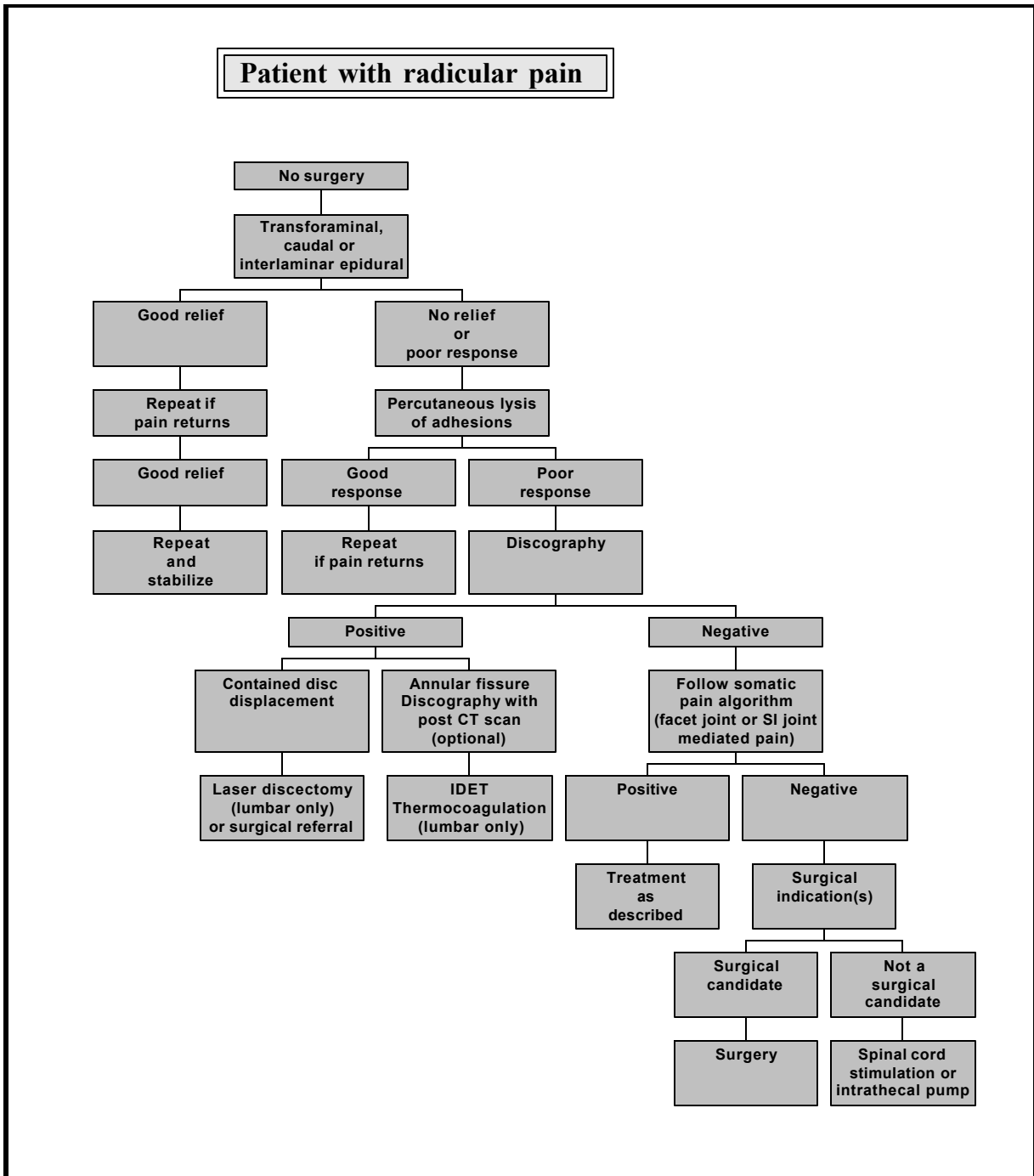
Kikuchi and colleagues (415) estimated that approximately 20% of the patients presenting with apparent radicular pain required diagnostic nerve root blocks or epidural blocks. Van Akkerveeken (420) recreated data from his 1989 thesis regarding sensitivity, specificity, and predicative values for diagnostic, selective nerve root blocks. A positive block required concurrent symptom reproduction during root stimulation and full relief following anesthetic infusion (416). Derby et al (413) correlated surgical outcome with pain relief following transforaminal epidural injections with local anesthetic and steroids and reported that patients who failed to obtain sustained relief of radicular pain following the block were less likely to benefit from subsequent surgical intervention.

The controversial aspects of epidural injections include the terminology and technique (58). The terminology describing nerve root injections has varied from transforaminal epidural to selective nerve root block, selective nerve root sleeve injection, selective epidural, selective spinal nerve block, or selective ventral ramus block. However,

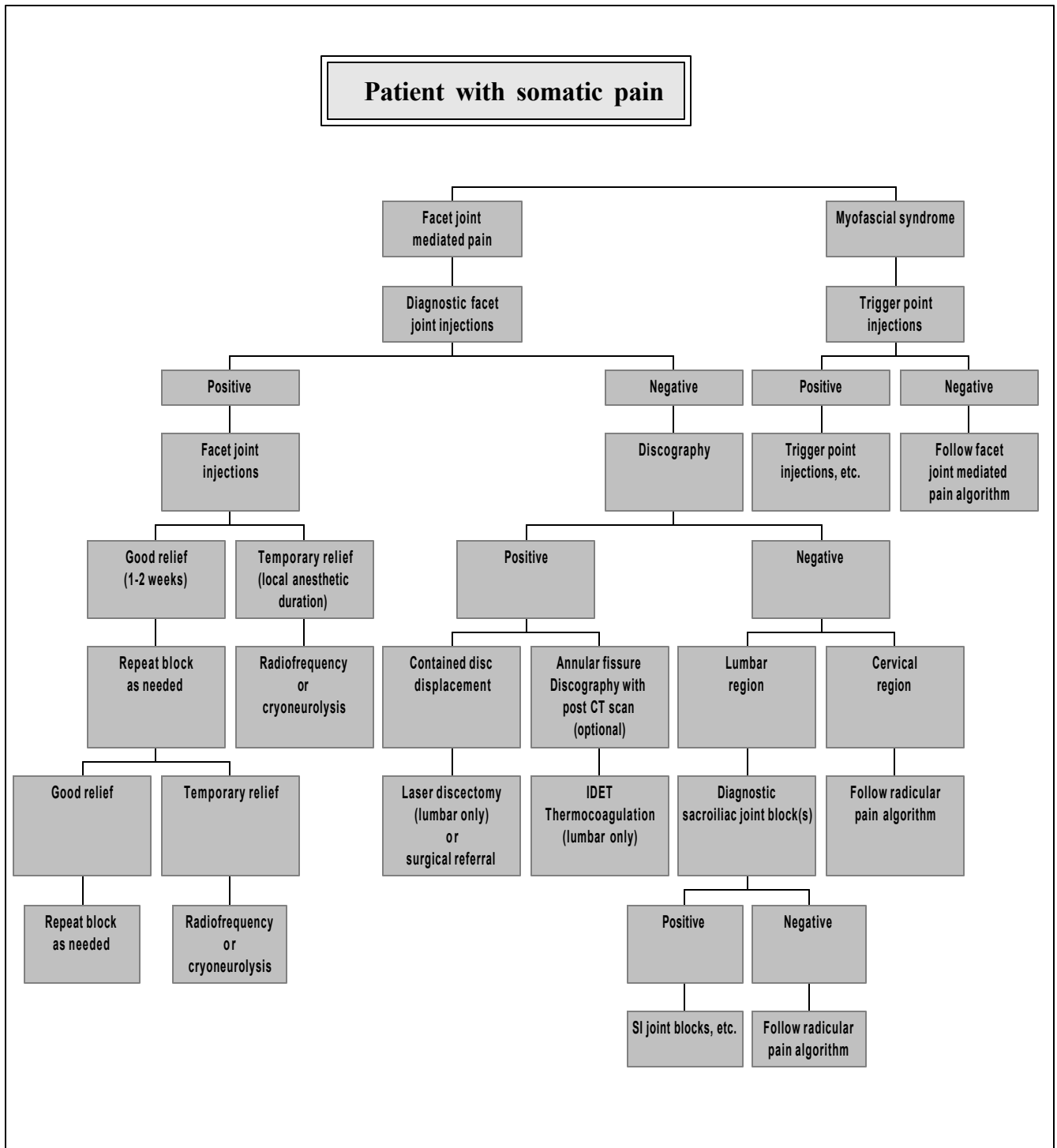


**Fig. 3A.** A suggested algorithm for application of interventional techniques in conservative care of chronic spinal pain: A patient with radicular pain

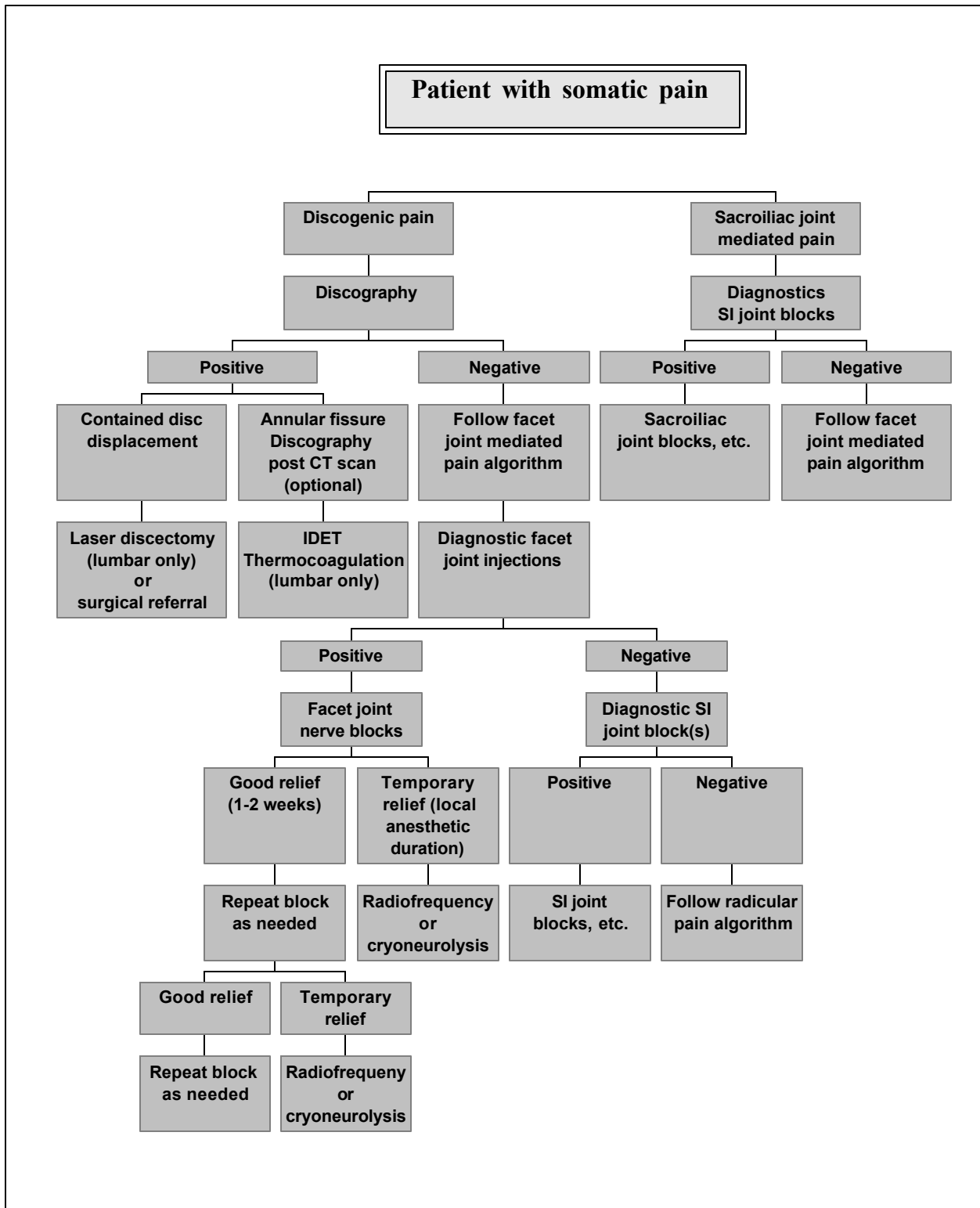




**Fig. 3B.** A suggested algorithm for application of interventional techniques in conservative care of chronic spinal pain: A patient with radicular pain



**Fig. 4A.** A suggested algorithm for application of interventional techniques in conservative care of chronic spinal pain: A patient with somatic pain



**Fig. 4B.** A suggested algorithm for application of interventional techniques in conservative care of chronic spinal pain: A patient with somatic pain

nerve root block was the first term developed to describe the technique for diagnosing the source of radicular pain when imaging studies suggested a possible compression of several roots. Early studies of selective nerve root injections described an extra-foraminal approach, in which the needle is advanced at a right angle to the spinal nerve outside the neural foramina. Subsequently, a variation of this procedure has emerged which has been termed selective epidural and is also referred to as transforaminal epidural.

### ***Sacroiliac Joint Injections***

Sacroiliac joint has regained interest as a primary source of low back pain in recent years, but confirming the diagnosis of sacroiliac joint dysfunction and pain remains difficult. Even though intra-articular sacroiliac joint injections have provided information on pain referral patterns (166, 167, 359), detecting symptomatic joints in patients presenting with low back pain continues to be a difficult venture (358, 360-371). Thus, provocative injections remain the only direct method to distinguish symptomatic from asymptomatic joints. Schwarzer et al (191), utilizing single local anesthetic block reported a prevalence of 30% in chronic low back pain population. Maigne et al (192), utilizing a double block paradigm with comparative local anesthetics reported prevalence in chronic low back pain population of 19% with a false-positive rate of 29%.

### ***An Algorithmic Approach***

Two suggested algorithms for the application of interventional techniques in conservative care of chronic spinal pain describing steps for diagnosis and management are shown in Fig. 3 and 4. These are only suggested algorithms and are limited to the management of chronic spinal pain. Further, clinical evaluation in spite of drawbacks is extremely important, as is the documentation of indications for interventional techniques.

The clinical algorithms presented on the following pages show an effort to blend conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients. When this is combined with the clinician's experience and judgment, and patient preferences, it should result in improved outcomes and significantly improved quality of care. These guidelines are intended to establish a boundary of reasonable care giving latitude to the individual physician.

## **THERAPEUTIC INTERVENTIONAL**

## **TECHNIQUES**

### ***Rationale***

The rationale for therapeutic interventional techniques in the spine is based upon several considerations: the cardinal source of chronic spinal pain, namely discs and joints, are accessible to neural blockade; removal or correction of structural abnormalities of the spine may fail to cure and may even worsen painful conditions; degenerative processes of the spine and the origin of spinal pain are complex; and the effectiveness of a large variety of therapeutic interventions in managing chronic spinal pain has not been demonstrated conclusively (27-32, 66-69, 261-291, 421-456). Tulder et al (421) evaluated conservative treatment of chronic low back pain and studied the evidence for effectiveness of numerous conservative modalities used in managing chronic low back pain, including drug therapy, manipulation, back schools, electromyographic biofeedback therapy, exercise therapy, traction and orthoses, behavioral/cognitive/relaxation therapy, and transcutaneous electrical nerve stimulation. Overall results were highly variable for various conservative modalities of treatment in managing chronic low back pain. They have not studied either the differences between various types of epidural steroid injections, or lysis of adhesions. In addition, they also omitted facet joint injections, facet joint nerve blocks, and medial branch neurotomy. Similarly, surgical treatment of lumbar disc prolapse and degenerative lumbar disc disease was also without conclusive evidence (290). There are a multitude of interventional techniques in the management of chronic pain which include not only neural blockade but also minimally invasive surgical procedures ranging from peripheral nerve blocks, trigger-point injections, epidural injections, facet joint injections, sympathetic blocks, neuroablation techniques, intradiscal thermal therapy, disc decompression, morphine pump implantation, and spinal cord stimulation.

In developing these guidelines, we have evaluated the effectiveness of the most common interventional therapeutic interventions for chronic pain in general, and specifically chronic spinal pain. Koes et al (66) concluded that the methodological quality of clinical trials of the efficacy of the commonly used interventions in low back pain was disappointingly low. For these guidelines, a modest approach including a blend of scientific evidence together with expertise and consensus was utilized. All the trials were scored according to the criteria described (45).

Whenever applicable, we used the original scores of pre-

viously published systematic reviews (45, 66, 67, 421). A study was considered positive if the therapeutic intervention was more effective than the reference treatment with regard to at least one of the outcome measures, which included pain intensity, overall improvement, functional status, and return to work. The level of evidence was also a blend of evidence from AHCPR guidelines (28), as well as evidence based guidelines from McQuay and Moore (7). The blended rating system consisted of five levels of evidence based on the strength as shown in Table 1.

### **Facet Joint Mediated Pain**

A preponderance of evidence supports the existence of lumbar facet joint pain (31, 32, 41, 56, 152, 154-157, 177-183, 374, 376-380, 457-472); however, there are also a few detractors (348, 351, 473, 474). The diagnosis of the so called lumbar facet syndrome depends on a clinical presentation with mechanical low back pain described by the patient as mainly in the low back with radiation to the buttocks and upper posterior thigh. Some investigators have attempted to identify facet syndrome and predictors of outcome of facet joint injections, which has been rather futile. The results of most studies failed to show a correlation between radiologic imaging findings, clinical examination, and the controlled diagnostic blocks (183). However, the features of somatic pain may be utilized as a guide presumably to differentiate somatic pain and radicular pain, at least initially (Table 4). Similarly, there is also a preponderance of evidence supporting the existence of cervical facet joint pain (31, 32, 42, 158-164, 184, 185, 475-480). Interestingly, the controversy appears to be less in the cervical spine than in the lumbar spine.

Facet joint mediated pain may be managed by either intra-articular injections, medical branch blocks, or neurolysis of medial branches.

**Intra-articular Injections:** Therapeutic benefit has been reported with the injection of corticosteroids (458, 460, 462, 463, 470), local anesthetics (457, 474), or normal saline (347, 457, 468) into the facet joints. The literature describing the effectiveness of these interventions is abundant, however, only six randomized clinical trials offer data on the use of intra-articular injections in the spine (379, 380, 457, 468, 469, 475). Open, uncontrolled clinical studies, which evaluated the long term relief of back and leg pain from intra-articular facet joint injections reported variable relief in 18% to 92% of subjects (458-460, 464-467, 470, 471, 476-480). Five studies of intra-articular corticosteroid lumbar facet joint injections, and one study in

cervical spine were performed comparing the results to those of a similar group not receiving intra-articular steroids (Table 6).

In a prospective, controlled study Carette et al (457) studied 101 patients who received more than 50% relief with a single intra-articular lidocaine block. Those patients who responded were randomized into two treatment groups: intra-articular saline or intra-articular methylprednisolone. At 1-month follow-up after the injection, 42% of the methylprednisolone group (20 patients) had significant pain reduction, whereas 33% of the saline group (16 patients) achieved significant pain relief. At 6-month follow-up, however, 46% of the patients in the methylprednisolone group and 15% of patients in the saline group continued to experience marked pain relief, with a statistically significant difference.

Lilius et al (468) studied 109 patients with chronic, unilateral, nonradicular low back pain who had failed to respond to conservative treatment, including medication and physical therapy for a period of 3 to 36 months. A total of 27 of the 109 patients were postsurgical and had continued pain despite previous discectomy. They were randomly divided into three treatment groups: 1) intra-articular lumbar facet joint injection with cortisone and local anesthetic; 2) intra-articular injection with saline alone; or 3) pericapsular injection of cortisone and local anesthetic. Significant pain relief was reported by patients in all groups for up to three months. A total of 64% of the patients showed relief one hour after injection, and 36% of these patients reported relief from pain over a 3-month period, independent of the treatment given.

Lynch and Taylor (469) in a controlled, prospective (but not randomized or blinded) study, reported effectiveness of intra-articular placement of the corticosteroid without anesthetic in 50 patients. Extra-articular injection was used for patients in the control group. Total pain relief was reported in 9 of 27 patients who received intra-articular corticosteroids compared with none of the 15 patients who received extra-articular corticosteroids. Only two patients in the intra-articular group did not obtain at least partial benefit, whereas 7 of the 15 control patients had no relief at all.

Marks et al (380) compared the effects of intra-articular anesthetic and corticosteroid with medial branch blocks in a study of 86 patients with chronic low back pain. Patients were randomized and assigned to either facet joint injections or medial branch blocks using methylprednisolone

acetate, 20 mg, and lidocaine, 1.5 mL, 1% at each level. They concluded that “Facet joint injections and facet nerve blocks may be of equal value as diagnostic tests, but neither is a satisfactory treatment for chronic low back pain.”

Nash (379) compared facet joint injections with medial branch blocks in a randomized study of 67 patients in two treatment groups and a 1-month follow up period. No appreciable difference was evident in evaluations between the groups at follow-up.

Barnsley et al (475) studied 41 patients with neck pain caused by whiplash injury in a randomized, double-blinded investigation with a therapeutic trial of cervical intra-articular local anesthetic, or local anesthetic with steroid. Results from this study indicate that the time to return to 50% of baseline pain was three 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 one week, and fewer than one in five patients reported relief for more than one month, regardless of whether injection was with steroids or local anesthetic. They (475) concluded that intra-articular injection of steroid was not an effective treatment for cervical facet joint pain associated with whiplash injuries. They cautioned that these results should not be extrapolated to the treatment of patients with cervical facet joint pain from other causes, because response to intra-articular steroid injections is not known in cervical facet joint pain of spontaneous origin.

However, all of the controlled studies summarized faced substantial criticism. Lilius et al (468) used overly broad inclusion criteria of patients with neurologic deficits, and the patient’s diagnosis of lumbar facet joint mediated pain was not confirmed by the diagnostic blocks; furthermore, excessive volumes, ranging from 3 mL to 8 mL of active agents, were injected, and placebo responders were not excluded. Although the study by Carette et al (457) was praised for its design, these authors failed to exclude placebo responders, which may account for the relatively high incidence of patients in their study with presumed facet joint pain. Failure to exclude the placebo responders invariably dilutes the findings of true responses, making detection of difference between the study and control groups more difficult. Additional criticism against Carette’s study (457) was that intra-articular lumbar facet joint corticosteroids were evaluated in isolation and not as part of a comprehensive, conservative treatment plan provided equally to both groups (472). Lack of randomization, poor outcome assessment tools, failure to select patients with isolated facet joint pain as determined by diagnostic blocks,

and lack of third party review were among the weaknesses of the study by Lynch and Taylor (469). Marks et al study (380) is limited by failure to select patients with facet joint pain established by controlled diagnostic blocks; failure to have a blinded, independent observer; poor limited outcome assessment tools; and absence of a control or placebo group. Nash’s study (379) is limited by lack of established diagnosis or confirmation of facet joint mediated pain; lack of a blinded observer; poor assessment tools; and lack of a controlled or placebo group. Barnsley et al (475) included a small number of patients (20 in each group), whose origin of neck pain was post traumatic, following whiplash.

Due to negative results of intra-articular injections, additional studies of observational nature with good-quality data were considered (Table 6). Of the multiple studies available on managing facet joint mediated pain, only six met the criteria for inclusion as observational studies with at least minimum of 50 patients and a reasonable follow up. Of these, four were prospective, including Jackson et al (351), Desoutet et al (460), Murtagh (465), Mironer and Somerville (471). The observational studies, which were of a retrospective nature, included Lippitt (462) and Lau et al (463). Jackson et al (351) prospectively evaluated 454 patients from 2,500 patients, with 390 patients completing the study. Even though this was a prospective study, there was no long term follow-up. Immediate relief was seen in only 29% of the patients. Desoutet et al (460) studied 54 patients, with immediate relief noted in 54% of the patients whom they considered as facet syndrome. Of the 54% of the patients diagnosed with facet syndrome by local anesthetic blocks, they reported 62% of the patients experiencing relief for 1 to 3 months, whereas 38% of the patients experienced relief for 6 to 12 months. Murtagh (465) studied 100 patients with a follow-up of up to 4 years reporting immediate relief in 94% of the patients and long term relief up to 6 months in 54% of the patients. Mironer and Somerville (471) evaluated 148 patients, injecting the facet joints with bupivacaine and steroid reporting 28% of patients obtained greater than 60% relief with a duration longer than two months. They also reported that these patients were observed and that eight patients required re-injection on an average of 4.8 months later with similar good results; thus, 28% of the patients, with or without repeat injections, reported relief up to 15 months at follow-up. Among the retrospective studies, Lau et al (463) reported the results in 50 patients with a follow-up period of 4 months to 18 months with initial relief in 56% of the patients, 44% at 3 months, and 35% at 6 to 12 months. Lippitt (462) reported results in 99 patients with a 12-month

**Table 6.** Results of published reports of effectiveness of spinal facet joint intra-articular injections

Study	Study Characteristics	No. of Patients	Drugs Utilized	Initial Relief 1-4 weeks Controls vs Treatment	Long-term Relief Control vs Treatment		Results
					3 Months	6 Months	
<b>Controlled Studies</b>							
Carette et al (457)	P, PC, RA	101	NS, LA, S	33% vs 42%	N/A	15% vs 46%	N
Barnsley et al (475)	P, RA	41	LA, S	50%	N/A	N/A	N
Lynch and Taylor (469)	P, C	50	LA, S	50% vs 92%	62%	56%	P
Lilius (468)	P, PC, RA	109	NS, LA, S	N/A	64%	N/A	N
Nash (379)	P, RA	66	LA, S	58%	N/A	N/A	N
Marks et al (380)	P, RA	86	LA, S	45%	18%	N/A	N
<b>Observational Studies</b>							
Jackson et al (351)	P	390	LA, S	29%	N/A	N/A	N
Murtagh (465)	P	100	LA, S	94%	54%	54%	P
Lippit (462)	R	99	LA, S	51%	51%	14%	P
Lau et al (463)	R	50	LA, S	56%	44%	35%	P
Desoutet et al (460)	P	54	LA, S	62%	38%	38%	P
Mironer and Somerville (471)	P	148	LA, S	28%	28%	28%	N

P= prospective; RA= randomized; C= controlled; PC= placebo controlled; R= retrospective; LA= local anesthetic; NS= normal saline; S= steroids; N/A= not available; VS= versus; P= positive; N= negative

follow-up period with greater than 50% relief in 51% of the patients, which declined to 14% at 6 months and 8% at 12 months.

Of the six controlled studies, one was considered as of high quality (457), one as of moderate quality (475), and the remaining four as of low quality (379, 380, 468, 469). The results were positive in only one study (469). Observational evidence was positive with four of the six studies showing positive results. Based on the available evidence, both from randomized, controlled trials and observational studies, type and strength of efficacy evidence for intra-articular injections of facet joints is level III to IV - moderate to limited. Level III - moderate evidence is defined as evidence obtained from well-designed trials without randomization, single group pre-post, cohort, time series, or matched case controlled studies. Level IV - limited evidence is defined as evidence obtained from well-designed non-experimental studies from more than one center or research group.

**Medial Branch Blocks:** The role of medial branch blocks

in the diagnosis of facet joint pain has been well described and superior to intra-articular comparative local anesthetic blocks (31, 32, 56, 161, 162, 178-185, 372-380) even though controversy continues to exist (471). The therapeutic role of medial branch blocks with various adjuvants was evaluated only in one prospective randomized clinical trial (481). However, an additional three studies, which are controlled and randomized evaluated the role of initial blockade with its therapeutic effect (182, 379, 380). In addition, two uncontrolled studies evaluated the medial branch blocks with respect to long term relief (375, 377) (Table 7).

Manchikanti et al (481) studied patients who had a diagnosis of facet joint mediated pain confirmed by controlled diagnostic blocks. These patients were randomly allocated into two groups, either receiving therapeutic medial branch blocks with a local anesthetic and Sarapin® or receiving therapeutic medial branch blocks with a mixture of local anesthetic, Sarapin, and methylprednisolone. A total of 73 patients were enrolled in the study with ability to per-

form at least two injections. The injections consisted of medial branch blocks with a mixture of local anesthetic 0.5 to 1 mL mixed with equal volumes of Sarapin in group I, with addition of 1 mg of methylprednisolone per mL to the mixture in group II. This study showed significant improvement with therapeutic medial branch blocks in both groups in all aspects including functional status, drug intake, return to work, and improvement in the psychological status. This study showed that cumulative significant relief with 1 to 3 injections was 100% up to 1 to 3 months, 82% for 4 to 6 months, 21% for 7 to 12 months, and 10% after 12 months with a mean relief of  $6.5 \pm 0.76$  months. There was significant difference noted in overall health status with improvement not only in pain relief, but also with physical, functional, and psychological status, as well as return to work status.

Manchikanti et al (182) evaluated the diagnostic validity and therapeutic value of lumbar facet joint nerve blocks with adjuvant agents. The study population consisted of 180 consecutive patients who were divided into three groups, with 60 patients in each group. The facet joints in all patients were investigated with diagnostic blocks using lidocaine 1%, initially followed by bupivacaine 0.25% on separate occasions, usually 2 to 4 weeks apart, with or without the addition of Sarapin and/or methylprednisolone. All the patients who underwent double blocks with a definite response were considered as positive for facet joint mediated pain, yielding a prevalence of facet joint pain in chronic low back pain of 36% on average; however, the duration of pain relief associated with each injection by members of the three groups was significantly different. It was shown that patients who were finally judged to be positive for facet joint mediated pain showed mean cumulative relief with both the blocks of  $20.6 \pm 3.97$  days, with a range of 3

to 98 days, in patients receiving local anesthetic; whereas it was  $29.6 \pm 4.86$  days, with a range of 12 to 98 days, in patients receiving local anesthetic with Sarapin; compared to  $49.8 \pm 9.04$  days, with a range of 5 to 160 days, in patients receiving local anesthetic, Sarapin, and methylprednisolone. Thus, this study showed that addition of adjuvant agents, either Sarapin with or without methylprednisolone, increased the duration of the relief and retained the diagnostic validity.

Marks et al (380) studied 86 patients with refractory chronic low back pain who were randomly assigned to receive either facet joint injections or facet nerve block, using local anesthetic and steroid. Using methylprednisolone acetate, 20 mg, along with lidocaine, 1.5 mL, 1%, their results indicate good to excellent relief in 38% of patients following facet joint injection. A total of 25% of the patients achieved good to excellent relief after medial branch block immediately after infiltration. Good to excellent response was seen in 43% of patients receiving facet joint injection and 46% of patients with medial branch blocks in the first 2 weeks. At 1-month follow-up, 35% of the patients with facet joint injection and 21% of the patients with medial branch blocks reported good relief. At 3-month follow-up, 22% of patients with facet joint injections showed good to excellent relief; and only 14% achieved the same level of relief following medial branch blocks.

In a prospective, randomized, single-blinded sequential analysis of 66 patients, Nash (379) reported comparable effectiveness of the medial branch of the posterior primary rami nerve blockade with reference to intra-articular injection of local anesthetic and steroid. He used 2% lidocaine, 1 mL, and 0.5% bupivacaine, 1 mL, for each medial branch, treating the nerve above and at the same

**Table 7. Results of published reports of effectiveness of medial branch blocks**

Study	Study Characteristics	No. of Patients	No. of Injections	Initial Relief	Long-term Relief			Results
					3 Months	6 Months	12 Months	
Manchikanti et al (481)	P, RA	73	1-3	100%	100%	82%	21%	<i>P</i>
Manchikanti et al (481)	P, RA	73	1-10	100%	100%	100%	95%	<i>P</i>
Manchikanti et al (182)	P, RA, D	180	2	100%	NA	NA	NA	<i>P</i>
Nash (379)	P, RA, D	66	1	58%	NA	NA	NA	<i>N</i>
Marks et al (380)	P, RA, D	86	1	46%	14%	NA	NA	<i>N</i>

P= prospective; RA= randomized; D= diagnostic blocks only; NA= not available; P= positive; N= negative



level. For intra-articular injection he used 2% lidocaine, 1 mL, and 0.5% bupivacaine, 1 mL, along with a 20-mg methylprednisolone acetate suspension. The two treatments were equally effective but were disappointing in their therapeutic effect. A total of 58% of patients in each group demonstrated significant pain relief at 1-month follow-up. Based on this report, as a therapeutic measure, posterior ramus medial branch nerve blockade was proven to be as effective as intra-articular injection of steroid in low back pain of probable facet origin, suggesting that facet joint pain does not have an inflammatory component.

In another study, North et al (377) used diagnostic facet blocks and incorporated assessment by a disinterested third party. Following the diagnostic medial branch blocks, 42% of the patients reported at least 50% relief of pain. Among 40 patients who underwent temporary blocks but did not undergo radiofrequency denervation, 13% reported relief of at least 50% at long term follow-up with mean interval of 3.2 years.

Barnsley and Bogduk (375) studied 16 consecutive patients with chronic neck pain from motor vehicle accidents and reported complete or definite relief of their pain in 11 patients.

All of the trials described above face criticism. The randomized clinical trial by Manchikanti et al (481) is limited by failure to incorporate a placebo group and to utilize a major instrument to evaluate the progress. Other studies by Manchikanti et al (182), Marks et al (380), and Nash (379) were also limited by failure to incorporate a placebo group, lack of long term follow-up, and lack of reporting of outcomes.

Of the four controlled reports evaluating medial branch blocks, one study evaluating the therapeutic role was of moderate quality (481). The remaining three studies were of low quality for therapeutic purposes (182, 379, 380).

In analyzing the type and strength of evidence due to the availability of only a total of four controlled studies for consideration, the evidence from two observational studies was also utilized. The analysis of type and strength of efficacy evidence shows that medial branch blocks provide level III (moderate) evidence. Level III - moderate evidence is defined as evidence obtained from well-designed trials without randomization, single group pre- post, cohort, time series, or matched case controlled studies.

### ***Medial Branch Neurotomy***

Multiple investigators have studied the effectiveness of radiofrequency denervation of medial branches in the spine. Percutaneous radiofrequency neurotomy is a procedure that offers temporary relief of pain by denaturing the nerves that innervate the painful joint (482), but the pain returns when the axons regenerate. Fortunately, relief can be reinstated by repeating the procedure. Radiofrequency neurolysis as a treatment of chronic intractable pain began in the early 1930s. Shealy (483, 484) pioneered spinal facet rhizotomy in the 1970s, and Sluijter and Koetsveld-Baart (319) initiated minimally invasive radiofrequency lesioning for pain of spinal origin.

Numerous reports describe the technique and effectiveness of radiofrequency thermoneurolysis (319, 377, 482-511). Neurolytic blocks (512) and cryogenic neurolysis (513) also have been described. Success with radiofrequency neurotomy has been reported in the range of 17% to 90% for management of lumbar facet joint pain. There were four prospective randomized studies by Lord et al (487), Van Kleef et al (488) Dreyfuss et al (510), and Gallagher et al (510).

Lord et al (482) conducted a prospective, double blinded, placebo-controlled study of percutaneous radiofrequency neurotomy for management of chronic cervical facet joint pain. Lord et al (482) compared percutaneous radiofrequency neurotomy, in which multiple lesions were made and the temperature of the electrode was raised to 80°C, with a control treatment using a procedure that was identical except for the facet that the radiofrequency current was not turned on. This study included 24 patients (9 men and 15 women) with a mean age of 43 years who presented with pain in one or more cervical facet joints after motor vehicle injury. The mean duration of pain was 34 months. Facet joint pain was diagnosed with the use of double-blinded, placebo-controlled local anesthetic blocks. 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. At 27 weeks, seven patients in the active treatment group and one patient in the control group were free of pain. The authors concluded that, in patients with chronic cervical facet joint pain confirmed by double-blinded, placebo-controlled local anesthesia, percutaneous radiofrequency neurotomy with multiple lesions of target nerves could provide lasting relief.

Van Kleef et al (487), in a randomized trial of radiofre-

quency lumbar facet denervation for chronic low back pain, studied 31 patients with a history of at least one year of chronic low back pain and facet pathology on the basis of a positive response to a diagnostic nerve blockade. Patients were subsequently randomly assigned to one of the two treatment groups. Each patient in the radiofrequency treatment group (15 patients) received an 80° radiofrequency lesion of the dorsal ramus of the segmental nerve roots, L3, L4, and L5. In contrast, patients in the control group (16 patients) underwent the same procedure but without the use of radiofrequency current. Both the treating physician and the patients were blinded to the group assignment. A blinded investigator evaluated physical impairment, pain rating, degree of disability, and quality of life. The results showed that, 8 weeks after treatment, there were 10 successful treatments in the radiofrequency group and 6 in the control group. 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. This study results demonstrated that radiofrequency denervation of the lumbar facet joints can be effective for pain reduction in patients with lumbar facet joint pain.

Dreyfuss et al (488) examined the role of lumbar radiofrequency neurotomy for chronic zygapophysial facet joint pain in a pilot study using medial branch blocks. Their inclusion criterion was greater than 80% pain relief following two separate sets of medial branch blocks. The first set was performed with 0.5 mL of 2% lidocaine, and the second set with 0.5 mL of 0.5% bupivacaine. Treatment was successful, and statistically significant improvement was shown in the VAS scores, the Roland-Morris disability scale, physical function and bodily pain subscales of the SF-36 questionnaire, and the McGill pain questionnaire. Overall treatment success, defined as 50% or more pain relief at 1-year postneurotomy, was achieved in 87% of patients. The investigators noted that, even in patients who suffered with pain for more than five years, radiofrequency neurotomy of the medial branch nerves proved helpful, cost effective, and less time consuming than other interventions, such as exercised-based physical therapy or manipulative care.

Gallagher et al (510) studied 60 patients in a prospective manner by identifying those who had low back pain for more than 3 months for radiofrequency neurotomy. They used screening blocks as inclusion criteria for denervation with 0.5 cc of 0.5% bupivacaine “into and around appropriate joints” under fluoroscopy. Of the 60 initial patients, 30 patients had a good response, and 11 had an equivocal response. The 30 patients with good response were ran-

domly divided into four groups and received either medial branch radiofrequency neurotomy at 80° C for 90 seconds with active denervation, or a placebo. Statistically significant improvement was shown in the active denervation group compared with the placebo group. At 6-month follow up, however, only 24% of the patients with active denervation and 3% of the patients with placebo showed significant improvement.

All of the controlled studies faced criticism. All of them had a very small number of patients. In addition, Van Kleef et al (487) utilized a single block for a diagnosis of facet joint mediated pain. Further, Van Kleef et al (487) and Dreyfuss et al (488) included a number of patients with VAS scores at low levels. Many of the patients in both of the studies of Van Kleef et al (487) and Dreyfuss et al (488) were also young and working. Dreyfuss et al (488) recruited the patients by advertising and failed to incorporate a control or placebo group.

Among the observational reports, King and Lagger (511) looked at 60 patients with chronic low back pain undergoing radiofrequency neurotomy of the medial branches, which provided greater than 50% pain relief in only 27% of the patients. North et al (377) reviewed their experience with percutaneous radiofrequency denervation at a mean follow-up interval of 3.2 years, reporting at least 50% relief of pain at long term follow up. In another study, Sluijter (491) studied the use of radiofrequency lesioning for pain relief in failed low back surgery syndrome. They defined the success as better than 50% relief and reported that percutaneous facet denervation had a success rate of 40% in these patients as opposed to 80% in those who did not undergo back surgery. Ogsbury et al (509) reported results of radiofrequency rhizotomies in 71 patients; 35% of the patients showed a successful long term result. Sluijter and Koetsveld-Baart (319) studied the effectiveness of percutaneous facet denervation in 64 patients with cervical pain syndromes and reported good results in 41% of the patients. Schaerer (502, 505) reported good pain relief in 50% of the patients. Rashbaum (489) studied 100 patients with radiofrequency neurotomy, reporting relief in 82% of the patients at 3 to 6 months, and 68% at 3 years.

The studies by Lord et al (482) and Van Kleef et al (487) were double-blinded and placebo controlled. They were also considered as high quality. The remaining two studies by Dreyfuss et al (488) and Gallagher et al (510) were considered as low quality.

As shown in Table 8, three of the four controlled trials,

**Table 8.** Results of published reports on effectiveness of facet joint (medial branch) radiofrequency neurolysis

Study	Study Characteristics	No. of Patients	Initial Relief 1-4 Weeks	Long-term Relief			Results
				3 Months	6 Months	12 Months	
Lord et al (482)	P, PC, RA, DB	24	75%	58%	58%	50%	<i>P</i>
Van Kleef (503)	P, PC, RA, DB	31	67%	60%	47%	47%	<i>P</i>
Dreyfuss et al (504)	P, C	15	93%	100%	87%	87%	<i>P</i>
Gallagher et al (510)	P, PC, RA	60	42%	NA	24%	NA	<i>N</i>

C= controlled; P= prospective; RA= randomized; PC= placebo controlled; DB= double blind; NA= not available; *P*= positive; *N*=negative

and both randomized, placebo-controlled, double-blind studies showed the significant pain relief, along with improvement in other parameters, indicating strong evidence from multiple controlled trials. In addition, evidence from uncontrolled studies also supports the contention that radiofrequency is effective, even though (contrary to the popular belief), controlled trials showed better improvement than uncontrolled studies. Thus, the type and strength of efficacy evidence for radiofrequency neurotomy in managing facet joint mediated pain is level II – strong, defined as evidence from at least one properly designed randomized controlled trial of appropriate size and high quality or multiple adequate studies. In addition, in a randomized, double-blind placebo-controlled trial, Wallis et al (514) also showed resolution of psychological distress of whiplash patients following treatment by radiofrequency neurotomy.

**Epidural Injections**

Approaches available to access the epidural space are interlaminar (cervical, thoracic, and lumbar), transforaminal (cervical, thoracic, lumbar, and sacral), and caudal. Epidural steroid injections are the most commonly used interventional techniques in pain management clinics. In fact, the first reports of neural blockade in managing low back and lower extremity pain secondary to lumbar nerve root compression were of epidural injections caudally (307-309). The first administration of epidural steroids was by transforaminal epidural injections, reported by Robechi and Capra in 1952 (315), and Lievre et al in 1957 (316). Access to the lumbar epidural space through a paramedian approach was proposed by Pages in 1921 (311). Lievre et al (316) reported their experience with injection of a hydrocortisone and contrast into the epidural space of 46 patients with sciatica in 1953. They thought that 23 had

good or very good results and 8 had mediocre results; and the rest were considered failures. The effects of caudal and interlaminar epidural steroid injections were first reported independently by Goebert and colleagues (317) and Brown (515) in 1960. Goebert and colleagues (317) administered three injections of procaine and hydrocortisone into the epidural space to 239 patients with sciatica, and reported greater than 60% relief of symptoms in 58% of the patients. Since that time, the technique and indications of epidural steroid injections have been changing constantly. Numerous reviews have appeared in the literature evaluating the effectiveness of epidural steroid injections.

The first systematic review of effectiveness of epidural steroid injections was by Kepes and Duncalf in 1985 (51). They concluded that the rationale for epidural systemic steroids was not proven. However, in 1986 Benzon (52), utilizing the same studies, concluded that mechanical causes of low back pain, especially those accompanied by signs of nerve root irritation, may respond to epidural steroid injections. The difference in the conclusion of Kepes and Duncalf (51) and Benzon (52) may be due to the fact that Kepes and Duncalf (51) included studies on systemic steroids whereas Benzon (52) limited his analysis to studies on epidural steroid injections only. The debate concerning the epidural steroid injections is also illustrated by the recommendations of the Australian National Health and Medical Research Council Advisory Committee on epidural steroid injections (47). In this report, Bogduk et al (47) extensively studied caudal, interlaminar, and transforaminal epidural injections, including all the literature available at the time, and concluded that the balance of the published evidence supports the therapeutic use of caudal epidurals but does not vindicate it. They also concluded that the results of lumbar interlaminar epidural steroids strongly refute the utility of epidural steroids in acute sciatica.

Bogduk (57) updated recommendations in 1999, recommending against epidural steroids by the lumbar route as requiring too high a number necessary for treatment, but supporting the potential usefulness of transforaminal steroids for disc prolapse. In 1995, Koes et al (45) reviewed 12 trials of lumbar and caudal epidural steroid injections and reported positive results from only six studies. However, review of their analysis showed that there were five studies for caudal epidural steroid injections and seven studies for lumbar epidural steroid injections. Four of the five studies involving caudal epidural steroid injections were positive, whereas five of seven studies were negative for lumbar epidural steroid injections. Koes et al (46) updated their review of epidural steroid injections for low back pain and sciatica, including three more studies with a total of 15 trials which met the inclusion criteria. In this study, they concluded that of the 15 trials, eight reported positive results of epidural steroid injections. Benzon (516) and Benzon and Molly (60) considered the role of epidural steroid injections controversial but recommended the continued use of epidural steroid injections as part of the overall management of patients with acute radicular pain, herniated disc, or new radiculopathy superimposed on chronic back pain. Watts and Silagy (48) in 1995 performed a meta-analysis of the available data and defined efficacy in terms of pain relief (at least 75% improvement) in the short term (60 days) and in the long term (1 year). They concluded that epidural steroid injections increased the odds ratio of pain relief to 2.61 in the short term and to 1.87 in the long term (odds ratio greater than one suggests efficacy; equal to or greater than two suggests significant efficacy). Tulder et al (421), in analyzing numerous treatments based on scientific evidence in conservative treatment of chronic low back pain, also included seven studies of epidural steroid injections. They concluded that there was conflicting evidence with inconsistent findings with regards to the effectiveness of epidural steroid injections. McQuay and Moore (517) in 1998 reviewed the literature and concluded that epidural corticosteroid injections are effective for back pain and sciatica. They also concluded that, even though epidural steroid injections can optimize conservative therapy and provide substantial pain relief for up to 12 weeks in patients with acute or subacute sciatica, few patients with chronic pain report complete relief; the majority must return for repeated epidural injections. The perceived advantages of each of the three approaches include (33, 41, 42, 47, 58, 518-543):

1. The interlaminar entry is directed more closely to the assumed site of pathology, facilitating delivery of the injectate directly to its target and re-

- quiring less volume;
2. The caudal entry is relatively easily achieved, with minimal risk of inadvertent dural puncture; and
3. The transforaminal approach is target specific in fulfilling the aim of reaching the primary site of pathology.

The disadvantages of each of the three approaches are illustrated in Table 9.

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

**Table 9.** *Disadvantages of caudal, lumbar, interlaminar and transforaminal epidural injections*

<b>Caudal</b>	Requirement of substantial volume of fluid Dilution of the injectate Extraepidural placement of the needle Intravascular placement of the needle Atypical anatomy Dural puncture
<b>Interlaminar</b>	Dilution of the injectate Extraepidural placement of the needle Intravascular placement of the needle Preferential cranial flow of the solution Preferential posterior flow of the solution Difficult placement in postsurgical patients Difficult placement below L4/5 interspace Deviation of needle to nondependent side Dural puncture Spinal cord trauma
<b>Transforaminal</b>	Intraneural injection Neural trauma Technical difficulty in presence of fusion and/or hardware Intravascular injection Spinal cord trauma

Modified and adapted from Manchikanti (58)

discussed as such below.

**Caudal Epidural Injections:** Extensive literature available on caudal epidural injections includes six controlled studies (544-549) and numerous uncontrolled reports (543, 550-559).

Breivik et al (544) in a prospective, randomized, crossover study, evaluated 35 patients with chronic low back pain, allocated to treatment with up to three caudal epidural injections of bupivacaine and methylprednisolone or bupivacaine and normal saline at weekly intervals. The study followed a parallel, cohort design and allowed patients who failed to obtain relief with one of the treatments to receive the reciprocal treatment. During initial therapy 56% of patients receiving methylprednisolone experienced significant relief, compared to 26% with bupivacaine with saline. In the crossover, only one of seven patients who had methylprednisolone therapy got relief from the subsequent bupivacaine and saline injection (14%), in contrast to 73% of patients who failed to respond to bupivacaine and saline injection reported satisfactory relief after receiving the methylprednisolone injection. While 50% of the patients treated with steroids returned to work, 20% of the patients treated with bupivacaine returned to work.

Bush and Hillier (545) in a double-blind, randomized evaluation studied 23 patients with lumbar radicular pain allocated either to receive two caudal epidural injections of either a 25 mL mixture of normal saline, procaine and 80 mg triamcinolone, or 25 mL of normal saline alone. Patients were assessed for pain levels, improvement in straight-leg raise, and lifestyle. The follow-up, at four weeks demonstrated significantly greater pain relief and mobility with a significantly improved quality of life following triamcinolone injection. However, at one year follow-up while the treated patients showed greater improvement than placebo patients, the significant difference was limited to straight-leg raise tolerance.

In contrast to the above studies, Beliveau (547) found no difference in pain relief between 24 patients treated with caudal injections of 40 mL of 1% procaine and 80 mg (2 mL) of methylprednisolone, and an equal number of patients treated with 42 mL of procaine alone. The patients in this study had moderate or severe unilateral sciatica, thought to be caused by an intervertebral disc lesion with or without neurological signs. They assessed the effect of the injection a week later according to the symptoms and the findings of physical examination. Injections were re-

peated if improvement was seen after the first injection, with a total of 82 injections for 48 patients. One to three months later they saw complete relief in 42% of the patients in the steroid group, and in 29% in the normal saline group. This study demonstrated the efficacy of caudal epidural injections in sciatica with or without steroids. It failed, however, to demonstrate superiority of steroids over local anesthetic except in cases of long standing severe sciatica.

Yates (549) treated patients with low back pain and sciatica by epidural injection of normal saline or 0.5% lignocaine, with or without triamcinolone given at weekly intervals in random order. Subjective and objective criteria of progress were measured. Greatest improvement was noted after the injection containing steroid. Lignocaine 0.5%, and normal saline used individually produced less marked improvement. No specific benefits of local anesthesia were found other than comfort during injection. His report did not address pain relief but focused on improvement in straight leg raising, which seemed to correlate with pain relief.

Matthews et al (546) compared the responses of patients treated with caudal epidural injections of bupivacaine and methylprednisolone or a control injection of 2 mL of lignocaine over the sacral hiatus. At assessment after one month, there was no significant difference between the two groups. However, at three months, the treated group was reported to be significantly more pain free.

Czarski (547) evaluated the use of caudal epidural injections comparing novocaine and hydrocortisone and procaine hydrochloride alone in the treatment of patients with prolapsed lumbar intervertebral disc, with 60 patients in procaine hydrochloride group and 123 patients in procaine hydrochloride and hydrocortisone group. He demonstrated statistically significant and clinically significant differences in outcomes comparing the use of caudal epidural injections. Unfortunately, however, the duration of follow-up was not specified even though complete relief was reported in 22 of the 123 patients, with significant relief in 64 of 123 patients; whereas marginal relief was reported in 14 patients with no relief or patients getting worse on 23 occasions in hydrocortisone group. In comparison, in procaine hydrochloride group, 8 of 60 patients obtained significant relief, none of the patients obtaining complete relief, 35 obtaining marginal relief and 17 patients getting no relief or becoming worse.

Numerous uncontrolled reports on the use of caudal epi-

**Table 10.** Results of published reports on caudal epidural steroid injections

Study	Study Characteristics	No. of Patients	Drugs Utilized	No. of Injections	Initial Relief	Long-term Relief		Results
					Control vs. Treatment	Control vs. Treatment		
					3-4 Weeks (%)	3 Months (%)	6 Months (%)	
Breivik et al (544)	P, RA, DB	35	S, LA, NS	1-3	25 vs. 63	20 vs. 50	20 vs. 50	<i>P</i>
Bush and Hillier (545)	P, RA, PC, DB	23	NS, LA, S	2	100	N/A	64 vs. 83	<i>P</i>
Yates (549)	P, RA, PC, DB	20	S, NS, LA	1-4	N/A	N/A	N/A	<i>P</i>
Matthews et al (546)	P, RA, PC	34	S, LA	1-3	56 vs 67	SMPR	N/A	<i>P</i>
Czarski (548)	P, RA	183	S, LA	N/A	13 vs 72	N/A	N/A	<i>P</i>
Beliveau (547)	P, RA	48	LA, S	1-2	70 vs. 75	70 vs. 75	N/A	<i>N</i>

P = prospective; RA = randomized; PC = placebo controlled; DB = double blind; LA = local anesthetic; NS = normal saline; S = steroids; SMPR = significantly more pain relief; N/A = not available; *P* = positive; *N* = negative

dural injections have shown favorable response with respectable benefit (313, 317, 550-559). In 1930, Evans (313) reported a cure rate of 61% after injecting large volumes of procaine and saline to treat sciatica. The first uncontrolled study of epidural steroids with 86 patients receiving caudal epidural injections reported greater than 60% relief of pain in 72% of patients (317). Mount et al (556) reported greater than 85% relief in 65% of the patients suffering with lumbar intervertebral disc syndrome. Cyriax (551) reported his extensive experience with 20,000 patients, who showed significant improvement. Ciocon et al (552) studied the efficacy of caudal epidural blocks for elderly patients with lumbar canal stenosis. In this descriptive, prospective study, 30 patients with a mean age of 76 ± 6.7 years with leg pain were studied, with a 10-month follow-up evaluation utilizing Roland’s five point pain rating scale. They were treated with a total of three injections of 0.5% Lidocaine with 80 mg of methylprednisolone administered at weekly intervals. The results showed significant pain reduction up to 10 months from a mean pain level of 3.4 ± 0.82 to a mean level of 1.5 ± 0.86, with satisfactory relief in 90% of patients. Manchikanti et al (553), in evaluating the effectiveness of caudal epidural steroid injections under fluoroscopic visualization, showed significant improvement that was better than that of blind lumbar interlaminar epidural injections. Sharma (557) studied 201 patients with lumbago, sciatica, backache with sciatica, and other conditions reporting favorable results in 56% of the patients.

The quality of randomized, controlled studies for caudal epidural injections is considered as high quality for four of the six studies (544-547) and of low for the two (548, 549). As shown in Table 10, the data from six of the controlled

studies show positive effect in five studies. In addition, multiple systematic reviews were also favorable for caudal epidural steroid injections (45-47). Multiple observational studies also provided favorable results consistent with controlled trials. The type and strength of efficacy evidence is of level II – strong, with research-based evidence from at least one properly designed randomized controlled trial of appropriate size and high quality or multiple adequate scientific studies.

**Interlaminar Epidural Injections:** Interlaminar epidural injections may be administered either in the cervical, thoracic, or lumbar regions. Studies in the literature evaluating the efficiency of interlaminar epidural injections, specifically the lumbar epidural injections, are extensive. This includes ten controlled studies involving lumbar epidural steroid injections (258, 560-568); but only three controlled studies involving cervical interlaminar epidural injections (569-571); along with multiple uncontrolled studies and case reports (571-612).

Dilke et al (561) treated 100 patients with unilateral sciatica with either lumbar epidural injection with 80 mg of methylprednisolone and 10 mL of normal saline or an injection of 1 mL of normal saline into an interspinous ligament. All patients received physical therapy with hydrotherapy and exercise. Follow-up was at two weeks and three months, measuring time of bed rest, days of hospitalization, pain relief, consumption of analgesics, and resumption of work three months later. Sixty percent of the patients in the treated group and 31% in the control group improved immediately after the injections. A greater proportion of actively treated patients had no pain at three months, took no analgesics, resumed work, and fewer of

them underwent subsequent surgery or other non-surgical treatment. Ninety-one percent of the patients in the treated group improved at three months, whereas 74% of the patients in the control group improved; however; there was only one patient in the treated group with severe pain, in contrast to six in the control group (2% vs. 16%).

Ridley et al (564) corroborated the findings of Dilke et al (561) in 35 patients with sciatica in a randomized study that compared an epidural injection of 80 mg of methylprednisolone in 10 mL of normal saline to injection of 2 mL of normal saline into interspinous ligament. They reported improvement in 90% of the patients in the treated group compared to 19% in the control group at one and two weeks following treatment, which was maintained up to 12 weeks but deteriorated by 24 weeks to pre-treatment levels.

Carette et al (258) in a randomized, double-blind trial administering up to three epidural injections of methylprednisolone acetate (80 mg and 8 mL of isotonic saline) or isotonic saline (1 mL) to 158 patients with sciatica due to a herniated nucleus pulposus, reported negative results. The patients were evaluated utilizing Oswestry Disability Scores with follow-up at 3, 6, and 12 weeks after treatment. There were 78 patients in the treatment group and 80 patients in the placebo group, with L4/5 disc herniation in 50% and L5/S1 disc herniation in 46% of the patients. After 6 weeks, a significant difference was seen with improvement in leg pain in the methylprednisolone group. However, after 3 months, there were no significant differences between groups. At 12 months, the cumulative probability of back surgery was equal in both groups.

Snoek et al (567) studied 51 patients with lumbar root compression documented by neurological deficit and a concordant abnormality noted on myelography. They compared the effects of 80 mg of methylprednisolone (2 mL) and 2 mL of normal saline injected into the epidural space by the lumbar route. They found no significant differences between the two groups with respective relief of pain and a variety of physical parameters.

Cuckler et al (560), in a prospective, randomized, double-blind trial, evaluated 73 patients, comparing 7 mL of methylprednisolone (80 mg with procaine) and 7 mL of normal saline with procaine. The patients were suffering with radicular pain due to either acute herniated nucleus pulposus or spinal stenosis. They reported no significant differences in outcomes. This study was considered negative, condemning lumbar epidural steroid injections.

Klenerman et al (563) randomized patients with sciatica into four treatment groups: epidural steroid injection, epidural saline, epidural bupivacaine and needling with a Touhy needle inserted into the interspinous ligament. The results were the same in the four treatment groups, with approximately 75% of the patients responding to the treatments.

Serrao et al (566) evaluated the effectiveness of epidural steroid injections compared to subarachnoid midazolam in mechanical low back pain, concluding that epidural steroid injections are comparable to subarachnoid midazolam in patients with mechanical low back pain.

Stav et al (570) studied 52 patients with chronic, resistant cervical brachialgia in a randomized, controlled study. They divided patients into two groups, with 25 patients in Group A who were treated with cervical epidural steroid and lidocaine injections, and 17 patients in Group B who were treated with steroid and lidocaine injections into the posterior neck muscles. One to three injections were administered at two week intervals, according to the clinical response. All patients continued with their various prestudy treatments: nonsteroidal anti-inflammatory drugs, nonopioid analgesics, and physiotherapy. One week after the last injection, very good and good pain relief were reported in 76% of the patients in Group A, as compared to 36% of the patients in Group B. At one year 68% of the Group A patients continued to have very good and good pain relief, whereas only 12% of Group B patients reported similar pain relief, with statistically significant differences. They also reported that they were unable to achieve significant improvement of tendon reflexes or of sensory loss in both groups; but the increase in the range of motion, the percentage of the patients who were able to decrease their daily dose of analgesics, and recovery of the capacity for work was significantly better in Group A.

Castagnera et al (569) evaluated long term results of cervical epidural steroid injection, with and without morphine, in chronic cervical radicular pain in 24 patients, without need of surgery, but suffering for more than 12 months from cervical radicular pain, in a prospective randomized study. The patients were randomly allocated into two groups: the steroid group, with 14 patients receiving an equivalent volume of 0.5% lidocaine plus triamcinolone acetonide (10 mg per mL) and the steroid plus morphine group, with 10 patients receiving the same combination plus 2.5 mg of morphine sulfate. The success rate was 79% in the steroid group and 80% in the steroid plus morphine group. They reported an initial success rate of 96%,

followed by a 75% success rate in one month, 79% success rate at three months, 79% at six months, and 79% at 12 months.

Bush and Hillier (571) described the response to cervical epidural steroid injections of 68 patients with neurologic deficits of two months duration and an abnormal MRI in a prospective study with independent clinical review. They initially utilized a nonfluoroscopically guided lateral approach at C7. If significant improvement was not seen after the first injection, a repeat injection was performed transforaminally, with fluoroscopic guidance within one month. Similarly, a third injection was performed if needed in the same manner as the second injection. An average of 2.5 injections per patient was required for adequate pain control. Overall, 93% of the patients reported pain relief lasting seven months.

Among the remaining controlled trials, Helliwell (562) studied 20 patients utilizing normal saline and steroid with one to three injections reporting 70% positive results at three months; Rogers et al (568) studied 30 patients utilizing steroid and local anesthetic with one injection reporting only 48% positive results compared to 20% in the control group; and Rocco et al (565) studied 22 patients uti-

lizing local anesthetic and steroids with one to three injections reporting only 13% relief at three months.

Fukusaki et al (580) concluded that epidural steroid injections had no beneficial effects on the pseudoclaudication associated with spinal canal stenosis as compared with local anesthetic alone. Fifty-three patients with pseudoclaudication were randomly divided into three groups: Group 1 (n=16) underwent epidural injection with 8 mL of saline; Group 2 (n=18) underwent epidural injection of 8 mL of 1% mepivacaine; Group 3 (n=19) underwent epidural injection with a combination of 8 mL of 1% mepivacaine and 40 mg of methylprednisolone, with each patient receiving a total of three injections during the first week. After one week, 12.5% of patients in Group 1, 55.5% of patients in Group 2, and 63.2% of patients in Group 3 showed good or excellent result. However, at one month and three months the improvement deteriorated to 6.5% in Group 1, 16.7% and 5.6% in Group 2, and 15.8% and 5.3% in Group 3.

Most of the control studies faced criticism. Dilke et al (561) and Ridley et al (564) were criticized for the lack of epidural anesthetic and limited outcome measures, as well as for early crossover and a small sample size in Ridley's

**Table 11.** Results of published reports on interlaminar lumbar and cervical epidural steroid injections

Study	No. of Patients	Study Characteristics	Drugs Utilized	No. of Injections	Initial Relief Control vs. Treatment	Long-term Relief Control vs. Treatment		Results
					3-4 Weeks (%)	3 Months (%)	6 Months (%)	
Dilke et al (560)	100	P, PC	NS, S	1-2	31 vs. 60	74 vs. 91	N/A	P
Ridley et al (564)	35	P, RA, PC	NS, S	1-2	19 vs. 90	19 vs. 90	65	P
Helliwell et al (562)	20	P, C, PC	NS, S	1-3	70	70	N/A	P
Stav et al (570)	42	P, RA, PC	LA, S	1-3	76	68	68	P
Castagnera (569)	24	P, RA	LA, S, M	1	75	79	79	P
Serrao et al (566)	28	P, C	NS, S	2	71	71	N/A	N
Klenerman et al (563)	63	P, RA, PC	NS, S, LA	1	79	N/A	N/A	N
Rogers et al (568)	30	P, C	S, LA	1	20 vs. 48	N/A	N/A	N
Rocco et al (565)	22	P, C	LA, S	1-3	N/A	13	N/A	N
Cuckler et al (560)	73	P, RA, DB, PC	S, LA, S	1-2	26 vs 40	N/A	13 vs. 26	N
Snoek et al (567)	51	P, PC	NS, S	1	25 vs. 33	N/A	N/A	N
Carette et al (258)	158	P, RA, DB, PC	NS, S	1-3	29 vs. 33	No sig. diff.	No sig. diff.	N
Bush and Hillier (571)	68	P, C	LA, S	1-6	76	76.	76	P

P = prospective; C = controlled; PC = placebo controlled; RA = randomized; DB = double-blind; LA = local anesthetic; S = steroids; NS = normal saline; M = morphine; N/A = not available; P = positive; N = negative; vs = versus



study (564). Carette et al (258) also failed to include local anesthetic in the injection. In addition, Carette et al (258) used the same target level of epidural injection in all patients irrespective of location or pathology and discounted the short term facilitating effects of epidural steroid injections. There were also no structured co-interventions (258). Cuckler et al (560) included patients with prior surgery. They also evaluated responses at 24 hours which was felt to be inappropriate as it was quite a short period over which to evaluate the effectiveness of an invasive procedure and the anti-inflammatory effect of long-acting steroid preparation. In addition, they also made injections at the L3/4 level in all of the patients rather than injecting close to the site of pathology. Bush and Hillier (571) study was not randomized and there were no outcome parameters. Fukusaki et al (580) utilized three epidural injections in a one week period with no pharmacologic basis, and failed to enter the epidural space in a significant number of patients. Interestingly none of the controlled studies were performed under fluoroscopic visualization.

Numerous uncontrolled trials reported good results in 18% to 90% of patients receiving lumbar epidural steroid injections. Berman et al (583) reported good to excellent results at three months, six months, and one year in 87%, 77% and 69% of patients, respectively. Brown (572) reported even better results with 80% relief at one year. Other selective uncontrolled trials also reported six months of relief in approximately 60% of the patients, and 1 year relief in 36% of the patients (573-578). Pawl et al (588), in evaluating the records of 136 patients with typical radicular symptoms reported that 29 patients or 80% indicated that the relief of pain from epidural steroid injection was 50% or more, and 50% of the patients were able to avoid surgery with the help of epidural injections. Various other evaluations have shown success rates with cervical epidural injections varying from 64% to 79% for less than three months, 50% to 68% for 3 to 6 months, and 25%-68% for over 6 months (584-586, 591). Manchikanti et al (553) compared blind lumbar interlaminar epidural steroid injections with fluoroscopically directed caudal and transforaminal injections and concluded that blind interlaminar epidural injections were not cost effective.

In terms of quality of the 13 studies considered in the interlaminar lumbar and cervical epidural steroid injections, two were of high quality (258, 567); six were of moderate quality (560, 561-563, 566, 568), whereas remaining five were of low quality (564, 565, 569-571). Of the 13 studies, three of nine interlaminar lumbar epidural steroid injections and three of three cervical epidural steroid injections

were judged to be positive, while the remaining were considered negative (Table 11). Thus, evidence from controlled studies is predominantly negative for lumbar interlaminar and positive for cervical interlaminar epidural injections. However, multiple observational studies showed positive results. Hence, type and strength of efficacy evidence is level III to IV moderate to limited. Level III - moderate is defined as evidence from well-designed trials without randomization, single group pre-post, cohort, time series, or matched case controlled studies. Level IV - limited is defined as evidence from well-designed non-experimental studies from more than one center or research group.

**Transforaminal Epidural Injections:** Caudal epidural injection of drugs was introduced as the first type of entry into the epidural space in 1901, and transforaminal epidural injection was introduced as the first and earliest use of epidural steroids (315, 316). In 1952, Robechhi and Capra (315) administered periradicular injection of hydrocortisone into the first sacral nerve root and reported relief of lumbar and sciatic pain in a woman in the Italian literature. Subsequently, Lievre and colleagues (316) also reported transforaminal injection of steroids into the first sacral nerve root, in the French literature. The sacral transforaminal epidural injection of steroids was popularized largely in the Italian literature (315, 613-618), and to a lesser extent, in the French literature (316, 619-621). There were no significant American reports until 1971, when McNab described the diagnostic value of selective nerve root infiltration in patients with suspected radicular etiology of pain (405). In contrast to reports of caudal and interlaminar epidural injections, reports of transforaminal injections are sparse in the literature (622-631). Review of the literature showed three prospective, randomized controlled, trials (622-624); two prospective evaluations (571, 625); and multiple retrospective studies (415, 553, 609, 626-628) (Table 12).

Riew et al (622), in a prospective, randomized, controlled, double-blinded study, evaluated the effectiveness of transforaminal epidural cortical steroids in subjects with disc herniations and/or spinal stenosis. The study included 55 patients with disc herniations or spinal stenosis referred for surgical evaluation. All subjects had clinical indications for surgery, and radiographic confirmation of nerve root compression. All had failed a minimum of 6 weeks of conservative care or had unrelenting pain. Exclusion criteria consisted of patients who had sustained trauma, patients with evidence of other serious diseases, patients demonstrating adverse reactions to the medications employed

**Table 12.** Results of published reports on lumbar and cervical transforaminal epidural steroid injections

Study	Study Characteristics	No. of Patients	Drugs Utilized	No. of Injections	Initial Relief	Long-term Relief		Results
					Control vs. Treatment	Control vs. Treatment		
					3-4 Weeks (%)	3 Months (%)	6 Months (%)	
Riew et al (622)	P, RA, DB	55	LA, S	1-4	33 vs. 71	33 vs. 71	33 vs. 71	<i>P</i>
Kraemer et al (624)	P, RA, PC, DB	49	S, NS	N/A	E	E	E	<i>P</i>
Kraemer et al (624)	P, RA	87	LA, S	N/A	E	E	E	<i>P</i>
Shah et al (623)	P, PC	48	LA, S	1-4	84	84	84	<i>P</i>
Lutz et al (625)	P, C	69	LA, S	1-4	79	79	79	<i>P</i>
Manchikanti et al (553)	R, RA	225	S, LA	1-10	91	75	70	<i>P</i>
Bush and Hillier (571)	P, C	68	LA, S	2-3	93	93	93	<i>P</i>
Kikuchi et al (415)	R	332	S, LA	N/A	N/A	N/A	64	<i>P</i>

P = prospective; R = retrospective; C = controlled; PC = placebo controlled; RA = randomized; DB = double-blind; LA = local anesthetic; S = steroids; N/A = not available; NS = normal saline; E = effective; *P* = positive; VS = versus

in the study, and any patient with more than two levels of disease. Progress was monitored using the NASS Outcome questionnaire and a specifically designed nerve root injection questionnaire. All subjects were assessed at baseline; at 2, 4, and 8 weeks post-injection; and again at 1 year. The primary outcome measure was whether patients underwent surgery; but pain, disability, patient satisfaction, and treatment expectations were also evaluated. Both groups of patients had similar demographic and clinical characteristics. They were randomly allocated to receive an injection of a corticosteroid plus a local anesthetic, or the anesthetic alone, in a double-blinded manner. All patients received injections under fluoroscopy, up to four over the course of the study. All patients had the option of choosing surgery or participating in the study. Each patient received one or more additional injections as randomized. Authors concluded that 71% of the patients studied with nerve root injections of corticosteroids avoided surgery, compared to 33% of control subjects. However, patients who opted not to have surgery showed greater improvement in terms of pain reduction, functional status improvement, and expectation of recovery than those who went on to have surgical intervention. The authors concluded that selective nerve root injection(s) of corticosteroids were efficacious in preventing typical spine surgery. They also speculated that selective nerve root injections might be effective because they provided more focal delivery of corticosteroids to the compressive nerves than other types of epidural injections. This study also showed that the first

injection had the greatest impact on symptoms, with subsequent injections having less of an effect. The injections appear to provide benefit for patients with both acute and chronic complaints. However, it is also important to note that 33% of the patients in the local anesthetic injection group also avoided surgery.

Kramer et al (624), in a prospective, randomized, controlled trial, evaluated the role of lumbar epidural perineural injections. They included two controlled studies to evaluate single-shot, selective nerve root injection with a double-needle approach to the anterior epidural space of the lumbar spinal canal. The trial comprised two controlled studies on 182 patients. One study compared prospectively randomized results of patients with lumbar radicular syndromes: 47 received epidural perineural injections, 40 received conventional posterior epidural injections and, 46, as a control group, received paravertebral local anesthetic injection. Along with this, a second, prospective, double-blind study compared the effect of epidural perineural injections with triamcinolone in 24 patients and normal saline in 25 patients. Epidural perineural injections were more effective than conventional posterior epidural injections. Both epidural groups had better results than the paravertebral local injection group. Epidural perineural injections with steroids utilizing 10 mg of triamcinolone were more effective than saline alone. A systemic steroid effect was excluded by additional intramuscular steroid injections in the normal saline group. The authors con-

cluded that in both studies, the single-shot epidural perineural injection is effective in the treatment of lumbar radicular pain.

Shah et al (623) compared the efficacy of fluoroscopically guided transforaminal epidurals for lumbar radiculopathy due to disc herniation with another group of patients who underwent trigger point injections in an office setting. Fifty patients were assessed with an average follow-up of 1.4 years. Patients who had documented lumbar disc herniation on MRI, greater than 50% of the total pain present in the leg and/or buttock, at least 6 weeks of symptoms, and who failed to improve with oral medications and rehabilitation were included. They excluded patients with history of previous spinal surgery. Patients were randomly divided into two groups. Group I with 25 patients with average age of 41.3 years, received an average of 1.7 fluoroscopically guided transforaminal injections combined with home lumbar stabilization program and a back cryobracer. Group II with 23 patients with average age of 42.4 years received an average of 1.6 saline trigger point injections combined with home lumbar stabilization program and a back cryobracer. At three months, the nonresponders in group II were crossed into group I. The outcomes consisted of patient satisfaction rated from poor to excellent, pain score, Rolland-Morris questionnaire, and distance from finger to floor in centimeters collected pre-, and 3 weeks, 6 weeks, 3 months, 6 months, and 1 year post-treatment. They defined a successful outcome as good or better satisfaction combined with greater than 50% reduction in pain score. The results showed that in Group I, average Rolland-Morris score was 8.8 pre- and 22.1 post-treatment, pain score was 8.8 pre- and 1.6 post-treatment, and distance from finger to floor was 69.6 cm pre- and 20.3 cm post-treatment. Overall, Group I had 84% successful outcome. Group II also showed significant improvement but only resulting in 48% successful outcome. For Group II, the average Rolland-Morris score was 9.6 pre- and 18.3 post-treatment, pain score of 9.4 pre- and 3.6 post-treatment, and distance from finger to floor was 64.8 pre- and 24.4 post-treatment. Thus, Group I had a significantly better outcome than Group II at 1.4 year average follow-up ( $P>0.05$ ). They also reported that the nonresponders who crossed over from Group II to Group I experienced 67% successful outcome. They reported that presence of spondylolisthesis, in addition to disc herniation, was a negative prognostic factor for Group I, whereas symptom duration greater than six months was a negative prognostic factor for Group II patients.

Lutz et al (625) studied 69 patients in a prospective case

series. They investigated the outcome of patients with lumbar herniated nucleus pulposus and radiculopathy using administration of fluoroscopically guided transforaminal epidural steroid injections. Patients were evaluated by an independent observer and were followed for an average period of 80 weeks, with a range of 28 to 144 weeks. Among the 69 patients, 75% of the patients had a successful long-term outcome, reporting at least a greater than 50% reduction between preinjection and postinjection pain scores, as well as an ability to return to or near their previous levels of functioning after 1.8 injections per patient (range, one to four injections). They concluded that fluoroscopic transforaminal epidural steroids are an effective nonsurgical treatment option for patients with lumbar herniated nucleus pulposus and radiculopathy in whom more conservative treatments are not effective.

Bush and Hillier (571) described the response of 68 patients to cervical epidural steroid injections with some of them undergoing transforaminal epidural injections if they failed non-fluoroscopically guided lateral approach at C7. Following the first blind cervical epidural injection, if significant improvement was not seen, a repeat injection was performed transforaminally with fluoroscopic guidance within one month. Similarly, a third injection was also performed if needed in the same manner as the second injection. Overall, an average of 2.5 injections per patients was required for adequate pain control; 93% of the patients were reported to have good pain relief lasting for seven months.

Weiner and Fraser (626) treated 28 patients with severe radiculopathy secondary to foraminal or extraforaminal herniation of lumbar disks. In these patients, the disk herniation was proven by imaging studies; and it failed to respond to rest and anti-inflammatory therapy, epidural injections, and physical therapy. The only remaining choice for these patients was surgical intervention due to the severity of pain and functional disability. The authors showed that 22 of the 28 patients improved dramatically, with sustained relief lasting an average of 3.4 years, with a range of 1 to 10 years. Further analysis showed that, of the 28 patients, three obtained no relief and subsequently underwent discectomy; but three obtained immediate relief and relapsed within 6 months. In addition, one patient obtained minimal relief but was able to tolerate continuing symptoms; and seven patients received moderate relief that allowed them to return to most activities but with caution and occasional symptomatic treatment. Of the 28 patients, 14 had complete relief of their pain at follow-up that ranged from 1 to 10 years.

Kikuchi et al (415) studied the therapeutic effect of transforaminal nerve root injections in 332 patients. They reported that this procedure not only had therapeutic effect but also had great diagnostic value in functional as well as morphological aspects. They reported that 22 of 45 patients with disk ruptures, 30 of 39 patients with spondylosis, and five of six patients with degenerative spondylolisthesis all experienced more than 6 months of pain relief and thus were able to avoid surgical intervention. Furthermore, they reported that, over the long term, relief was seen in 64% of these patients.

Manchikanti et al (553) compared the three routes of epidural steroid injections in the management of chronic low back pain. This retrospective evaluation included 225 patients, randomly derived from a total sample of 624 patients suffering with low back pain from a total of 972 patients referred for pain management. The evaluation was performed by an independent evaluator. The study design included three groups: Group I, which received interlaminar epidurals with a midline approach in the lateral position, with entry between L3/4 or L4/5 in nonsurgical patients and above the scar either at L2/3 or L1/2 in postsurgical patients, using a loss-of-resistance technique; Group II, which received caudal epidurals, the procedures being performed in prone position, under fluoroscopy, with confirmation of the position by injection of contrast; and Group III, which received transforaminal epidural corticosteroid injections, using either sacral or lumbar transforaminal technique under fluoroscopy. The results of the study showed that all three routes of administration of epidural corticosteroid administration were clinically effective, though administration by caudal and transforaminal routes was more successful in obtaining longer term relief. Further, this study also showed that the transforaminal injections were the ideal, as the most significant improvement was noted with the least expense compared to fluoroscopically directed caudal epidural, and to blind interlaminar epidural. This study showed significant relief, which was defined as greater than 50% per procedure for all patients in the study as 3.45 +/- 0.17 weeks, 6.06 +/- 1.27 weeks, and 7.69 +/- 1.20 weeks for blind intralaminar epidural, fluoroscopically directed caudal and transforaminal epidural injections, respectively.

Devulder (627) also studied transforaminal epidural injections, which he termed *nerve root sleeve injections with corticosteroids*; however, they were in combination with hyaluronidase. In a study of 20 patients with persistent pain after surgery, ranging from 1 to 9 years in duration

and diagnosed as failed back surgery syndrome, they reported that 55% of the patients reported greater than 50% relief at 1 month, while 50% of the patients experienced continued relief after three months.

Slipman et al (628), in a retrospective analysis with independent clinical review, evaluated the role of therapeutic selective nerve root block in the nonsurgical treatment of atraumatic cervical spondylotic radicular pain. Of 20 subjects, 10 men and 10 women, with a mean age of 56.6 years and an average symptom duration of 5.8 months, were treated with an average of 2.2 therapeutic injections. They reported an overall good or excellent result in 60% of the patients, with significant reduction in pain scores, as well as significant reduction in medication usage.

Of the five prospective clinical trials available for evaluation of transforaminal epidural injections, three were considered of moderate quality (622-624) and the remaining two were considered of low quality (571, 625). In terms of the evaluation of the type and strength of efficacy evidence of transforaminal epidural injections is level II to level III, strong to moderate. Level II - strong is defined as evidence with research-based evidence with at least one properly designed randomized controlled trial of appropriate size and with 60 patients and high quality or multiple adequate scientific studies. Level III - moderate is defined as evidence obtained from well-designed trials without randomization, single group prepost, cohort, time series, or matched case controlled studies.

### ***Percutaneous Lysis of Epidural Adhesions***

Percutaneous epidural adhesiolysis, lysis of epidural adhesions, percutaneous neuroplasty, or epidural neurolysis is an interventional pain management technique that played an active role since its emergence during the latter part of 1980s in managing chronic intractable low back pain (632, 633). Postlumbar laminectomy syndrome or pain following operative procedures of the spine is a common entity in modern medicine (261-292). Ross and coworkers (267), in a study of the relationship between peridural scar evaluated by MRI and recurrent radicular pain after lumbar discectomy, showed that subjects with extensive peridural scarring were 3.2 times more likely to experience recurrent radicular pain. Park and Watanabe (269) analyzed the frequency and location of lumbar and ventral dural adhesions in elderly cadavers, showing significant evidence of adhesions in 40% at L4/5 levels, in 36% at L5/S1 levels, and in 16% at L3/4 levels. Even though epidural adhesions are most commonly observed following surgical

intervention of the spine, leakage of the disc material into the epidural space following an annular tear has also been reported to cause fibrocyte deposition and an inflammatory response that can subsequently result in the formation of epidural adhesions (227, 636, 637). It has been presumed that inflammation and compression of nerve roots by epidural adhesions is the mechanism of persistent pain in patients. The causes of failed back surgery syndrome or postlumbar laminectomy syndrome are epidural scarring, arachnoiditis, recurrent disc herniation with neural encroachment, mechanical instability, and facet degeneration. While it is largely agreed that peridural scarring contributes to a considerable amount of morbidity and mortality following lumbar surgery, further surgery is not a solution, as results show disappointing success rates as low as 12% (280, 638). Further, epidural adhesions are not readily diagnosed by conventional studies such as myelography, CT, and MRI, even though modern technology has made significant improvements in this area (637). The epidural adhesions are best diagnosed by performing an epidurogram, which is most commonly performed via the caudal route, followed by other routes, including the lumbar interlaminar route, and thoracic and cervical interlaminar routes (525, 527, 632-634, 636, 639-641). Epidural filling defects have also been shown in a significant number of patients with no history of prior surgery (525). While peridural scarring in itself is not painful, it can produce pain by “trapping” spinal nerves so that movement places tension on the inflamed nerves (633, 634, 639). Kuslich and coworkers (153) reported that back pain was

produced by stimulation of several lumbar tissues, even though the outer layer of the annulus fibrosus and posterior longitudinal ligament innervated by the sinuvertebral nerves were the most common tissues of origin.

Adhesiolysis of epidural scar tissue, followed by the injection of hypertonic saline, has been described by Racz and coworkers in multiple publications (632-635, 636, 639, 644, 645). The technique described by Racz and colleagues involved epidurography, adhesiolysis, and injection of hyaluronidase, bupivacaine, triamcinolone diacetate, and 10% sodium chloride solution on day 1, followed by injections of bupivacaine and hypertonic sodium chloride solution on days 2 and 3. Manchikanti and colleagues (632, 646, 649) modified the Racz protocol from a 3-day procedure to a 1-day procedure.

The purpose of percutaneous epidural lysis of adhesions is to eliminate deleterious effects of scar formation, which can physically prevent direct application of drugs to nerves or other tissues to treat chronic back pain. In addition, the goal of percutaneous lysis of epidural adhesions is to assure delivery of high concentrations of injected drugs to the target areas.

Clinical effectiveness of percutaneous adhesiolysis was evaluated in one randomized controlled trial (647, 648) and four retrospective evaluations (636, 646, 649, 650). Racz and colleagues (647), and Heavner and coworkers (648), studied percutaneous epidural adhesiolysis, with a

**Table 13.** Results of published reports of percutaneous lysis of lumbar epidural adhesions and hypertonic saline neurolysis for a single procedure

Author(s)	Study Characteristics	No. of Patients	Drugs Utilized	No. of Days of Procedure	Initial Relief 1-4 Weeks	Long-term Relief	
						3 Months	6 Months
Heavner et al (648)	P, RA, PC	59	B, T, H, HS, NS	3	83%	49%	43%
Racz and Holubec (636)	R, RA	72	B, T, H, HS	3	65%	43%	13%
Manchikanti et al (646)	R, RA	103	M, L, HS	2	74%	37%	21%
Manchikanti et al (646)	R, RA	129	M, L, HS	1	79%	26%	14%
Manchikanti et al (649)	R	60	L, HS, CS	1	100%	25%	10%
Arthur et al (650)	R, RA	100	L, HS, CS, H	1	82%	NA	14%

P = prospective; PC = placebo controlled; R = retrospective; RA = randomized; B = bupivacaine; L = lidocaine; T = triamcinolone; M = methylprednisolone; CS = celestone soluspan; H = hyaluronidase; HS = hypertonic saline; NS = normal saline; NA = not available

**Table 14.** Results of 1-year follow-up of patients following percutaneous lysis of lumbar epidural adhesions

Author(s)	Study Characteristics	No. of Patients	No. of Days of Procedure	Patients with Significant Relief			
				1 Month	3 Months	6 Months	12 Months
Racz et al (647) and Heavner et al (648)	P, C, RA	59	3	83%	49%	43%	49%
Manchikanti et al (649)	R	60	1	100%	90%	72%	52%

R= retrospective; P= prospective, RA= randomized; C= controlled

prospective evaluation of 0.9% sodium chloride solution versus 10% sodium chloride solution with steroids, with prospective 1-year follow-up. They concluded that percutaneous epidural neuroplasty, as part of an overall pain management strategy, reduces pain in 25% or more of patients with radiculopathy plus low back pain refractory to conventional therapies. They also noted that the use of hypertonic saline and hyaluronidase may reduce the number of patients that require additional treatments. However, adhesiolysis was effective, even in the patients receiving normal saline. They also showed that the percent of patients requiring additional treatments during 1-year follow-up was approximately 70%, at on average, around 70 days. This percentage was approximately 60% in patients receiving hypertonic saline, and 80% in patients receiving normal saline. Finally, Heavner and coworkers (648) concluded that the most significant finding of the study was that at 1-year follow-up, 49% of the patients had pain relief in the body area targeted for the lesion-specific therapy.

Manchikanti and coworkers (646), evaluating 232 patients, with modification of the Racz protocol from a 3-day procedure to a 2-day procedure and a 1-day procedure, showed significant pain relief lasting at least 1 month in 52%, 2 months in 35%, 3 months in 11%, and 6 months in 7% of patients with the first injection; and with better results with the second injection. However, no significant differences were noted between 1-day, 2-day, or 3-day procedures.

Racz and Holubec (636), in their earliest publication, reported favorable results with good-to-excellent pain relief for up to one month in 65% of the patients, for one to three months in 43% of the patients, and for three to six months in 13% of the patients. Arthur and colleagues (650), in studying 100 patients, concluded that when hyaluronidase

was added to the injected, 82% reported initial pain relief compared to 68% in those without the hyaluronidase. However, no difference was seen in long-term improvement (14% vs 12%).

In a study evaluating the effectiveness of nonendoscopic adhesiolysis in postlumbar laminectomy syndrome in 60 patients, Manchikanti and colleagues (649) reported relief of  $12 \pm 3.2$  weeks relief with the first procedure, whereas with the second procedure it was  $13 \pm 2.9$  weeks using a modified 1-day adhesiolysis. This study also showed 1-year relief in 52% of patients, with repeat procedures of  $2.98 \pm 0.16$  over a 1-year period per patient. Tables 11 and 12 show the results of published reports of nonendoscopic adhesiolysis and hypertonic neurolysis with their effectiveness or lack thereof.

In contrast to the above reports, Devulder and coworkers (642) concluded that epidurography might confirm epidural filling defects, but a better contrast spread, assuming scar lysis does not guarantee sustained pain relief, as filling defects were confirmed in 88% of the patients with epidurography; but significant pain relief was seen in only 33% of the patients at 1 month, 13% at 3 months, and 0% at 12 months. However, the problem with this study was that lysis of adhesions was not lesion specific. Consequently, the delivery of drugs was also nonspecific (651-653).

The quality of evidence presented above includes one randomized clinical trial which is of moderate quality, followed by three retrospective trials, two of which were randomized (Tables 13 and 14). The type and strength of efficacy evidence is type III – moderate, defined as evidence obtained from well-designed trials without randomization, single group prepost, cohort, time series, or matched case controlled studies.

### ***Epiduroscopy or Spinal Endoscopy***

Epidural lysis of adhesion and direct deposition of corticosteroids in the spinal canal are also achieved with a three-dimensional view provided by epiduroscopy or spinal endoscopy.

Buurman (654) in 1931 pioneered direct visualization of the spinal canal and its contents. In 1985 Blomberg (655) of Sweden described a method of epiduroscopy. In 1991, Saberski and Kitahata (656) started using fiberoptic endoscopes for epiduroscopy. Heavner and colleagues (657) also reported in 1991 on endoscopic evaluation of the epidural and subarachnoid spaces in animals and human cadavers. By 1996, epidural spinal canal endoscopy was used frequently for delivery of epidural steroid medication (658-663).

There have been a few retrospective analyses performed to evaluate the efficiency of spinal endoscopy; however, there are no randomized, controlled trials (650, 661, 663).

Manchikanti et al (650), in a study evaluating the effectiveness endoscopic adhesiolysis in post lumbar laminectomy syndrome in 60 patients, showed that 100% of the patients reported significant pain relief at one month, whereas 75% reported significant relief at three months; 40% reported at six months, and 22% reported at 12 months. It was concluded that endoscopic adhesiolysis with administration of corticosteroids is a safe and possibly cost-effective technique for relief of chronic intractable pain failing to respond to other modalities of treatments.

Manchikanti et al (661) studied the value and safety of epidural endoscopic adhesiolysis. In this retrospective evaluation on 85 consecutive patients undergoing 112 epidural endoscopic procedures. They reported significant pain relief in 100% of the patients, initially decreasing to 94% at one to two months, to 77% at two to three months, to 52% at three to six months, to 21% at six to twelve months, and to 7% after 12 months. They concluded that epidural endoscopy with adhesiolysis is a relatively safe and possibly cost-effective technique in the management of chronic refractory low back pain.

Saberski (663), in a retrospective analysis of spinal endoscopy and laminectomy, reported outcome data in a pilot study. This pilot study included two groups of patients, Group I, with 22 patients treated via spinal endoscopy;

and Group II with 13 patients treated via laminectomy. After spinal canal endoscopy, only 32% of Group I patients were continued on opioid medication; whereas 92% of Group II patients were continued on opioid medication after laminectomy. In addition, 72% from the spinal canal endoscopy group and only 28% from the laminectomy group returned to work. He concluded that this study suggested remarkable differences in outcomes when comparing patients who underwent spinal canal endoscopy to a similar population who underwent lumbar laminectomy. Based on the above, the type and strength of efficacy evidence analysis places spinal endoscopy into type IV-limited, which is defined as evidence from well designed non experimental studies from more than one center or research group: but this evidence is also complemented by clinical experience.

### ***Intradiscal Electrothermal Annuloplasty***

Primary discogenic pain is a common entity with or without internal disc disruption and is responsible for chronic low back pain in approximately 39% of patients (174). This is in contrast to disc herniation, which is seen in a small number of patients ranging from 4% to 6% (173, 222, 223, 255-260). Intradiscal electrothermal annuloplasty (IDET) is a minimally invasive treatment for chronic discogenic low back pain that is an alternative to interbody fusion surgery (664). Application of thermal energy to the disc alters collagen structure and may perform a functional deafferentation on the disc. The technique of intradiscal electrothermal annuloplasty utilizes this principle to treat patients with intractable low back pain. Multiple investigators have studied the effectiveness of intradiscal thermal annuloplasty (664-674). However, only one published study included a control group (669), whereas another study incorporated results of a multicenter cohort study (670) and the remaining five studies were descriptive in nature (664, 666-668, 674). Apart from these, there were presentations at multiple meetings, some of which are listed here; however, it appears many of them included the same patients but were presented repeatedly.

Karasek and Bogduk (669) studied 53 patients with back pain determined by CT discography to be due to internal disc disruption. The outcomes of 35 patients treated with IDET were compared with those of a convenience sample of 17 patients treated with a physical rehabilitation program, by using VAS scores, use of analgesics, and return to work as measures. They reported that, at 3 months, only one control patient obtained any significant degree of relief of pain, compared with 23 in the index group. Re-

lief of pain was sustained at 6 and 12 months and was associated with improvement in disability, reduced drug use and a return to work rate of 53%. 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, with a success rate as low as 23% or as high as 60%, with confidence intervals of  $\pm 16\%$ .

Wetzel et al (670) reported the preliminary results of a multicenter prospective cohort study of intradiscal electrothermal annuloplasty to treat discogenic low back pain. The study group included patients from centers in Chicago, Dallas, Plano, Roseland, and Syracuse. A total of 78 patients were entered in the intent-to-treat group. The inclusion criteria were: complaint of predominantly low back pain, persistence of symptoms for greater than 3 months, and failure of at least 6 weeks of conservative care. Exclusion criteria were: sequestered disc herniation, greater than two levels of symptomatic degenerative disc disease, spinal stenosis, spondylolisthesis or previous surgery at the treated level. Patients were reevaluated at 1 month, 3 months, 6 months, and 1 year. There were eight withdrawals from the study. Seventy patients completed the study, with five failures, four who went to fusion, and one who received a second IDET. In all, 93 levels were treated in 65 patients. Twenty-nine patients underwent two-level treatment and thirty-five underwent one-level treatment. They reported significant improvement in VAS scores, bodily pain, physical function, social function, reported health transitions, physical health and pain, treatment expectation, patient satisfaction and pain disability at 3, 6, and 12 months. Significant changes in a greater work ability were also seen at one year, along with improvement in ability to sit and walk. The initial failure rate was 6.9%; however, the authors have not described success rate with the number of patients.

Saal and Saal (667), in a prospective case series, reviewed outcomes of 62 patients with unremitting chronic discogenic low back pain who were faced with a choice of long term pain management or fusion surgery. They treated these patients with IDET, with a mean follow-up of 16 months, and mean preoperative duration of symptoms of 60 months. They reported improvement in 70% of the patients, not only with physical pain but also with return to work. Saal and Saal (674) also reported their findings with a 2-year follow up. Outcome scores at 1-year follow up were not statistically different from outcome scores as-

sessed at 2-year follow-up.

Singh (668) published a preliminary report evaluating 23 patients at 6 months with improvement in 70% of the patients. Derby et al (666) reported their findings of IDET in a 1-year pilot outcome study with 32 patients. They reported that 63% of the patients had a favorable outcome, with no change in outcome measures at 6-month and 12-month follow-ups. Derby and O'Neill (671) evaluated the effects of IDET on referred leg pain, reporting significant relief of referred leg pain. Even though the mechanism of relief is unknown, a reduction in the chemical sensitivity and reduction in inflammatory chemical substances in the outer annulus and adjacent epidural space are proposed to explain the results. Liu et al (675) attempted to identify factors associated with favorable outcomes in 50 patients treated with IDET. They reported overall favorable clinical results in 60% of the patients. They also reported that the results were less favorable with time decreasing to 43% at 12 months and 33% at 18 months. They concluded that the IDET procedure for degenerative discs achieved clinically favorable results in 60% of the patients. However, these results can be substantially improved by proper patient selection and careful attention to correct catheter placement. Predictive clinical factors included: age less than 40; nonsmoker status; female sex; symptoms of less than 4 years; modified Dallas type 1, 2, 3 annular tears; and perfect spine catheter placement along the entire posterior annulus. Maurer et al (673) investigated 36 consecutive patients in a prospective case series who underwent IDET. They reported that at six months, 94% of patients had a mean decrease of four points on VAS. Functional scales (sitting, standing, walking) increased on average 75%. Lee et al (675) evaluated the stability of the spine after intradiscal electrothermal therapy. This was an in vitro study to analyze whether or not there was any significant change in human cadaveric disc stability after IDET. Preliminary results of this study suggested that there is no significant difference in spine segmental stability before and after treatment with IDET in vitro.

Based on the above reports which included two prospective evaluations and multiple observational studies, in terms of type and strength of efficacy evidence is type III – moderate, which is evidence from well-designed trials without randomization, single group prepost, cohort, time series, or matched case controlled studies complimented from well-designed non-experimental studies and also opinions



of respected authorities.

### ***Sympathetic Blocks***

Management options for reflex sympathetic dystrophy (RSD) and causalgia, also known as complex regional pain syndrome (CRPS) I and II, include sympathetic blocks utilizing regional anesthetic techniques and radiofrequency thermoneurolysis or neuromodulation with spinal cord stimulation or peripheral nerve stimulation. Radiofrequency neurolysis is an extension of a continuous regional sympathetic block or neurolytic block providing long term relief with added safety. Consideration of sympathetic blocks is to facilitate management of CRPS with analgesia commensurate with a program of functional restoration and sympathectomy to provide unequivocal evidence of sympathetically maintained pain. Once it is established that sympathectomy is effective in relieving not only the burning dysesthesia but also allodynia or hyperalgesia, it is important to repeat the procedure to determine whether an increasing duration of effect can be expected in any particular patient. If this is the case, these individual blocks may be all that are necessary to enable a patient to regain function. When sympathectomy completely relieves the symptoms and facilitates exercise therapy but is limited to its duration of effect, it is appropriate to consider a prolonged block using radiofrequency neurolysis. Radiofrequency has been described for lesioning of the cervical sympathetic chain, thoracic sympathetic chain, and lumbar sympathetic chain, in cases of CRPS I and II, as well as for neuropathic pain.

Multiple authors have described their experience with local anesthetic blockade, as well as radiofrequency neurolysis; however, there are no large scale either prospective or retrospective case study series (676-684). However, neurolytic celiac plexus block for treatment of cancer pain has received significant attention in the literature (685). Eisenberg et al (685) performed a meta-analysis of the efficacy and safety of neurolytic celiac plexus block for cancer pain. They reviewed a total of 24 papers which met inclusion criteria with two of them being randomized, controlled trials (686, 687). One was prospective (688), and the remaining 21 were uncontrolled, retrospective studies (685). Both randomized, controlled trials (686, 687) showed positive results. Eisenberg et al (685) concluded that short-term success rate of neurolytic celiac plexus block is approximately 90%, regardless of the underlying type of cancer. The data analyzed in this review suggested that neurolytic celiac plexus blocks can at least provide analgesia in addition to that achieved by opioids, and can re-

duce their consumption (685, 689, 690).

There is no significant evidence in the literature in the form of controlled trials for evaluation and management of sympathetically maintained pain either with local anesthetic blocks or neurolytic blocks, including radiofrequency thermoneurolysis. However, there is moderate evidence for neurolytic celiac plexus block for the treatment of cancer pain. Based on this, type and strength of efficacy evidence is level IV-limited, which is defined as the evidence from non-experimental studies from more than one center or research group.

### ***Trigger Point Injections***

Trigger point injections are probably the most extensively used modality of treatment, not only by interventional pain physicians, but all providers managing pain. Myofascial pain syndrome is a regional muscle pain disorder accompanied by trigger points. It has been described as a common phenomenon in multiple regions, including the spine (186-189, 202-209). Myofascial trigger points are small, circumscribed, hyperirritable foci in muscles and fascia, often found within a firm or taut band of skeletal muscle. In contrast, nonmyofascial trigger points may also occur in ligaments, tendons, joint capsule, skin, and periosteum (202). Trigger points assist in the proper diagnosis of myofascial pain syndrome, Simons (189) proposed major and minor criteria that should be met. The clinical criteria to establish a diagnosis of myofascial pain syndrome include five major criteria requiring all five to be present:

1. Regional pain complaint,
2. Pain complaint or altered sensation in the expected distribution of referred pain from a trigger point,
3. Taut band palpable in an accessible muscle,
4. Exquisite tenderness at one point along the length of the taut band, and some degree of restricted range of motion, when measurable.

Minor criteria of which only one of the three is required include:

1. Reproduction of clinical pain complaint,
2. Altered sensation, by pressure on the tender spot,
3. Local response elicited by snapping palpation at the tender spot or by needle insertion into the tender spot, and
4. Pain alleviated by elongating (stretching) the muscle or by injecting the tender spot.

Even though there is a substantial amount of anecdotal evidence, there is no controlled prevalence data on the prevalence of myofascial pain. The authors exploring the role of trigger points and myofascial pain and whiplash injuries believe that the theory of trigger points lacks demonstrated internal validity. Formal studies also have shown that myofascial experts have difficulty in agreeing as to the presence of a trigger point, which is the cardinal feature of regional myofascial pain syndrome. In addition to this, it has been shown that topographically, trigger points of the neck overlay the cervical facet joints, and it has been reported that pain patterns of cervical trigger points are identical to those of referred pain from the facet joints. The same theories can be extrapolated to the lumbar spine.

The literature describing effectiveness of trigger point injections is enormous. There were seven controlled studies (203-209) along with numerous observational studies.

Collee et al (205), in a double-blind, randomized evaluation of local injection therapy of iliac crest pain syndrome and low back pain, studied the effectiveness of a single local injection of 5 mL of lignocaine, 0.5%, with 5 mL isotonic saline in 41 patients. The results showed that in the local anesthetic group, 52% of the patients improved and in the saline group, only 30% improved. The data demonstrated an effect of the local injection with lignocaine that is somewhat larger than an injection with saline, which also has some beneficial effect. The difference was not consistent across all the settings (rheumatology practice vs general practice).

Bourne (206) compared corticosteroid - lignocaine injections with lignocaine alone in a trial of 57 patients suffering from chronic back pain. The results showed that corticosteroid - lignocaine mixture gave excellent results in 80% of 30 patients treated with the mixture and in only 16% of 19 patients treated with lignocaine alone.

Hamerhoff et al (207) compared bupivacaine, etidocaine, and saline for trigger point therapy in a randomized double-blind crossover study. They reported increased relief with local anesthetic as compared with normal saline.

Fine et al (208) evaluated the effects of myofascial trigger point injections, they reported pain relief in all subjects with the injection of 0.25% bupivacaine injection along with improvement in range of motion in those subjects who initially demonstrated the limitation of movement. They also showed that the relief achieved with trigger point injections was reversed with naloxone but not placebo.

Jaeger and Shootsky (209) in a double-blind study evaluated the effect of dry-needling, saline, procaine, and placebo. They concluded that the use of saline or local anesthetic appears to be more effective than dry-needling or placebo.

In a controlled double-blind evaluation of the comparison of mepivacaine injection versus saline injection for myofascial pain. Frost et al (203) studied 28 patients with acute, localized muscle pain by injecting four local injections of mepivacaine, 0.5%, in 28 patients, and local injection of an equal volume of normal saline in 25 patients. The group receiving saline tended to have more relief of pain, especially after the first injection. The results show that pain relief is not due merely to the local anesthetic. The study raises questions about the mechanism by which local injections into muscle relieve pain, since there is the possibility that a similar effect might also be achieved by merely inserting a needle into the trigger point. Normal saline is considered to be a more appropriate fluid for injection therapy than local anesthetic since it is less likely to produce side-effects. The positive aspects of this study include its inclusion of neck, shoulder, lumbar, and gluteal myofascial pain syndromes. The negative aspects include that normal saline was more effective than local anesthetic injection.

Garvey et al (204), in a prospective, randomized, double-blind evaluation of trigger point injection therapy for low back pain, evaluated 63 individuals with low back strain. Patients with nonradiating low back pain, with normal neurological examination, without sciatic tension signs, and with negative radiological evaluation and patients who failed two months of conservative treatment were included. Injection therapy was of four different types: lidocaine, lidocaine combined with a steroid, acupuncture, and vapor-coolant spray with acupressure. The results showed that noninjection therapy was effective in 63% of the patients whereas injection therapy was effective in only 42% of the patients. Thus, this study showed that trigger point therapy seems to be useful in the treatment of low back strain, but the injection substance apparently is not the critical factor, since direct mechanical stimulus to the trigger point seems to give symptomatic relief equal to that of treatment with various types of injected medication.

In terms of the quality of evidence presented with trigger point injection, the results were positive in five of the seven controlled studies (205, 209). Based on the above, type and strength of efficacy evidence is level III to level IV - moderate to limited. Level III - moderate is defined as

evidence from well-designed trials without randomization, single group pre-post, cohort, time series, or matched case controlled studies. Level IV- limited is defined as evidence obtained from well-designed non-experimental studies from more than one center or research group. In addition, there is overwhelming support from respected authorities along with clinical evidence and descriptive studies in support of judicious use of trigger point injections.

### ***Spinal Cord Stimulation***

Spinal cord stimulation uses electrical stimulation of spinal cord to control pain. There are multiple theories regarding how this effect causes pain control, but the exact mechanism is still controversial and may be a result of more than one of these mechanisms. In the United States, the primary indications for spinal cord stimulation are failed back surgery syndrome (691, 692), and both sympathetically maintained and sympathetically independent pain of complex regional pain syndrome (693-696). However, in Europe, most interest in spinal cord stimulation has been in the treatment of chronic intractable angina and pain and disability due to peripheral vascular disease (697-701). Spinal cord stimulation, for the clinical control of pain, was first introduced in 1967 by Shealy et al (702), in response to the publication of the gate control theory of pain by Melzack and Wall in 1965 (703).

In the field of spinal cord stimulation (SCS), as with other interventional techniques in chronic pain management, there are numerous retrospective studies that promote the efficacy of spinal cord stimulation, showing approximately 60% efficacy that lasts approximately two years (691, 704-710). Wetzell et al (704) reviewed the current literature regarding the treatment of chronic pain in failed back surgery patients with spinal cord stimulation. Turner et al (69) also reviewed the literature on spinal cord stimulation in chronic low back pain in an attempt to perform a meta-analysis, concluding that this was not possible based on the characteristics of the literature. They analyzed 39 reports, "all case studies", concluding that 50% to 60% of patients with failed back surgery syndrome reported greater than 50% pain relief with the use of spinal cord stimulation.

North et al (711), in a prospective study, randomized 27 patients into repeat laminectomy or spinal cord stimulation groups. Even though this is not quite a similar treatment, the initial results were published after a 6-month follow-up; crossover between the groups was permitted. In this study, there was a significantly higher crossover

rate from repeat laminectomy to spinal cord stimulation (67%) than vice versa (17%). Multiple observational studies in postlaminectomy syndrome reported 25% to 76% pain relief at various intervals (706-710, 712, 713).

In a prospective, multicenter study of spinal cord stimulation, Burchiel et al (697) demonstrated its effectiveness in the management of chronic low back and extremity pain. The permanent stimulating system was implanted in 182 patients. They reported at least 50% pain relief in 55% of the patients at 1-year follow-up.

Kemler et al (695) evaluated spinal cord stimulation in patients with chronic reflex sympathetic dystrophy utilizing a randomized trial involving patients who had had reflex sympathetic dystrophy for at least 6 months. Thirty-six patients were assigned to receive treatment with spinal cord stimulation plus physical therapy, and 18 were assigned to receive physical therapy alone. The health-related quality of life improved in the 24 patients who actually underwent implantation of a spinal cord stimulator. Of the 24 patients, 6 had complications that required additional procedures, including removal of the device in one patient. Thus, at 6 months, spinal cord stimulation was successful in 20 of 36 patients (56%); however, since only 24 patients received spinal cord stimulation, this is 20 out of 24 patients with an 80% success rate.

Tesfaye et al (714) evaluated spinal cord stimulation for painful diabetic neuropathy in 10 patients who had not responded to conventional treatment. The electrode was implanted in the thoracic/lumbar epidural space. Immediate neuropathic pain relief after connecting the electrode was measured using a VAS, and exercise tolerance was assessed on a treadmill. Eight patients had statistically significant pain relief with an electrical stimulator, and the system was made permanent. Seven of these eight had statistically significant relief of pain at three months, and this relief was sustained in six patients until the end of the study at 14 months. These six patients used the stimulator as the sole treatment for their pain with improvement in their exercise tolerance. They claimed that electrical spinal cord stimulation offers a new and effective way of relieving chronic diabetic neuropathic pain, with improvement in exercise tolerance, in patients with neuropathic pain who do not respond to conventional treatment.

In addition to the declining success rate, complications also are common (713). These were predominantly electrode related problems i.e., migration, fracture, etc. Infection was less common, even though it was reported in 5% of

the patients in 20 trials (713). Many new indications and techniques have evolved for SCS over the last several years including dual lead systems, retrograde cannulation, and transsacral stimulation for pelvic pain.

Spinal cord stimulation is an invasive interventional surgical procedure. The difficulty of randomized clinical trials in such situations is well recognized. There were three prospective studies evaluating effectiveness of spinal cord stimulation in postlumbar laminectomy syndrome (711), reflex sympathetic dystrophy (695), and diabetic neuropathy (714). In addition, there have been numerous observational studies (691-694, 706-710, 712, 713). Based on the above reports the evaluation of the type and strength of efficacy evidence is level III - moderate. Level III - moderate evidence is defined as evidence obtained from well-designed trials without randomization, single group pre-post, cohort, time series, or matched case controlled studies.

#### ***Implantable Intrathecal Drug Administration Systems***

Despite continued debate, chronic opioid therapy in the treatment of persistent pain of non cancer origin has gained broad acceptance (715-718), in addition to established chronic opioid therapy in cancer pain. The development of acceptable drug administration systems has been met with both enthusiasm (719) and controversy (720). Even though various guidelines have been proposed (721), much of the information is yet to come out or be absorbed about the long term effects of intrathecal opioid therapy. It appears that there is an increasingly large number of patients who have undergone intrathecal therapy for more than two years (722). Results indicating good to excellent outcome in nearly 70% of patient population which would have been considered quite refractory to standard types of management have been reported (721, 723-725).

Willis and Doleys (715), in a retrospective evaluation of 29 consecutive patients with a follow up duration of 31 months reported an average 63% improvement in pain, 46% improvement in activity level, and 54% improvement in ease of performing activities. Other results were of Doleys et al (723), with 61% relief; Paice et al (726), also with 61% relief, though in a large, retrospective, multicenter survey. In other studies, Tutak and Doleys (727) reported a good or excellent outcome in 78% of the patients, Kremes and Lanning (719) reported good or excellent outcome in 81% of patients, and others (724, 725) at 70%.

Other drugs also have been utilized in implantable sys-

tems. Hilten et al (728) studied intrathecal baclofen for the treatment of dystonia in patients with reflex sympathetic dystrophy. They performed a double-blind, randomized, controlled, crossover of bolus intrathecal injections of 25, 50, and 75 mg of baclofen in placebo. The results showed that in six women, bolus injections of 50 and 75 mg of Baclofen resulted in complete or partial resolution of focal dystonia of the hands but little improvement in dystonia of the legs. During continuous therapy, three women regained normal hand function and two of these three women regained the ability to walk. In one woman who received continuous therapy, the pain and violent jerks disappeared and the dystonic posturing of the arm decreased. In two women, the spasms and restlessness of the legs decreased, without any change in the dystonia. They concluded that in some patients, the dystonia associated with reflex sympathetic dystrophy responded markedly to intrathecal baclofen. Even though this was a double-blind, randomized, controlled, crossover trial, it included only a total of seven patients; but this probably is the best evidence available for this type of therapy in a randomized controlled trial.

Avellino and Loeser (729) also studied intrathecal baclofen for the treatment of intractable spasticity of the spine or brain etiology in a retrospective review of 62 consecutive adult patients who underwent placement of a programmable pump. They concluded that, intrathecal baclofen is an effective strategy for the relief of medically intractable spasticity of spine or brain etiology.

Intrathecal drug delivery system is an invasive surgical procedure. Again, this is met with difficulties with evaluation in a randomized clinical trial considering the various difficulties of a randomized clinical trial in such a situation along with the presence of one double-blind randomized controlled crossover study for baclofen and an enormous amount of evidence from observational studies. In consideration of multitude of factors, it is determined that, the evaluation of type and strength of efficacy evidence for intrathecal implantable drug delivery systems is level III - moderate. Level III - moderate is defined as evidence obtained from well-designed trials without randomization, single group pre-post, cohort, time series, or matched case controlled studies.

#### ***Complications***

The most common and worrisome complications of interventional techniques are two-fold. These include complications related to a technique of an interventional proce-

ture with placement of either the needle and/or catheter, and complications related to the administration of various drugs. Complications include dural puncture, spinal cord trauma, and infection.

Accidental dural puncture, subdural injection, neural trauma, injury to the spinal cord, and hematoma formation have been described. The incidence of dural puncture following lumbar epidural injections has been reported as 0.33% (60) and 0.25% after cervical epidural injections (730). Subdural intracranial air was also reported following epidural injections (731, 732). In addition, lumbar puncture has been reported following facet joint injections and sympathetic blocks (733-735). When C3/4, C4/5, or C5/6 facet joint blocks, the phrenic nerve may be compromised, especially if a large volume of local anesthetic is employed. This is also a complication of sympathetic block in the cervical spine. Spinal cord trauma, spinal cord or epidural hematoma formation is a catastrophic complication rarely seen following the interventional procedures in the cervical spine, thoracic spine or upper lumbar spine (60, 538-542, 736-738). It has been suggested to perform interventional procedures with placement of a needle only in an awake patient and in the cervical spine by limiting the midline injection to be performed only at C7/T1 except in rare circumstances (538-542). However, unfortunately, it has been reported that even an awake patient may not be able to detect spinal cord puncture (739). Injection of neurolytic solutions or placement of radiofrequency needle into the spinal cord could lead to disastrous complications.

Infectious complications include epidural abscess and bacterial meningitis (740-756). However, iatrogenic spinal epidural abscess (757) and iatrogenic mycobacterium infection after an epidural injection was also reported (758). Discitis is considered as a principle complication of cervical discography which is seen less frequently following lumbar discography in approximately 0.1% to 1% of the patients (759, 760). Other complications include inadvertent subdural injection of local anesthetic and steroids (761, 762), development of complex regional pain syndrome (763), chemical meningism (764), lightheadedness, flushing, sweating, nausea, hypotension, syncope, pain at the injection site, and nonpostural headache (60). Retinal hemorrhage also has been associated with rapid injection of large volumes of caudal steroid injections (765).

Side-effects related to the administration of steroids are generally attributed either to the chemistry or to the pharmacology of the steroids. The major theoretical compli-

cations of corticosteroid administration include suppression of pituitary-adrenal axis, hypercorticism, Cushing's syndrome, osteoporosis, avascular necrosis of bone, steroid myopathy, epidural lipomatosis, weight gain, fluid retention, and hyperglycemia (766-774). However, Manchikanti et al (775) in evaluating the effect of neuraxial steroids on weight and bone mass density showed no significant difference in patients undergoing various types of interventional techniques with or without steroids. Catheter shearing and inadvertent injection of hypertonic saline into the subarachnoid space as well as complications of hypertonic saline injection also have been described (632, 776-783). The most commonly used steroids in neural blockade in the United States, methylprednisolone acetate, triamcinolone acetonide, and betamethasone acetate and phosphate mixture have been shown to be safe at epidural therapeutic doses in both clinical and experimental studies (784-790).

Potential side-effects with radiofrequency denervation include painful cutaneous dysesthesias, increased pain due to neuritis or neurogenic inflammation, anesthesia dolorosa, cutaneous hyperesthesia, pneumothorax, and deafferentation pain, and finally inadvertent lesioning of the spinal cord and its contents (791).

Complications related to IDET, spinal cord stimulation, and intrathecal morphine implantation include various technical complications described above, other complications related to surgical technique itself, and fracture of the electrodes, shearing of the catheter, and complications related to long-term implantables.

## **DELIVERY OF INTERVENTIONAL TECHNOLOGY**

### *Dosage, Frequency, And Number of Blocks*

There is no consensus among the interventional pain management specialists with regards to type, dosage, frequency, total number of injections, or other interventions (31, 33, 41-62, 338, 339, 607, 608, 792). 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 (DepoMedrol<sup>®</sup>), triamcinolone diacetate (Aristocort<sup>®</sup>) triamcinolone acetonide

**Table 15. Pharmacologic profile of commonly used steroids**

Name of the Drug	Equivalent Dose	Epidural Dose	Anti-inflammatory Potency	Sodium Retention Capacity	Duration of Adrenal Suppression		
					IM	Single Epidural	Three Epidurals
Triamcinolone acetonide (Kenalog)	4 mg	40-80 mg	5	0	2-6 weeks	N/A	2-3 months
Betamethasone (Celestone Soluspan)	0.6 mg	6-12 mg	25	0	1-2 weeks	N/A	N/A
Triamcinolone diacetate (Aristocort)	4 mg	40-80 mg	5	0	1-2 weeks	1-5 weeks	N/A
Methylprednisolone acetate (Depo-Medrol)	4 mg	40-80 mg	5	0.5	1-6 weeks	1-3 weeks	N/A

Reproduced with permission from Manchikanti (338, 339) IM = Intramuscular; N/A = Not Available

(Kenalog<sup>®</sup>), and betamethasone acetate and phosphate mixture (Celestone Soluspan<sup>®</sup>) appear to be safe and effective (Table 15) (41-62, 338, 339, 607, 608, 784-791). Based on the present literature, it appears that if repeated within two weeks, betamethasone probably would be the best 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 a key issue, although controversial and rarely addressed. Some authors recommend one injection for diagnostic as well as therapeutic purposes; others advocate three injections in a series irrespective of the patient’s progress or lack thereof; still others suggest three injections followed by a repeat course of three injections after 3-, 6-, or 12-month intervals; and, finally, there are some who propose an unlimited number of injections with no established goals or parameters. Limitation of 3 mg/kg of body weight of steroid or 210 mg per year in an average person and a lifetime dose of 420 mg of steroid, equivalent to methylprednisolone also have been advocated. While some investigators recommend one injection and do not repeat if there has been no response to the first, others recommend one or two more injections in the absence of response to the first injection. Some authors have reported good pain relief in previously unresponsive patients after an additional one or two injections. Similarly, some have believed that more than three injections do not result in additional improvement (572), whereas, others have reported the use of 6 to 10 injections if they are of benefit, however not to exceed 3 if they are not beneficial (607, 608). Such descriptions

for other interventional techniques have been extrapolated from the limitations described for epidural steroid injections, even though there is no scientific basis or justification for such an extrapolation, as the techniques and type and dosage drugs are vastly different. It also has been shown in a multitude of publications that relief following multiple injections or interventions demonstrated a staircase-type phenomenon, even though it reached a plateau after three to four interventions.

**Facet Joint Injections:**

- In the diagnostic or stabilization phase, a patient may receive injections at intervals of no sooner than one week and preferably two weeks.
- In the treatment or therapeutic phase (after the stabilization is completed), the frequency should be two months or longer between each injection provided that at least > 50% relief is obtained for six weeks. However, if the neural blockade is applied for different regions, they can be performed at intervals of no sooner than 1 week and preferably two weeks for most type of blocks. The therapeutic frequency must remain at least two months for each region.
- In the diagnostic or stabilization phase, the number of injections should be limited to no more than four times.
- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary judging by the medical necessity criteria and these should be limited to a maximum of

- six times for local anesthetic and steroid blocks for a period of one year.
- Under unusual circumstances with a recurrent injury or cervicogenic headache blocks may be repeated at intervals of six weeks after stabilization in the treatment phase.

#### ***Medial Branch Neurolysis:***

- The frequency should be three months or longer between each neurolytic procedure provided that at least > 50% relief is obtained for 10 weeks. However, if the neural blockade is applied for different regions, they can be performed at intervals of no sooner than one week and preferably two weeks for most type of blocks. The therapeutic frequency for neurolytic blocks must remain at three months for each region.
- Neurolytic procedures should be repeated only as necessary judging by the medical necessity criteria and these should be limited to a maximum of four times for a period of one year.

#### ***Epidural Injections:***

- In the diagnostic or stabilization phase, a patient may receive injections at intervals of no sooner than one week and preferably two weeks except for blockade in cancer pain or when a continuous administration of local anesthetic is employed for RSD.
- In the treatment or therapeutic phase (after the stabilization is completed), the frequency of interventional techniques should be two months or longer between each injection provided that at least >50% relief is obtained for six weeks. However, if the neural blockade is applied for different regions, they can be performed at intervals of no sooner than one week and preferably two weeks for most type of blocks. The therapeutic frequency must remain two months for each region.
- In the diagnostic or stabilization phase, the number of injections should be limited to no more than four times except for RSD, in which case six times should be reasonable.
- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary judging by the medical necessity criteria and these should be limited to a maximum of six times.

- Under unusual circumstances with a recurrent injury, carcinoma, or reflex sympathetic dystrophy, blocks may be repeated at intervals of 6 weeks after stabilization in the treatment phase.

#### ***Percutaneous Lysis of Adhesions:***

- For percutaneous non-endoscopic adhesiolysis with a 3-day protocol, 2 to 3 interventions per year are recommended; with a 1-day protocol, a maximum of four times per year is recommended.
- For endoscopic adhesiolysis, it is recommended that there be no more than two interventional procedures per year.

#### ***Sympathetic Blocks:***

- In the diagnostic or stabilization phase, a patient may receive injections at intervals of no sooner than one week and preferably two weeks except in cancer pain or when a continuous administration of local anesthetic for sympathetic block is employed. However, the total number of injections in the stabilization phase should be limited to 4 to 6.
- In the treatment or therapeutic phase, that is after the stabilization phase, the frequency of sympathetic blocks should be limited to two months or longer between each injection provided that at least greater than 50% relief is obtained for six weeks.

#### ***Sacroiliac Joint Injections:***

- In the diagnostic or stabilization phase, a patient may receive injections at intervals of no sooner than one week and preferably two weeks.
- In the treatment or therapeutic phase (after the stabilization is completed), the frequency should be two months or longer between each injection provided that at least > 50% relief is obtained for six weeks. However, if the neural blockade is applied for different regions, they can be performed at intervals of no sooner than one week and preferably two weeks for most type of blocks. The therapeutic frequency must remain at two months for each region.
- In the diagnostic or stabilization phase, the number of injections should be limited to no more than four times.
- In the treatment or therapeutic phase, sacroiliac

joint injections should be repeated only as necessary judging by the medical necessity criteria and these should be limited to a maximum of six times for local anesthetic and steroid blocks for a period of one year.

#### **Trigger Point Injections:**

- In the diagnostic or stabilization phase, a patient may receive trigger point injections at intervals of no sooner than one week and preferably two weeks.
- In the treatment or therapeutic phase (after the stabilization is completed), the frequency should be two months or longer between each injection provided that at least >50% relief is obtained for six weeks.
- In the diagnostic or stabilization phase, the number of trigger injections should be limited to no more than four times per year.
- In the treatment or therapeutic phase, the trigger point injections should be repeated only as necessary judging by the medical necessity criteria and these should be limited to a maximum of six times for local anesthetic and steroid injections.
- Under unusual circumstances with a recurrent injury or cervicogenic headache trigger point injections may be repeated at intervals of six weeks after stabilization in the treatment phase.

**Combination of Blocks/Interventions:** It may be essential to combine, in certain circumstances, more than one block. This may include an epidural for the cervical region and facet-joint blocks for the lumbar region; epidural and facet-joint blocks for the same region in case of identification of pain generators from both sources; a sympathetic block and facet-joint block if there are two different sources of pain or if two different regions are affected in combination with trigger-point injections. Consequently, blocks also may be combined with other interventional techniques.

#### **OUTCOMES AND COST-EFFECTIVENESS**

Outcomes may be assessed by evaluation of the quality of life, which is also known as functional status, health status, health-related quality of life; well-being of the patient, satisfaction with care, health services utilization/economic analysis, and medical findings (793-802). The quality-of-life assessment is designed to evaluate the patient's abilities to function in his/her own world. Physical functioning

measures the ability to perform physical activities such as walking, climbing stairs, or carrying things. Evaluation focuses on the patient's major perceived functional impairments, improvement in areas such as playing with children/grandchildren, having sexual relations, returning to work, going to school, homemaking or performing other activities of daily living. Quality of life also measures social functioning, which determines whether health problems affect normal social activities, such as seeing friends or participating in group activities.

Similarly, confusion abounds over what is meant by the term *cost-effectiveness*. *Cost-effectiveness* analysis has taken on an increasingly large role in health care policy debates about interventions for various types of interventions in managing low back pain. Growing health care costs and productivity losses, disappointing treatment results, and changing beliefs about health and pain have led to this increasing concern about the amount of money spent on chronic pain in general and low back pain in particular. In recent years, more and more studies in the field of the management of chronic low back pain have been incorporating cost issues in their analysis (795, 803-809). While economic evaluation designs describe cost minimization-analysis (CMA), cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), or cost-utility analysis (CUA), in chronic low back pain, CEA and CUA would be the most appropriate methods to use, since in these studies the effects are measured in natural units and quality of life. The outcome measures used in CEA studies in chronic pain research mainly include outcomes, such as disability days saved, pain-free days, or improved quality of life, etc. (803). Cost of inpatient chronic pain programs range from \$17,000 to \$25,000 and the cost of outpatient treatment programs range from \$7,000 to \$10,000 (802). In addition, chronic pain patients may incur health care bills in excess of \$20,000 annually for repetitive and, in some cases, redundant diagnostic work ups, physical therapy, psychological interventions, and drugs. Guo and colleagues (810) estimated that back pain accounted for 150 million lost work days in the United States every year, which worked out to be about \$14 billion in wage costs alone. The study showed that the magnitude of the back pain problem is so large that even a 1% reduction in overall prevalence could considerably reduce morbidity and save billions of dollars. The cost-effectiveness of lumbar discectomy for the treatment of herniated intervertebral discs has been based on the conclusion that surgery increased the average quality-adjusted life expectancy by 0.43 years during the decade following treatment compared to conservative treatment, a result comparable to extending a healthy life by five



months (807). Malter et al (807) also concluded that for carefully selected patients with herniated discs, surgical discectomy is a cost-effective treatment at a discounted cost of \$12,000 per discectomy or \$29,000 per life year adjusted for quality. However, this study did not take into consideration chronic pain patients when initial surgical treatment for herniated disc fails. In such a study, it was shown that the success of a second operation was 50%, with an additional 20% considering themselves worse after the surgery (266). With a third procedure, the success rate was 30%, with 25% considering themselves worse; and after four operations, only a 20% success rate was achieved, with 45% of these patients considering themselves worse (266). Hence, if additional costs of repeat surgery are taken into consideration, the cost of lumbar surgery will probably be much higher. Kuntz et al (809) studied the cost-effectiveness of fusion with and without instrumentation for patients with degenerative spondylolisthesis and spinal stenosis. They showed that laminectomy with a non-instrumental fusion costs \$56,500 per quality-adjusted year of life versus laminectomy without fusion. The cost-effectiveness ratio of instrumented fusion com-

pared with noninstrumented fusion was \$3,112,800 per quality-adjusted year of life (809). However, they also stated that if the proportion of patients experiencing symptom relief after instrumented fusion was 90% as compared with 80% for patients with non-instrumented fusion would \$82,400 per quality-adjust year of life. Mueller-Schwefe and colleagues (808), in evaluating the cost-effectiveness of intrathecal therapy for pain secondary to failed back surgery syndrome, compared alternative therapies for achieving a defined outcome, reporting the cost of medical management to be \$17,037 per year, or \$1,420 per month. They also showed that intrathecal morphine delivery resulted in lower cumulative 60-month costs of \$16,579 per year and \$1,382 per month.

The cost-effectiveness evaluations for blind interlaminar, fluoroscopically directed caudal or transforaminal epidural injections for the management of low back pain showed the cost-effectiveness of caudal epidural steroids to be \$3,635 and transforaminal steroids to be \$2,927 per year, in stark contrast to blind interlaminar lumbar epidural steroid injections at \$6,024 per year (553). Cost-effective-

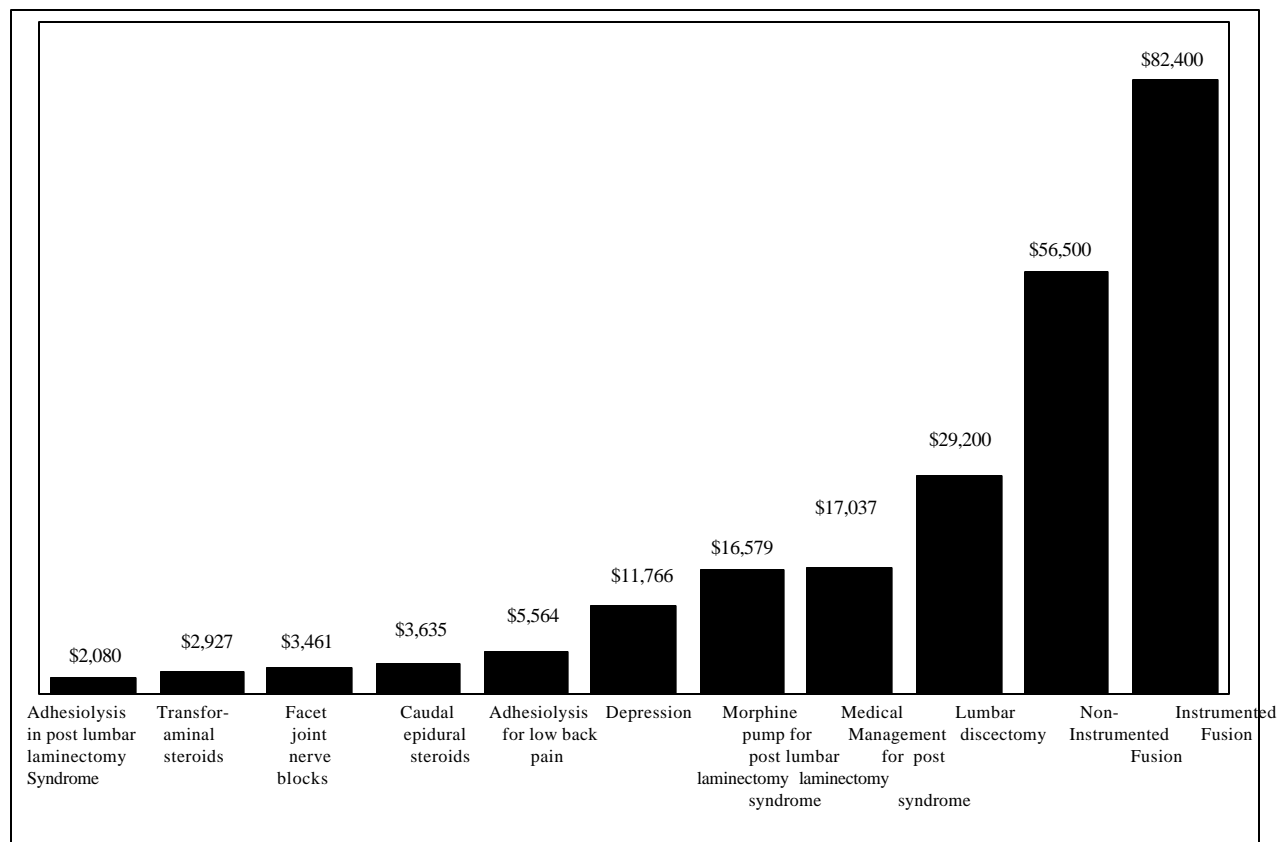


Fig. 5. Cost effectiveness of various types of therapy in managing medical conditions including chronic low back pain

ness of percutaneous nonendoscopic adhesiolysis and hypertonic saline neurolysis was demonstrated to be \$5,564, for improvement of one year of quality of life for patients with chronic low back pain nonresponsive to numerous other modalities of treatment (647). Similarly, the cost-effectiveness with nonendoscopic adhesiolysis was shown to be \$2,028 per year, whereas it was \$7,020 with endoscopic adhesiolysis in postlumbar laminectomy patients (649).

Evaluation of cost-effectiveness of lumbar facet joint nerve blocks, with or without steroids, by Manchikanti et al (481) showed that one year improvement of quality of life was achieved at \$3,461. This is similar to various investigations in the past with neural blockade but also significantly better than the cost-effectiveness, either with intrathecal morphine delivery, lumbar laminectomy, or lumbar laminectomy, with or without instrumented fusion. In addition,

the interpretation of the current results should be placed in the context of other surgical interventions and other modalities of treatments also. Lave et al (811) demonstrated the cost-effectiveness of medical treatment of depression management as \$11,766 per year of quality adjusted life. It was also shown that a simple reduction of diastolic pressure from 110 to 90 mm of hg was achieved at a cost of \$16,330 for a 60-year old man in 1974 (793). Total hip arthroplasty for osteoarthritis of the hip costs \$61,000 per quality adjusted year of life gained (812). Lumbar discectomy for the treatment of herniated intervertebral discs cost \$39,500 per quality adjusted year of life gained (807, 809); coronary artery bypass grafting for patients with triple-vessel coronary disease and severe left ventricular function cost \$41,800 per year quality-adjusted year of life gained (813). Hence, it appears that precision percutaneous injection therapy and other interventional techniques are cost effective if performed properly, as

**Table 16.** Effectiveness of various commonly used interventional techniques in managing chronic pain

<b>Intervention</b>	<b>Randomized Trials</b>	<b>Observational Studies</b>	<b>Effectiveness /Evidence Strength</b>	<b>Complications /Risks</b>	<b>Cost per One Year of Quality of Life</b>
Intra-articular facet joint injections	Six	Multiple	Moderate/Limited	Minimal	NA
Facet joint nerve blocks	Four	Two	Moderate	Minimal	\$3461
Medical branch neurotomy	Four	Multiple	Strong	Minimal	NA
Caudal epidural steroids	Six	Multiple	Strong	Minimal	\$3635
Interlaminar epidural steroids	Thirteen	Multiple	Moderate/Limited	Minimal	\$6024
Transforaminal epidural steroids	Five	Multiple	Strong/Moderate	Minimal	\$2927
Epidural lysis of adhesions	One	Three	Moderate	Minimal	\$2080 TO \$5564
Spinal endoscopy	None	Three	Limited	Minimal	\$7020 TO \$8127
Intradiscal electrothermal annuloplasty	One	Multiple	Moderate	Minimal	NA
Spinal cord stimulation	Three	Multiple	Moderate	Significant	NA
Intrathecal pumps	None	Multiple	Moderate	Minimal	\$16,579
Sympathetic blocks	None	Multiple	Limited	Minimal	NA
Trigger point injections	Seven	Multiple	Moderate/Limited	Minimal	NA

NA= not available

shown in Fig. 5.

Thus, determining whether a service is worthwhile involves a number of different issues. It involves not only knowing whether the various components of the intervention are effective, but also how much they cost and if the delivery system is efficient. The preceding discussion concentrated on trying to determine whether interventional techniques in managing chronic pain could be shown to be effective through a systematic review. To achieve this goal, numerous relevant studies and reviews were reviewed for the quality and application to the subject of interventional techniques in chronic pain. Finally, the relative efficiency and safety of the possible interventions, and then the cost, have to be the key determinants. Table 16 shows various interventional techniques in managing chronic pain classified by evidence of effectiveness, as well as risk of side effects and cost of the procedure.

### CONCLUSION

The practice guidelines for interventional techniques in the management of chronic pain were developed utilizing the best available evidence combined with consensus. These guidelines include discussions of the purpose, rationale, and importance. The guidelines also have discussed the importance of randomized controlled trials, the development of type and strength of efficacy evidence and various controversial aspects relating to guidelines. Chronic pain and its epidemiology, as well as discussion of chronic pain vs chronic pain syndrome, the pathophysiologic basis of persistent pain, and the evaluation of the patient presenting with chronic pain, have been discussed. Diagnostic and therapeutic interventional techniques are discussed extensively including all types of evidence available from randomized clinical trials as well as some observational studies. The levels of effectiveness for the most commonly used interventions were developed based on review of diagnostic and therapeutic interventional techniques. Additionally, effectiveness evidence and an algorithmic approach to managing a patient presenting with chronic spinal pain were also developed.

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- David Kloth, MD, Medical Director, Connecticut Pain Care, PC, 69 Sand Pit Road, Suite 204, Danbury, CT, 06810, Email: dkmd@ctpaincre.com.
- Curtis W. Slipman, MD, Medical Director, Penn Spine Center, Rehabilitation Medicine, Assistant Professor, University of Pennsylvania Health System, 3400 Spruce Street, Great White, PA 19104, Email: slipman@mail.med.upenn.edu.
- Joseph F. Jasper, MD, Medical Director, Advanced Pain Medicine Physicians, 1628 South Mildred Street, Suite #105, Tacoma, WA 98465, Email: apmedicine@qwest.net.
- Andrea M. Trescot, MD, Medical Director, Pain Center, 1895 Kingsley Ave. Suite 903, Orange Park, FL 32073, Email: amt57@aol.com.
- Kenneth G. Varley, MD, Medical Director, Southern Pain Specialists, 7500 Hugh Daniel Drive, #360, Birmingham, AL 35242, Email: gaynes@aol.com.
- Sairam L. Atluri, MD, Medical Director, Eastern Cincinnati Pain Management Associates, 8000 State Road, Suite 325, Cincinnati, OH 45230, Email: atluri\_ps@sprynet.com.
- Carlos Giron, MD, Medical Director, Georgia Pain Institute, 797 Poplar Street, Macon, GA 31201, Email: cgiron@worldnet.att.net.
- Mary Jo Curran, MD, Medical Director, Advanced Pain Treatment Centers, 676 N St. Clair, Suite 360, Chicago IL 60611, Email: mj@bepainfree.com.
- Jose Rivera, MD, Interventional Pain Physician, Pain Management Center of Paducah, 2831 Lone oak Road, Paducah, KY 42003, Email: painmgmt@apex.net.
- A Ghafoor Baha, MD, Interventional Pain Physician, Pain Management Center of Paducah, 2831 Lone oak Road, Paducah, KY 42003, phone (270) 554-8373, fax (270) 554-8987 or Email: painmgmt@apex.net.
- Cyrus E. Bakhit, MD, Medical Director, Pain Management Center of Roanoke, 1119 South Jefferson Street, Roanoke, VA 24016, Email: cbakhit@pmcr.org.
- Merrill W. Reuter, MD, Medical Director, Lake Worth Medical Center, 7625 Lake Worth Road, Lake Worth, FL 33467, Email: aospine@doctor.com.

## APPENDIX I

Laxmaiah Manchikanti, MD, Medical Director, Pain Management Center of Paducah, 2831 Lone Oak Road, Paducah, KY 42003, Email: drm@asipp.org.

Vijay Singh, MD, Medical Director, Pain Diagnostic Associates, 1601 Roosevelt Road, Niagara, WI 54151, Email: vsingh@netnet.net.

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